Ancillary to Accompany

Intervention Research: Designing, Conducting, Analyzing, and Funding

EXAMPLES OF SUCCESSFULLY FUNDED RESEARCH GRANTS

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SPRINGER PUBLISHING COMPANY
NEW YORK

ISBN: 978-0-8261-9969-0
Digital Product

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Comparing Teen Mentors to Adult Leaders to Prevent Appalachia Childhood Obesity

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Grant # 1R21 HD060082-01A2

Funding: NICHD

PI: **Smith, Laureen**	**Title: Comparing Teen Mentors to Adult Leaders to Prevent Appalachia Childhood Obesity**	
Received: 07/09/2009	FOA: PA07-391	Council: 01/2010
Competition ID: ADOBE-FORMS-A	FOA Title: REDUCING HEALTH DISPARITIES AMONG MINORITY AND UNDERSERVED CHILDREN (R21)	
1 R21 HD060082-01A2	Dual:	Accession Number: 3212628
IPF: 6218701	Organization: OHIO STATE UNIVERSITY	
Former Number:	Department: Nursing Administration	
IRG/SRG: NSCF	AIDS: N	Expedited: N
Subtotal Direct Costs (excludes consortium F&A) Year 1: 125,000 Year 2: 125,000	Animals: N Humans: Y Clinical Trial: N Current HS Code: 30 HESC: N	New Investigator: N Early Stage Investigator: N
Senior/Key Personnel:	*Organization:*	*Role Category:*
Laureen Smith PhD	The Ohio State University Research Foundation	PD/PI
Pamela Salsberry PhD	The Ohio State University Research Foundation	Other (Specify)-Co-Investigator
Robert Murray MD	Nationwide Children's Hospital	Other (Specify)-Co-Investigator
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Appendices

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appendix_a_r21_application_7_091009032047

Childhood obesity is a significant problem nationwide, but certain subgroups are at higher risk. This study targets one high risk subgroup, children living in a rural, low-income Appalachian area. This study will test the effectiveness of an innovative delivery model of health curriculum using trained high school-aged mentors compared to the usual condition of using adult group leaders. The content of the curriculum includes information regarding healthy eating and activity. Of primary interest is the delivery mode of the information, through a child and teen mentor relationship, compared to an adult group leader in a classroom setting. The curriculum used in this study combines concepts from Social Cognitive Theory, Theory of Planned Behavior, and Self Determination Theory. This between-group study compares a control (adult leader) and an experimental treatment (teen mentor) group. The target population is third and fourth grade students in a rural, low-income county in the Appalachian region. Children enrolled in an after-school program are eligible to participate. Tenth and 11th graders will participate as mentors. All participating elementary aged children will be randomly placed into either the control or experimental group. The difference between the pre-test and post-test scores for independent variables: (a) nutritional knowledge, (b) attitudes toward eating healthy,

(c) attitudes toward being physically active, (d) self-efficacy for eating healthfully, (e) self-efficacy for being physically active, (f) perceived support for eating healthfully, and (g) perceived support for being physically active will be included. Outcome measures include intentions to toward eating healthfully, intentions toward physical activity, current eating activity and current physical activity as well as health status measures of BMI z-scores and measured blood pressure. Data will be analyzed using multi-level linear models. The models will be augmented with an additional independent variable of the number of sessions attended by the child, entered as a moderating co-variate. Each outcome measure (intentions, current behaviors and health status) will be modeled separately. Independent variables will include the treatment group (between subjects), time period (within subjects), mentor/adult group leader ID (random effect), child ID and (random effect nested within mentor/adult group leader). Grade, gender, school and baseline z-scores will be included to account for the stratification in the experimental design, except in the model for BMI. Interaction effects will be tested. Results will indicate if the teen mentoring approach is more effective in promoting healthy eating and physical activity as the traditional adult group leader approach. If successful, teen mentoring may be a more effective way to promote healthy behaviors among children in poor rural areas with very limited resources for formal adult-mediated health promotion programs.

Obesity in children is a national epidemic, but certain subgroups are at higher risk. This study targets one high risk subgroup, children living in a rural, low-income Appalachian area. The study will test an innovative mentoring model that pairs school aged children with trained high school teen mentors to promote the adoption of healthier eating patterns and regular physical activity. The mentoring delivery method is compared to the usual condition of using adult group leaders in a classroom setting. If successful, teen mentoring may be a more effective way to promote healthy behaviors among children particularly in poor rural areas with very limited resources for formal health promotion programs.

A. SPECIFIC AIMS

Childhood obesity is a national epidemic. This proposed pilot study will test an innovative mentoring model that pairs teens with school aged children to promote adoption of healthier dietary patterns and regular physical activity. The traditional models of mentoring consist of adults supporting children to reverse academic failure, substance use/abuse, and other social risks.[1,2] The adult mentor model has not been used to improve health behaviors in children at high risk for obesity and its consequences. Alternatively, teens can have a significant influence on school-aged children because teens are powerful role models for younger children.[3] There are reports that using teens as mentors was equally effective compared to adult mentors in promoting more positive classroom behavior and attitudes toward risk behaviors.[4,5] Effects of using teens rather than adults as health mentors have not been reported in the literature. The proposed study will utilize an established healthy eating and activity curriculum intended to be delivered in a classroom setting by adults that has been shown to improve physical fitness, nutrition knowledge, and body mass index when used with elementary aged children in predominantly

urban settings.[6,7] We posit that having teens provide the same content via structured mentoring will increase motivation of children to perform the target behaviors — making healthy dietary choices and engaging in regular physical activity. The target population in this pilot study consists of 3rd and 4th grade students in a predominantly poor rural county of Appalachia. They are an understudied aggregate with disproportionately higher rates of obesity and diabetes compared to the U.S. population.[8,9] In the targeted community, over 31% of 3rd graders are obese and 47% are classified as overweight while nationwide, 18.8% of children aged 6–11 are classified as obese.[10] Four elementary schools and two high schools have agreed to participate; currently there are 188 3rd and 4th graders enrolled in after school programming at the target elementary schools. If successful, teens as mentors may be a more effective way to promote healthy behaviors among children particularly in poor rural areas with very limited resources for formal health promotion programs.

Primary Aim: The primary aim of this pilot study is to determine the effectiveness of a health education curriculum for third and fourth grade children delivered by trained high school aged mentors compared to the same content delivered in a classroom setting by an adult group leader (usual format) in an after school setting. Outcome measures for the child participants include: (a) behavioral intention (intention to eat healthfully and intention to be physically active); (b) behavioral outcomes (healthy eating and physical activity; and (c) health status (BMI percentiles and blood pressure). Variables to be measured include; (a) cognitive variables (nutritional knowledge; attitudes toward eating healthfully and attitudes toward engaging in physical activity); (b) self-efficacy (self-efficacy for eating healthfully and self-efficacy for being physically active); (c) perceived autonomy supports (perceived autonomy support for eating healthfully and perceived autonomy support for engaging in physical activity).

A ***secondary aim*** of this pilot study is to determine if all the measured concepts need to be included in a larger R01 study for testing of adult versus teen and classroom verses mentoring approaches to improve nutrition and exercise behaviors in this vulnerable population of underserved school-aged children in Appalachia.

Hypothesis: 1. Compared to the adult-mediated group, children in the teen mentored group will report a greater mean increase at post-intervention in: (a) intention to eat healthfully; (b) intention to be physically active; (c) engaging in healthy eating; (d) engaging in physical activity.

Hypothesis: 2. Compared to the adult-mediated group, children in the teen mentored group will demonstrate greater improvement in health status outcomes: (a) BMI percentile for age and gender; and (b) blood pressure.

Hypothesis: 3. Compared to the adult-mediated group, children in the teen mentored group will report a greater mean increase at post-intervention in: (a) nutritional knowledge; (b) positive attitudes toward eating healthfully; (c) positive attitudes toward engaging in physical activity; (d) perceived autonomy support toward eating healthfully; (e) self-efficacy toward eating healthfully; (f) self-efficacy toward engaging in physical activity; (g) perceived autonomy support toward engaging in physical activity.

Hypothesis: 4. Within *each group, children attending a greater number of sessions will show more improvement in each outcome, compared to children attending fewer sessions*.

B. BACKGROUND AND SIGNIFICANCE

B.1 Overweight Children in Rural and Appalachian Areas

Obesity is defined as being at or above the 95th percentile of body mass index for age and gender[11] and "overweight" is defined as being between the 85th percentile and the 95th percentile of body mass index for age and gender.[11] Obesity and overweight status among American children and adolescents are escalating rapidly and both conditions portend current and future health crises.[12] Traditionally, rural areas have experienced lower prevalence of overweight and obesity due to the increased physical demands characteristic of an agrarian lifestyle. However, this no longer is the case; rural residents, especially children, now show an increased prevalence of obesity and overweight compared to their urban counterparts.[13] Numerous studies support the findings that childhood overweight and obesity are worse in rural areas all across the United States.[14–16] This situation is especially prevalent in rural Appalachia.[12,17] Researchers estimated that the proportion of third and fourth grade children in the U.S. who meet criteria for obesity is fast approaching 20%.[18] Of even greater concern, estimates for rural dwelling children exceed the national averages by as much as double[17] with Appalachian areas having the highest prevalence rates even when compared to other rural areas.[15,19]

Ohio is one of the 10 states with exceptionally high prevalence rates of childhood obesity.[20–22] Twenty nine of Ohio's 88 counties are Appalachian. Appalachian areas report fewer normal or underweight children and more overweight and obese children with some estimates being double the national average.[23] Appalachian children have a child obesity prevalence rate of 31%; this rate exceeds all other racial or demographic groups.[9] The target population for this study mirrors the national Appalachian estimates. Effective interventions to reduce childhood overweight and obesity are sorely understudied in rural Appalachian populations where the residents are skeptical of "outsiders" and recommendations for health-related behavior changes.[24,25] Public health campaigns intended to decrease obesity and overweight in children is not resonating with this community; it is time to try a new approach. This study provides a unique opportunity *to evaluate a novel intervention* in an Appalachian community that per capita has a dearth of health care providers and lacks obesity prevention programs targeted to children.[9]

Childhood obesity is highly associated with obesity in adulthood, which has well known co-morbidities. The problem is particularly severe among lower income and rural populations[26] who also have elevated rates of diseases related to diet and physical activity, such as type 2 diabetes, hypertension, and cardiovascular disease.[27] This is a major concern in rural Appalachian populations that have relatively poor health and health related self-care behaviors compared to other populations.[17,25] Furthermore, there is evidence that rural life

presents special challenges to maintaining a healthy weight, including structural and cultural factors that prevail in Appalachian areas.[13] Cultural factors include: higher fat and caloric consumption, less exercise,[14] preference for sedentary activities,[14] reliance on non-professional health advice, preference for informal communication channels, and less confidence in the recommendations of teachers or health professionals.[13] Finally, rural and Appalachian peoples lack nutrition education,[28] access to nutritionists,[29] adequate school resources for either healthful eating or exercise, and community environments that support exercise. According to the 2006 Appalachian Rural Health Institute II Needs Assessment Survey, adult residents reported the highest rates of obesity (39.7%) compared to other rural areas and have disproportionately higher rates of heart disease, heart attacks, strokes, hypertension when compared to the total United States.[23]

Conversely, many health benefits, including healthy weight, are associated with participation in regular physical activity and eating foods that are low in saturated fat and high in and complex carbohydrates. Both patterns of eating and physical activity tend to track strongly into adulthood and become increasingly resistant to change as people age. Children in the third and fourth grades are one of the most active segments of the Appalachian population. This is an ideal time to influence an increase in regular physical activity and healthy dietary choices, as children's behaviors in these two areas usually become less healthy as they progress through the pre-teen period.[30,31]

B.2 Theoretical Bases of the Health Curriculum

This study will use an adaptation of the *Just for Kids!* Curriculum,[32] a healthy eating and activity program designed to be delivered in a group setting, such as a classroom, over an eight week period, for one hour each week. *Just for Kids!* is designed for 3rd and 4th graders and is modeled after the "Shapedown" program developed at the University of California San Francisco incorporates current scientific and clinical understanding, including contributions from nutrition, exercise physiology, endocrinology, psychology, family therapy, family medicine and behavioral and developmental pediatrics. It addresses the roles of exercise and food in promoting health, moderation in sedentary activities, and encourages children to set reasonable behavioral goals for themselves. *Just For Kids!* dietary recommendations are consistent with the U.S. Recommended Dietary Allowances, the National Cholesterol Education Project Guidelines, and the Food Pyramid.[32] Additional food behaviors targeted include eating regular meals and eating in response to hunger and satiety. It also addresses self-acceptance, processing emotions, assertiveness, and positive attitudes and efficacy. When delivered in an adult-led group format, the *Just for Kids!* curriculum has resulted in significant differences in physical fitness, flexibility, nutritional knowledge[6,7] and positive trends in cardiovascular fitness and body mass index[6,7] when used with elementary aged children. The curriculum uses four of the most commonly employed behavior modification methods for children, reinforcement, goal setting, self-monitoring, and planning ahead. The four goals of the *Just for Kids!* Curriculum are: (a) learn to eat more healthy foods; (b) learn to be more active, build muscle, and make your body strong; (c) feel better about yourself and like your body; and (d) learn how to speak up and talk about

your feelings. Suggested goals from which each child can choose each week include: (a) eating one fruit a day, (b) having a fruit instead of a cookie for an afternoon snack, (c) using the stairs instead of the elevator, (d) jumping rope for 5 minutes a day, and (e) dancing to music for 5 minutes a day.

Consistent with the focus of the *Just for Kids!* curriculum, the effectiveness of the health education curriculum will be measured using concepts from the Theory of Planned Behavior (TPB), Self Determination Theory (SDT), and Social Cognitive Theory (SCT). The following sections explain the specific concepts and measures. The effects of the delivery of the health curriculum are shown in Figure 1 and further described below. Participation in the curriculum will impact the child's attitudes, perceived autonomy support, and behavioral capacity toward eating healthfully and engaging in physical activity. In turn, the child's attitudes, perceived autonomy support and behavioral capacity influence self-efficacy for eating healthfully and engaging in physical activity. Attitudes have a reciprocal relationship with self-efficacy. Self-efficacy, behavioral capacity, and attitudes impact behavioral intention which in turn influences actual behavior. Actual behavior is then directly influenced by behavioral capacity and self-efficacy. Actual behavior will impact health status. The curriculum will be delivered either by a teen mentor to one or two assigned children (experimental group) or by an adult leader to a group of children (control group).

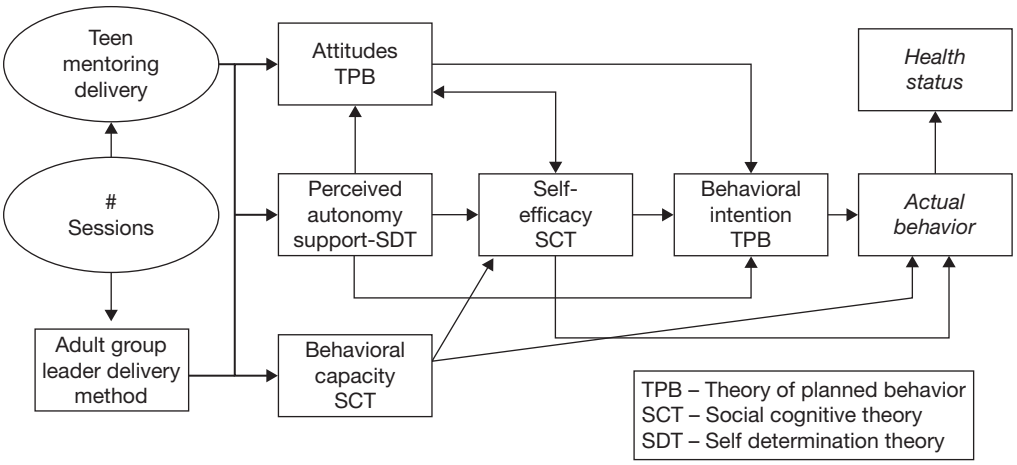

Figure 1. Effects of the Health Curriculum Delivery on the Mediators and Outcomes

B.2.1 Theory of Planned Behavior

According to the TPB,[33,34] the likelihood that a person will perform X behavior is explained largely by intention to perform and (actual and perceptual) control to perform X behavior. Intention is influenced by three factors: (a) Attitude, (b) Subjective Norm, and (c) Perceived Behavioral Control. Attitude is the valuation of the behavior, positive or negative, and is

the summation of beliefs about the behavior. Subjective norms are the perceived social pressures from significant others to perform or not perform the behavior; they are weighted by the strength of desire to comply or not comply with the wishes of these others. Perceived Behavioral Control (PBC) is the summation of beliefs the person has about being able to perform the behavior in various circumstances, especially the ability to overcome expected barriers. PBC is thought to influence behavior through Intention and also directly. TPB seeks to explain the immediate influences on behavior in the moment of decision. TPB has been tested in physical activity studies and accounted for a substantial percent of the variance in physical activity intentions and behavior.[33–35] Studies of dietary choices and amount of television viewing[36] were done with children. Subjective Norms [SN] has been the least reliably predictor for both intentions and behavior. For this intervention, mentors and adult group leaders are conceptualized as indirectly influencing Behavioral Intention through the mediating concept of Attitudes. The concepts of Attitudes and Behavior Intention will be measured; subjective norms and perceived behavioral control will not.

B.2.2 Self Determination Theory

SDT[37,38] is a higher-order theory, accounting for relatively stable, overarching, goal-related motives that generate the more immediate determinants of behavior accounted for by the TPB. SDT posits three basic human needs: competence, autonomy, and relatedness that enhance motivation and well-being when met and diminish them when thwarted. SDT differentiates between two kinds of interpersonal contexts: (a) autonomy supportive, in which significant others encourage choice and participation in decision-making, provide meaningful rationales, minimize pressure, and acknowledge feelings and perspectives, and (b) controlling, in which significant others do not explain why performance of a behavior is important, use pressuring language (e.g. should and must), and do not acknowledge difficulties in performing the behavior. Perceived Autonomy Support (PAS) has been found to have discriminant validity from Subjective Norms and a stronger relationship with attitudes.[39,40] Based on these findings, a measure of PAS will be added to measures of TPB components. For this intervention, Perceived Autonomy Support will be measured instead of Subjective Norms found in TPB and is conceptualized as directly influencing Self-Efficacy and Attitudes while being directly influenced by the intervention delivery method.

According to the SDT, providing autonomy support increases motivations to perform X behavior (making healthy dietary choices and engaging in regular physical activity). Expectations of authority figures such as teachers and significant others such as mentors have a stronger influence on physical activity intention in young people compared with adults.[41] A study of health behaviors in elementary aged students[42] found that children with encouragement from adults were 1.7 times more likely to perform the behaviors; children with encouragement from peers were 1.5 times more likely, and students who felt in control were 1.9 times more likely. Elementary age students are beginning to move away from parental and other adult influence, may be more receptive to messages from a source closer to their age.[1,4]

B.2.3 Social Cognitive Theory

Behavioral Capacity, the knowledge and skill to perform a given behavior, is a component of SCT.[43] Behavioral Capacity maintains that if a person is to perform a particular behavior such as eating healthfully, he or she must understand the ramifications of the behavior, for example, choosing healthy food alternatives.[43] Behavioral Capacity is the result of the individual's training, intellectual capacity and learning style.[43] For this study, nutritional knowledge, a component of Behavior Capacity, will be measured using a food choice questionnaire. Self-efficacy (S-E), the self-evaluation that one is competent and able to perform the given behavior, is the most important prerequisite for behavioral change[43] and is the primary predictor of intention to engage in healthy eating in 3rd and 4th grade students.[44] According to Ajzen,[33,34] PBC from the TPB is synonymous with self-efficacy. However, a study of physical activity intentions among 13 year olds[45] found that self-efficacy was a strong predictor of physical activity intention whereas PBC was not. This intervention used "tighter" definitions to distinguish PBC from S-E; PBC referred to control over difficult situations and barriers and S-E referred to internal evaluations of competence and ability to perform the behavior. The addition of S-E increased the percentage of variance in intentions accounted for, and S-E both attenuated the relationship of Attitude with Intention and reduced the effect of PBC on Intention to zero. For this study, participation in the curriculum delivery method is conceptualized indirectly influencing S-E through the concepts of Behavioral Capacity, PAS, and Attitudes. A reciprocal relationship exists between S-E and Attitudes.[33,34] S-E indirectly influences behavioral intention and actual behavior.[43] Self-efficacy will be measured using behavioral specific self-efficacy for eating healthfully and being physically active.

B.3 Mentoring

Youth mentoring programs for disadvantaged children increasingly are advocated as a means of redressing the decreased availability of adult support and guidance in the lives of youth.[46,47] Mentoring is a dyadic psychosocial intervention wherein a more experienced or knowledgeable individual is brought into a close relationship with a less knowledgeable person in order to provide support and guidance.[1,48] The presence of a "positive" mentor in the life of a young person supports healthy growth and development and serves as a protective buffer against many risks faced by today's children.[49] Mentors help children overcome personal and social barriers, expose them to new relationships and opportunities, and assist in developing decision making and problem solving skills that facilitate success in everyday life.[50] A growing number of evaluations suggest that mentoring relationships can positively influence behavior change and health outcomes including academic underachievement[51] and substance use/abuse.[52] The use of mentoring to address other health risks has not been adequately tested. Particularly puzzling is that the use of older teens to mentor younger children has not merited more attention in the scientific literature.

Teen or cross-age mentoring of younger children to reverse health risks is a sorely understudied approach to impacting the rising problem of childhood obesity in rural underserved populations. Most published studies were non-experimental, focused only on satisfaction levels as outcomes,[53,54] and did not distinguish between adult and teen mentors.[5,55] The few empirical studies of more recent vintage

suggest that teen mentoring is a promising approach. Karcher, et al[4] found that using teens as mentors was equally effective compared to adult mentors in promoting school connectedness in young children. Sheehan, et al.,[5] found a positive effect on mentee's classroom behavior and attitudes toward risk behaviors. Finally, Westerman[56] found that in a rural Appalachian area, teen mentors helped mentees achieve improved academic achievement and positive connectedness to parents and family.

Schools are an obvious setting for the implementation of mentoring.[4] *To broaden the range of processes and outcomes affected, many school based programs are beginning to infuse mentoring into their activities.[57] The inclusion of a mentoring component to curricula led to direct improvements for children in skill development, self-definition and sense of self-worth.[58]* Furthermore, school-based mentoring programs benefit not only the child and mentor but also the school by establishing social networks that integrate 'positive' mentors from the same community into the elementary school[49] thus enhancing connectedness to one's school and community. It has been suggested that school connectedness is the single most effective aspect of the school environment in predicting healthier behaviors and better health.[59] Based on what is known about successes of adult mentoring and promising results from earlier studies of teens as 'positive' mentors, it is worth exploring the use of 'positive' teen mentors to deliver health curricula to school-aged children.

B.3.1 Theoretical Basis for Mentoring Approach and Effectiveness

The framework that under-grids the effectiveness of the mentoring approach is social networking. Social networks are linkages between people that provide social support.[65] In this project, linkages are created through the mentor-mentee dyads. Social networking provides persons with emotional, informational and appraisal support that creates a sense of psychological safety (between the mentor and mentee) resulting in more positive attitudes toward changing behavior.[65] Learning (behavioral capacity), self-efficacy and behavior change is facilitated when people have a sense of psychological safety or the perception that attempts to change behavior can occur without fear or embarrassment.[66] Consequently, social networking facilitates psychological safety and subsequently learning. The mentoring approach's advantage over traditional adult-mediated classroom settings is the enhanced learning and support for behavioral change that results from the perceived social support and psychological safety that is promoted by teen mentoring.

Research has suggested that by providing supportive contexts, older siblings regularly serve as natural mentors and make considerable contributions to their younger siblings' social and cognitive development.[67] By modeling empathy and perspective taking, older siblings provide younger siblings opportunities to develop their own empathetic and perspective-taking skills.[3] Peers also are primary socializers for younger children. According to Harris,[68] older peers also are enormously powerful influencing agents. Harris[68] argues that compared to older peers, adults have less influence on younger children because from the child's point of view, the goal of development is "wanting to be like the bigger kid". . . It is the child's equating of maturity with status that makes younger children want to behave like older peers (pg. 267).

C. PRELIMINARY WORK AND STUDIES

The PI met with stakeholders in the target county including health professionals, educators and business leaders who expressed concern about the childhood obesity problem. All stakeholders agreed that children are not getting enough physical activity or education about healthy eating in school and children generally have unhealthy diets. Business leaders stressed community involvement and "buy-in" as further support for the project. Through the county After School Network (a coalition of health, business and school partners) successful after school programs have targeted academic outcomes and have recruited academically at risk youth. Adult mentoring and role modeling have been key components of the success of the programs. The proposed project will test an analogous approach using teen mentors to positively influence health behaviors, especially nutrition and physical activity of youth and comparing the teen mentoring approach to the adult-mediated classroom approach. Business leaders offered the use of community facilities and have offered support for transportation of the children and the mentors, if needed.

C.1 Preliminary Study

A preliminary study was completed to determine if teen mentors could deliver the health curriculum to a group of 3rd and 4th grade children. This preliminary project involved 13 high school aged trained mentors who provided autonomy support to twenty-five 3rd and 4th graders assigned to the intervention group. The attention-control group (N = 27) received structured after school activities such as safety education, tutoring, crafts and art that was delivered by high school teens employed by the after school program. Based on CDC guidelines, at the start of the preliminary study, nearly 20% of the participating children were classified as "overweight" and over 40% of the participating children were classified as "obese." Eighty-five percent of eligible children participated and the retention rate at the end of 8 weeks for the 3rd and 4th graders was 81%. Reasons given for leaving the program include transportation difficulties and moving from the catchment area of the target school. No children or their parents voiced dissatisfaction with either the program or assigned mentors as a reason for leaving the program. Students who completed the eight-week program attended 87% (6.4) of the sessions.

Findings from the preliminary study indicate: (a) access to teens and children is achievable; (b) most children and teens are able to complete the 8 week intervention; and (c) the mentoring relationship was an acceptable approach for both the elementary aged children and the teens. These results suggest that using teens as mentors is a feasible approach. Paired mentors/mentees reported that the mentoring relationship had a positive influence on them and the approach used was deemed "positive." Mentees reported that in addition to helping them make better choices about eating and physical activity, the mentoring process helped them with academic achievement and making better behavioral choices in other areas both at school and at home. In sum, both mentors and mentees reported general satisfaction with their mentor/mentee pair, and were positive about the sharing that occurred during the mentoring period. Anecdotal

data about other benefits to teens were increased awareness of their own eating and activity behaviors; most teens tried to eat healthier and increase their daily physical activity level.

A second purpose of this preliminary study was to estimate the **effect size for the proposed pilot study.** Analysis from the preliminary study revealed significant differences between the intervention and attention-control group (after 8 weeks). Further, pre-test and post-test analysis showed that, compared to the attention-control group, the intervention group had significant increases in several outcome measures (see Table 1 below). The data used to calculate effect size are presented in Table 2.

Table 1. Significant Findings from the Preliminary Study

Between Groups: Measures/Outcomes (pretest to post-test)	**t (df)**	**p value**
Nutritional Knowledge	2.913 (49)	.005
Positive Attitudes: Physical Activity	5.365 (48)	.000
Intention to Eat Healthfully	1.996 (48)	.05
Family Members Listen to How I Like to Eat (Perceived Autonomy Support)	2.322 (49)	.02
Within Group: Significant Increases in Measures/Outcomes within Intervention Group (at post-test)		
Positive Attitudes: Eating Healthfully	1.996 (23)	.05
Self-Efficacy: Physical Activity	2.090 (21)	.04
Intention to Eat Healthfully	2.115 (23)	.04

Mentors were perceived as offering more autonomy support than family members as indicated by: (a) listening (more) about how the child would like to be physically active; (b) listening (more) about how the child would like to eat; and (c) encouraging the child to be physically active.

Table 2. Perceived Support Comparing Family Support to Mentor Support within the Intervention Group

Perceived Support from Mentors compared to Perceived Support from Family	**t (df)**	**p value**
Mentors Listen to How I would like to be Physically Active	2.040 (24)	.05
Mentors Listen to How I would like to Eat	1.996 (24)	.05
Mentors Encourage Me to be Physically Active	2.809 (24)	.02
Mentors Encourage Me to Eat Healthfully	1.004 (24)	Ns

In the preliminary study, the control group did not receive the *Just for Kids!* curriculum. In the proposed R21 pilot study, both groups will receive the curriculum, but the nature of the delivery process will differ. The experimental group will be paired one on one with a teen mentor, while

the control group will receive the curriculum in a classroom group setting taught by an adult (usual format). *Hence, the proposed study will test our hypothesis that having teen mentors provide the content will increase motivation of children to perform the target eating and exercise behaviors. We will also test the dose effect response of the number of sessions attended on the outcome variables and examine if the intervention influences short-term health outcomes.* Due to concerns over survey burden, the proposed study also will allow the PI to determine if all of the measured concepts need to be included in the larger R-01 study.

If our hypothesis supported, we plan a larger R01 study to unbundle the adult vs. teen, and classroom vs. mentoring components of the intervention to determine the most effective way to deliver this content to school aged children in Appalachia. The future R-01 study will also examine the contribution of family or parent support on healthful eating and physical activity of children in the targeted elementary grades as well as provide longer-term follow-up to determine whether the curriculum resulted in actual health behavior changes and whether these changes resulted in measurable differences in BMI and blood pressure in the children.

C.2 Principal Investigator Qualifications and Lessons Learned

The PI has conducted (a) a study of adolescent male sexuality and sexual behaviors using two waves of longitudinal data from Add Health, a nationally representative database[64]; (b) a cross-sectional study of 60 6th grade minority students that focused on their perceived internal assets, external assets and the relationship(s) between perceived assets and engagement in risk behaviors, health behaviors and thriving indicators[65]; and (c) a cross-sectional study of 90 teens using in home interviewing techniques that focused on risky sexual activity and correlates such as depression, delinquency acts, and family functioning.[66] The PI also served as a health consultant to local school districts in Michigan including projects that focused on environmental strategies to improve physical activity and nutrition in school settings. She do-authored an article that focused on the health risks of typical school lunch programs that described the state of the science and current trends in food options at schools, nutrition education at schools, food preferences of children, food marketing in schools, and health implications and challenges for future research as legislation.[67]

The PI and co-investigators of this proposed pilot study recently conducted a study that focused on the differences in health care access, utilization and health status of Ohio's Appalachian and rural dwelling children using the 2008 Ohio Family Health Survey [OFHS]. Health status included a measure for BMI and general health. A Bayesian hierarchical modeling strategy was used to model the complex relationships between the factors and to account for unequal sample probabilities of the individual respondents. This study better defined the health status of Appalachian children to be addressed in part by the proposed study. Serving as PI on the preliminary study described above, (funded by the OSU College of Nursing), refined my knowledge of training and support needs of teen mentors, informed me of the time needed to complete the weekly intervention, and the preferences and barriers of the children who completed the intervention.

D. RESEARCH DESIGN AND METHODS

D.1 Methods

The proposed study is a randomized controlled trial that will compare the effects of two curriculum delivery methods and assess the mediating effects of the number of sessions attended on the outcome measures. The control group will receive the *Just for Kids!* curriculum via an adult leader in a classroom (usual format) and the experimental group will receive the curriculum via individual teen mentoring. Both groups will meet during the same day of the week in an after school program but in separate areas of the school building. Each participating elementary school will host the program on a different day of the week. The teens will be assigned a child to meet with in a large room (such as a gymnasium) where other mentor-mentee dyads are present. *To minimize distractions, mentor-mentee dyads will not join with any other dyads (such as forming groups of 4) during curricular delivery rather the mentoring will maintain 1:1 ratios. The mentoring dyads will be distanced from other dyads as much as feasible during curricular delivery portion of the sessions. The PD will monitor the room for excessive loudness and instruct mentors to keep conversational voices if needed. Other outside distractions will be monitored by the PD and controlled as much as possible via limiting access to the room during the sessions and closing access doors to the room.*

During the mentoring session, a research assistant will be present to monitor all teen/child interactions. All teen/child pairs will remain fully visible to the research assistant. It is projected that with 3 participating elementary schools, approximately 8–10 mentors will meet with assigned students during each after school session. Each adult group leader will meet with approximately 15–17 assigned children in a traditional classroom setting. The Project Director and PI will perform supervisory checks on the sessions of both the teen mentoring and adult led groups. *We note that the control and experimental groups differ on two factors: adult/teen and classroom/mentoring. Although the individual contributions of these factors cannot be separated, this pilot study will allow us to compare the effects of the novel delivery approach (teen mentors) with the usual format and determine the suitability of outcome measures. To control for seasonal effects, the curriculum will be delivered during the same months (March–May) for both year one and year two. See D11: Two Year Timeline for Project Activities.*

D.2 Sample

Recruitment for child and teen participants will occur during the school year (February 2010). A total of 116 elementary aged and 29 high school aged children will be recruited for the study. *During year one of the study, all eligible 3rd and 4th graders will be recruited. Because of exposure bias concerns, during year 2 of the study, only 3rd graders and 4th graders who are new to the elementary schools or after school programming will be recruited.* Teen mentors will be recruited for interest both in working with elementary school children and in striving to cultivate their own health-supportive behaviors. Tenth and 11th graders attending the target high school at the start of the study will be eligible to participate as mentors as long they are not expected to move from the participating school before the conclusion of the study; can speak English and earn

predominantly As and Bs in most classes. *Teen mentors with a body mass index (for age and gender) that exceeds the 85th percentile at the start of the study will be excluded. This cut point excludes teens classified as overweight and obese.* Adult group leaders will be recruited through the After School Network. If more than five adults apply to become adult leaders, leaders will be selected based on: (a) recommendation(s) of the After School Network and/or host school, and (b) needs of the study such as matching gender with available child participants. Recruitment procedures, inclusion and exclusion criteria for the child participants, teen mentors and adult group leaders are discussed in Section F.1.1.

D.2.1 Random Assignment

Using BMI z-score as a stratifying variable, all participating elementary children will be randomly assigned to either the control or intervention group using SPSSv17.0. Children will be assigned an identification number once all consent forms and assent forms are returned. At the end of the recruitment period, the identification numbers will be entered into SPSS along with grade, gender, school, and an indicator of whether the child can be classified as "high BMI z-score" (greater than zero) or "low BMI score" (below zero). The sample will then be equally split using the stratified randomization procedures of SPSS controlling for grade, gender, school, and BMI z-score classification. The cases "selected" by SPSS will be placed in the intervention group and the remaining cases will be assigned to the control group. *The random assignment of subjects to the two groups within each stratum will control for cofounders such as parental influence on behavior.*

D.2.2 Sample Size

The primary focus of this study is on the difference in the size of the intervention effect between the control group and experimental group. Separate power calculations were performed for all of the outcomes of the study. In each case, the model was assumed to be a multilevel linear model with fixed effects for time period, group, and their interaction and random effects for mentor and students nested within mentor. No covariates were incorporated into the power analysis, although covariates will be included in the data analysis for this study. Furthermore, since the preliminary data were from a single school, no between-school variation was incorporated into the power analysis. For each of the dependent variables of interest, past data were used to determine the standard deviation for error, the mentor-to-mentor variation, and the student-to-student variation. Using these estimates, the effect that would be able to be detected with 40 subjects in each group at 80% power was determined. In this case, the effect is the difference between the efficacy of the intervention in the experimental group and the efficacy of the program in the control group. These analyses are summarized in Table 3. The power calculations were performed using a Monte Carlo approach.[68] In this approach data are randomly generated many times (1,000 in our case) from the hypothesized multi level model using the variance estimates from the historical data. The multilevel model is then fitted to each simulated dataset and the effect of interest is checked for significance. The fraction of simulated datasets in which the effect is found significant is an estimate of the power to detect the effect (i.e., the probability of detecting a difference between the experimental and control groups when such a difference truly exists). This process was repeated for several potential effect sizes until the effect size with 80% power for detection (alpha = 0.05, one-sided test) was found. Using this methodology, the effect with

40 subjects in each group at 80% power was detected. To account for the inclusion of the moderating impact of the number of sessions attended and the stratification variables, we anticipate requiring 4–5 subjects in addition to the number(s) given in the table. To account for a 20% attrition rate, we will recruit 29 teen mentors and 100 3rd/4th grade participants. Half of the child participants (n=50) will be assigned to the experimental group and half (n=50) will be assigned to the control group. Given the size of the student population, this would account for a 23% participation rate for the teens and a 55% participation rate for the 3rd/4th graders.

Table 3. Power Analysis Calculations

Corresponding Hypothesis	Variable	Estimates from Historical Data			Effect detectable with 80% power
		Error SD	Mentor SD	Subject SD	
Hypothesis 1	Intention: HE	2.99	4.64×10^{-6}	4.15×10^{-4}	2.4
	Intention: PA	1.91	1.012	1.58×10^{-4}	1.7
	HE behavior*	2.99	4.64×10^{-6}	4.15×10^{-4}	2.4
	PA behavior*	1.91	1.012	1.58×10^{-4}	1.7
Hypothesis 2	BMI	0.980	1.415×10^{-3}	5.963	3.5
	Blood Pressure: Systolic†	Estimated change: 4% Estimated SD of change: 1.25%			0.60
	Blood Pressure: Diastolic†	Estimated change: 3% Estimated SD of change: 1.00%			0.48
Hypothesis 3	Knowledge	2.062	2.300×10^{-4}	0.724	1.7
	Attitude: HE	5.051	2.647	1.494×10^{-3}	4.3
	Attitude: PA	3.959	3.798	7.107×10^{-4}	3.8
	Perceived Autonomy Support: HE	1.720	3.816×10^{-4}	0.619	1.4
	Perceived Autonomy Support: PA	1.870	0.654	0.765	1.6
	Self-efficacy: HE	2.641	2.002×10^{-4}	1.590	2.3
	Self-efficacy: PA	1.492	1.869	1.735×10^{-4}	1.6

*Error estimates were not available from the previous study and so were estimated from the analogous intention variables.

†Error estimates were not available from the previous study and so were estimated from experience.

D.3 Data Collection

A research assistant, blinded to group assignment, will collect quantitative data in a designated private room at each participating elementary school at all data collection time points (T1 and T2). The research assistant will read questions aloud to compensate for any reading difficulties among children and will be available to answer any questions. Two adaptations will be made in light of the young age of the children. First, children's data will be collected on over two days for each

time point to minimize response burden. At each collection time point, half will respond first to physical activity questions and the other half will respond first to dietary questions. Secondly, the TPB scales will use a.5-point response format rather than the usual 7-point format, which is more cognitively complex. Height, weight, and blood pressures will be collected at the time when the dietary questions are answered. The height, weight, and blood pressure measures will be collected from each child privately. Body Mass Index for Age and Gender will calculated via computer using the CDC guidelines. *Table 4 depicts the data collection plan and process at each time point.*

Table 4. Data Procedures and Process

Time	Process	Research Team Member Responsible	Person Providing Data
Consent	My Child's Personal Questionnaire	RA or PD	Parent of Child
End of Recruitment	1. Assignment of identification numbers ⇩ 2. Randomization of child participants stratifying by BMI z-score, grade and gender	PI PI	
End of Recruitment	Teen height and weights to calculate BMI (for age and gender)	RA (blinded to group)	Teens with Consent and Assent to be a Mentor
Baseline (T1)	Dietary Questionnaire‡ Blood Pressure, height and weight# Physical Activity Questionnaire‡	RA (blinded to group) RA (blinded to group)	Child
T1: Follow Up	Blood Pressure Follow up Letter to Parent	PD	
Weekly	Debriefing Sessions: observations and notations: adults and mentors Measures of Fidelity (adults and mentors) Data Interim Reports.	PD PD PD	PD PD
Monthly	Measures of Fidelity (adults and mentors)	PI	PI
Post-Intervention (T2)	Dietary Questionnaire‡ Blood Pressure, height and weight# Physical Activity Questionnaire‡	RA (blinded to group) RA (blinded to group)	Child
T2: Follow Up	Blood Pressure Follow up Letter to Parent	PD	

RA = Research Assistant; PD = Project Director; PI — Principal Investigator

‡ = ½ will complete dietary questionnaires and ½ will complete physical activity questionnaires during Day 1. The process will be repeated for Day 2 with participants completing the other set of questions.

when completing the dietary questionnaire: height, weight and blood pressure will be measured at that data collection session.

Questionnaires and data forms will be kept in a locked cabinet in the PI's office. Immediately after the completion of the pre-intervention questionnaire (T1), the PI will assign each participant an identification number. Any demographic information or identifiable data will be immediately removed from the questionnaire, transported and stored separately from the

questionnaire. For subsequent data collection (T2), the identification number will be used instead of any identifiable information. *See Section F.1.2.4 of the Data and Safety Monitoring Plan for more details.*

D.4 Health Education Curriculum

For this study, the curriculum developer[3] was consulted and the curriculum was adapted to allow for one-on-one delivery over an 8-week period using teens to deliver the content and to be delivered in an after school setting. To ensure program and study integrity, teen mentors and adult group leaders will meet weekly (in separate sessions) with the PD for debriefing. During these 30 minute debriefing sessions, the PD will assess consistency of messages delivered; reinforce follow up messages to be delivered; provide prompts and review for the following week; and troubleshoot any concerns. The PD will supervise teen and child interactions as well as adult and child interactions during the weekly curricular sessions. *The PD will complete a "Measures of Fidelity" form (Appendix A) for each observation.* The PD will terminate any sessions or interactions not complying with mentoring/adult leader duties, such as failure to follow curriculum, child objections to interactions, or parent objections to interactions. The PD will immediately contact the child's parent, after-school network program leader and Pl should a termination occur. The PI will contact parent and ask to interview the child about the terminated session: The child may have another adult present during the interview, if desired. The PI also will interview the teen mentor or adult group leader regarding the terminated session. Based on the outcome of the interviews, the PI may reassign the child to another mentor/leader or have PD be directly present at all future sessions between the mentor/leader and assigned child; the data for this child will be excluded from the analysis. The PI will meet every other week with the PD to debrief and assure compliance with these procedures.

To further assess program fidelity, the PI will "drop in" to observe both mentor-led and adult group led sessions at least once each month. *During these "drop ins" the PI will complete a "Measure of Fidelity" form (Appendix A).* The control group will receive the same structured curriculum as originally designed, i.e., in a group setting conducted by a trained adult group leader. The adult group leader will be an adult who meets the criteria to work with children in the State of Ohio, will be approved by the school system, and will have worked previously in after school programming. The adult group leaders will be members of the cultural community. Recruitment, inclusion criteria and exclusion criteria for teen mentors and adult group leaders is further discussed in Section F.1.1.

To maintain curricular integrity, each teen mentor and adult group leader will be trained in the delivery of the curriculum and be provided with an Instructor's Guide that contains: (a) overview and purpose of the program, (b) weekly lesson plans, (c) cues and prompts to deliver the content, (d) structured activities, (e) needed materials for the weekly activities, (f) content summaries to end each session, and (g) copies of all forms and handouts. The use of the Instructor's Guide serves as a reference or reminder to the adult leaders and teen mentors about the message(s) to be delivered and support to be provided to the participants. Curricular consistency is insured through the structured training of the mentors and adult group leaders. Curricular training will include

training video courses provided by *Just for Kids!* lasting approximately 2 hours. At the time of training, study manuals, study materials and the Instructor's Guides will be provided to mentors and adult group leaders. The study manuals contain: (a) outline of weekly objectives, (b) copies of all forms, handouts and worksheets, (c) contact information for study personnel, (d) locations of sessions, and (e) lists of supplies and/or equipment needed as well as location of needed materials. Finally, curricular workbooks will be provided to each child participant that contain manipulation checks (homework), worksheets, themed stories, and take home (family) activities. *The PD will review the weekly "Measures of Fidelity" data and report to PI any curricular non-compliance. The PI will conduct curricular retraining to a mentor or adult leader if more than one instance of curricular non-compliance is observed for that individual. All instances of curricular non-compliance and redirection will be discussed with all mentors and adults during the weekly debriefing sessions*. A Table of Content that is linked with the theoretical concepts, manipulation checks and family activities follows.

Table 5. Schedule of Topics and Activities over 8 Weeks

Week	Content Focus & Theoretical Concepts (TC)	Methods/Materials
1	Welcome, Goals, Ground Rules and Expectations	"One thing I do for fun" — getting to know each other Scoreboard (weekly log) Read Story Closing Circle "Human Pretzel"
	TC: Behavioral Capacity	Scoreboard & Fit Kid Chart: Set Goals (manipulation check) "My Turn" worksheets & Scoreboard (manipulation checks) Take Home (receipt): Parent & Child "Family Nutrition Review"
2	Taking Care of your Body and Keeping it Healthy	Toss & Talk – "Things that keep your body from being healthy" Sharing Homework Body Drawings Read Story
	TC: Attitudes, Self-Efficacy	"My Turn" worksheets & Scoreboard (manipulation checks) Take home (receipt): fruit recipes, "Family Activity Review"
3	Talk about Food Groups & Food Pyramid	Toss & Talk – "Call out favorite fruit or vegetable" Role Plays – making healthy food choices Categorize foods using Table Tents
	TC: Behavioral Capacity, Attitudes, Self-Efficacy, Intention	Food Bingo Make a Healthy Lunch with lunch bags "My Turn" worksheets & Scoreboard (manipulation checks) Take home (receipt): "Be a Fat Finder" Activity
4	Importance of Exercise	Toss & Talk – pantomime favorite activity or exercise Read Story Draw self being active
	TC: Behavioral Capacity, Attitudes, Self-Efficacy, Perceived Support, Intention	Teach an exercise or dance "My Turn worksheets & Scoreboard (manipulation checks) Take home (receipt): "Walking Trips for the Family"
5	Feelings: Emotional Eating	Sharing from My Food Record Door & Key Activity Writing Friendship Letters
	TC: Attitudes, Self-Efficacy, Perceived Support	Acting Out Feelings Warm up Exercises to music "My Turn" Worksheets & Scoreboard (manipulation checks) Take home (receipt): "Family Minute Vacations"

(continued)

Table 5. ***(continued)***

Week	Content Focus & Theoretical Concepts (TC)	Methods/Materials
6	My Cravings: Why I Eat When I Am Not Hungry TC: Behavioral Capacity, Attitudes, Self-Efficacy	Share from My Dinner Log Eating Cue Activity My Craving Activity Read Story Warm Up Exercises "My Turn" Worksheets & Scoreboard (manipulation checks) Take home (receipt): "Family TV and Commercials Activity"
7	Making Each Day Healthy and Active TC: Self-Efficacy, Perceived Support, Intention	Read Story Activity Rainbow Activity List of Active Chores Special Occasion Role Plays Active Chores Scenarios "My Turn" Worksheets & Scoreboard (manipulation checks) Take home (receipt): "Making Family Activities Physical"
8	Farewell & Celebration	Toss & Talk-"What I have learned" Mystery Food Game 2 Changes 1 Can Make Program Award Certificates

D.5 Mentoring by High School Students

Children randomly assigned to the teen mentor intervention group will be matched according to gender with a high school student trained by the PI. The PD will attend all training sessions. Training will be conducted over a two-day period. Training for the teen mentors will follow the developmental mentoring program provided to the PI by the Developmental Mentoring Research Team at the University of Texas but adapted for use with this project.[69] The training manual is provided in the Appendices. Training will stress providing autonomy support and use both didactic and experiential methods, such as role-play. Components of the mentor training include: mentoring responsibilities; sharing points of view; working with different points of view; role playing, and motivating your mentee. The PI will continuously reinforce employing autonomy-supportive methods and messages. In addition, teens will be trained on the health curriculum and its delivery during the training session. At the weekly meeting led by the PD, all mentors will be debriefed, asked to discuss experiences, provided with an opportunity to ask questions, and problem solve any concerns or issues. The PI will attend at least one debriefing session per month.

The mentor/mentee dyads/triads will spend the first 50 minutes of the face-to-face meetings held at the school during the after school program, interacting around the structured program activities. Additional time will be spent interacting together as part of the structured after school physical activity sessions or for free time for a total of one hour of face-to-face contact. At the conclusion of the intervention session, the child participants will be released to their parents as is standard protocol for the After School Network Program.

D.6 Group Sessions by Adult Group Leaders

Children randomly assigned to the adult group leader (control) group will attend 8-weekly sessions in a classroom setting located away from the mentor/mentees during the after school program. It is expected that in a group setting, the completion of curricular activities will take a longer time. Consequently, each session will last 60 minutes. At the conclusion of the session, the children will be released to their parents. The PI will train the adult group leaders on study protocols and the health curriculum. The PD will attend the training sessions. Training will occur over a two-day period. The PI will continuously reinforce employing autonomy-supportive methods and messages. At the weekly meeting led by the PD, all adult leaders will be debriefed, asked to discuss experiences, provided with an opportunity to ask questions, and problem solve any concerns or issues. The PI will attend at least one debriefing session per month.

D.7 Measurements

All measurement tools are included in Appendix A. Scales using TPB components follow the guidelines for developing a TPB questionnaire given in Ajzen and Fishbein.[33] Scales are comprised of items adapted from published studies showing acceptable psychometrics ranging from α of .65–.95 and validity when used with children.[39,43,45,70–78] See Table 6 below. All items referring to future activity will be qualified as pertaining to the "next week" except as otherwise noted. All measures will be collected at T1 and T2. In the preliminary study, participants completed all survey measures in approximately 20 minutes. Height and weight measurements were completed in approximately 3 minutes per child. It is expected that the study participants should complete all study measures in approximately 25 minutes. Table 6 depicting the study measures' reliability and validity when used with children follows.

Table 6. Measures and Psychometrics

Hypotheses	Measures	Reliability Cronbach's α	Validity
Hypothesis 1			
Behavioral Intention	Intention to Eat Healthfully Intention to be Physically Active	.87–.95 .72–.94	Predictive Predictive
Current Eating Behavior	Healthy Eating Behavior	.65–.75	Predictive
Current Physical Activity	Healthy Physical Activity	Test-retest r = .75	Predictive
Hypothesis 2			
Health Status	BMI Percentile for Age and Gender	NA	
	Blood Pressure	Intra-rater	

(continued)

Table 6. ***(continued)***

Hypotheses	Measures	Reliability Cronbach's α	Validity
Hypothesis 3			
Behavioral Capacity	Nutrition Awareness & Knowledge	NA	
Attitude(s)	Attitudes Toward Eating Healthfully	.83–.84	Predictive
	Attitudes Toward Physical Activity	.83–.90	Predictive
Perceived Autonomy Support	Perceived Autonomy Support for Eating Healthfully	.81	Predictive Discriminant
	Perceived Autonomy Support for Being Physically Active	.81	Predictive Discriminant
Self-Efficacy	Self-Efficacy for Eating Healthfully	.81	Predictive
	Self-Efficacy for Being Physically Active	.81	Predictive

D.8 Variables Measured in Children

D.8.1 Demographics

Demographic data will be collected for both the child participants and the teen mentors. Parents will be asked to complete a demographic profile for their child during the consent/assent process. Data collected will include: age, date of birth, gender, race or ethnicity, grade in school, and name of school. The number of sessions attended will be recorded for all child participants in both groups.

D.8.2 Health Status

Body Mass Index [BMI] for Age: Normal weight status is defined as having a BMI percentile for age and gender between the 25th and the 85th percentile for age and gender.[11] Overweight status is defined as having a BMI percentile for age and gender between the 85th and 95th percentile.[11] Obese is defined as having a BMI percentile for age and gender above the 95th percentile.[11] BMI for age will be measured by obtaining a height and weight for each child and possible teen mentor. BMI measurement calculations are further described in Appendix A.

Systolic and Diastolic Blood Pressure: Blood pressure readings will be obtained after a 15 minute resting period.[24] The diastolic blood pressure will be obtained through standard protocol. It is the fourth Korotkoff (phase V) sound for children younger than 12 years of age. Participants will be seated with feet resting flat on a surface and the right arm resting at heart level. The appropriate cuff will be selected from five cuff sizes and placed around the upper arm. Using a standard mercury sphygmomanometer four blood pressures will be obtained by rapidly inflating to the maximum inflation level and deflating at a rate of 2 mm HG per second, with 30 to 60 seconds between blood pressure determinations. All study participants will have their systolic blood pressure measured twice.

D.8.3 Behavioral Outcomes

Current Eating Behavior: "Free" and "light" foods will be defined then children will respond to the prompt: "In the past week I. . . ." (a) ate at least one fruit a day; (b) ate free or light foods at lunch each day; (c) ate only free or light foods at dinner each day; (d) ate only free or light foods 5 or more days a week; and (e) ate breakfast each day.

Current Physical Activity Behavior: Children will respond to the prompt: "In the past week, I did an activity on my own time, in addition to what I did in school that. . ." (a) made my heart beat faster; (b) made me out of breathe; and (c) made me sweat.

D.8.4 Mediators

Nutrition Awareness and Knowledge: 15-item food choice questionnaire developed for pre- and post-test use with the *Just for Kids* program. Respondents are asked to circle the healthier food of two choices, e.g. baked potato or French fries. Correct responses will be summed for a total correct score.

Attitude Toward Eating Healthfully: Children will respond to the prompt "I think for me, eating healthfully in the next week would be. . ." with six semantically differential items ("bad/good, "fun/boring"), scored from one to five. Children's attitudes toward eating have been found to have predictive validity regarding intentions.[75]

Attitude Toward Being Physically Active: Children will respond to the prompt "I think for me, being physically active in the next week would be. . ." with six semantically differential items ("bad/good, "fun/boring"), scored from 1 to 5. Half of the responses will present the positive descriptor first, and the other half will present the negative descriptor first.

Perceived Autonomy Support for Eating Healthfully: Six items, two sets of three items taken from the scale used by Chatzisarantis, et al.[39] for the global behavior of eating healthfully, rather than the 4 target behaviors individually. One set of three items will ask children to rate autonomy support elements from "People important to me," which will be administered to all children. Children with teen mentors will also rate autonomy support from their mentor.

Perceived Autonomy Support for Being Physically Active: Six items, two sets of three items taken from the scale used by Chatzisarantis, et al.[39] for the behavior of being physically active, as defined previously. One set of three items will ask children to rate autonomy support elements from "People important to me," which will be administered to all children. Children with teen mentors will also rate autonomy support from their mentor ("_____ listens to how I would like to be physically active."). Predictive and discriminant validity of the concept in exercise over 4 weeks has been found in previous studies.[79,80]

Self-Efficacy for Eating Healthfully: Eight items, two for each of the four targeted eating behaviors ("I feel I will be good at. . .") These items are designed to specifically assess internal evaluations of competence rather than control over environmental obstacles or ability to

perform the behavior despite barriers (the definition of PBC). A growing body of research[39,49,75] suggests that self-efficacy, thus defined, has a stronger relationship than does PBC with intentions. Behavioral specific self-efficacy has been found to predict intention to eat healthy and actual eating behaviors.[73,81]

Self-Efficacy for Being Physically Active: Two items for the target behavior of being physically active, as defined earlier ("I feel I will be good at. . ." and "I'm sure I am able to. . ."). Predictive validity has been found for behavioral self-efficacy and intention to be physically activity as well as actual activity levels.[82]

Intention to Eat Healthfully: 12 items ("I plan to. . .), three for each of the four target diet behaviors of (a) eating at least one fruit daily, (b) eating healthy foods at lunch, (c) eating healthy foods at dinner, and (d) eating breakfast. The term "free or light foods" will be used in place of the term "healthy foods." A brief definition of "free, light, and heavy" foods will be provided at the top of the measurement tool. In studies with children, intention to eat healthy has been found to be predictive of eating behavior.[76]

Intention to Be Physically Active: Three items (e.g. "I plan to. . .") for the target behavior of being physically active, defined as doing something on your own time, outside of what you have to do in school, that makes your heart beat faster or makes you out of breath, for at least 20 minutes each day.[83] Predictive validity has been found regarding intention of children to engage in physical activity and engagement in healthy activity.[70,77,82–85]

D.9 Data Management

Data from the questionnaires will be coded by the PD before being entered into a database. No identifying information will be kept or recorded. Only participants first and last initials will be recorded when needed. Items will be coded so that higher values indicate a higher degree of the attribute. Multiple item scales assess most of the variables in the study. The internal consistency reliability of these scales will be assessed. Items that lower the overall reliability of the scales will be dropped. Scales with alpha of .70 will be considered acceptable for use. Data will be analyzed using SPSSv17.0. *See Data and Safety Monitoring Plan — Plans for Assuring Data Accuracy and Protocol Compliance (F.1.2.4) for additional data management details.*

D.10 Statistical Analysis and Issues

To reveal the basic structure of the findings and for data editing purposes, all study variables will be analyzed using measures of central tendency (means, medians), frequency distributions, and standard deviations. For each scale measure, items will be summed to generate a total score.

Hypotheses 1a-1d*: To address hypotheses 1a-1d, the data collected at the Pre-Test and Post-Test time points will be analyzed using multilevel linear models. Each of the four outcome measures will be modeled separately. As an example, consider the "intention to eat healthfully" outcome. This score will be the*

dependent variable, and independent variables will include treatment group (between subjects), time period (within subjects), school ID (random effect), mentor/adult group leader ID (random effect partially nested within school), and child ID (random effect nested within mentor/adult group leader). Grade, gender, and baseline BMI z-score will also be included as covariates to account for the stratification in the experimental design. The treatment group and time period variables will be interacted, and the significance tests of the coefficients associated with this interaction will directly address hypotheses 1a-1d. In addition, the mentor/adult ID random effect will be interacted with time period to account for different improvement effects between mentors. Given the interest in improvement from the pretest to the post-test, one-sided t-tests on the intervention effect will be conducted.

Hypotheses 2a and 2b: *For these hypotheses, multilevel linear models similar to those for hypothesis 1 will be constructed. For these models, covariates (grade, gender, and baseline BMI z-score) will again be included, although baseline BMI score will not be a covariate in the model for BMI.*

Hypotheses 3a–3g: *Multilevel linear models similar to those for hypothesis 1 will be constructed. These models will include the three covariates, and the interaction of treatment group and time period will allow for direct testing of the hypotheses of interest.*

Hypothesis 4: *Multilevel linear models will be built and testing will be performed in similarly to what will be done for the other three hypotheses. The multilevel linear models built for hypotheses 1–3 will be augmented with an additional independent variable, the number of sessions attended by the child. This variable will be entered as a moderating covariate, so it will be interacted with treatment group, time period, and their interaction. The significance of the coefficients associated with these interactions will allow us to directly test hypothesis 4. The effects of treatment group, random school effects, random effects of mentors/adult group leaders, and necessary interactions will be included in the models as was done in the models for hypotheses 1–3.*

D.11 Two-Year Timeline for Project Activities

4/2010–3/2012	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
Prepare Protocol and Materials	X	X	X										X	X	X									
Hire Research Assistant (RA) and Project Director (PD)				X	X																			
Finalize protocol and materials					X	X										X	X							
Orient and train PD and RA to protocol						X											X							
Hire Adult Group Leaders					X																			
Enroll teen participants						X												X						

(continued)

D.11 ***(continued)***

4/2010–3/2012	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
Enroll child participants—random group assignment						X												X						
Training of mentors and group leaders						X												X						
Pre-Test T1 Measures							X												X					
Conduct Intervention							X	X	X										X	X	X			
Post-Test T2 Measures									X												X			
Data Entry and Analysis							X	X	X	X	X	X									X	X		
Dissemination of Findings and Prepare Manuscripts																						X	X	X
Prepare and Submit Final Report																						X	X	X

D.12 Limitations

The proposed study has several limitations. First of all, even though healthy eating and increased physical activity will be promoted and encouraged, children may not engage in healthy eating or physical activity outside of the structured program. Second, for this pilot work, the intervention was adapted and restructured into an 8-week program, a length of time that may not result in a long-term behavioral intention to engage in increased physical activity or to eat healthfully. Third, behavioral change is only being measured for a short period after the intervention. The true long-term impact of the intervention may not be fully understood. Fourth, the parent component relies on the children taking the family activities home; this pilot study does not include a formalized parent component. Lastly, the intervention is only being offered to a small group of children at each participating school. Other children, who may benefit from the intervention, will not be included.

Furthermore, teens selected as teen mentors will vary in their own personal health behaviors and health status. Thus, teen mentors who may not adhere to the goals of the curriculum may be included in the intervention delivery. It is not known if the teen's health status or own health behaviors will impact the mentoring relationship with their assigned child[ren]. During this pilot study, the PI will make note of any observed or verbalized issues regarding the mentor-mentee relationship that may be related to mentor health behaviors or mentor health status found during the debriefing sessions or observed during mentor supervision. These observations will be recorded in the study log.

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BUDGET JUSTIFICATION

Principal Investigator

Laureen H, Smith. Ph.D.. RN, Assistant Professor. The Ohio State University College of Nursing (2.70 person months)

Dr. Smith will serve as the Principal Investigator and will devote 30% effort to this project. Dr. Smith will ensure the scientific quality of the project and assume primary responsibility for the planning, administration, and management of the proposed study. She will develop and implement the research protocol as well as train and supervise the adult group leaders, teen mentors and research assistants at The Ohio State University College of Nursing, Columbus OH. Dr. Smith will work closely with the research team through the project period. She will be responsible for coordinating the efforts of Dr. Pamela Salsberry, Co-Investigator. Dr Smith will maintain twice monthly contact with Dr. Holloman, Project Consultant to discuss the research design and statistical analysis issues. Dr. Smith will meet with the adult group leaders, teen mentors and research assistants during the project: for ongoing training, to ensure that the intervention is being delivered appropriately, to ensure that the data are being collected appropriately and, to ensure that the data are being managed correctly. Dr. Smith will share responsibility for developing the data analytic strategy and data interpretation with co-investigator Dr. Pam Salsberry and consultant Dr. Christopher Holloman. In addition, Dr. Smith will take primary responsibility for data management, as well as designing the databases and training materials. Dr. Smith will have primary responsibility for most reports, presentations, and manuscripts that are an outcome of the project. Salary will increase 3% per annum consistent with NIH guidelines.

Co-Investigators

Pamela Salsberry. Ph.D, RN, Professor, The Ohio State University College of Nursing (0.45 person months)

Dr. Salsberry will serve as co-investigator of the project and devote 5% of effort to the study. She is an experienced investigator who has several years of research experience with the development of childhood overweight. Dr. Salsberry has extensive experience with database management and the use of large datasets. Dr. Salsberry will share the responsibility of ensuring the scientific quality of the project as well as the planning and implementation of the entire project. She will share responsibility for providing on-going supervision of the research assistants as The Ohio State University and assist Dr. Smith with the initial implementation of the study. In addition, Dr. Salsberry will assist Dr. Smith and Dr. Holloman in developing the data analytic strategy and interpreting the data. She will be a co-author on all reports, presentations, and manuscripts that are an outcome of this project.

Robert Murray, MD, Professor of Pediatrics, Gastroenterology, The Ohio State University College of Medicine and the Director, Center for Healthy Weight and Nutrition, Nationwide Children's Hospital (.18 person months)

Dr. Murray will serve as co-investigator of the project and devote 2% effort to the study. He is an expert medical clinician in pediatric gastroenterology with extensive experience in treating children who are overweight and obese. Dr. Murray serves on state-level organizations that will serve as a recruitment base for this study. Dr. Murray is an experienced collaborator within the host institution and is recognized for his efforts to implement school based obesity prevention programs targeting elementary aged children within the local region. Dr. Murray will assist with recruitment of subjects and assist with data interpretation, specifically the interpretation of findings related to health status. He will be co-author of all reports, presentations and manuscripts that are an outcome of the project.

Consultant

Christopher Holloman, Ph.D. Associate Director, Statistical Consulting Service, The Ohio State University (0.45 person months)

Dr. Holloman will act as the statistical consultant throughout the project. Dr. Holloman has assisted us in developing the data analytic strategy for the proposed study. Dr. Holloman provided excellent guidance in helping address moderating variables and has conducted the power analysis to project our needed sample size. He will provide consultation on data analytic strategies, programming an interpretation of results. Dr. Holloman will consult a total of 72 hours over the project's two year period. He will be compensated $150.00 per hour for a total cost of $10,800.

Research Associate

Erica Draher-Twersky, MPH. Program Manager with Department of Nutrition, The Ohio State University Extension Office (.18 person months).

Ms. Draher-Twersky will serve as a Research Associate and devote 2% effort to the study. As Program Manager at the OSU Extension Office, she has established effective networks and working relationships with school districts in 10 Appalachian counties. These counties will serve as a recruitment base for this study. Ms Draher-Twersky will assist with the recruitment of subjects and assist with the preparation of project reports and manuscripts.

Project Director — to be Arranged (1 person month)

A Project Director will be a doctoral student that resides in the regional geographical community. The project director has been budgeted for 12 months a year for each year and will devote 30% effort to the project. The project director will assist with recruitment efforts. The project director will meet regularly with the teen mentors and adult group leaders. The project director will coordinate the location the meeting times and place at each school. The project director will assess integrity and fidelity of the delivered curriculum and will be responsible for

supervising the teen mentors and adult group leaders. The project director will oversee data collection and entry by the research assistants. The project director will organize all curriculum materials at each intervention site.

Research Assistants — to be Arranged (0.5 person months each)

Two graduate students will be hired as the Assessment Research Assistants. Both research assistant positions have been budgeted for 10 months for both years. The Assessment Research Assistants will be blind to study condition and will be responsible for the data collection at all time points. The Assessment Research Assistants will be responsible for data entry into the database. Each Assessment Research Assistant will be needed for 10 hours a week for both year one and year two.

Education and Skill-Building Intervention for Caregivers of Hospice Patients

Kathryn Lindstrom, PhD Student, MSN, Arizona State University, 2006–2010

Sponsor: Bernadette Mazurek Melnyk, PhD, RN, CPNP/PMHNP, FNAP, FAAN
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Funded by NIH/NINR 5F31NR010418-02 (Pre-doctoral Fellowship)

A growing number of family caregivers, defined as spouses, adult children, and significant others who provide physical, emotional, spiritual, and/or social care to family members at end-of-life and have become an invaluable part of our healthcare system. Although spousal caregivers may have been caring for their loved one for years, the decision for hospice care, deemed to be in the last six months of life, is a sudden realization that there is a definite end to the life of their loved one, and can bring heightened anxiety and depression. This heightened anxiety can be explained by a lack of an appropriate cognitive schema of knowing how to cope and perform in this role and can lead to poor emotional coping, functional coping and role outcomes. Self-regulation theory posits that through an accurate cognitive schema, a caregiver will come to believe they are able to care for their loved one and thereby decrease negative emotional coping and improve functional coping outcomes. Role theory suggests that receiving information and skills on how to perform in their role as a caregiver to a dying loved one, will result in improving the caregivers' belief that they are able to be involved in the care of their loved one. Thus, they will feel prepared and experience less demand and distress in this role. A literature review of interventions for family caregivers caring for a loved one on hospice revealed a paucity of studies. Therefore, there is an urgent need to develop effective theory-based interventions that specifically target caregivers of newly admitted hospice patients to help them develop an appropriate schema so they can optimally function in the role of caring for their dying loved one. Role interaction theory and self-regulation theory have been used together as the theoretical basis for a reproducible intervention designed to enhance coping outcomes for family caregivers of hospitalized elders. The proposed study builds upon seminal work and proposes a theory-based intervention, Education & Skill- building Intervention for Caregivers of Hospice patients (ESI- CH) to assist spousal caregivers of a dying loved one with appropriate schema development for enhance coping and mental health outcomes in this new role. The proposed study will test: 1) feasibility and acceptability of a theory-based intervention (ESI- CH), 2) examine recruitment and retention strategies for this population, 3) test the reliability of a newly adapted instrument, Family Beliefs of Caregivers of Hospice patients),

and 4) explore relationships among the proposed mediator (caregiver beliefs) and proposed outcomes (anxiety, depressive symptoms, caregiver preparedness and caregiver perceived physical health) for a future program of research designed to improve the health outcomes of spousal caregivers of family members on hospice.

A. SPECIFIC AIMS

A growing number of family caregivers, defined as spouses, adult children, and significant others, provide physical, emotional, spiritual, and/or social care to family members at end-of-life[1] and have become an invaluable part of the U.S. healthcare system.[2, 3] Although spousal caregivers may have been caring for their loved one for years, as in dementia, the decision for hospice care, deemed to be in the last six months of life, is a sudden realization that there is a definite end to the life of their loved one and can bring heightened anxiety and depression.[4–6] This heightened anxiety can be explained by a lack of an appropriate cognitive schema of knowing how to cope and perform in this role and can lead to poor emotional coping, functional coping and role outcomes.[7–10]

Caregivers of family members on hospice report being uninformed about: 1) what hospice services include,[11] 2) the skills necessary to assess and provide symptom management,[12–16] 3) what to expect in a disease and dying trajectory,[12, 13] 4) being unprepared in their new role as a caregiver to a dying person,[17–19] and 5) how to better care for themselves while in the midst of this stressful time.[20] Spousal caregivers of hospice family members are reported to have higher levels of depression and strain than adult children caregivers[21] and females report more health problems.[22] In other studies, caregivers of family members at end-of-life commonly report higher levels of depression, anxiety, burden (defined as demand and difficulty), poorer overall health,[20, 22–25] and poor role outcomes, even when these caregivers recognize positive aspects in providing care for their loved one.[26, 27] The need to involve and educate family caregivers of dying patients has become a common underlying theme in current literature,[28–31] especially if their loved one is to remain in their home.[32–34] However, there is a paucity of intervention studies directed specifically for the family caregiver of a dying loved one on hospice.[35]

In a prior study by the late Dr. Hong Li and the sponsor for this application, an innovative educational skills building intervention, based on the combination of self-regulation and role theories, resulted in positive mood improvement and role outcomes for family caregivers of hospitalized elders.[10] The theory of self-regulation contends that when emotional features of an experience are emphasized, a person's emotions will escalate and result in poor coping outcomes. It is proposed that providing concrete objective features of the experience of caring for a dying person will assist a person to develop an accurate cognitive schema of what to expect during this experience. Through an accurate cognitive schema, a caregiver will come to believe they are able to care for their loved one and thereby decrease emotional coping and improve functional coping outcomes. In addition, receiving information and skills on how to perform in their role as a caregiver to a dying loved one, will result in improving the caregiver's

belief that they are able to be involved in the care of their dying loved one. As a result, they will feel prepared and experience less demand and distress in this role.

A review of intervention literature for caregivers of hospice patients revealed six intervention studies; however, none specifically targeted the spousal caregiver of a newly admitted hospice patient that focused on the formation of a cognitive schema, analogous to the real life event, that would transform their beliefs that they have the ability to care for their dying loved one. Therefore, there is an urgent need to develop efficacious theory-based interventions that specifically target schema development for the caregiver of a newly admitted hospice patient to better equip family caregivers with the knowledge and skills needed to perform in their role as caregivers. Thus, this proposed pilot study, a first step in a program of research, will promote NINR's goals of developing interventions to assist family caregivers of a loved one newly admitted to hospice.

Aim 1. 1a. Evaluate feasibility (timing, format, length) of the intervention: Education & Skill-building Intervention for Caregivers of Hospice patients (ESI-CH), **1b.** Evaluate acceptability (content and general acceptability) of ESI-CH, **1c.** Evaluate recruitment strategies, **1d.** Evaluate retention strategies to refine the research protocol in preparation for a future randomized controlled trial (RCT).

Aim 2. Evaluate internal consistency reliability of **2a)** a newly adapted scale, Beliefs for Caregivers of Hospice Patients and **2b)** instruments new to caregivers of hospice patients (Preparedness, Demand, Difficulty).

Aim 3. Evaluate whether the intervention (ESI-CH) improves emotional coping (anxiety, depressive symptoms), functional coping (caregiver involvement in family member's care), and role outcomes (preparedness, demand and difficulty).

Aim 4. Explore the relationship between the proposed mediator (caregiver beliefs) and outcome variables (anxiety, depressive symptoms, caregiver involvement in family member's care, preparedness, demand and difficulty).

B. BACKGROUND AND SIGNIFICANCE

An Overview of Family Caregivers of Chronically Ill Patients. Caregivers have become an integral part of the American healthcare system, now numbering between 30 and 38 million with an annual value in unpaid caregiving services of $350 billion,[3] up from 27 million caregivers and $257 billion in 2003.[2] A recent study from MetLife estimates there are more than 15 million caregivers who work full time while providing care to their parents or spouse, and spend an estimated 20 hours or more a week on caregiving activities.[3, 36] Even though many caregivers report positives or uplifts from their caregiving experience,[34, 37–39] the extensive body of research examining the caregiving role has found it to be physically and emotionally demanding and difficult for the caregiver,[18, 40–44] resulting in depression, anxiety,

burden, poor physical health and complicated bereavement outcomes.[23, 37, 45, 46] Researchers have identified health problems, family economic problems, difficulty balancing work and caregiving role responsibilities, feeling isolated and lacking support, learning what to expect as a caregiver in this new role, monitoring and interpreting symptoms in their family member to be primary stressors for the caregiver.[42, 43, 46–53] Husband caregivers also experience detrimental health changes, specifically higher levels of depression then non-caregiving husbands.[54] Finally, the costs of caregiving associated with depression alone have been estimated at $9 billion a year[51] and 23% of caregivers report that caregiving has negatively impacted them financially.[55]

Review of Intervention Studies for Family Caregivers of Patients with Alzheimer's disease or Cancer. A review of intervention studies for caregivers of patients with cancer or dementia prior to hospice referral is prolific and widespread throughout many disciplines and shows that well-designed coping interventions can positively affect caregiver depression, anger, quality of life, and burden.[56–66] Interventions that teach skills to cope with the stress of caregiving have assisted these caregivers to utilize support services, help them to feel competent and positively adapt to their caregiving role.[35, 67–72] Three types of interventions have been reported to be effective models for interventions for caregivers: 1) skill-training programs, 2) cognitive-behavioral therapy, and 3) programs using at least two distinct theoretical approaches.[57] However, the sample for these studies was not the caregiver of a dying family member recently admitted to hospice (personal conversation, Dolores Gallagher-Thompson at GSA Conference, November 19, 2007).

Review of an Intervention Study with Family Caregivers of Hospitalized Elders using Self-Regulation Theory and Role Theory. In an effort to assist family caregivers adapt to their new role as a family caregiver of their hospitalized elder and prepare them for what to expect during hospitalization, Li, Melnyk and colleagues[10] developed an educational and skills building theory-based intervention (CARE: Creating Avenues for Relative Empowerment) based on the previous efficacious theory-based intervention (COPE: Creating Opportunities for Parent Empowerment) for parents of critically ill hospitalized children and low-birth-weight premature infants by the sponsor of this application.[73–75] In the CARE study, self-regulation and role theories were combined to assist a family caregiver to develop an appropriate cognitive schema for their new role in caring for their loved one in the hospital. The two-phased audio-taped intervention (i.e., CARE) consisted of two educational sessions about the anticipated behaviors and emotions that caregivers could expect to observe in their hospitalized elder, and strategies to assist their family member cope with hospitalization, based on self-regulation theory. A mutual agreement, based on role theory, allowed the caregiver to choose two, from a list of five, options of how they would become involved in their family member's care from a list of common complications for hospitalized elders (i.e., delirium, urinary incontinence). In the CARE study, it was hypothesized that a caregiver's cognitive belief about what to expect from their hospitalized loved one and in their ability to care for him or her would be strengthened by the intervention, leading to less anxiety, fewer depressive symptoms, a positive role adjustment and fewer complications for their family member during and after hospitalization.[10]

Participants were recruited the first day or two after admission, consent was obtained and baseline measures collected (T1). The Phase One audio-tape and matched written script was immediately delivered to the caregiver, followed by 10 manipulation check questions, and instructions for the mutual agreement for their identified concerns were provided. The Phase Two intervention and data collection (T2) occurred 1 to 3 days prior to discharge. Follow-up measurements were collected during a home visit two weeks and two months following discharge. In addition, nurses who cared for the patients, blind to the study group, recorded the extent to which the caregivers were involved in their elders' emotional and physical care and the patients' chart record data were collected to determine symptom complications. Findings from this CARE pilot study indicated that as a new cognitive schema developed, caregivers developed stronger beliefs in their ability to understand the changes in their elders' conditions and how to care for them. Further, skills were learned on assessing potential complications and led to fewer complications in the hospital and fewer re-hospitalizations. Although preparedness was not significant in this pilot study, the intervention led to fewer re-hospitalizations for the elder, implying that the caregiver had learned effective caregiving skills. Furthermore, caregivers had fewer depressive symptoms and higher scores on role reward. Medium to large effect sizes (.57–.64) were found in this pilot study on many of the outcome variables. This study was used to launch a larger RCT study (N = 300) that has now been completed and analyses are currently being conducted (personal communication, Bernadette Melnyk, November 15, 2007).

Caregivers of Hospice Patients

In the U.S., hospice care differs from palliative care in that hospice care needs a doctor's referral,[76, 77] and is provided in the last six months of life, whereas palliative care can begin as early as the diagnosis of a terminal disease and last for months to years.[76, 78–83] Although some caregivers may have been caring for their loved ones for a long time, especially in the case of dementia patients, the transition to caring for a dying loved one has been described by family caregivers as a period of "being in the dark", and "not having a clue what we are in for"[84] to "I never realized how bad it was."[6] Spousal caregivers of family members on hospice experience higher levels of depression than adult children and women caregivers report the highest levels of all caregivers,[21] especially when they didn't become aware their husband was dying until the very end.[85] In spite of the fact that hospice services are highly rated by caregivers and patients, caregivers of hospice patients continue to report higher levels of stress, anxiety and depression than other caregivers.[26, 86] A recent study reported that hospice nurses do not regularly respond to caregiver concerns of family members' pain, causing increased distress for the caregiver.[87] Further, caregivers of patients on hospice face a unique, often short (ranging from 56 to 60 days) length of stay on hospice, making development of an appropriate new schema impossible without guidance.[88, 89] Multiple studies report that caregivers need assistance in knowing what to expect and how to provide symptom control and intimate care to their dying loved one.[5, 14, 16, 80, 90–94] Therefore, educational and skills building information targeted to this new stage of caregiving for a dying family member will help the caregiver to develop an appropriate cognitive schema and skills to take care of their dying loved one.

Needs of Caregivers of Loved Ones on Hospice. The extensive body of descriptive research has revealed that the needs of caregivers of hospice patients include: 1) information and skills on how to perform better in their role, 2) a better understanding of the trajectory of the patient's illness, demystification of the dying process, what to expect as death nears, and how to provide help, 3) help assessing and managing symptoms, especially pain management and delirium, 4) information about what hospice services offer, and 5) education and skills regarding how to care for themselves.[11–13, 16, 19, 26, 64, 93, 95–101] As a result of the stressful experience during the time that their loved one is on hospice, caregivers are reported to use more anxiety medications, experience higher levels of depression and exhibit lower social functioning.[21]

In a recent study, more than half (60%) of caregivers of newly admitted hospice patients (n = 237) reported they knew little about hospice and the services they offered and were unaware of the severity of their family member's condition.[11] A qualitative study of 21 female (14 were older female spousal) caregivers of patients with advanced cancer reported that caregivers wanted information on the disease trajectory and what to expect during this terminal phase.[12] One caregiver reported, "I just wish I knew what was going to happen. I have no sense of how this is going to play out, how long will this go on? They never told us any side effect… but it was really a torturous experience to go through without knowing." (p. 277). A small study of 6 caregivers of patients on hospice with end-stage lung disease and severe dyspnea reported similar experiences of being most fearful of the unknown and unexpected changes in symptoms and wanted understandable information in a timely manner specifically addressing expected stages of the illness and how to manage their family members' symptoms.[13]

A recent qualitative doctoral dissertation reviewed materials given to caregivers of hospice patients and reported that the majority of hospice companies use a booklet, originally published in 1985, reviewing signs and symptoms of the dying process.[102] However, the booklet does not provide skills for management of these symptoms nor does it contain information on ideas to improve caregiver self-care or what hospice can provide for the family and family member during this special and often difficult time in life. Without targeted information to assist caregivers with the development of an appropriate schema for this event and new role, caregivers are at risk for poor emotional and functional coping outcomes[103] and role confusion. In summary, when educational information and skills are provided to family caregivers regarding what to expect once their loved one is enrolled in hospice and how to be effectively care for their loved one, appropriate cognitive schema development should occur and the caregiver will develop a belief they are capable of providing care, and, ultimately improve caregiver outcomes.[28–31, 37, 104]

Review of Intervention Studies with Family Caregivers of Loved Ones on Hospice (see Appendix). The original systematic search used for my first NRSA application utilized the following databases through November 15, 2006: Cochrane, Medline, CINAHL, PubMed, PsycInfo, Sigma Theta Tau, and Dissertations with MESH terms: family caregiver, hospice care and keyword, intervention. A broader search through November 22, 2007 has been added with MESH terms palliative care and terminal care and nineteen studies have been identified, thirteen studies from other countries and six from the United States. Although one can gain insights from the studies abroad in a palliative care population,[104–115] these studies do not address the unique regulations

in being admitted to hospice services in the U.S. Nevertheless, major findings of these studies abroad include: 1) recruitment of caregivers of terminal patients is possible, 2) distress went down the first nine weeks after an advice and support intervention, 3) qualitative evaluation is effective when sample sizes are too small to run statistical analysis, and 4) when anxiety was measured (3 studies), it was lower after the intervention. Limitations of these studies include lack of theoretical perspective reported in four of the thirteen studies, lack of ethnic groups, and frequent use of only cancer patients when cancer patients now number less than half of hospice patients in the U.S.[88] One RCT study for caregivers of cancer patients in Australia developed a psycho-educational stress and coping intervention for nurses to implement in the home which consisted of two sessions of an audio-taped intervention complemented with a manual and telephone calls in between visits.[104] Proposed components of the intervention included giving information to caregivers related to palliative care services, caring for a dying person and self-care strategies with data collection occurring at enrollment, five weeks later and eight weeks following the patient's death. Although the caregivers positively evaluated the intervention and reported feeling more prepared, the author explains the lack of significance for all but one variable (rewards) by: 1) the mastery scale had a low Cronbach alpha (.59–.61), 2) a less common measure for anxiety and depression (Hospital Anxiety and Depression Scale) was used, and 3) the nurse interveners emphasized the positives of caregiving during the intervention which was not part of the original format (fidelity). However, this sample was not being cared for under the U.S. Medicare benefit of hospice services where services are different. For example, bereavement services were not included for caregivers nor did a nurse come to the home when their loved one died.[34]

Therefore, given that these studies are not hospice care specific to the U.S., six intervention studies for caregivers of patients actively receiving hospice services in the U.S. were reviewed and critically analyzed to identify knowledge gaps and needed areas for study.[60, 62, 87, 116–118] Two studies stand out as having developed potentially effective skills and coping programs although several methodological issues exist.[60, 116] The first program designed a 14-week educational skills program for caregivers of cancer patients in the home prior to hospice and a second population of caregivers whose family members were on hospice. However, not only is the length of the program unrealistic for caregivers of hospice patients (the average hospice stay is 56 days or 8 weeks), but it was unable to be successfully implemented due to staffing and funding cutbacks.[60] As a result, the only known results are that the hospice nurses reported that family caregivers needed the information in the intervention and were supportive of the intervention being implemented. The second study developed a problem solving and therapy coping intervention delivered in 3 sessions during the first nine days after hospice admission, with baseline data collection within 72 hours of admission and post-intervention data at two weeks after hospice admission. Results showed a decrease in caregiver burden and distress and increase in quality of life; however, the attrition rate was reported to be over 70%,[116, 119] presumably because the sample included all cancer patients who typically have a shorter length of stay on hospice than patients with other diagnoses.[120, 121] A third study utilized technology to incorporate the family and patient in the hospice interdisciplinary (IDT) meeting via videophone from their home.[87] Preliminary results show that, although family centered care is a universal model for hospice care, family concerns about control of patient pain were not being discussed during hospice IDT meetings. In summary, limitations of these six studies

include: 1) inconsistent use of theory-based interventions and outcomes, 2) no interventions specifically addressed cognitive schema development for this new role, 3) little attention to recruitment and retention strategies for this population, and 4) frequent use of cancer patients when less than 50% of hospice patients have a cancer diagnosis. While these interventions provide a needed focus on caregivers of hospice patients, there have been no theory-based intervention studies that target cognitive schema and skills development to enhance emotional and functional coping and role outcomes in caregivers of newly admitted hospice patients when role changes and care may be less familiar.

C. A THEORETICAL FRAMEWORK GUIDING DESIGN, IMPLEMENTATION AND EVALUATION OF THE INTERVENTION

The proposed theoretical framework combines Self-Regulation[8, 9, 122–125] and Role[126–128] theories and builds on previous successful theory-based interventional work by Li and Melnyk, and colleagues.[10]

The Theory of Self-Regulation. The Theory of Self-Regulation is a coping theory that hypothesizes a person processes internal and external stimuli through emotional and behavioral pathways and develops a cognitive schema (a picture in the mind to know what to expect and how to respond) that guides emotional and functional coping responses to an event as it unfolds.[8, 9] Each person decides on the meaning of an event, and this meaning guides a person's coping responses. When a person does not have an appropriate schema to anticipate what will happen during a new event, increased levels of anxiety and depressive symptoms and less involvement in the activity are apt to occur.[9, 129] For this study, less involvement in caregiving is hypothesized to be a decreased involvement in providing physical and emotional care as observed by the Hospice RN. Self-regulation processes use two coping pathways in reaction to a stressor, one concerned with regulating emotional responses and one regulating a person's functional responses to the event. When emotional responses are emphasized, a person's emotional reactions will increase, causing further ineffective coping responses. Johnson[8] proposed that by giving objective concrete features of an experience (i.e., physical sensations and symptoms experienced, temporal characteristics, environmental features, and the cause of symptoms and experiences), a person would be able to develop an appropriate cognitive schema of what to expect during a new experience. Through an accurate cognitive schema, a caregiver will come to believe they are able to care for their loved one and thereby decrease negative emotional coping (i.e., anxiety and depressive symptoms) and improve functional coping outcomes (an ability to be involved in the physical and emotional care of their loved one). However, the missing component to this theory was the component of teaching skill building in order to successfully perform in the new role. Building upon Li and Melnyk's[10] work, role theory will also be added to this intervention study.

Role Theory. Recent studies continue to report that caregivers of loved ones on hospice do not know what to do or how to help their loved ones[130] and find themselves providing unfamiliar and intimate tasks.[131] Caregivers want to do well but report they wished they had done a better

job in their role as a caregiver of their dying family member.[52] Role theory posits that roles are negotiated within families which contends that role enactment is a process and related to the clarity of role behaviors.[126, 132] Providing general skills information on how to assess and respond to common symptoms in their loved one as well as the importance of for their own health care needs, should assist a spousal caregiver in believing they are able to care for their loved one. This increased belief in their abilities should lead to the caregiver feeling more prepared for this role to their dying loved one, and decrease the demand and difficulty often felt in this role.

Building on the CARE intervention,[10] a mutual agreement contract will be implemented to allow each caregiver to individually decide what two symptoms or potential complications (i.e., pain, constipation, delirium) for their loved one they would like to focus on during the intervention.[90, 112, 133–139] Only focusing on two specific areas at a time should lead them to believe that fewer activities are prescribed for their role, resulting in less demand. Therefore, assisting a caregiver in developing the skills necessary for knowing how to help their loved one is expected to assist them in believing they are prepared for this new role and that caring for their dying loved one is less difficult.

Mediating Variables. Mediators provide researchers with greater understanding of the process through which interventions work.[140–145] Although measures for concepts have varied, a possible mediator in recent caregiver research and proposed in this study is a caregiver's belief in their ability to provide care.[10, 104, 140] Sherwood, et al[140] reported a caregiver's belief in themselves in the role of a caregiver, measured by mastery, meditated intervention effects on outcomes. Li and Melnyk, et al[10] also found that a caregiver's belief in their abilities to perform in their new role mediated the effects of their intervention on caregivers' depressive symptoms, increased a caregivers' participation in the physical and emotional care of their elder and led to an improved role outcome (role reward).

Therefore, it is hypothesized that providing concrete objective information on the physical sensations and symptoms experienced, temporal characteristics, environmental features, and the cause of symptoms and experiences while caring for a dying family member newly admitted to hospice will develop a new cognitive schema that matches their experience of caring for their loved one as it unfolds. This new cognitive schema is hypothesized to strengthen a caregiver's belief about their ability to care for their dying loved one. Furthermore, an accurate cognitive schema will assist the spousal caregiver to believe they are capable of caring for their dying loved one and lead to a decrease in depressive and anxiety symptoms and an increase in their involvement in the physical and emotional care of their dying loved one. Finally, by being taught the skills necessary for the care of themselves and their loved one, a stronger belief in their abilities should result. This stronger belief in their abilities should lead to a feeling of being more prepared for the role of caring for a dying loved one, and decrease their feelings of demand and difficulty in this role.

Significance of the Proposed Research. The proposed intervention builds on an evidence-based intervention grounded in self-regulation and role theories with family caregivers of hospitalized elders and represents a significant effort in addressing a gap in intervention literature in a new

population. It is hypothesized that the intervention will improve emotional and functional coping and role outcomes of a growing number of family caregivers of newly admitted hospice patients by developing an innovative educational information and skills intervention. The proposed intervention is designed to foster development of a cognitive schema in a spousal caregiver of a newly admitted hospice patient for their new role to increase their belief that they are capable of providing care. In addition, feasibility and acceptability of the intervention will be determined to inform future studies. Furthermore, strategies for recruitment and retention for this population will be evaluated for future research. Finally, the newly adapted Beliefs scale will be evaluated for reliability and content validity in this population. The proposed pilot study will closely attend to the methodological components of the intervention protocol for the possibility of achieving positive outcomes in a future randomized control study.[73, 146]

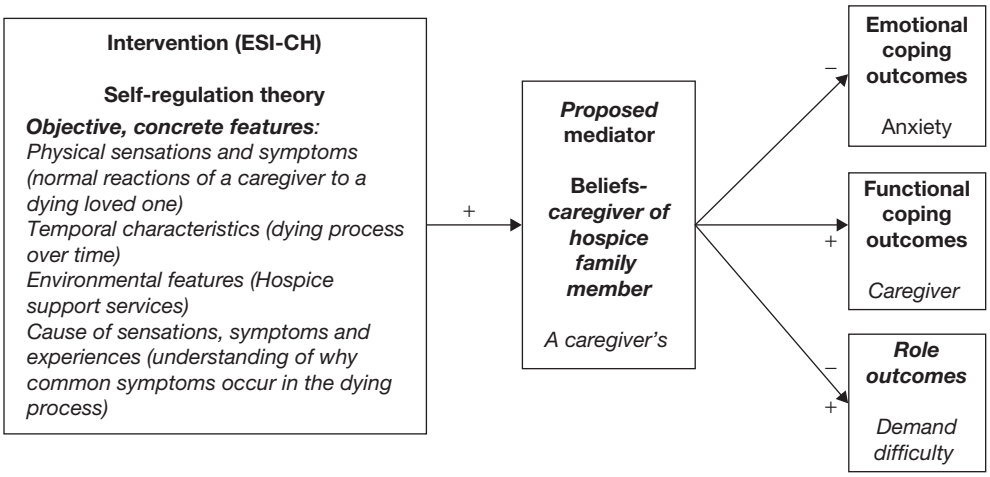

Figure 1. Hypothesized effects of the ESI-CH program on the process and outcomes of caregivers of hospice patients.

D. PRELIMINARY STUDIES/PROGRESS REPORT

N.A.

E. RESEARCH DESIGN AND METHODS

Design. A one-group repeated measures feasibility pilot study as proposed is the first step in a program of research with an aim of developing a theory-based efficacious intervention to improve emotional and functional coping and role outcomes of spousal caregivers of newly admitted hospice family members.[147–149] Introduction of the study, informed consent and data collection will be delivered by a graduate/doctoral nursing research assistant (RA) whereas the intervention will be performed by the Principle Investigator (PI).

Sample. The sample will consist of 20 spousal caregivers of newly admitted hospice patients. Assuming a minimum correlation of .6, three time points, an alpha level of .05 and effect size of d = .75, a sample size of 17 would be needed for a power of .80.[150] Thus, 20 will be recruited to address the possibility of attrition in the sample. Furthermore, this is an adequate sample size for a pilot study and allows investigators to first test the feasibility and acceptability of their interventions and study protocols.[146, 151–154] Based on previous studies, inclusion criteria for the proposed sample of spousal caregivers will include: 1) being a spousal family caregiver of a newly admitted hospice patient with any disease diagnosis and any ethnicity, 2) not having a self-reported diagnosis of total hearing loss resulting in an inability to listen to CD, 3) not having a self-reported diagnosis of dementia or Alzheimer's, 4) can read, speak and understand in English, 5) be willing and able to participate in the study and 6) having a family member score 50 or above on the Palliative Performance Scale (PPS) as routinely evaluated by the hospice nurse upon admission to hospice will indicate the family member is not imminently dying.[116, 155]

Setting. Hospice care takes place where the patient resides; for this study, the setting will be in the residence where the spousal caregiver and patient reside together, a more familiar and less stressful environment,[156] keeping added burden to a minimum and potentially increasing recruitment and retention.

Recruitment and Retention. Through established relationships with a local hospice in Phoenix, Arizona, spousal caregivers will be identified during the first hospice RN visit, usually the day after admission.[157] Initial recruitment will be performed by the Hospice RN on his/her first nursing visit to a newly admitted family member. For this study, no ethnic groups will be excluded.[158] Participants who have a loved one die before they have completed the intervention will be given the choice to stay in or leave the study, although their data will be kept separate from those who complete the intervention. Specific recruitment and retention strategies are discussed under Protection of Human Subjects.

Procedures. A detailed, manualized protocol for the intervention will be developed to standardize key tasks and implementation of the intervention and will be strictly followed. The manual will be reviewed and approved by the Institutional Review Boards of Infinity Hospice and Arizona State University.

Intervention Protocol. Spousal caregivers will be given initial information by the hospice RN at his/her first visit following admission, and if willing to meet and learn more about the study, will sign an initial referral form allowing the nurse to screen for inclusion criteria[157] The hospice RN will call the PI or RA who will speak with the caregiver to set a mutually acceptable meeting time to explain the study background, purpose, risks, benefits and procedures one to two days later. Time 1 (T1) will include completion of informed consent and data collection with the RA. The spousal caregiver will be given the CD player and 8 batteries, and shown how to operate it with return demonstration. The RA will schedule the next visit, 1 to 2 days later for the PI to deliver the intervention, consisting of two sessions of 15 minute CDs with a matching written script for the caregiver to follow along. T2 and T3 sessions will follow similar formats by the PI: 1) each session will begin with a scripted overview of the

session, 2) the caregiver will listen to a 15 minute CD pertinent to Session One or Two with a matched written script, 3) the caregiver will complete a mutual agreement contract, and will listen to the appropriate 5 minute CDs and matched scripts, 4) at T3 (session two), the PI will collaborate with the caregiver to determine whether they a) need to continue to concentrate on the previously identified problems on the Mutual Agreement, b) want to choose up to 2 more areas to listen to, or c) decide they have no other needs, and 5) the caregiver will be given the CD tracking form to record the date and time they listen to any of the CDs between visits, dates and times they read the matched scripts, and any questions they have; this form will be reviewed at the beginning of the following session. At T3, the PI will use a scripted questionnaire to guide the conversation on the Tracking Form. At T4, the RA will use a scripted questionnaire to guide the conversation on the Tracking form from Session Two, prior to T4 data collection. Caregivers will be given $20 per completed data collection point (T1, T4, T5) and will be allowed to keep the CD player and CDs for future reference.

Table 1. Timeline of Intervention (ESI-CH) and Data Collection

Hospice Day 1	Hospice Day 2 Time 0 (T0)	Hospice Day 3–4 (T1)	Hospice Day 4–5 (T2)	Hospice Day 6–8 (T3)	Hospice Day 17–20 (T4)	Hospice Day 30–33 (T5)
Admission to Hospice	Hospice RN Visit #1 Screened for Inclusion Criteria	Informed Consent **Data Collection** Delivery of CD Player 45 minutes	**Session One: ESI-CH** Manipulation Check Mutual Agreement 45 minutes	**Session Two: ESI-CH** Manipulation Check Mutual Agreement Hospice RN Observation 45 minutes	**Data Collection** Hospice RN Observation 45 minutes	**Data Collection** Hospice RN Observation 45 minutes

Fidelity: Manipulation Check for Caregivers. Caregivers will be asked 5 multiple choice questions covering concepts discussed on each CD immediately following each CD listened to during T2 and T3 sessions. If the intervention has been implemented with high fidelity and caregivers have understood the information presented, they should perform well on the questions.

Training of Hospice Nurses and Staff and Intervention Fidelity. It is recognized that because the nurses will not be blinded to the intervention group, bias is introduced into this feasibility pilot study. However, thorough training of the RA, hospice RNs and staff and audio-taping of each intervention session will counteract some of the pitfalls of a one-group study. Each tape will be listened to by the RA for consistency and adherence to the protocol and recorded on a fidelity check sheet.[159–161]

Dose of the Intervention: CD Tracking Form. The caregiver will initially listen to each CD with the PI at T2 and T3. Between visits, the caregiver may listen to the CDs as many times as they want and will record the date and time they listen to a CD and/or read the matched script on the CD tracking form. In addition, the caregiver will write down any questions they have between visits which will be discussed at the next meeting.

Evaluation of the Intervention and Protocol: Feasibility and Acceptability. Feasibility and acceptability of the intervention and protocol will be measured qualitatively and quantitatively. A 100-cm visual analog scale will be used to evaluate feasibility, specifically the timing, format and length of the intervention. Acceptability questions will use a 100-cm visual analog scale to rate the content and general overall acceptability of the intervention. Reliability and validity of single-item indicators for capturing the phenomena of interest has been supported.[162] A Caregiver Interview Protocol (see Appendix) will be used by the RA during data collection to guide semi-structured questions, including: 'Please describe how the intervention was helpful or not helpful' to 'Was there anything you wanted to know that wasn't included in the intervention?'

Evaluation of Recruitment Strategies. Recruitment strategies will be measured with the hospice RNs by asking them to 'rate the difficulty of recruiting participants' on a 100-cm visual analog scale, followed by a semi-structured question to explain their answer (see Appendix).

Evaluation of Retention Strategies. Retention will be measured quantitatively by comparing participant completers to drop-outs. A Caregiver Interview Protocol (see Appendix) will be used to guide one question for participants and will range from "Can you share with me why you are leaving the study so I can understand if I need to change anything about the study? to "What has helped you stay in the study?"

Variables and Measures. The independent variable is the proposed intervention, ESI-CH. Dependent variables are categorized as emotional coping, functional coping and role outcomes (Table 2). This study has one within-subjects factor (time; T1, T4, T5) for all variables.

Table 2. Measures for Data Collection with Caregivers

Aim	Construct	Instrument	Data Collection
	Demographics	Demographic Questionnaire	T1
	Emotional Coping Outcomes		
3,4	Trait Anxiety (A-Trait)	State-Trait Anxiety Inventory (STAI)	T1
3,4	State Anxiety (A-State)	State-Trait Anxiety Inventory (STAI)	T1, T4, T5
3,4	Depressive Symptoms	Center for Epidemiological Studies (CES-D)	T1, T4, T5
	Functional Coping Outcomes		
3,4	Caregiver Participation	RN Observation Scale	T3, T4, T5
	Role Outcomes		
2,3,4	Caregiver Preparedness	Caregiver Preparedness	T1, T4, T5
2,3,4	Demand (Time)	Caregiver Burden Scale	T1, T4, T5
2,3,4	Difficulty (Bother)	Caregiver Burden Scale	T1, T4, T5

Aim	Construct	Instrument	Data Collection
	Proposed Mediator		
2,3,4	Beliefs for Caregivers of Family Members on Hospice	Family Belief Scale for Caregivers of Family Members on Hospice	T1, T4, T5
	Fidelity: Manipulation Checks		
1	Receipt of Intervention after each CD	5 Multiple Choice Questions for each Intervention CD	T2, T3
	Dose of the Intervention		
11	Times listened to CD Questions about CDs	Tracking Form	T2, T3
	Evaluation of the Intervention & Protocol		
1a	Feasibility for Spousal Caregiver	Visual Analog Scale and Interview Protocol	T4
1b	Acceptability for Spousal Caregiver	Visual Analog Scale and Interview Protocol	T4
1c	Recruitment Strategies by RN	Visual Analog Scale and Interview Protocol	T4
1d	Retention Strategies for Spousal Caregiver	Interview Protocol	T4

Demographic Variables. Based on previous research,[10, 18, 49, 127, 163–166] demographic variables to be measured will include: age, ethnicity, gender, education completed, combined household income, marital status, years in current status, relationship to patient, work outside the home, number of children living in the home, list of caregiver's health issues, and duration of caregiving. Patient age, diagnosis and PPS score will be obtained upon consent signing from the family member's chart. (see Appendix).

Independent Variable: ESI-CH Intervention (see Figure 1). Based on self-regulation and role theories as previously described, ESI-CH will be a reproducible, manualized educational and skill building intervention that will provide information targeting three main outcomes: emotional coping, functional coping and role outcome, adapted from Li and Melnyk's[10] intervention for family caregivers of hospitalized elders. Experts in caregivers (Dr. David Coon), end-of-life nursing symptom management and pain control (Dr. Betty Ferrell), and hospice (Mary Bertram) will review the intervention and mutual agreement content prior to the IRB review and commencement of this study.

Dependent Variables: Emotional Coping Outcomes. Anxiety will be measured using the State-Trait Anxiety Inventory, comprised of 2 self-report 20-item scales on a 4-point Likert scale with well established construct validity and excellent internal consistency reliability (Table 2). A-State will be used as the dependent variable to assess a caregiver's current anxiety level at three time points whereas trait anxiety will be measured at baseline only.[10, 167] This commercial measure (Mind Garden) is widely used in research and clinical settings and constructs of this measure include subjective feelings of tension, apprehension, nervousness and worry. Each item is given a weighted score from 1 to 4, total scores range from 20 to 80, is geared at a fourth or fifth reading ability and reports a Cronbach alpha of .80–.91.

Depressive symptoms will be measured with the Center for Epidemiological Studies-Depression (CES-D). The CES-D is an acceptable self-report measure comprised of 20 questions with high internal consistency reliability and is sensitive to change over time.[168, 169] Construct of the measure is depression and includes questions on: depressed mood, feelings of guilt and worthlessness, feelings of helplessness and hopelessness, psychomotor retardation, loss of appetite and sleep disturbance which are all part of depression. Four questions are reverse worded and a total score is obtained by summing the individual item scores where higher numbers mean the presence of more depressive symptoms. Cronbach alphas have been reported to be .80–.92 for all groups and lower test-retest scores when measured at short intervals, indicating the measure is sensitive to change over time. All CES-D scales will be scored shortly after completion while still in the home by the PI and anyone scoring higher than 16 will be immediately referred to their primary care provider or community services.

Functional Coping Outcome: Caregiver Participation in Family Member's Care. Participation in the family member's care will be measured three times by the hospice RN, beginning the week after the start of the intervention for a total of three observations (T2–3, T3–4, T4–5), using 2 100-cm visual analog scales from 'no involvement' to 'extremely involved' for the questions: 1) How involved is the family caregiver in the physical care of the hospice patient? and 2) How involved is the family caregiver in the emotional care of the hospice patient? The PI is aware that this evaluation will not be blinded in this pilot study. If the intervention has been implemented with high fidelity and caregivers have understood and used the information presented, the hospice RN should observe the spousal caregiver to be involved in the physical and emotional care of the family member. Melnyk and Li[10] have used these questions to assess caregiver involvement in their loved one's care and have gathered data to support that these measures are significantly related to caregiver self-report. Therefore, caregiver self-report is excluded from this feasibility study (see Appendix).

Role Outcomes: Caregiver Preparedness. A caregiver's perception of being prepared in their role to take care of a loved one will be measured using the Family Preparedness Scale,[170] with established content and construct validity.[127] Eight questions are quantitatively measured, from "not at all prepared' to 'very well prepared' and range from 'How well do you think you are to take care of your family member's physical needs?' to 'How well prepared do you think you are for the stress of caregiving?' to 'How well prepared do you think you are to get the help and information you need from hospice?' The higher the score, the more prepared a caregiver would feel in his/her role. Internal consistency reliability (Cronbach alpha) has been reported from .83–.94[10, 171] and will be explored during this study (see Appendix).

Caregiver Demand and Difficulty will be measured using two subscales of Caregiver Burden Scale: 1) the objective measure of demand or time spent doing the task (Cronbach alpha .80) and, 2) the subjective measure of difficulty or bother a task is for the caregiver (Cronbach alpha .88).[24, 44, 171] This fifteen item scale consists of rating tasks on a 5-point Likert scale for each of the two subscales as follows: 'none to 'a great amount' for "demand" and 'not difficult' to 'extremely difficult' for "difficulty." Examples of items include: 'medical treatments' to 'emotional support' to 'watching for and reporting patient's symptoms, watching how the

patient is doing, monitoring the patient's progress' to 'additional household tasks for the patient.' Construct validity has been demonstrated by showing that difficulty was associated with measures of emotional distress and demand more associated with patient dependency[172] (see Appendix).

Proposed Mediating Variable: Family Belief Scale for Caregivers of Hospice Patients. This scale, originally developed for parents of young children in the hospital,[173] and then adapted for caregivers of hospitalized elders to measure their beliefs about their ability in their role in caring for their family member in the hospital,[10] has been revised for this study population and will be evaluated for its reliability with this sample. Previous Cronbach alphas for the beliefs scales have consistently been above .85.[7, 10, 73] A Likert scale is used from strongly disagree to strongly agree and includes 20 questions such as: "I know what changes in behavior to expect in my family member while he/she is on hospice" and "I am sure of what things I can do to best help my family member with problems as a result of his/her illness." Higher scores indicate a higher belief in their ability to manage as a caregiver. Content validity of the scale will be established by having 5 experts review and confirm that the items tap beliefs about providing care for patients on hospice.

Data Management

Prior to data collection, files will be set up in the locked research office for all collected measures at each data collection point for each participant. All quantitative measures will be coded to a master code book, beginning each code with zero to streamline computer data entry. As data are collected, the PI will review measures for missing data and allow the participants to complete any missing questions or indicate they prefer not to answer the question. Missing data will be coded 99. Quantitative data will be entered and verified into Statistical Product for Service Solution (SPSS) 15.0 software by the PI and RA on computers with virus and hacking protection, password protection for systems and files, frequent backups and archiving in two separate locations. Qualitative data will follow the same protocol using ATLAS-ti software and will be learned during future coursework.

Data Analysis

The proposed design will be a single group, pre-experimental repeated measures research design developed and implemented as a feasibility pilot study. Data analysis will begin with a review of the data to get a sense of the data and include descriptive and inferential statistics. Descriptive statistics (frequencies, means and standard deviations) will be computed on all quantitative measures. For those who drop out of the study, t-tests will be run on demographics and outcome variables and will be compared to those who stay in.

Analysis for Aim 1. Descriptive statistics will be used to describe and summarize participant feasibility and acceptability questions and RN evaluation from analog scales. Audio transcripts of each interview will be transcribed to create verbatim written accounts by the RA and checked for accuracy by the PI. All tapes will be identified by participant code number. Transcripts will

be read repeatedly until no new themes or patterns are identified. Qualitative methods will guide the analysis of feasibility, acceptability, and retention interview protocol questions to the spousal caregivers, RN evaluation of recruitment strategies and spousal caregiver CD tracking form. Additional qualitative coursework has been added to the training plan in order refine methods and analysis for this aim.

Analysis for Aim 2. Cronbach alpha will be used to measure internal consistency reliability on the newly adapted test measure (Caregiver Beliefs). The distribution of the variables will be examined for skewness and kurtosis, item to total correlations, and stability of the measure by computing correlations between time points.

Analysis for Aim 3. If assumptions of sphericity are met, the univariate approach of repeated measures will be used because of its power for small sample sizes.[150] If assumptions of sphericity are not met, then the multivariate approach will be used to evaluate whether there was improvement over time. Planned comparisons will then be tested to look at differences between all time points with a Bonferroni correction used for multiple comparisons.

Analysis for Aim 4. The correlation between T1 and T5 for each outcome will be compared with the correlation after partial correlation for the mediator at T4 to explore the relationship between the mediator and outcome variables.[174] Looking at the difference in coefficients is more appropriate than using regression with a small sample size.

Limitations. The investigator acknowledges the limitations of this study. Lack of a comparison group with random assignment to group substantially weakens the internal validity of this study. In addition, the self-report measures, hospice RNs not being blinded to study participants and selection bias in a convenience sample are also limitations of the design. However, as a first step in a program of research, it is necessary to rigorously evaluate the feasibility and acceptability of the intervention and research protocol before moving to a randomized controlled pilot study.[146, 175]

Burden. Although participant burden is a recognized concept by the investigator and the number of intervention sessions and data collection have been kept to a minimum, recent research studies report that caregivers of hospice patients are, in fact, interested in participating in research studies for the betterment of end-of-life care.[104, 176, 177] However, further protective measures have been put into place as noted in the section on Protection of Human Subjects to keep burden to a minimum.

E. PROTECTION OF HUMAN SUBJECTS

E.1. Risks to Subjects

Human subjects comprise the participants in the proposed study and the researcher will adhere to all policies and regulations as set forth by the Institutional Review Board of

Arizona State University. Coursework has been completed to obtain certification through the Collaborative Institutional Training Initiative in Human Research (Fall Semester, 2007) and through the National Cancer Institute, division of the U.S. National Institute of Health (Spring Semester, 2007). The PI will coordinate with the hospice company regarding adherence to all policies written for the protection of human subjects. The study has been developed to keep burden to a minimum by having either the PI or the RA present with the participant during each session, decreasing the number of original sessions, and keeping instruments to a minimum. The intervention has been changed from four sessions over four weeks to two sessions and three data collection sessions by the PI and four by the hospice RN during the weekly visit over four weeks. Participants will reminded at each encounter of the phone number for the PI and that they can withdraw from the study at any time without any negative outcome for their loved one on hospice. Participants will be assured that all their questions will be answered at any time and that all information will remain confidential. The PI will remain flexible in scheduling all meetings. Further, breaks during sessions will be taken as needed to accommodate the participant. Finally, this PI is committed to following the guidelines of the Office for Protection of Human Subjects and Arizona State University's policies for the protection of all research participants to maintain and preserve public trust in the research process.

Human Subjects Involvement and Characteristics. The activities of this study will involve collecting self-report data from 20 spousal caregivers of dying family members newly admitted to hospice, participation in two 15 minute CD sessions with a Mutual Agreement component for individualized care. Inclusion criteria for the proposed sample will include: 1) being a spousal primary caregiver and reside with the patient in a private, community home of a newly admitted hospice patient, 2) not having a self-reported hearing loss, 3) not having a self-reported diagnosis of dementia or Alzheimer's, 4) being able to speak and write in English, 5) being willing and able to complete measurements, and 6) having a family member score 50 or above on the Palliative Performance Scale (PPS) as routinely evaluated by the hospice nurse upon admission to hospice will indicate the family member is not imminently dying.

Depression measures will be scored while in the home by the RA and if a score over 16 occurs, the caregiver will be referred to their primary healthcare provider or community services. If a participant shows signs of cardiac or respiratory compromise, 911 will be called. In addition, the hospice company will be called for care of the patient. The PI or RA will remain in the home until the crisis is resolved. If at any point during the study, the PI or RA believes that a participant is at risk for excessive depression or elder abuse, the PI or RA will follow the protocol to refer the participant for depression to their primary care provider community clinic or collaborate with the hospice for issues of abuse and call Adult Protective Services.

Sources of Materials. The PI will be responsible for the protection of the study materials. Data for this study will be derived from participant interviews (using interview protocols), self-report data such as: demographics (age, ethnicity, gender, education completed, combined household income, marital status, years in current status, relationship to patient, work

outside the home, number of children living in the home, list of caregiver's health issues, and duration of caregiving), documentation from their family member's hospice chart (Patient age, diagnosis and PPS score), and objective data (RN observation). All intervention sessions for each participant will be audio-taped for transcription, data analysis and to evaluate fidelity. Data will be collected explicitly for the proposed study and tapes will be destroyed following transcription and analysis

Potential Risks. There is potential for minimal psychological or social discomfort when completing data instruments. Participants will be willing to participate. The PI is trained on recognizing, reporting and resolving adverse events, such as major depression, suicide ideation, and elder abuse, and will develop a standardized protocol to respond to adverse events as part of the intervention manual. The depression instrument will be scored while the PI is still in the home and if a score of 16 or greater is reported, the participant will be referred to their primary care provider for follow-up. In the event of suspicion of elder abuse, consultation with the Hospice Company and mentors will occur, and if necessary, Adult Protective Services will be called by the PI.

E.2. Adequacy of Protection Against Risk

Recruitment

The study will be initially introduced to the potential spousal caregiver in person, accompanied by a letter and brochure, by the hospice nurse on his/her first home visit, the day following admission. The nurse will tell the spousal caregiver that the hospice company is supporting a researcher, a nurse practitioner advanced certified in hospice and palliative care, who has developed an intervention for caregivers of patients recently admitted to hospice. The nurse will give them an introductory letter and brochure and ask if they would be interested in talking further with the researcher. This letter will state that participation is completely voluntary, that they can withdraw at any time and that confidentiality of all data collected for this study will be addressed each step of the recruitment process. In addition, the letter will state that if they leave the study, the care of their loved one will not be affected. Also included will be the phone number for the Chair of the Human Subjects Institutional Review Board through ASU Research Compliance Office who can be contacted at any time for any problems or questions related to the research (480-965-6788). Further, the letter will discuss the benefits that the participant may experience; that is, a good feeling knowing that they are contributing to science and humanity in an effort to improve the health and welfare of family caregivers caring for newly admitted hospice patients. If the caregiver is willing to meet and learn more about the study, the caregiver will sign an initial referral form with the nurse allowing him/her to screen the caregiver for inclusion criteria. If the caregiver meets inclusion criteria, the hospice nurse will call the PI or RA while still in the home for the caregiver to speak directly with the Pi or RA. The PI or RA will introduce herself, thank the caregiver for taking the time to participate and schedule a 90 minute appointment within the next 48 hours to further explain the study.

The RA will greet the caregiver formally, with a smile and gratitude for taking the time to learn more about the study. The spousal caregiver will be asked if they have any questions

periodically and given ample time to respond to this material. The RA will thoroughly explain the study background, purpose, risks, benefits and procedures to the caregiver and, if they are in agreement, the caregiver will read and sign an informed consent which will also contain all this information. This explanation will be scripted to increase internal validity. If at any time, a caregiver requests to contact a family member for support (i.e., an adult child), they may do so and the researchers will remain flexible in scheduling meetings.

Multiple methods will be used to recruit the sample and will include:

- Face-to face meetings, a way of building trust, will be used (recruiting in this study will be done in person by a trained hospice nurse who will introduce the study to the caregiver, the caregiver's second meeting with the hospice, as it has been recommended that primary recruiting not be done during the first admission meeting
- The PI will teach the hospice staff and herself to not be over zealous in recruitment, and being thoughtful and reflective to self-issues of racial bias
- The hospice RN will be trained to give out study brochures to the caregiver during the first RN visit and elicit questions from the caregiver to enhance recruitment
- Findings of the study will be disseminated back to the community, in this case, the hospice company
- Although most hospices train employees to be culturally sensitive, they do not go out purposefully to recruit patients of ethnic groups. In addition, hospices in Arizona have a representative sample of ethnic groups at any given time in their census and it is not anticipated that it will be difficult to obtain a culturally representative sample in a timely fashion (personal communication, October 16, 2007, Mary Bertram, RN, President Infinity Hospice).
- The PI will make every effort to hire a research assistant who is of one of the major ethnic groups (Latino or African American in Phoenix).
- Hospice staff training will be manualized to ensure consistency in recruitment strategies, program delivery and data collection procedures to increase internal validity

Decreasing attrition and retaining participants has been a challenge for caregivers of family members on hospice due to late referrals into hospice for people with cancer who are often imminently dying. Inclusion criteria attends to this by not recruiting a caregiver whose loved one is considered to be imminently dying, as determined by the hospice nurse using a standard measurement, the Palliative Performance Scale, and a common assessment performed by hospice nurses at admission to hospice care.

Informed Consent. Spousal caregivers will be respected for their autonomous decisions as autonomous individuals and will enter the study completely voluntarily. Care will be taken to provide adequate time and information to caregivers so they can make an informed decision, including contact numbers for future questions. All materials will be provided with both large and normal size print on white paper so as to assist anyone with normal gerontological visual changes that can occur in older adults. Obtaining informed consent can be controversial when one doesn't have an appropriate level of literacy in English; hence, these elements are part of the inclusion criteria.

Components of the informed consent document will include:

- the purpose of the study (to assist spousal caregivers of newly admitted hospice patients to care for their loved one and themselves),
- number of people will participate (for this study, there will be 20 spousal caregivers of family members newly admitted to hospice),
- responsibilities of participants while in the study (participate in 2 sessions and 3 data collection appointments, all lasting approximately 45 minutes, with the overall study length of 30 days/4 weeks and completion of activities, i.e., mutual agreement contract),
- participation in the study is completely voluntary,
- rights as a participant (the right to refuse to answer questions, the right to stop the study at any time, the right to make autonomous decisions, the right to be notified of any new or changed information), without affecting the care of their loved one,
- risks of the study (minimal risk: may bring up sad thoughts as their loved one declines; further, if unexpected emotional reactions should occur during any session or clinically significant levels of depression are reported on the depression scales at any time during the study, a participant will be referred to their primary care provider or appropriate services within the community),
- benefits of being in the study (benefits should outweigh risks in that participant will be given information to be better prepared to care for their dying family member and participate in activities to assist them in their caregiving role),
- that the other option is not to participate and brings no consequences,
- confidentiality (strict confidentiality and HIPAA regulations will be maintained),
- costs of participation (their time to participate in the sessions but no monetary costs anticipated),
- payment for participating (CD player and up to $60 if all 3 data collections are completed),
- what happens if an injury occurs during the study (the PI does not cover any costs of injury to the participant; however, if necessary, will assist in calling 911 if needed), and
- 24-hour phone number to call if they have questions during the study.
- One of the two intervention sessions will be taped to ensure consistency in the intervention process.

Retention. Strategies to build trust and improve retention for all participants include:

- Designing an intervention that is attentive to learning styles (both listening and written materials and if necessary, can be read to the participant), and in-person
- Allow flexibility in scheduling
- Makes use of a 24-hour phone number so the participant can call with any concerns at any time
- Educating hospice staff and participants about the importance of research, suggesting an altruistic motive and its ability to guide practice and help others who have similar experiences.

Incentives. The use of incentives has been a controversial topic with some researchers concerned that incentives are a form of coercion. Careful consideration was given to this issue and it was decided to give CD players to all participants and the CDs they chose as part of the

intervention. In addition, the participants will be paid a token of $20 for each data collection appointments. Thank you cards will be sent weekly during data collection (4 weeks), a week after the final visit and monthly thereafter for 6 months.

Protection against Risk

Confidentiality. All pieces of data will have a number identifier to ensure confidentiality. Participants will be assured that their involvement is voluntary, there are no hazards or cost beyond time involvement and they can withdraw at any time. Participants are informed that all information will be safely and confidentially stored. There will be a signed consent form with the participants name and identifier number on one form and this form with both identifiers on it will be kept in a separate locked file cabinet apart from data files. Only the PI and the administrative assistant, who keeps all keys to the building, will have a key. All data collected in the participant's home will be brought to the research office at Arizona State University for safe storage in the locked storage cabinet. Data materials will be stored in a locked file cabinet in the PI's research office and stored by the investigator for 5 years following the completion of the study. The PI recognizes that all researchers have an obligation to uphold these critical tenets in order to avoid any kind of deception leading to a lack of privacy and confidentiality and to maintain public trust in the research process. The PI is committed to protect the participants from harm by attention to details during every phase of the research study. The PI is committed to adhering to the Office for Protection of Human Subjects and carrying out the responsibilities defined by the Arizona State University Multiple Project Assurance.

E.3. Potential Benefits of the Proposed Research to the Participants

The potential benefits of this study to the participants include an increased ability and feeling that they are capable to be caregivers for their dying loved ones through the development of an appropriate schema. Through the intervention, the participants will become familiar with hospice services and how to obtain assistance when they need it, acquire an increased understanding of normal reactions to the dying process, become aware of the process of dying, symptoms their loved one may experience at end-of-life and skills they can use to assist their family members during this special time in life. It is the belief of the PI that the participants will benefit from the intervention to feel more prepared and better able to care for their dying loved one. Research studies report that providing attention and support for caregivers of family members on hospice prior to death has the potential to decrease complicated bereavement periods and optimize the caregiver's functioning and health after the death of their loved one. The paucity of interventions for this growing population makes it imperative to design theory-based interventions to assist spousal caregivers of family members to care for their dying loved ones.

E.4. Importance of the Knowledge to be Gained

This research is based on a theoretically sound successful intervention and is currently being tested in a new and growing population. This intervention has the potential to successfully

assist caregivers of family members newly admitted to hospice to develop an appropriate schema for caring for a dying loved one. Because there has been little theory-based research on which to develop interventions for spousal caregivers of family members newly admitted to hospice, it is important to begin building a base of theoretically-driven reproducible interventions to increase the knowledge to assist spousal caregivers of family members newly admitted to hospice in the important work they are doing and decrease negative outcomes in this population. It is an exciting time to forge new frontiers in helping a large and critically important growing segment of our healthcare system. Thus, the proposed research represents a significant effort in addressing a knowledge gap in the literature on interventions directed at the self-regulation needs and role of spousal caregivers with family members newly admitted to hospice. In addition, attention to recruitment and retention issues will also support future research by improving methodological issues such as sample size and generalizability. By developing a theory-based, methodologically sound intervention, the ability to promote health for a vulnerable population is possible and the potential of translation to caregivers of hospice patients at large.

E.5. Collaborating Sites

This research will be conducted in collaboration with Infinity Hospice in the Phoenix Metropolitan area. Research will be conducted under the auspices of the Arizona State University Institutional Review Board and the hospices' Institutional Review Boards to review all research protocols. A letter of support in included in the Appendix. The PI currently works with Infinity Hospice assisting with patient care on an as needed basis. Collaboration with Infinity Hospice has included understanding their census and it has been concluded that there is a realistic ability to recruit the sample in a reasonable time frame. Further, Infinity Hospice has an average of 2 per month ethnic patients at any given time so recruiting an ethnic sample is also deemed to be possible for a total of two in this pilot study.

Training. A graduate Research Assistant will be hired and thoroughly trained in the Protection of Human Subjects and study protocol in a two day session with booster session half way through the study. The RA will be CPR trained. The RA will be responsible for delivery of the intervention, data entry and work in the research office whereas the PI will be responsible for overall management of the study, development of materials, recruitment, data collection, analysis and publications. Training for staff in the hospice company will occur in two segments: the general hospice staff and hospice nurses. The general hospice staff will be trained on the basic principles in the protection of human subjects, the importance of research, and the purpose of this study in an interactive one hour session in two groups of 10 employees at a time. Hospice staff will not be told the details of the active components of the intervention to avoid bias and increase internal validity but they will be given general research information (i.e., this is a study to assist family caregivers take care of a newly admitted hospice patient) in order for them to be able to answer questions from the caregiver or family and know where to direct them for answers. They will be given the PI's phone number in order for the PI to follow-up. Hospice nurses will be thoroughly trained in the Protection of Human Subjects. In addition, 2 hospice RNs will be trained on the purpose of this study, obtaining initial consent,

screening for exclusion and inclusion criteria, and data collection (RN observation scale) in a four hour session. The nurse training session will include training and role playing on how to deliver the study introduction to the potential participant and observation measure completion. However, given the nature of the one-group design and lack of a control group, the RN will know who the participants are and it is recognized this may affect internal validity. A second booster training session will occur midway through the research process to ensure scientific integrity. Further, in the event that new staff are hired by the hospice, additional training by the PI will occur during the study when needed. The investigator is committed to making a difference in this population and will be diligent in developing all intervention materials to protect the caregiver participants.

E.6. Data and Safety Monitoring Plan

In compliance with the National Institutes of Health policy for protection of human subjects in clinical cases and intervention studies, the Nursing Advisory Committee of ASU-CON has implemented a Data Safety Monitoring Board (DSMB) policy. The potential risk of this randomized controlled trial is considered to be minimal because of the nature of the motivational, informational intervention program. This study is not expected to have any adverse events associated with its completion, based upon similar previous research. A plan for appropriate oversight and monitoring of the conduct of the research to ensure the safety of the participants and the validity and integrity of the data has been developed consistent with the recommendations of the National Institutes of health and the PHS 398 document.

- The PI has obtained the policies of the Arizona State University IRB specifically regarding the adverse events associated with clinical trials. The PI will adhere to those policies, and maintain a current copy of the policies in the study files.
- The PI will meet with the RAs on a weekly basis during the data collection phase, and identify any risks of adverse effects identified from the data collection process and data/participant review. This information will be relayed to the Data and Safety Management Board (DSMB) for this study.
- The PI, co-investigators, and consultants will make decisions about necessary protocol and operational changes based on input from the DSMB, discussion, and review of data and the data collection process. Any proposed changes in the consent form or research procedures resulting from these meetings and reports will be prepared by the PI and submitted to the ASU IRB for approval.
- The following policies required by the ASU IRB and NIH will be adhered to: (1) any adverse events that are serious and unexpected and are related (possibly or probably) to the study will be reported to the IRB and NIH within 15 calendar days, including any injuries which occur as a result of participating in moderate intensity physical activity; (2) adverse events that are both unexpected and related that are either life-threatening or result in death will be reported to IRB and the NIH Project Officer immediately; and (3) all adverse events that do not meet the criteria above will be documented in the summary report to be submitted to the ASU IRB annually at the time of the study's continuing review. Because the proposed study is a low risk intervention, we do not anticipate any serious adverse effects/events described

in the first two categories from a result of participating in this study. In any event, should an adverse event occur, the DSMB and the NIH Project Officer will be promptly notified.
- The PI will obtain and strictly adhere to the principles and policies of the DSMB and/or human subjects review boards of all participating organizations.
- The PI in conjunction with the DSMB will be responsible for reporting adverse events or unanticipated problems involving risks to subjects or others to the ASU IRB. If problems are considered related to this trial, the IRB at the recruiting and intervention sites will be notified as soon as possible and recruitment/enrollment will cease until the events can be thoroughly reviewed.
- The PI will be responsible for the monitoring of this plan throughout the study.
- The DSMB will retain the right to make independent representation to the regulatory bodies if there has been a failure or lapse in reporting by the Principal Investigator. The DSMB also will have the capacity to instruct the faculty mentor of the project, Dr. Bernadette Melnyk, to pause or terminate pursuance of the research if there is contradictory evidence for the study to be terminated. The DSMB will provide an independent report on its findings on the project within three business days to the Institutional Review Board at Arizona State University.

E.7. Inclusion of Minorities

The proposed sample size is 20 participants. No ethnic group will be excluded. In order to accomplish recruitment of a representative sample for this small sample pilot study, 1 Latino and 1 African American will need to be recruited, a reasonable sample size to recruit given their hospice census (personal communication, Mary Bertram, Infinity Hospice, September 6, 2007). It is acknowledged that this sample may not be representative of the ethnic group at large since under-representation of ethnic groups being admitted to h**o**spice services may actually be a different group. Latinos currently make up approximately 4.3% and African Americans 9.2% of the hospice population in Phoenix, Arizona, the site for this study.

Participants recruited for the study will not be excluded on the basis of ethnicity and will be screened for the study's inclusion criteria. Participants will be asked to self-identify their ethnicity to obtain a clear description of the sample for future work.

Strategies to increase recruitment and retention of ethnic groups will include:

- Participants will be addressed by title and surname unless the PI is told otherwise
- The PI will remain flexible in scheduling and rescheduling appointments
- Short, simple and clear words will be used for all components of the intervention and presented in both large and small print on white paper

The PI has been competently doing home visits in Phoenix, Arizona for over 8 years as a nurse and nurse practitioner to ethnically diverse populations at end-of-life and on hospice and has the expertise to execute this protocol. However, continued collaboration will occur throughout the study with experts in ethnically diverse populations (Dr. David Coon and

Dr. Maureen Campesino). This PI recognizes the ethical obligation of adhering to all policies for the protection of all human subjects.

Inclusion of Women

Women will be included in this study and are expected to be the majority gender as over 60% of caregivers tend to be female. Participants will be monitored for any problems with increased emotional reactions to their role as a caregiver during the intervention. No deception will be used to recruit participants and they will be freely able to leave the study for any reason without affecting the care of their family member. Further, they will be given the PI's and Arizona State University Office of Research and Scholarship's phone number to call at any time for questions pertaining to the study.

Inclusion of Children

No children will be included in this study due to developmental issues and the nature of this study being a preliminary feasibility pilot study. Although the PI is aware of the needs of children dealing with a dying parent or taking care of a dying parent, this first stage of intervention development will be targeted to spouses of dying family members as a first step in a program of research.

F. VERTEBRATE ANIMALS

No vertebrate animals will be included in this study.

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Principal Investigator/Program Director (Last, First, Middle): Lindstrom, Kathryn B.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2. Follow this format for each person.
DO NOT EXCEED FOUR PAGES.

NAME Melnyk, Bernadette Mazurek	POSITION TITLE Dean and Distinguished Foundation Professor
eRA COMMONS USER NAME: bmelnyk	

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)

INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
West Virginia University, Morgantown, WV	BS	1979	Nursing
University of Pittsburgh, Pittsburgh, PA	MSN	1983	Nursing Care of Children
University of Rochester, Rochester, NY	PhD	1992	Clinical Nursing
University of Rochester, Rochester, NY	Post- Master's	2002	Psychiatric Mental Health Nurse Practitioner

A. POSITIONS AND HONORS

Positions and Employment

1979–1983	Staff Nurse, Children's Hospital of Pittsburgh, Pittsburgh, PA
1980–1982	Pediatric Nursing Instructor, Shadyside Hospital School of Nursing, Pittsburgh, PA
1984–1986	Pediatric Nurse Practitioner, Guthrie Clinic Pediatric Associates, Sayre, PA
1984–1986	Instructor in Parent-Child Health Nursing, Robert Packer Hospital School of Nursing, Sayre, PA
1986–2004	Pediatric Nurse Practitioner Consultant, Children & Youth In-Patient Unit, Psychiatric Mental Nurse Practitioner, Child/Teen Day Treatment Program, Elmira Psychiatric Center, Elmira, NY
1987–1988	Pediatric Nurse Practitioner, Speno, Perry and Kiernan Pediatrics, Ithaca, NY
1986–1988	Assistant Professor of Nursing, Keuka College, Keuka Park, NY
1988–1991	Research Assistant, University of Rochester, Rochester, NY
1989–1992	Senior Associate, University of Rochester School of Nursing, Rochester, NY

1990–1992	Pediatric Nurse Practitioner, Hillside Children's Center, Rochester, NY
1992–1998	Assistant Professor of Pediatrics, Univ. of Rochester School of Medicine & Dentistry
1992–1998	Assistant Professor of Nursing, University of Rochester School of Nursing, Rochester, NY
1998–2002	Associate Professor of Nursing (with tenure), University of Rochester School of Nursing, Rochester, NY
1998–2002	Associate Professor of Pediatrics, University of Rochester School of Medicine & Dentistry
1999–2004	Associate Dean for Research and Director, Center for Research and Evidence-Based Practice, University of Rochester School of Nursing, Rochester, NY
2002–2004	Professor of Nursing and Pediatrics, University of Rochester, Rochester, New York
2005–present	Dean and Distinguished Foundation Professor in Nursing, Arizona State University College of Nursing, Tempe, AZ

Selected Honors and Awards

1978	Sigma Theta Tau International
1979	West Virginia University Alumni Award for service, leadership and scholarship
1988	Professor of the Year: Keuka College
1990	National Research Service Award Predoctoral Fellowship, National Center for Nursing Research
1991	University of Rochester School of Nursing Excellence in Teaching Award
1995	Dean's Award for Excellence in Teaching, University of Rochester, School of Nursing
1996	Most Promising New Investigator, University of Rochester, School of Nursing
1996	Mead Johnson Nutritionals Nursing Research Scholar
1997	Haggerty-Stanford Friedman Scholar, University of Rochester
1998	Professional Advancement Award, University of Rochester School of Nursing
1998	Professional Advancement Award. The Upstate New York Chapter of the National Association of Pediatric Nurse Practitioners
1999	New Child Health Leader, Rochester Child Health Congress (competitively selected from a pool of national candidates)
2000–2001	Sigma Theta Tau International Distinguished Lecturer
2001	Distinguished Contributions to Nursing Research Award, Eastern Nursing Research Society
2002	Elected Fellow, National Academies of Practice
2002	Elected Fellow, American Academy of Nursing
2002	Invited Participant, Research Themes Expert Panel on Settings Priorities for Nursing Research, National Institutes of Health/National Institute of Nursing Research
2003	Professional Advancement Award, Upstate New York Chapter of the National Association of Pediatric Nurse Practitioners
2003	Professional Advancement Award, University of Rochester School of Nursing
2003	Faculty, Leadership Academy, Maternal-Child Nursing, Sigma Theta Tau International
2003	President's Award. National Association of Pediatric Nurse Practitioners' (NAPNAP) (for national leadership in improving the psychosocial health of children and adolescents)
2003	Audrey Hepburn Award (for substantial contributions to improving the health of children globally), Sigma Theta Tau International
2004	2004 Jessie M. Scott Award (for the significant improvement of nursing and health care through the integration of research, practice, and education), American Nurses Association

B. SELECTED PUBLICATIONS (*DATA-BASED, +REFERRED) (TOTAL = 100)

1. Melnyk, B.M. (1994). Coping with unplanned childhood hospitalization: Effects of informational interventions on mothers and children. Nursing Research 43(1), 50–55. +*
2. Melnyk, B.M. (1995). Coping with unplanned childhood hospitalization: The mediating functions of parental beliefs. Journal of Pediatric Psychology, 20(3), 299–312.*+
3. Melnyk, B.M. (1995). Parental coping with childhood hospitalization: A theoretical framework to guide research and interventions. Maternal-Child Nursing Journal, 23(4), 123–131. +
4. Melnyk, B.M., & Alpert-Gillis, L.J. (1996). Enhancing coping outcomes of mothers and young children following marital separation: A pilot study. Journal of Family Nursing, 2, (3), 266–285.*+
5. Melnyk, B.M., Alpert-Gillis, L.J. Hensel, P.B., et al. (1997). Helping mothers cope with a critically ill child: A pilot test of the COPE Intervention. Research in Nursing and Health, 20, 3–14.*+
6. Melnyk, B.M. & Alpert-Gillis, L.J. (1997). Coping with Marital Separation: Smoothing the transition for parents and children. Journal of Pediatric Health Care, 11(4), 165–174. +
7. Melnyk, B.M. & Baggs, J.G. (1998). Partnerships in PICU: Nurse-parent and nurse-physician collaboration. In G. Greensmith (Ed.), Bailliere's Clinical Paediatrics: Paediatric Intensive Care. London: Harcourt Brace.
8. Melnyk, B.M. & Alpert-Gillis, L.J. (1998). The COPE program: A strategy to improve outcomes in critically ill young children and parents. Pediatric Nursing, 521–527.+
9. Melnyk, B.M. et al. (2000). Evidence-Based Practice: The Past, the Present and Recommendations for the Millennium. Pediatric Nursing, 26, (1), 77–80.+
10. Melnyk, B.M. (2000) Intervention studies involving parents of young hospitalized children: An analysis of the past and future recommendations. Journal of Pediatric Nursing, 15 (1), 4–13.+
11. Melnyk, B.M., Fairbanks, E., & Feinstein, N.F. (2002). Informational/behavioral interventions with parents of LBW premature infants: An evidence-base to guide practice. Pediatric Nursing, 28 (5), 511–516.
12. Melnyk, B.M., Feinstein, N.F., Tuttle, J., et al. (2002). Mental health worries, communication, and needs of children, teens, and parents during the year of the nation's terrorist attack: Findings from the National KySS survey. Journal of Pediatric Health Care, 16 (5), 222–234+*
13. Melnyk, B.M., & Fineout-Overholt, E. (2002). Putting research into practice. Rochester ARCC. Reflections on Nursing Leadership, 28 (2), 22–25.
14. Melnyk, B.M., Brown, H., Jones, D., Kreipe, R., & Novak, J. (2003). Improving the Mental/Psychosocial Health of U.S. Children and Adolescents: Outcomes and Implementation Strategies from the National KySS Summit. Journal of Pediatric Health Care, 17 (2), S1–S24 (Supplement).
15. Melnyk, B.M., Alpert-Gillis, L., Feinstein, N.F., (2004). Creating opportunities for Parent Empowerment (COPE): Program effects on the mental health/coping outcomes of critically ill young children and their mothers. *Pediatrics* (Electronic Pages), 113 (6), e597–607.+*
16. Melnyk, B.M., & Fineout-Overholt, E. (2005). Evidence-Based Practice in Nursing & Healthcare. A Guide to Best Practice. Philadelphia: Lippincott, Williams, & Wilkins.+

17. Melnyk, B.M., & Moldenhauer, Z. (2006). The KySS Guide for Child & Adolescent Mental Health Screening, Early Intervention and Health Promotion. Cherry Hill, New Jersey: NAPNAP.
18. Melnyk, B.M., Feinstein, N.F., Alpert-Gillis, L., Fairbanks, E., Crean, H.F., Sinkin, R., Stone, P.W., '' Small, L., Tu, X., & Gross, S.J. (in press). Reducing premature infants length of stay and improving parents' mental health outcomes with the COPE NICU program: A randomized clinical trial. Pediatrics.+*
19. Melnyk, B.M., Crean, H.F., Feinstein, N.F., & Alpert-Gillis, L. (in press). Testing the theoretical framework of the COPE program for mothers of critically ill children: An integrative model of young children's post-hospital adjustment behaviors. Journal of Pediatric Psychology.+*
20. Melnyk, B.M., Small, L., Morrison-Beedy, D., Strasser, A., Spath, L., Kreipe, R., Crean, H.F., Jacobson, D., & Van Blankenstein, S. (in press). Mental health correlates of healthy lifestyle attitudes, beliefs, choices & behaviors in overweight teens. Journal of Pediatric Health Care.+*

C. RESEARCH PROJECTS ONGOING OR COMPLETED DURING THE LAST 3 YEARS

Ongoing Research Support

R01 NR05077 Melnyk, B. (PI) 5/1/01–1/31/07
NIH/National Institute of Nursing Research
"Improving Outcomes of LBW Premature Infants and Parents"
The primary aim of this multi-site study is to ev**a**luate the effects of a theoretically-driven, reproducible intervention (COPE = Creating Opportunities for Parent Empowerment) on the process and outcomes of mothers and fathers/significant others' copying with a LBW premature infant developmental outcomes. The secondary aims are to: (a) explore how the coping process and outcomes of mothers and fathers together contribute to the outcomes LBW premature infants; (b) determine the cost-effectiveness of the COPE program; (c) explore what factors moderate the effects of the intervention program (e.g. temperament, family structure, SES).
Role: PI

R01 NR05077-S1 Melnyk, B. (PI) 8/1/2004-1/31/07
NIH/National Institute of Nursing Research
"COPE for Parents and Preterms: 2 ½ and 3 Year Follow-Up"
The primary aim of this supplemental study is to: (a) conduct 2 ½ and 3 year old follow-up assessments of LBW premature infants and their parents who are currently enrolled in our NIH/NINR funded randomized clinical trial that is testing the effects of a theoretically-driven reproducible intervention program (COPE= Creating Opportunities for Parent Empowerment) on child and parent outcomes, through 2 years corrected age; and (b) determine the effects of a booster intervention at 2½ years of age for half of the children and parents in our COPE experimental group in order to determine whether the effects of the COPE intervention can be enhanced during the pre-school years.
Role: PI

R01 NR008455-01 Li, H (PI) 4/1/03-12/31/06
NIH/National Institute of Nursing Research
"Improving Outcomes of Hospitalized Elders and Family Caregivers"
The primary aim of this study is to evaluate the effects of theoretically-driven, reproducible intervention (CARE: Creating Avenues for Relative Empowerment) on the process and outcomes of hospitalized elders and their family caregivers. The secondary aims are to: (a) explore if type of relationship with the elderly patient moderates the effects of the CARE program, and (b) determine the cost-effectiveness of the CARE program.
Role: Co-PI

Completed Research Support

Type: External Funding Melnyk, B. (PI) 2/2002-2/2003
Agency: The National Association of Pediatric Nurse
Practitioners (NAPNAP) & Lowe's Home Safety Council
The KySS (Keep your children/yourself Safe and Secure) National Survey: Mental Health Worries, Knowledge, and Needs for Intervention by Children, Teens, Parents, and Healthcare Providers
The primary aim of this national survey was to assess the mental health knowledge, attitudes, worries and needs of school-age children/adolescents, parents, and healthcare providers. In addition, healthcare provider screening practices and satisfaction with level of preparation to assess and manage mental health problems in primary care.

2 T71 MC00012-06 Kreipe, R (PI) 07/1/02 -12/30/04
MCH Department of Health and Human Services
Health Resources and Services Administration
"Rochester MCH Leadership Education in Adolescent Health"
The major goal of this study is to improve the health of adolescents by providing interdisciplinary leadership education that prepares trainees for leadership roles in training for, conducting research on, and developing organized systems for, the delivery of innovative and effective adolescent health services.

1 T21 MC00108-01 Melnyk, B. (PI) 06/01/02-5/31/05
MCHB, Department of Health and Human Services
"Improving Mental Health and Safety of Children and Teens"
The goals of the program are to: (a) develop and implement a strategic plan to improve the mental healthoutcomes and safety of children and adolescents, and (b) enhance the knowledge and skills of nurse practitioners, nurses, and physicians who care for children and adolescents in the areas of assessment, early intervention, and prevention of pediatric mental health/psychosocial morbidities.
Role: PI

1 D09 Hp00358-01 Melnyk, B. (PI) 07/01/02-6/30/05
Bureau of Health Professions, Advance Nursing Education
"Dual PNP/Psych Mental Health Nurse Practitioner Program"

The proposed program will target baccalaureate prepared nurses at the local, regional, and national level who desire dual preparation as both a PNP and PMHNP in their master's program. One of the purposes of this program is to produce a new model of care in pediatric primary care practice by getting to the "root" of the problem and infusing the healthcare system with nurse practitioners who have the knowledge and skills to effectively meet the complex gio-psycho-social healthcare needs of children and youth and their families in today's society.
Role: PI

Type: Internal Funding Melnyk, B. (PI) 11/2002-1/2005
Agency: Project Believe, University of Rochester Medical Center
"COPE/Healthy Children: An Intervention to Promote Healthy Lifestyles and Mental Health in Overweight
Children/Teens and Parents"
The primary aim of this study is to pilot-test the effects of a theoretically-driven, reproducible intervention on the lifestyle behaviors and mental health outcomes of pre-school children, school-age children, and adolescents as well as their parents.

COPE/Healthy Lifestyles for Teens: A School-Based Randomized Controlled Trial

PI: Bernadette Mazurek Melnyk, PhD, RN, CPNP/PMHNP, FNAP, FAAN

Contact Information: Bernadette Mazurek Melnyk, PhD, RN, CPNP/PMHNP, FNAP, FAAN
Associate Vice President for Health Promotion
University Chief Wellness Officer; Dean, College of Nursing
The Ohio State University
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Columbus, OH 43210
Melnyk.15@osu.edu

Grant # 1R01HD059063-01A2

Funding: NIH/NINR

March 9, 2009

Dear NIH Referral Officer,

Please find enclosed my R01 revised grant application entitled, *COPE/Healthy Lifestyles for Teens: A School-Based Randomized Controlled Trial* (#1R01HD059063-01A2). I am asking that this application be assigned to be reviewed again by the Community-Level Health Promotion (CLHP) Study Section Health of the Population Integrated Review Group, and be dually assigned for funding consideration to NICHD and NINR if the application is competitively selected for an award. Please note that I am a standing member of the Nursing Science: Children and Families Study Section at NIH.

Thank you for your thoughtful consideration.

Sincere regards,

Bernadette Mazurek Melnyk, PhD, RN, FAAN
Dean and Distinguished Foundation Professor

500 North 3rd Street, Phoenix, AZ 85004-0698
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www.nursing.asu.edu

1. INTRODUCTION TO THE REVISED APPLICATION

We appreciate the reviewers' thoughtful critiques of our last application as they were very helpful in assisting us in revising and strengthening this application. Our revisions in response to the reviewers' comments and suggestions are *italicized* throughout the text. The reviewers noted that our study addresses significant public health problems (i.e., obesity and depression) in adolescents, has very high potential, and is innovative in the integration of mental health and obesity prevention, especially in a mostly Hispanic population.

Response to Issues Raised by Reviewer #1. It was noted that the hypotheses for our study are ambitious and include physiological as well as mental health outcomes. After much thoughtful consideration and discussion, our study team has decided to streamline our hypotheses and measures to focus on the primary outcomes of healthy lifestyle behaviors and depressive symptoms. Based upon our extensive pilot work, we expect the teens who receive our COPE/Healthy Lifestyles TEEN (Thinking, Emotions, Exercise and Nutrition) Program to report more healthy lifestyle behaviors (e.g., engaging in physical activity, choosing healthier foods) and less depressive symptoms than teens who receive the attention control program, which should ultimately result in the prevention of overweight in normal weight teens and less weight gain in teens who are overweight and obese at the commencement of the study. An objective measure of physical activity in the teens also will be obtained with pedometers.

There was a question about the type of pedometer that we will use in the study as well as how the data from the pedometer will be used. The New Lifestyles SW-200 Digi-Walker Pedometer step counter will be provided to the teens in both the COPE and attention control groups at the beginning of the study. This is a simple, easy to use step counter that tracks the number of steps taken each day. This model is approximately 2″ × 1 1/2″ × 3/4″ and weighs less than 3/4 ounce. We established the feasibility of using pedometers with the teens in our preliminary study #4. The teens will record their steps for 7 days at four time points, including at: (a) baseline, (b) the end of the intervention program, (c) 6 months following the intervention program, and (d) 12 months following the intervention program. The mean number of pedometer steps per day over 7 days will be used as a measure of healthy lifestyle behaviors (a primary outcome in the proposed study) along with the Healthy Lifestyle Behaviors Scale, which has excellent psychometric properties (see preliminary study #6).

The reviewer asked us to report specific effect sizes for each of the primary endpoints, which we have now included in our revised Table 12. We also have included the effect size for our secondary endpoint (i.e., weight) in this table. In addition, the reviewer asked us to report the power analysis for the cluster randomized design in greater detail. Therefore, we have modified our analysis plan to respond to this issue.

A suggestion also was made by the first reviewer to provide constructs in Table 9 that correspond to each session. They are now included in the table. We also have linked the constructs in our conceptual model to the measures that we have chosen.

More information was requested about the Community Advisory Board (CAB). The CAB will help to ensure that our research is conducted in a culturally responsive manner and will address any cultural and community concerns. The investigators and other team members will attend CAB meetings, present research plans and findings, and solicit commentary from the board members. A key role of the board will be to keep the research team thinking about the cultural appropriateness of the approach and the applicability of the findings. The board also will provide support regarding the translational aspects of the study. The key questions guiding the board's work will be: 1) Why is this study significant for our communities? 2) How can its findings help improve the healthy lifestyle behaviors and mental health of our youth? and 3) Are we utilizing methods that are culturally responsive and sustainable? The board will have 12 members, comprised of parents, teachers, and community leaders, who will meet bi-monthly. Dr. Flavio Marsiglia, a co-investigator for the proposed study, is a seasoned NIH-funded Hispanic researcher who has devoted his career to testing culturally responsive school-based interventions for Hispanic children. He has been highly successful in establishing CABs and conducting research within the Hispanic community. Dr. Marsiglia will assist us in establishing an active CAB and ensuring that all aspects of our study are culturally responsive and trust-building.

Response to Issues Raised by Reviewer #2. It was noted that there was a tremendous amount of measures from many data collection instruments and, subsequently, Reviewer #2 expressed concern about subject burden. Because of so many measures included in the last application, the reviewer also noted that there was some lack of clarity on the specific measures for the hypotheses to be tested. In addition, a comment was expressed about the wisdom and cost of taking blood samples to measure metabolic syndrome in the study. After thoughtful consideration by the team, the hypotheses have been streamlined and the number of measures decreased in order to focus on our two key primary outcomes of healthy lifestyle behaviors and depressive symptoms as well as to decrease subject burden and increase the chances of successful follow-up at 6 and 12 months after the intervention. As recommended, we have eliminated the blood work from the study although we will still obtain body mass index percentage as we believe that enhancing healthy lifestyle behaviors will ultimately result in the prevention of obesity in normal weight teens and less weight gain in teens who are overweight and obese at baseline.

Another issue noted was that it was not clear to what extent the information presented in the intervention is contained in other information that students would have received in junior high or senior high school. Although students typically receive basic information about nutrition in their health courses in junior and senior high school, findings from research have indicated that the provision of information alone does not usually lead to changes in healthy lifestyle behaviors. We have further evidence to support this finding from our recent study with 404 high school teens to establish the psychometric properties of a few of our instruments to be used in this application (see preliminary study #6). In this instrumentation study, we collected measures of healthy lifestyles knowledge, beliefs and behaviors on 404 high school teens at the beginning and end of the semester. During the semester, students were presented healthy lifestyles information through a newly revised curriculum by their school

district that included the following topics: fitness for life, exercise as the best vehicle for managing stress levels and boosting self-confidence, healthy nutrition, and establishing self-efficacy for performing healthy lifestyle behaviors. Despite a new enhanced district led health curriculum that semester, no positive changes occurred in the students on any measures from the beginning to the end of the semester, including nutrition and activity knowledge, healthy lifestyle beliefs, healthy lifestyle choices and behaviors. Specifically, the mean knowledge score on physical activity questions at the beginning and end of the semester was the same at 8.2 (i.e., the students answered only 68% of the activity knowledge items correctly). The nutrition knowledge score also stayed the same from the beginning to the end of the semester, with a mean score of 11.1 (i.e., the students answered only 55.5% of the nutrition knowledge items correctly) at the beginning of the term and a mean nutrition knowledge score of 11.4 (i.e., the students answered only 57% of the items correctly) at the end of the semester. In addition, the students' healthy lifestyle beliefs remained essentially unchanged from the beginning of the term (mean score of 58.07) to the end (mean score of 57.63). Thus, receiving educational information only on these topics did not improve the teens' knowledge, healthy lifestyle beliefs or healthy lifestyle behaviors and indicates that other types of interventions are necessary in order to strengthen their cognitive beliefs about healthy lifestyles and to stimulate behavioral change.

Our COPE program is unique as it not only provides nutrition and exercise educational information, but the intervention includes physical activity along with a cognitive behavioral skills building component with homework assignments that facilitate the students to take the information that they are learning and put it into daily practice. Based upon the positive findings from our preliminary studies with the intervention, we expect that the COPE program will result in healthier lifestyle beliefs and behaviors along with less depressive symptoms in the teens who receive it. The importance of including a strong cognitive behavioral skills building component in our intervention is further supported by a recently published study that examined the relationship between mental health problems and weight in a population-based study of 35,184 youth from the 2003 National Survey on Children's Health data who were 12 to 17 years of age.[1] Compared with non-overweight adolescents, overweight white and Hispanic teens were significantly more likely to report depression and feelings of worthlessness. This study concluded that, when dealing with overweight in youth, mental health issues need to be addressed as the co-morbidity of mental health conditions may deter any efforts at achieving a healthy weight status.

Reviewer #2 noted that we had a strong investigative team, but stated that the project appears to be top-heavy with multiple PhD investigators. Our team of interdisciplinary investigators has a long history of working together on healthy lifestyles interventions for adolescents. Each member of the team brings expertise that adds strength to the design (Melnyk, Marsiglia), conceptual framework (Melnyk, Small), school-based interventions (Melnyk, Marsiglia, O'Haver), physical activity (Shaibi), statistical analysis (Mays, Belyea), adolescent health (Melnyk, O'Haver), interpretation of the study's findings (Melnyk, O'Haver, Small), and cultural responsiveness (Marsiglia, Shaibi). Although there are multiple investigators, we have kept the percent of time allocated to the study for each investigator very reasonable, and decreased the time for two of the co-investigators from 10 to 5 percent.

Response to Issues Raised by Reviewer #3. The issues with the study raised by Reviewer #3 focused on the analysis plan. The first concern was that the intraclass correlation had not been taken into account in the analysis plan or calculation of power. Responding to the other reviewers' concerns led us to simplify the project and emphasize two primary outcomes (i.e., healthy lifestyle behaviors and depressive symptoms). Furthermore, since the last submission, we have added four more schools to the plan, for a total of eight schools that will be included in the proposed study. Thus, we have modified our analysis plan to match the new aims and methods, and have expanded our description of the power analyses that support it. We have addressed in detail the issues of clustering and provide specific estimates of effect sizes for our key outcomes.

Second, the third reviewer recommended that we use multiple imputation (MI) to handle missing data and requested that we identify what software we would use to do the imputation. We will use this strategy as recommended, taking advantage of the recently published work of Taljaard and colleagues[2] on adapting MI to cluster randomized trials. Furthermore, we will use the recently released upgrade (v17) to the SPSS Missing Values module or SAS v9 PROC MI to complete the imputation and pooling procedures, depending on the presumed cause of the missing data, the type of distributions seen in the data,[3–10] and ease of use.

Dr. Michael Belyea, a very seasoned biostatistician and an expert in structural equation modeling as well as hierarchical linear modeling (see biosketch), assisted Dr. Mays in our revised analysis plan for this application. He also will assist her in planning the final details for all aspects of the analysis in Year 1 and conducting the analyses in Year 4 of our study. The percent time originally allocated for Dr. Mays on the project in years 1 and 4 is now divided between Dr. Mays and Dr. Belyea.

2. SPECIFIC AIMS

The prevention and treatment of overweight/obesity and mental health disorders in adolescence are two major public health problems in the United States (U.S.) today.[11, 12] The incidence of adolescents who are overweight or obese has increased dramatically over the past 20 years, with approximately 17.1 percent of teens now being overweight (i.e., a gender and age-specific body mass index [BMI] at or above the 85th percentile, or obese, which is defined as a gender and age-specific body mass index (BMI) at or above the 95th percentile.[13, 14] Key factors influencing the obesity epidemic include an increase in sedentary activities (e.g., television viewing; computer games) and changes in dietary patterns and food consumption (e.g., large portion sizes, fast foods). Being overweight predisposes adolescents to adverse health outcomes compared to their non-overweight counterparts, including Type 2 diabetes, hypertension, dyslipidemia, sleep apnea, increased asthma symptoms and a shortened life span.[15–17] Overweight and obese adolescents, in comparison to normal weight adolescents, also have a higher prevalence of school and mental health problems, including poor academic performance and self-esteem, depressive disorders, and a greater number of reported suicide attempts.[18–24] ***In addition,***

compared to their non-overweight peers, both Hispanic and White teens who are overweight are significantly more likely to report depression and feelings of worthlessness.[1]

Furthermore, approximately 15 million children and adolescents in the U.S. have a mental health problem that is interfering with their functioning at home or at school, but less than 25 percent receive treatment for these disorders.[21, 25] Depression among adolescents is associated with disabling morbidity, significant mortality, and substantial healthcare costs[26, 27] Recent annual prevalence data[11] from the national surveillance of high school students (9th to 12th graders) indicate that depressive symptoms severe enough to impair daily functioning are reported by 37% of girls and 20% of boys. Depressed adolescents also typically have altered psychosocial and academic functioning, even after these conditions resolve.[28–31] The prevalence rates of obesity and mental health problems are even higher in Hispanic teens, with the two conditions often co-existing.[13, 32–35]

Despite the rapidly increasing incidence and adverse health outcomes associated with both overweight and mental health problems, very few theory-based intervention studies have been conducted with adolescents to improve both their *healthy lifestyle behaviors* and mental health outcomes.[36] Unfortunately, physical and mental health services continue to be largely separated instead of integrated in the nation's healthcare system, which often leads to inadequate identification and treatment of these significant adolescent health problems. Furthermore, most obesity treatment and prevention trials have focused on school-age children.[37–45]

Middle adolescence is a key time in development to implement prevention programs as teens are beginning to establish long-term health behavior patterns. However, intervention studies focused on the adolescent age group have had several important limitations, including lack of well delineated theoretical frameworks to guide the interventions and selection of study variables, lack of attention control or comparison groups, and measurement of short-term outcomes only.[46, 47] Recent systematic reviews of treatment and prevention studies for childhood and adolescent obesity and *an integrated literature review on school-based intervention studies concluded that additional research is urgently needed, especially with culturally diverse groups*.[46, 48] **Another recent evidence review by Kropski, Keckley and Jensen (2008) noted that they were not able to draw strong conclusions about the efficacy of school-based obesity prevention programs because there are a small number of published studies, and the ones that have been published have methodological flaws.**

Our preliminary work indicates that the cognitive beliefs of adolescents are related to their healthy lifestyle behaviors and level of depressive symptoms.[49] In our most recent descriptive correlational study (see preliminary study #6) with over 400 high school students conducted since our first application, findings indicate that teens with stronger beliefs/confidence about their ability to engage in healthy lifestyle behaviors and perceptions that they are less difficult to perform, engage in more healthy behaviors. Additionally, teens with higher levels of negative mood had less healthy lifestyle beliefs and behaviors. Therefore, a novel innovative approach to healthy lifestyle interventions with teens may be cognitive-behavioral skills building (CBSB), which could assist adolescents with cognitive change/strengthening their healthy lifestyle

beliefs in order to facilitate healthy lifestyle behaviors. A second benefit of incorporating CBSB into healthy lifestyle interventions is that numerous studies have demonstrated its positive impact on depression in both adolescents and adults.[50]

Findings from our recent pilot studies of the feasibility and efficacy of the COPE/Healthy Lifestyles TEEN Program, a theory-driven, CBSB healthy lifestyles intervention program, with overweight and normal weight culturally diverse adolescents have indicated promising short-term positive physical and mental health outcomes (e.g., an increase in healthy lifestyle behaviors, decrease in weight, decrease in depressive symptoms) (see preliminary studies). **Therefore**, **the primary goal** of the proposed study is to test the short and more long-term efficacy of the COPE/Healthy Lifestyles TEEN Program on the healthy lifestyle behaviors and depressive symptoms of *800* culturally diverse teens enrolled in Phoenix, Arizona high schools for the ultimate purpose of preventing overweight and mental health disorders.

Specific aim 1. *Use a randomized controlled trial (RCT) to test the short- and more long-term efficacy of the COPE/Healthy Lifestyles TEEN Program to improve healthy lifestyle behaviors and depressive symptoms of 14 to 16 year old culturally diverse adolescents enrolled in Phoenix, Arizona high schools.*

- **Hypotheses 1a *(primary outcomes).*** *Immediately following the COPE program and at 6 and 12 months post-intervention, teens who receive the COPE program versus teens who receive an attention control program (i.e., Healthy Teens) will report:*
  - *more healthy lifestyle behaviors*
  - *less depressive symptoms*
- **Hypothesis 1b (*subgroup analysis: secondary outcome*).** Immediately following the COPE program and at 6 and 12 months post-intervention, *among teens with elevated depressive symptoms at baseline,* those who receive the COPE program versus teens who receive the attention control program will have less depressive symptoms.
- **Hypotheses 1c (*subgroup analysis: secondary outcome*).** Immediately following the intervention and at 6 and 12 months post-intervention, overweight teens at baseline who receive the COPE program versus teens who receive an attention control program will have less weight gain.
- **Hypothesis 1d (*subgroup analysis: secondary outcome*).** Fewer normal weight teens in COPE versus the attention control program will convert to *overweight* at 6 and 12 months post-intervention.

Specific aim 2. Examine the role of cognitive beliefs and perceived difficulty in leading a healthy lifestyle in mediating the effects of the COPE program on healthy lifestyle behaviors and depressive symptoms in 14 to 16 year old adolescents.

- **Hypothesis 2 (*theory building exploratory*).** The effects of the COPE program on the teens' healthy lifestyle behaviors and depressive symptoms will be mediated by their beliefs about their ability to make healthy lifestyles choices and perceived difficulty in leading a healthy lifestyle.

Specific aim 3: Explore variables that may moderate the effects of the intervention on healthy lifestyle behaviors and depressive/anxiety symptoms (e.g., race/ethnicity, gender, SES, family composition, acculturation, structural barriers to activity, and parental healthy lifestyle beliefs and behaviors).

3. BACKGROUND AND SIGNIFICANCE

The prevalence of unhealthy lifestyle behaviors leading to overweight and obesity as well as mental health problems in adolescents continue to be significant public health concerns. Data from the National Health and Nutrition Examination Survey (NHANES) from 2003–2004 indicate that, in all youth 12–19 years of age, 34.3% had a body mass index (BMI) percentile greater than or equal to the gender and age adjusted 85th percentile (overweight). For all adolescents, the prevalence of obesity (≥95th percentile) was 17.4%. Furthermore, **the combined prevalence of overweight and obesity for Mexican American adolescents was 34%.** Perhaps more troubling than the high prevalence of overweight among youth are the associated metabolic co-morbidities including hypertension, dyslipidemia, abdominal adiposity, and glucose dysregulation. These co-morbidities, collectively known as the metabolic syndrome, tend to cluster around a common pathophysiology related to insulin resistance and confer greater risk for cardiovascular disease morbidity and mortality in adults.[51] National estimates suggest that 90% of overweight youth have at least one risk factor for the metabolic syndrome and approximately 30% exhibit the metabolic syndrome phenotype.[52] Prospectively, the metabolic syndrome in childhood predicts adult cardiovascular disease and thus offers an intermediate target for preventing adiposity-related diseases.[53]

Being overweight during adolescence is a risk factor for adult obesity,[54–57] which can lead to serious co-morbidities (e.g., Type 2 diabetes mellitus, hyperinsulinemia, hypertension, dyslipidemia, heart disease, sleep apnea, increased asthma symptoms, gastroesophageal reflux and non-alcoholic fatty liver disease.[17, 21, 55, 58, 59] In addition, being overweight as an adolescent is associated with mental health problems, including depression and lower health related quality of life. Schwimmer and colleagues (2003) found that, in the sample of obese children (n = 106), self reported quality of life was similar to children who had been diagnosed with cancer.[59] Overweight and obese adolescents also are more likely to have elevated depressive symptoms compared to their normal weight peers.[18, 22]

Mental health/psychosocial problems, risk-taking behaviors, and injuries, many of which are preventable, currently cause more morbidity and mortality in the pediatric and adolescent population than do physical diseases and disorders.[30] Children and adolescents who are affected by depression often have lower self-esteem, underdeveloped social skills, and poor academic functioning.[30] Depression in adolescents also has been associated with risk-taking behaviors, such as alcohol and drug use, cutting behaviors, and high-risk sexual behaviors. Unfortunately, childhood and adolescent mental health is often underestimated as the foundation for adult health. Less than 25% of teens with a significant mental health disorder are seen by an

appropriate mental health service provider.[30, 60] As most of the major mental health disorders begin in adolescence, intensified efforts must be placed on preventing and treating these disorders during this critical time in development.[12]

The increasing incidence, substantial prevalence, extreme morbidity, excess mortality and high cost of treating depression create an urgent need for prevention programs in school-based and primary care settings. The majority of mental health problems in children and adolescents remain under-diagnosed and under-treated, in large part due to inadequate screening and early intervention by primary care providers (PCPs).[30, 61] Substantial stigma about mental health problems still exists and results in families denying that their children have problems or being reluctant to talk with their PCPs about them.[62]

Recent findings from our research with over 400 adolescents indicate that a negative relationship exists between negative mood (i.e., depressive symptoms) and healthy lifestyle behaviors. **Specifically, higher levels of negative mood in teens were associated with less healthy lifestyle beliefs and fewer healthy behaviors. Thus, targeting both changes in cognition/healthy lifestyle beliefs as well as decreasing depressive symptoms through CBSB may be key in helping teens to engage in healthier lifestyle behaviors and ultimately preventing overweight and mental health disorders.**

Adolescent Development. Adolescence, between the ages from 10 to 22 years, is a time of transition from childhood to adulthood that spans from puberty to the achievement of adult roles and responsibilities.[63] It is a unique and critical period in human development, during which time changes in physical and brain developments as well as cognitive, emotional, social and behavioral development occur. **Habits, coping and healthy lifestyle behavior patterns formed during adolescence set the stage for adult behavior.**

Adolescence is divided into 3 phases: (a) early adolescence (10 to 13 years), (b) middle adolescence (14 to 17 years), and (c) late adolescence (18 to 22 years).[64] Children move from Erikson's state of industry versus inferiority in the school-age years to identity versus role diffusion in adolescence, where teens strive to determine who they are and what role they will play in society. Early adolescents tend to lack emotional regulation, but late adolescents tend to have better emotional regulation and control over their behaviors.[12] As part of the developmental struggle during this time period, adolescents tend to test limits and experiment with unhealthy/risky behaviors (e.g., smoking, sexual risk-taking, alcohol consumption, overeating). Some key psychosocial attributes of adolescence include: (a) having mood swings, (b) being extremely group minded with conformity being the norm, (c) desiring popularity and peer engagement, (d) developing intimate interpersonal relationships, and (e) testing limits and rules. Teens also are frequently preoccupied with body image concerns and tend to resist parental authority as a means of gaining independence.[65]

There are dramatic changes in brain development during adolescence, including maturation of myelin, changes in the relative volume and level of activity of different areas of the brain, and a major decrease in the number of synapses.[63, 66] Cognitively, the adolescent transitions from

concrete operational thinking to formal operational thought patterns.[67] As part of formal operational thinking, adolescents are able to think about the future, reason in a more abstract nature, imagine new possibilities, think about the consequences of their behaviors, and engage in scientific reasoning.[68] They are typically egocentric and believe in an imaginary audience, which leads to preoccupation with the self and the perception that their behavior is the focus of others' attention. Their illusions of immortality often lead to risk-taking behaviors. Key developmental tasks of adolescence include: (a) transitioning from concrete to formal operational thought, (b) accepting physical changes, (c) achieving independence from parents, (d) adopting peer codes and lifestyles, (e) establishing relationships outside of the home, (f) assigning increased importance to self-concept and the formation of a realistic body image, (g) establishing appropriate value systems, (h) finishing formal schooling, and (i) choosing a formal career, or further education.[25, 69] *As a result of the cognitive strides made in adolescence, it is an excellent developmental phase to introduce cognitive change (i.e., strengthening cognitive beliefs/confidence) to promote healthy lifestyle behaviors.*

Key Factors Influencing Adolescent Development and Risk for Obesity and Mental Health Disorders. Multiple factors influence adolescent development and place adolescents at risk for adverse outcomes, including obesity and mental health disorders. Key factors influencing overweight in adolescents include: (1) one or both parents being overweight, (2) decreased physical activity, (3) large portion sizes, (4) increased sedentary time, (5) demographic variables, such as socioeconomic status, (6) the built environment, and (7) school policies limiting time in physical education and allowing minimally nutritious food to be served.[70–73] Family connectedness, commitment to family meals and a positive mealtime environment also have been found to be positively associated with psychological well-being and inversely associated with depressive symptoms and unhealthy weight-control behaviors in adolescents.[74] Factors influencing the development of adolescent depression and other mental health disorders include parental depression or other family mental health disorders, family dysfunction or violence, abuse, acute or chronic illness, life stressors and changes, trauma and/or losses, poor self-esteem, poor coping skills, lack of social or peer support, substance abuse or other psychopathology.[21, 30] It has been hypothesized that the increased rate of mental health problems from childhood to adolescence could be related to: (a) genes that may not be triggered until late childhood or adolescence, (b) sex hormones that are activated at puberty, (c) an increase in life stressors, (d) lack of protective factors (e.g., family support), and (e) cognitive advances that may lead to depressogenic thinking.[75] Adolescents also are able to imagine the future and think about consequences to their actions.[76]

Health Disparities in the Prevalence of Obesity and Mental Health Disorders in Teens. Childhood and adolescent obesity has reached epidemic proportions in the United States, and particularly in Arizona. The incidence of overweight among children and adolescents has tripled in the past 30 years. Childhood obesity has been determined to be an independent risk factor for adult obesity,[54, 55] and predicts adult cardiovascular disease.[77] Furthermore, there are significant health disparities related to childhood overweight/obesity in Mexican American children (6–11 and 12–17 years) and Latino children. Obesity estimates are as high as 50% in Mexican American children and teens. Beyond obesity, Latino youth are more insulin resistant than their Caucasian

counterparts[78] and exhibit lower cardiorespiratory fitness levels,[79] which may contribute to the high incidence of prediabetes[80] and metabolic syndrome in this population.[81]

There also are substantial disparities in child and adolescent mental health among minority groups in Arizona. Data on mental health disparities indicate that depression and suicide are more common among some minorities compared to whites and less common among others. Saluja and colleagues (2004) studied 9863 students, aged 10 to 16 years of age and found that 29% of American Indian youth displayed symptoms of depression, compared to 22% of Hispanic, 18% of White, and 15% of African-American youth. National surveillance data of 9th to 12th graders[11] indicate that depressive symptoms occurred in 18% of White boys, 20% of African American boys, and 26% of Hispanic boys. Depressive symptoms occurred in 33% of White girls, 37% of African American girls, and 47% of Hispanic girls. Utilizing the 2003 National Youth Risk Behavior Survey (YRBS), Paxton and colleagues (2007) found that Hispanic and ethnic minorities classified as "other" teenagers were more likely to report depressed mood than Caucasian and African American teenagers.[82] *Furthermore, in a recent population-based study of 35,184 adolescents from the 2003 National Survey on Children's Health data, Hispanic and White teens who were overweight were significantly more likely to report depression and feelings of worthlessness than their non-overweight peers.*[1] Despite the release of the Surgeon General's National Action Agenda on Children's Mental Health, only a small percentage of children and adolescents in need of mental health services receive them.[83] Furthermore, minority children have even greater difficulty accessing mental health services.[60, 84, 85]

Minority children, teens, and young adults in the U.S. also have persistently lower utilization rates for mental health services, less access to providers, lower treatment rates, and lower satisfaction with quality of care than non-Latino Whites.[86, 87] African American and Hispanic youth have been found less likely to receive treatment for mental health problems than non-Hispanic Whites, independent of socioeconomic status and insurance variables.[88] Poverty and lack of health insurance contribute to racial/ethnic disparities in mental health services, but some disparities persist even when these variables are controlled.[89] Kataoka and colleagues (2003) wrote that Latinos have been found to be less likely than others to receive health care services because of such factors as disproportionate numbers without health insurance, parental preferences and help-seeking patterns, and an unrecognized need for services.[90] They observed, "although this underserved group has been found to consistently underutilize mental health care, there has been little effort in developing and evaluating accessible and evidence-based interventions specifically for Latino children."[90] Thus, there is a great need to test culturally responsive interventions that can tackle health disparities in children and teens.

Cultural Factors that Impact Perceptions of Healthy Behaviors. Many factors contribute to the high prevalence of overweight and obesity among Hispanics/Latinos, including poor diets affected by acculturation, sedentary lifestyles, and low SES. The rapid increase in obesity-related behaviors and obesity between the first and second generations in Hispanic communities is well documented with Latinos demonstrating worsening preventive health behaviors across generations since immigration.[91–93] Flores and Brotanek (2005) describe the worsening

of health and health behaviors from the first to subsequent generations of Latino immigrants.[94] They theorize that cultural factors such as family cohesiveness and respect for parents may be protective. Hulme and colleagues (2003) also describe the Hispanic values of allocentrism (emphasis on the community versus the individual), simpatia (getting along smoothly and pleasantly with others) and familialism (strong attachment to family) as entities that strengthen health-promoting behaviors. Hispanics in this study also subscribed to the belief that health was a matter of "good luck" and participated in relatively few behaviors that demonstrated responsibility for their own health.[95] Although the Mexican diet is traditionally rich in foods with complex carbohydrates and protein, acculturation of Mexican Americans into the new dominant culture has increased the consumption of fried and processed foods, fats, salad dressings, margarine and sugary drinks and sodas at the expense of fruit and vegetable consumption. Kepka, Ayala and Cherrington (2007) found that self-rated health was not associated with BMI for recent Latino immigrants but better health was reported from adult participants who consumed more fruits and vegetables, watched less television and participated more often in leisure-time physical activity.[96] Maternal and child perceptions of actual and ideal body size was influenced by BMI and acculturation with Mexican-American female children and mothers of acculturated families more likely to select thinner figures as the ideal body size.[97] In the proposed study, we will assess how acculturation moderates the effects of the COPE TEEN intervention.

Structural and Environmental Barriers to Healthy Behaviors. Latino children living in impoverished areas are confronted with many barriers that impede their ability to be physically active and lead a healthy lifestyle.[98] Lack of time is reported to affect food preparation and a parent's ability to take their children to activities.[99] Furthermore, safety issues are a concern in both the children and parents. Kerr and colleagues (2006) supported the notion that parental concerns about neighborhood safety are correlated with a child's activity level.[100] In this study, children whose parents had few concerns about their safety in their neighborhood were five times more likely to walk or ride a bike to school than those whose parents were very concerned about safety in their neighborhood. Social support and access to neighborhood facilities also are significant predictors of physical activity for both normal and overweight Latinos.[98] Families often live in urban areas where there is little access to grocery stores and especially groceries that carry high quality fruits and vegetables. Reidpath and colleagues (2002) reported that families living in lower SES neighborhoods were 2.5 times more likely to be exposed to fast food outlets than those in higher SES neighborhoods.[101] Fast food restaurants are plentiful but their inexpensive food is high in fat, sodium and calories and provides very few fresh ingredients or fiber. Because of the potential impact of these barriers, we will measure neighborhood safety that assesses safety and access to public spaces and perceived social support as potential moderators in our study along with SES.

Prior School-Based Intervention Studies to Facilitate Healthy Lifestyle Behaviors and Prevent and/or Treat Overweight in Adolescents. Table 1 outlines the published studies that have been conducted with adolescents in high schools targeting the prevention and/or treatment of overweight/obesity.

Table 1. Studies with Teens in High Schools Targeting Prevention and/or Treatment of Overweight

Author/Location/ Design/Theory	Purpose/Sample/ Setting	Intervention/Outcomes/ Follow-up	Significant Findings	Strengths/ Limitations
Killen, Robinson, Telch, Saylor, Maron, Rich, & Bryson (1989)[102] Northern California The Stanford Adolescent Heart Health Program Two Group RCT Theoretical Framework: Social Cognitive Theory Social Inoculation Theory	**Purpose:** Create, implement and test a school-based multiple risk factor reduction program for high school students. **Sample:** 4 high schools N = 1447 (1130 in F/U) 10th grade students Age 15 (70%), 14 (14%), 16 (14%). 69% White 13.1% Asian 6.4% Latino 2% AA 0.3% American Indian 0.4% Pacific Islander 8.9% other **Setting:** High School PE Classes	**Intervention:** 20 classroom sessions for 50 min. (3X per week for 7 weeks). Delivered by school staff and research team with local guest instructors CVD Risk factors, physical activity, nutrition, cig smoking, stress, goal setting, problem solving skills, self-managed incentives, & action plan creation for behavior change **Control:** Traditional PE class **Outcome Measures:** **Knowledge:** physical activity, nutrition, and smoking, PA checklist, Nutrition checklist Cig smoking / drug use, Height, weight, skinfold, HR & BP resting **F/Up:** 2 months post-intervention	Increased knowledge in physical activity, nutrition and cigarette smoking Increase in the number of non-exercisers that became exercisers More likely to choose healthy snacks More experimental smokers that quit Decrease in resting HR Beneficial effect on BMI & skinfold	**Strengths**: No significant differences at baseline between groups; Theoretical Framework; Randomization to group; Multicomponent intervention; Pre/post testing; Self-monitoring skills taught **Limitations**: F/Up: only short-term effects; No equal attention comparison group; No measurement of mediating and moderating variables to understand the process through which the intervention worked and under what circumstances the intervention best worked.
Fardy, White, Haltwanger-Schmitz, Magel, McDermott, Clark, & Hurster (1996)[103] New York City Coronary Disease Risk Factor Reduction and Behavior Modification in Minority Adolescents: The PATH Program Two Group RCT	**Purpose**: Evaluate a health promotion program combining circuit training and health lecture for its effect on knowledge, behavior, CVD risk factors, and CV fitness **Sample:** One inner city public high school 346 students (80% 9th & 10th grade, 20% 11th & 12th grade) **Treatment group:** 181 (91 Females 90 Males) **Control group:** 165(109 Females 56 Males) 9% Asian 47% AA 21% Hispanic 3 % White 19% Other **Setting:** High School PE Classes	**Intervention:** 30 min classes 5 days per week for 11 weeks. 4 weeks of intervention; 7 weeks of testing. Taught by PE teachers **Each session**: circuit training 20–25 minutes (resistance & aerobic) and health behavior lecture 5 minutes (exercise, nutrition, smoking cessation, stress management, heart disease, cancer, & motivation). **Control:** Volleyball Class for 11 weeks **Outcome Measures:** Height, weight, total cholesterol, % body fat (skin fold), resting sys/diastolic BP **Questionnaires**: PA Checklist, Dietary Habits Food Frequency, Luckhohn's Value Orientation Schema, (health attitude), 3 Minute step test, CV Health **Knowledge F/U:** Immediate post-intervention	(Both boys & girls) Cardiovascular health knowledge significantly greater (Girls) Significant improvement in self-report dietary habits (Girls) Significant decrease in cholesterol (Girls) Significant improvement in CV fitness (Boys) Control group activity improved fitness	**Strengths:** Placebo attention controlgroup; Randomization to group; Multi-component intervention; Pre/post testing **Limitations:** Both groups at same school—potential for cross group contamination; No measurement of mediating and/or moderating variables

O'Neil & Nicklas (2002)[104] New Orleans, Louisiana Gimme 5: An Innovative, School-Based Nutrition Intervention for High School Students Two group RCT (matched pair randomization)	**Purpose:** Evaluate a 4-year, school-based intervention designed to increase daily fruit and vegetable consumption by high school students to 5 or more servings. **Sample:** 12 high schools N = 2213 9th grade students 56% girls 84% White 4% AA 12% other **Setting:** Catholic High Schools	**Intervention:** 1. School media marketing: promote positive attitudes toward fruit and vegetables 2. Workshops: Five 55 minutes workshops on eating habits, eating and athletic performance, evaluate fast food, reading labels, and cooking 3. Increase availability, variety, and taste of fruits and vegetables in school meals. 4. Parent: taste-test activities, recipes and media displays at PTO meetings. Brochures & newsletters mailed to parents. **Control:** Program not reported, presumably usual school curriculum **Outcome Measures:** Knowledge, Attitudes, and Practices questionnaire Intake of fruits and vegetables **F/Up:** 4 years	Knowledge scores were significantly higher in intervention group. Increased awareness in intervention group. Increased consumption of fruits and vegetables in the intervention group	**Strengths:** Longitudinal study; Randomization to group; Large sample; Parent component; Multi-component intervention; Pre/post testing **Limitations:** No equal attention control for comparison group; No measurement of mediating and/or moderating variables
Neumark-Sztainer Story, Hannan, Stat, & Rex 2003[105] Twin Cities, Minnesota New Moves: A School-based Obesity Prevention Program for Adolescent Girls Two group RCT cluster randomized trial)	**Purpose:** Test the feasibility of an innovative school-based program for obesity prevention among adolescent girls. **Sample:** 6 schools N = 201 high school girls 41.9% White 28.6% AA 21.1 % Asian American 4.4% Latino 1% Native American 3% Other **Setting:** High school PE Class	**Intervention:** 1 semester (16 weeks) PA 4X per week (1 day community guest, 1 day strength training, 2 days PE teacher PA); Nutrition class QO Week; Social Support Class QO Week; 8 weekly lunches after the program for maintenance. **Control:** Program not reported, presumably school curriculum **Outcome Measures:** BMI, PA Stages of change, Participation in PA, Dietary intake, Binge eating, Personal Factors, Harter's Self Perception Profile for Children, Media internalization, Self-efficacy to be active, Socio-environmental support. **F/Up:** 16 weeks & 8 months	Trend in intervention group for increase time in PA, decrease soda pop intake, and increase fruit and vegetable intake. High program satisfaction among participants: girls, parents, and school staff.	**Strengths:** RCT Pre-post test; Parent Component No significant differences at baseline between groups; Acceptable attrition Collected information from different sources using quantitative and qualitative methods; Theory-based: Social Cognitive Theory **Limitations:** Allocation by unit, but evaluated by individual; No equal attention comparison group; No measurement of mediating or moderating variables

(Continued)

Table 1 (Continued)

Author/Location/ Design/Theory	Purpose/Sample/ Setting	Intervention/Outcomes/ Follow-up	Significant Findings	Strengths/ Limitations
Pate, Ward, Saunders, Felton, Dishman, & Dowda (2005)[106] Promotion of Physical Activity Among High-School Girls: A Randomized Controlled Trial South Carolina Two Group Randomized Controlled Trial (school unit of randomization) Theory: Social Ecological Theory, Social Cognitive Theory Model: Coordinated School Health Program Model	**Purpose:** Examine effects of a school-based intervention on PA among high-school girls. Aim was to increase % of girls who meet PA guidelines by increasing the intensity and the duration of PA during PE classes and promoting PA participation in other settings. **Sample:** 24 high schools 9th grade girls in 2 cohorts 2744 @ baseline, 1604 with complete data (pre & post) 48.7% AA 46.7% White **Setting:** High school	**Intervention:** Change instructional practices: content/delivery of PE and health education, enhance PA self-efficacy and enjoyment, teach physical and behavioral skills to adopt and maintain an active lifestyle, and adopt moderate to vigorous PA to >50% of PE **Change school environment:** Role model PA, increased communication about PA, promotion of PA by school nurse, and family and community-based activities. **Control:** Program not reported, presumably school curriculum **Outcome Measures:** Height & Weight, 3 Day Physical Activity Record, amount of vigorous or moderate physical activity **F/Up:** Post-Intervention 9 mo.	**Findings:** Prevalence of regular vigorous physical activity was greater in the LEAP intervention schools than in the control schools ($p = .05$). 8% greater participation in vigorous physical activity in intervention schools vs. control schools.	**Strengths:** Large sample and number of schools in intervention; RCT Design; Diversity of schools participating; Measures well validated; Theory-**based:** Social Cognitive Theory **Limitations:** Self-report measure for physical activity; No equal attention comparison group; No measurement of mediating or moderating variables
Chehab, Pfeffer, Vargas, Chen, & Irigoyen (2007)[107] New York City "Energy Up": A Novel Approach to the Weight Management of Inner-City Teens Non-experiment one group design	**Purpose:** Evaluate an innovative program for inner-city girls that focused on addictive food avoidance, exercise, and self-esteem building. **Sample:** 46 girls 98% girls of color, predominantly Latina. **Setting:** All girls high school	**Intervention:** 9 month program. 29 weekly 2 hour sessions. Content focus on: 1. Doing something nice for others 2. Positive affirmations 3. Avoid foods containing flour, sugar, and salt. 4. Regular exercise **Outcome Measures** Height & Weight **Follow-up:** Intervention completion @ 9 months	**Findings:** Obese and overweight subjects: + Pearson's correlation of 0.6 ($p < .10$) between weight loss and extent of program participation Obese girls lost an average of 12.9#	**Strengths:** Innovative concepts: food addiction Positive weight loss Minority sample **Limitations:** Small sample size; Not equal attention comparison group; No measurement of mediating or moderating variables; Sample-may have attracted more motivated girls

Overall, a critical analysis of the studies in Table 1 reveals the following strengths: (a) interventions targeting the prevention/treatment of adolescent overweight are feasible in school settings, (b) multi-component interventions that provide education about nutrition and exercise and include physical activity seem to have the best positive outcomes, (b) the length of effective programs varied, from as little as 7 weeks to several months, (b) a few of the studies used RCT designs, which strengthens their internal validity, and (c) some of the studies used theoretical frameworks to guide the interventions and selection of outcome variables.

However, there are major limitations in this body of studies. Many of the studies did not have an attention control group, which substantially weakens the internal validity of the research. In addition, the majority of the studies did not assess more long-term outcomes, therefore sustainability of the interventions are unknown. None of the studies analyzed mediating variables to explain the processes through which the interventions worked. Explaining the processes through which interventions work is important to extend the science in this area and increase the probability that clinicians will use evidence-based interventions in their clinical practices.[108] Furthermore, analysis of moderating variables also would have been useful in extending the science by shedding light on the circumstances under which the interventions worked best. Additionally, none of the studies assessed the impact of the interventions on mental health outcomes of the adolescents, besides one that included measurements of self-esteem and self-efficacy. Assessing the impact of the interventions on both healthy lifestyle behaviors and depressive symptoms would further substantiate the positive benefit of the programs and extend the science in the area. Furthermore, **only one study involved a high percentage of Hispanic teens,[107] a population that is at high risk for overweight and mental health problems, and that study had major limitations as it was not a RCT and it involved a very small sample of only Latina adolescent females.**

Prior School-Based Intervention Studies with School-Aged Children. A recent integrative review that searched for and critically analyzed effective school-based interventions for children between the ages of 4 to 14 years found 10 studies that achieved significant positive effects for the interventions used.[109] These 10 studies included children up to age 12 years. The intervention programs ranged in length from 8 weeks to 2 years, and 9 out of the 10 programs included healthy lifestyles education interventions, focused mainly on nutrition education, and physical activity as part of the program. A few of the programs included behavior modification strategies (e.g., self-monitoring and regulation of food intake and physical activity, including the use of diaries for documentation). Four studies included only overweight children, and only two of the 10 studies reported measuring additional follow-up outcomes after the post-intervention period. **Therefore, sustainability of intervention effects is unknown for the majority of these studies.** Social cognitive-theory was used as the conceptual framework for many of the studies, but **none of the studies assessed mediating or moderating variables.** Despite emphasizing a cognitive approach in a number of interventions, few studies measured variables beyond the narrower outcomes of nutrition and physical knowledge attainment and weight loss (e.g. self-esteem, depressive symptoms).[110–115]

Prior School-Based Intervention Studies to Prevent Mental Health Disorders in Adolescents. The universal promotion of mental health and early prevention of mental disorders should be critical components of comprehensive healthy lifestyle interventions for children and adolescents. Preventive mental health intervention studies have focused solely on the promotion of positive mental health outcomes and the prevention of mental illness in children and adolescence without also targeting the promotion of healthy lifestyle behaviors and physical health.[31, 116–121] These prevention programs typically include a variety of cognitive, affective, behavioral, and skill-building techniques, such as the promotion of self-esteem, reduction of violent, bullying and aggressive behavior, and the teaching of coping, problem solving and alternative thinking strategies. Yet, other researchers have focused their interventions on specific mental health disorders, such as anxiety,[122] depression,[123] decreased social and emotional

competency,[124] improving self-esteem,[125] decreased coping in response to stress[126] and anger/violence prevention[127] Effect sizes, at average follow-up of 6-months, tend to be small to moderate with selective prevention programs more effective than universal programs.[128, 129] Common limitations in these studies are the absence of long-term follow-up, lack of detail regarding the intervention, fidelity of the intervention, specification of program goals and outcomes, and the limited documentation of process factors that contribute to the success of interventions. In addition, theoretical frameworks did not guide most of the intervention programs, thus limiting explanations of the study findings. Other researchers have found little evidence to support the efficacy and effectiveness of preventive interventions that focus solely on preventing one particular mental disorder, such as depression, among children and adolescents.[123, 130, 131]

Theoretical Framework for the Proposed Study. Cognitive behavioral theory (CBT) has guided the development of the COPE/Healthy Lifestyles TEEN program and selection of study variables. It is based in cognitive theories formulated by Ellis (1962) and Seligman (1975), as well as in the behavioral theories by Skinner (1953) and Lewinsohn (1974).[132–135] Ellis contended that irrational beliefs tend to lead individuals to overreact emotionally to certain preceding events.[133] Beck (1967) hypothesized a negative cognitive triad encompassing a negative view of oneself, the environment, and one's future, which leads to hopelessness and depression.[136] In learned-helplessness theory, Seligman proposed that depression stems from experiencing negative events with the belief that an individual's behavior has no impact on the outcome.[134] He also proposed that a depressogenic attributional style included internal attributions for negative events and unstable attributions for positive events. Lewinsohn stressed that lack of positive reinforcement from pleasurable activities leads to depression, deficits in social skills, and frequent negative experiences.[132]

The basic premise of CBT is that an individual's emotions and behaviors are, in large part, determined by the way in which he or she cognitively thinks and appraises the world.[137] Therefore, a person who has negative or irrational/distorted beliefs tends to have negative emotions (e.g., depression) and behaves in negative ways (e.g., overeating, risky behaviors).[21, 138] Specifically, elevated depressive symptoms are caused by how one perceives situations and events.[139] Negative emotions and behaviors are even more profound when there are skill deficits, (e.g., poor emotional regulation, poor problem-solving and assertiveness skills, and cognitive distortions that lead to negative perceptions, negative thoughts, negative views of self and future, and failure to attribute positive outcomes to one's behavior). *Based on this theory, we are predicting that adolescents who lack beliefs/confidence in their ability to engage in age appropriate developmental tasks and healthy lifestyle behaviors and perceive those behaviors as difficult to perform will report more depressive symptoms and engage in fewer healthy lifestyle behaviors.*

Driven by CBT, the COPE/Healthy Lifestyles TEEN program is a series of 15 educational and CBSB sessions that focuses on empowering teens to engage in healthy lifestyle behaviors (i.e., nutrition, physical activity, positive strategies to cope with stress, problem-solving, regulation of negative mood, and goal setting). It is designed to be easily integrated into high school health education classes. Based on cognitive theory, we teach the teens how to cognitively restructure their thinking when negative events/interpersonal situations arise that tend to lead them into negative thought patterns, and how to turn that thinking into a more positive interpretation of

the situation/interpersonal interaction so that they will emotionally feel better and behave in more healthy ways. Emphasis is placed on how patterns of thinking impact behavior and emotions (i.e., the thinking, feeling and behaving triangle). Goal setting to promote engagement in healthy lifestyle behaviors and problem-solving for typical adolescent challenges is part of the CBSB component of the program (e.g., peer pressure for fast food and unhealthy snacks, being ostracized by peers, unhealthy behaviors to cope with stress, conflicts with parents). The program also includes educational content to increase teens' knowledge of how to lead a healthy lifestyle and homework activities to reinforce skills that are being learned in the classroom, *which assists them with putting into daily practice what they are learning in the educational sessions*. Brief bouts of physical activity (i.e., 15 to 20 minutes) also are incorporated into each of the 16 sessions to assist the teens in raising their beliefs/confidence in their ability to develop regular activity patterns.

Based on CBT, it is hypothesized that the COPE program will first strengthen the teens' beliefs/confidence in their ability to engage in healthy lifestyle behaviors and manage their negative emotions, and lessen their perceived difficulty of performing the behaviors (i.e., the proposed mediating variables), which in turn, will result in more healthy lifestyle behaviors as well as less depressive symptoms (our primary outcomes). Ultimately, engaging in healthy lifestyle behaviors should lead to the prevention of overweight in normal weight teens and less weight gain in teens who are overweight at baseline. We chose the immediate outcomes of healthy lifestyle behaviors and depressive symptoms as our key primary outcomes because they are so important at this developmental phase and often precipitate later health outcomes (e.g., overweight and major depressive disorder).

This mediational model is illustrated in Figure 1. Mediational analyses of data are important to better understand the mechanisms through which treatments are effective.[139] However, prior studies have not tended to propose or test mediators of the effects of healthy lifestyle interventions. Thus, there remain large gaps in this body of literature about how interventions impact outcomes. Valid and reliable instruments will be used to measure each of the constructs in Figure 1 and are described in the instrumentation section of the text.

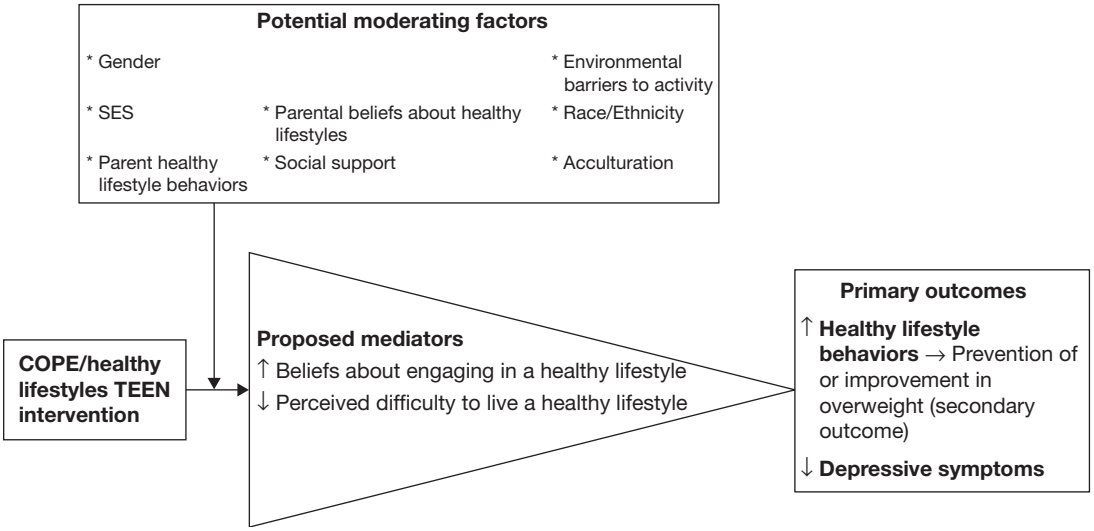

Figure 1. COPE conceptual model

Based on our literature review, there are likely to be key influences outside of cognition that may impact a teen's healthy lifestyle behaviors and mood. Therefore, we have added some key variables to our conceptual model as potential moderators of the effects of our COPE intervention. For example, we may find that our COPE TEEN program works better for certain sub groups of teens (e.g., those who do not have structural environmental barriers to physical activity near their home, or those who have parents who have stronger healthy lifestyle beliefs and engage in healthier behaviors). Analysis of both moderating and mediating variables will allow us to extend the science of healthy lifestyle interventions with adolescents.

Findings from our preliminary studies (study #1 and #6) support the inter-relationships among thinking, feeling and behaving that are central to CBT and our COPE/Healthy Lifestyles TEEN program. In our preliminary study #1 with 23 overweight teens[49] and our recent descriptive correlational study with over 400 teens in the Paradise Valley school district (one of the sites for the proposed study) (see preliminary study #6), we found that teens with higher depressive and anxiety symptoms had less healthy lifestyle beliefs and engaged in less healthy lifestyle behaviors. Stronger beliefs about the ability to engage in healthy lifestyles were related to healthier living attitudes, healthier lifestyle choices and healthier behaviors. Teens who perceived healthy lifestyles as more difficult had less healthy attitudes and reported less healthy choices and behaviors. Therefore, targeting cognitive change through increasing teens healthy lifestyle beliefs/confidence could potentially lead to healthier lifestyle behaviors, and ultimately to the prevention of overweight/obesity in adolescents. In addition, another benefit of having a strong CBSB intervention in our COPE intervention is that multiple studies have demonstrated its positive effects on depression. **What is currently not known, which can only be demonstrated by a large scale RCT like the proposed study, is whether CBSB also can have positive effects on healthy lifestyle behavior change.**

Summary, including Significance and Innovation of the Proposed Study. Schools are an ideal environment to test innovative interventions designed to increase healthy lifestyle behaviors to ultimately prevent or treat overweight/obesity as well as to enhance the highest level of mental health outcomes in adolescents. Preventive interventions that are implemented in schools need to be reproducible, teacher-friendly, and inexpensive to implement. There is some evidence indicating that healthy lifestyle interventions that incorporate education, physical activity and behavior modification may be the most promising strategies for preventing and treating overweight and obesity in teens, however, more long-term efficacy of these interventions are unknown.[140] Furthermore, the processes through which these interventions work are not known and moderating variables that could shed light upon under which circumstances or for whom the interventions work best have not been studied. **In addition, except for one study in Table 1, which was weak in terms of internal validity because it used a pre-experimental design, studies with adolescents have not included a substantial number of Hispanics, a population in which the incidence of overweight/obesity and mental health disorders are higher than Whites.**

In our prior pilot studies testing the feasibility and preliminary efficacy of our COPE/Healthy Lifestyles TEEN program as well as in our recent large descriptive correlational study with over 400 high school adolescents, we learned that: (a) adherence to after school interventions is

extremely challenging due to competing after-school priorities for adolescents, (b) interventions are best delivered in the context of the school day in health education curriculums, (c) normal weight as well as overweight teens' beliefs about healthy lifestyles and their perceived difficulty in implementing healthy behaviors is related to their healthy lifestyle behaviors, (d) elevated depressive symptoms are related to less healthy lifestyle beliefs, choices and behaviors, and (e) providing information alone does not influence knowledge gains, healthy lifestyle beliefs and healthy lifestyle behaviors. Therefore, we use a very strong CBSB component as part our COPE/Healthy Lifestyles TEEN program, which may be key in not only preventing negative mental health outcomes, but also in empowering teens to implement and sustain healthy lifestyle behaviors that could lead to a reduction in adolescent overweight. **Use of CBSB is a novel conceptual approach to targeting two of the most pressing public health problems in teens. Another innovative aspect of our proposed study is that we have powered it so that we have a large enough sample to study sub groups of the teens (i.e., those who are already overweight; those who are mildly to moderately depressed) where the effects of COPE may have the greatest impact.**

For the proposed study, we have chosen two school districts that will allow us to determine the efficacy of our COPE/Healthy Lifestyles TEEN program across a varied socioeconomic status (SES) and culturally diverse sample of students, including a high percentage of Hispanic teens. Our study also will extend the science in the area by evaluating the process through which our intervention produces positive effects. In addition, we will analyze potential moderating variables that may influence the effects of the intervention on key adolescent outcomes.

4. PRELIMINARY STUDIES

Principal Investigator (PI), **Bernadette M. Melnyk**, Ph.D., RN, CPNP/NPP, FNAP, FAAN is both a seasoned pediatric nurse practitioner and a child-family psychiatric nurse practitioner, whose specialty area is high-risk teens. Dr. Melnyk has practiced with and conducted research with high-risk adolescents for several years in primary care practices, schools and mental health settings. **Dr. Melnyk and her team have completed six studies that provide strong pilot data for the proposed study.**

Study #1: Mental Health Correlates of Healthy Lifestyle Beliefs, Attitudes, Choices & Behaviors in Overweight Teens. A descriptive correlational study was conducted with 23 overweight teens (see Melnyk et al., 2006 in Appendix A). Key variables measured included depressive symptoms, state and trait anxiety, self-esteem, beliefs/confidence about engaging in a healthy lifestyle, perceived difficulty in leading a healthy lifestyle, and healthy attitudes, choices, and behaviors. Findings indicated that teens with higher state and trait anxiety as well as depressive symptoms had less healthy lifestyle beliefs, although teens with higher self-esteem had stronger beliefs about their ability to engage in a healthy lifestyle. Stronger beliefs about the ability to engage in healthy lifestyles were related to healthier living attitudes and lifestyle choices. Teens who perceived healthy lifestyles as more difficult had less healthy attitudes and reported less healthy choices and behaviors. This pattern of relationships also was similar with Hispanic teens in our preliminary study #4. These data support that adolescent thinking is directly related to how they feel and how they

behave. Including a strong CBSB component into interventions with teens may be key in boosting their beliefs/confidence about being able to engage in healthy behaviors and lessening their perceived difficulty in performing them, which should result in healthier lifestyle behaviors.

Studies #2 and #3. The COPE Healthy Lifestyles TEEN Program: Feasibility, Preliminary Efficacy and Lessons Learned from an After School Group Intervention with Overweight Adolescents (see Melnyk et al., 2007 in Appendix A)**.** A Phase I and Phase II clinical trial were conducted with 23 overweight teens. The purposes of these two studies were to: (1) determine the feasibility of implementing the COPE/Healthy Lifestyles TEEN program with adolescents from two high schools (i.e., an urban high school and a sub-urban high school), (2) obtain feedback that could be used to refine/strengthen the program in preparation for a full-scale clinical trial, and (3) examine the preliminary efficacy of the COPE program on the participating adolescents' weight. The Phase 1 trial (Study #2) used a pre-experimental design with one group of 11 urban adolescents. The Phase 2 trial (Study #3) was conducted with 12 sub urban teens using a randomized controlled pilot study. COPE teens in both trials received a 9-week, 15 session CBSB program that included physical activity while the control group received an attention control safety program. Weight change and BMI were the key outcomes. Findings indicated that the COPE teens experienced a significantly greater reduction in weight and BMI than teens in the control group, who gained weight over time. Specifically, the seven teens in the sub urban high school COPE program lost a total of 32 pounds across the 9-week program, whereas the 5 teens in the comparison program gained a total of 11 pounds by the end of the program. This resulted in a very large positive effect size (i.e., 1.5)[141] for the COPE program ($p < .05$). Although the COPE program was well received by all of the teens, retention of subjects across time and parent involvement in the program were challenges in the urban high school.[142] The after school program was not well attended by the teens at the urban city high school. Six of the 11 teens who commenced the study dropped out of the program, many stating that there were too many after-school conflicts (e.g., having to care for younger brothers and sisters, work). None of the parents from the urban city school site attended any of the parent sessions, most reporting that they had too many other responsibilities (e.g., taking care of their other children, work).

All teens in both studies reported that the program was helpful. When asked the question, "have you changed anything as a result of this program, 5 of the COPE teens who completed the evaluation for Study #2 responded "yes" and one responded "no." The one COPE teen who responded "no" reported that she was not satisfied with the amount of sessions, reporting that more sessions were desired. All 6 teens responded that they were satisfied with the length of the sessions and that they were still practicing the skills from the program. All COPE teens responded they thought that all adolescents should receive the program. Responses about how the program was most helpful included: (1) "learning how to cope with stress," (2) being with other kids my age and not being on my own; not feeling like I had a problem, (3) learning nutritional values, (4) changing eating habits (increasing fruits and veggies), (5) increasing walking, and (6) getting tools to make the right decisions. One teen stated that after school sessions were difficult. Another stated that, "all kids should be in the program—those with and without weight issues." Reasons why the participants felt that all teens should

receive the program included, (1) it would open their eyes to all the junk food that they eat, (2) it gives you more to think about and makes you more confident, (3) all need to be taught healthier choices, and (4) because there are other teens who need help and are afraid to talk. Teens also commented that the COPE program helped their parents and them to get closer. One teen said, "We talked about more positive stuff instead of negative, and encouraged each other to make healthy choices."

Findings from these 2 studies indicated that the COPE program was well received by culturally diverse teens who completed the study and provides preliminary support for its efficacy on adolescent weight loss and BMI reduction. Conducting after-school intervention programs with adolescents is challenging as a result of competing demands and after school activities. Even some teens without after-school activities said that they did not want to extend their day at school any longer. The offering of incentives for participation (i.e., mall gift certificates) and bus tokens for travel from home to school was not successful in recruiting many teens, but it was a more effective strategy in the sub urban versus the urban school. Recruitment of both adolescents and their parents was challenging. At both urban and suburban high schools, teens were interested in participating in the program, but it was difficult to obtain a group of parents who would commit to study participation, especially at the urban school, even with incentives, child care, and food. As a result, it was decided to integrate COPE into regular health classes during the school day to enhance participation in the program.

Study #4. Improving Mental and Physical Health of Hispanic Adolescents. The purpose of this recently completed randomized controlled pilot study was to determine the effects of the COPE/Healthy Lifestyles TEEN program on the mental and physical health outcomes of 19 Hispanic adolescents (13 females, 6 males; ages 14 to 16) enrolled in an inner city high-school health course. The intervention programs (COPE versus attention control) were delivered in two separate classes of teens who were taking a required health class. Programs were 15 sessions over a nine-week school quarter, for both the intervention and comparison groups. Key variables measured included depressive symptoms, anxiety, beliefs/confidence about engaging in a healthy lifestyle, perceived difficulty in leading a healthy lifestyle, and healthy attitudes, choices, and behaviors. The COPE program content included CBSB along with information and activities on leading a healthy lifestyle (e.g., nutrition and exercise). It also included physical activity of 15 to 20 minutes duration during each COPE session. The comparison group class received information that focused on safety and other teen health issues (e.g., acne, personal hygiene).

Paired sample t-tests evaluating change over time indicated that teens in the COPE intervention group were less depressed, less anxious, and more committed to making healthy choices following the intervention (Table 2), while teens in the control group showed no appreciable change in depression or anxiety, but a similar change in commitment to making healthy choices (Table 3). The statistical significance of these changes is difficult to evaluate in two small samples, but the effect sizes and p values support the conclusion that both intervention and control programs engage teens and lead to healthy choices, but that only the COPE intervention addresses the symptoms of depression and anxiety.

Table 2. Results for COPE/Healthy Lifestyles TEEN Intervention Group (n = 11)

Instrument	Summary of change from baseline to post intervention	Effect size (d)	p value
Beck Depression Inventory—Youth	Decrease in depressive symptoms	–0.32	= 0.11
Beck Anxiety Inventory—Youth	Decrease in anxiety symptoms	–0.56	= 0.03
Choices Scale	Increased commitment to healthy choices	0.48	= 0.07

Table 3. Results for the Healthy TEEN Control Group (n = 6)

Instrument	Summary of change from baseline to post intervention	Effect size (d)	p value
Beck Depression Inventory—Youth	Increase in depressive symptoms	0.15	$p > 0.20$
Beck Anxiety Inventory—Youth	Decrease in anxiety symptoms	–0.20	$p > 0.20$
Choices Scale	Increased commitment to healthy choices	0.41	$p > 0.20$

This pilot work also provided evidence supporting the choice of screening and outcome instruments as well as the proposed inter-relationships of key components of the COPE model. For example, scores on the Beliefs Scale correlated highly with students' scores on the Choices ($r = 0.67$) and Difficulty ($r = -0.62$) Scales ($n = 19$; $p < 0.01$) confirming its convergent and discriminant validity and its congruence with the COPE model. Reliability of the instruments in the pilot sample was excellent. Cronbach alphas were 0.90, 0.96, and 0.92 for the Healthy Lifestyle Beliefs Scale, the Beck Depression Inventory, and the Beck Anxiety Inventory, respectively.

A sub-group analysis was completed on the 7 of 13 adolescents (58.3%) in the COPE intervention group who had a BMI percentile ≥ 85. Paired t-tests evaluating change over time indicated significant increases in their healthy lifestyles attitudes and choices. Nutrition knowledge and self-concept increased in this sub group of teens with a decrease in depressive symptoms. Additional findings indicated an increase in HDLs, decrease in HbgA1C, and a decrease in triglycerides from the pre-test to the post-intervention follow-up (see Table 4).

Table 4. Results for the COPE Intervention Sub-group of Teens with a BMI ≥ 85th percentile (n = 7)

Instrument or Biological Value	Pre-test Mean (SD)	Post-Test Mean (SD)	Effect size (d)*	p value
HgbA1c	5.46 (.41)	5.33 (.31)	0.35	0.08
Triglycerides	111.29 (56.38)	98.23 (53.06)	0.24	0.35
HDL Cholesterol	47.86 (5.01)	52.14 (5.58)	0.81	0.03
Choices Scale	56.83 (6.46)	62.00 (.31)	0.59	0.09
Nutrition Knowledge Scale	10.33 (5.05)	12.00 (4.19)	0.36	0.05
Beck Depression Inventory—Youth	53.33 (15.7)	49.67 (11.00)	0.27	0.35
Attitude Scale	52.17 (7.99)	54.83 (6.08)	0.38	0.41

*Small Effect = .2; Medium Effect = .5; Large Effect = .8

Study #5. Improving Mental and Physical Health of College Students with Freshman 5 to Thrive/COPE Healthy Lifestyles. The purpose of this quasi-experimental study was to test the efficacy of the COPE program in a sample of freshman students at a large state university. Seventy students who resided in the Living Well residential community (a campus dorm) were required to enroll in Freshman 5 to Thrive: COPE/Healthy Lifestyles (a 3-credit semester college course based on the COPE intervention). Thirty three of the students enrolled in the Freshman Course were recruited into our study to determine the effects of COPE on healthy lifestyle behaviors, and physical and mental health outcomes. Freshman students from other dorms and the College of Education were recruited to participate as a no attention control group (n = 16). The course was held weekly for three hours for 14 sessions during a 15 week semester. Each session consisted of 2 hours of didactic content that focused on nutrition and exercise education along with CBSB and 1 hour of physical activity, which was coordinated through the University's recreation center. Examples of activities included hiking a local mountain trail, water aerobics, and volleyball. Baseline findings for the entire sample included 36 females and 13 males; mean BMI was 22.43, mean age was 18.1 years. Ethnicity of the students was 75.5% Caucasian, 12.2% Hispanic, 8% Asian, 6.7% AA and 4% other. Anxiety was present in 22% of the sample (n = 5 mild and n = 6 moderate). Depression was present in 14% of the sample (n = 4 mild and n = 3 moderate). There were no significant differences in age or BMI between the COPE and control groups. Baseline differences between groups were found only for perceived difficulty in living a healthy lifestyle. One-way ANOVAs evaluating between group findings over time indicated significant differences in healthy lifestyle choices and perceived difficulty. Specifically, students in Freshman 5 to Thrive were making healthier choices by the end of the course whereas control students were making poorer healthy lifestyle choices. In addition, while there was no change in perceived difficulty to making healthy lifestyle choices in the COPE group, control group students perceived greater difficulty in making healthy lifestyle choices by the end of the semester (Tables 5 and 6).

Table 5. Results for the Freshman 5 to Thrive Group

Instrument	Pre Mean (SD)	Post Mean (SD)	Effect size (d)	p value
Choices Scale	64.61 (8.5)	69.00 (8.5)	0.25	p = .025
Perceived Difficulty Scale	27.75 (5.8)	27.22 (7.0)	–0.04	p = .014

Table 6. Results for the Control Group

Instrument	Pre Mean (SD)	Post Mean (SD)	Effect size (d)	p value
Choices Scale	60.77 (8.0)	59.43 (5.6)	0.1	p > .20
Perceived Difficulty Scale	33.69 (10.8)	36.79 (6.0)	.18	p > .20

A t-test evaluating change over time for the subgroup of Freshman 5 students with moderate to high levels of anxiety at baseline indicated a significant decrease in anxiety over the semester. Similarly, a t-test evaluating change over time for the sub-group of Freshman 5 students with moderate depression indicated a decrease in depression over the course of the semester. In addition, there was a small to moderate positive effect for pedometer of steps that students were taking in the Freshman 5 course by the end of the semester (Table 7).

Table 7. Results for sub-group analysis: Freshman 5 to Thrive

Measure	n	Pre Mean (SD)	Post Mean (SD)	Effect size (d)	p value
Anxiety at baseline	6	64.17 (6.7)	48.17 (7.6)	.74	p = .01
Depression at baseline	5	60.6 (5.0)	49.60 (9.3)	.59	p = .07
Pedometer	20	65654 (24401)	91007 (50032)	.41	p = .31

Study #6. Correlates of Healthy Lifestyle Behaviors in Adolescents. The purpose of this study was to: (1) determine the psychometric properties of the Healthy Lifestyle Beliefs, Perceived Difficulty, Healthy Lifestyle Choices, Healthy Lifestyle Attitudes, Healthy Lifestyle Behaviors, Nutrition Knowledge, and Physical Activity Knowledge Scales, (2) describe relationships among these variables and a mental health negative mood composite scale, and (3) describe relationships among these variables and anthropometric measures. The study was completed with 404 high school teens enrolled in a physical education/health course from two high schools in the Paradise Valley School District, one of the sites for our proposed study. The sample was 52.5% female. Eighty-nine percent of the students were freshman, with a mean age of 14.6 years. The mean BMI percentile of the sample was 59.71, with 25.5% having a BMI ≥ 85th percentile indicating overweight. Ethnicity of the participants was 69.1% Caucasian, 16.6% Hispanic, 6.9% other, 5% Asian, 3.2% African American, and 3% Native American/Alaskan Native. Construct validity of all scales was supported through factor analysis, with the following internal consistency reliabilities: (a) the Healthy Lifestyle Beliefs Scale (.94); (b) the Healthy Lifestyle Choices Scale (.92); (c) the Healthy Lifestyle Attitudes Scale (.84); (d) the Perceived Difficulty Scale (.88); (e) the Healthy Lifestyle Behaviors Scale (.90), (f) the Nutrition Knowledge Scale (.87), and (g) the Physical Activity Knowledge Scale (.69). Cronbach alphas for the scales were similar in the sub-sample of Hispanic teens.

Measures were collected from participants at two time points, the beginning and end of a semester. During the semester, students were presented with healthy lifestyles information through a newly revised health curriculum with emphasis that fitness is for life, exercise is the best vehicle for managing stress levels and boosting self-confidence, and establishing self-efficacy for performing healthy lifestyle behaviors. Despite an enhanced district led health curriculum, no significant positive changes occurred in the students on any of the above measures. For example, the average knowledge score for activity at the beginning and end of the term was the same at 8.2 (68% correct, SD = 2.45 and 2.99). The average nutrition knowledge score essentially stayed the same as well from 11.2 (55.5% correct, SD = 4.98) at the beginning of the term to 11.4 (57% correct, SD = 5.23) at the end. Average Healthy Lifestyle Beliefs scores also remained essentially unchanged from the beginning of the term to the end from 58.07(SD = 11.14) to 57.63 (SD = 11.32).

In the teens, key findings were that the healthy lifestyle beliefs scale was positively correlated at the $p < .01$ level with perceived difficulty in leading a healthy lifestyle ($r = .48$), nutrition knowledge ($r = .24$), activity knowledge ($r = .29$), healthy lifestyle attitudes ($r = .51$), and healthy lifestyle behaviors ($r = .65$). Perceived difficulty in engaging in a healthy lifestyle was positively related to negative mood ($r = .26$), and negatively related to healthy lifestyle behaviors ($r = -.40$). Healthy lifestyle attitudes were related to healthy lifestyle behaviors ($r = .22$) and perceived difficulty ($r = -.32$). Negative mood in the teens was significantly correlated with perceived difficulty in engaging in a healthy lifestyle ($r = .26$), healthy lifestyle behaviors ($r = -.20$), and healthy lifestyle beliefs ($r = -.27$). Nutrition knowledge was related to healthy lifestyle behaviors

(r = .34) and physical activity knowledge was related to healthy lifestyle behaviors (r = .36). This pattern of correlations was similar in the sub group of teens who were overweight and Hispanic, and supports cognitive behavioral theory (i.e., beliefs are related to healthy lifestyle behaviors and negative mood). Overweight and Hispanic teens rated their perceived health as lower than the rest of the sample and had lower knowledge scores on physical activity. Hispanic teens had lower scores on physical activity, nutrition knowledge and neighborhood safety.

Summary of Preliminary Studies. The preliminary studies by the PI as well as published studies in the literature support the need for and feasibility of conducting the proposed study. The strong multi-disciplinary research team collaborating on this project has extensive experience in conducting randomized control trials with culturally diverse populations in school-based settings as well as the needed expertise in adolescent and mental health to successfully conduct the proposed project.

5. RESEARCH DESIGN AND METHODS

Overview of design. This study is a prospective, blinded, randomized controlled test of the efficacy of the COPE/Healthy Lifestyles TEEN program and the mediational roles of cognitive beliefs and perceived difficulty in leading a healthy lifestyle in improving the healthy lifestyle behaviors and depressive symptoms of culturally diverse adolescents in high school. *Participants (N = 800) will be recruited from teens, ages 14 to 16 years, who are freshmen and sophomores enrolled in health education courses at 8 high schools in Phoenix, Arizona (i.e., 4 high schools in the Phoenix Union School District and 4 high schools in the Paradise Valley School District). Two of the four schools within each of the two school districts will be randomly assigned by a random number generator to receive either the COPE/Healthy Lifestyles TEEN Program or the Healthy Teens Program.* All teens in the health education courses in the *8* high schools will be invited to participate in the study. The teens in the health education courses will either receive: (1) an 8-week, 15 session (i.e., an average of two sessions per week) multi-component educational and CBSB program with physical activity (i.e., COPE/Healthy Lifestyles), or (2) an 8-week, 15 session attention control program (Healthy Teens). In addition to baseline assessments, outcomes will be measured at 3 time points: (a) immediately following completion of the 8 week intervention, (b) 6 months following completion of the intervention, and (c) 12 months following completion of the intervention.

		Baseline	Intervention	Post-intervention	6 month follow-Up	12 month follow-up
Phoenix Union High School District	R	O1	X1	O2	O3	O4
	R	O1	X2	O2	O3	O4
Paradise Valley High School District	R	O1	X1	O2	O3	O4
	R	O1	X2	O2	O3	O4

R = Random Assignment of 4 High Schools in the Same School District to COPE or Control for a *Total of 8 Randomly Assigned Schools*
O = Measurement times, X1 = COPE Program, X2 = Attention Control (Healthy Teens Program)

Rationale for three follow-up assessments, including post-intervention and at 6 and 12 months. Follow-up at three times is important to determine whether the effects of COPE can be sustained over time, and to determine the appropriate timing of booster interventions if needed for future studies.

Experimental blinding. *The four high schools in each of the two school districts* will be carefully chosen on the basis of similar demographics of the students and similarities in the built environment around them. Participating students will be blind to group assignment. Although teachers who present the intervention cannot be blind to assignment, staff members who collect, manage and analyze the data will be blind to study group.

Rationale for method of random assignment. We carefully considered the type of random assignment chosen and decided that, in order to decrease the chance of cross-group contamination between students in the same school, we will randomly assign the high schools to either the experimental or attention control programs, rather than randomly assigning classes within the same school to receive COPE or the attention control program. Random assignment of classes within the same high school to the 2 intervention programs carries a great risk of compromising the internal validity of the study due to cross-contamination (i.e., sharing of the information between students who would be attending the same school). *Clustering within districts, schools, and classes will be included in data analyses.*

Setting. *Teens will be recruited from four high schools in the Phoenix Union School District (the site of preliminary study #4) and 4 high schools in the Paradise Valley School district (the site of preliminary study #6) for a total of eight schools.* These school districts have agreed to participate in the study (see letters of support). The schools are located in the greater Phoenix metropolitan area and were chosen in order to provide diversity across race/ethnicity as well as economic status. Health education courses are taught in both of these school districts in 9-week blocks (Table 8).

Demographics. Paradise Valley Unified District has a wide range of socioeconomic status with schools that are predominantly either Caucasian or Latino. As a whole, district demographics include Caucasian 70.6%, Latino 21.5%, Black 3.4%, Asian 3.2%, and Native American 1.2%. Phoenix Union High School District demographics include: Latino 77%, Black 9.8%, White 8.2%, Native American 3.5%, and Asian 1.4%.

Sampling. *Freshmen and sophomores attending required health education classes in the selected high schools will be eligible for study participation.* We estimate, based on prevalence data nationally and in the state of Arizona, that *30% to 38%* of the teens in these schools will be overweight or obese *(depending on sex and race/ethnicity)*. Based on recruitment of teens in study #4, we conservatively anticipate that at least 50% of the students in these health classes will give assent and their parents will consent to participate in the study. Sample size was chosen on the basis of statistical power analysis (described in the analysis plan). *Power calculations were conducted for teen outcomes as a change in teen outcomes is the major determinant of the efficacy of the intervention. Two types of power analyses were run. This sample size provides adequate power for both omnibus analyses and* ***a priori*** *comparisons adjusted for clustering.*

We are *carefully planning for attrition because* we will follow the teens for a year after the intervention, and in anticipation that we intend to apply for supplemental funding to follow these subjects for yet a second year to determine even more long-term effects of the intervention. We will employ multiple strategies to obtain follow-up data that we have used successfully in our prior longitudinal studies with success (e.g., *rigorous tracking and regular contacts, including holiday and birthday cards*).The high schools in the two school districts typically run at least 12 health education classes per year (3 classes per each 9 week session with an average of 25 students in each class). *Thus, the pool of students in 8 schools is 2400 per year (12 × 25 × 8). We expect that all of the health education teachers will agree to participate in the study.* Based on recruitment from our preliminary studies, we should be able to *enroll* at least 50% of the students *approached.* Therefore, we estimate that we will be successful in enrolling *800* teens into the study during the project period *approximately 100 students from each of the 8 high schools across 4 semesters).* If a 25% attrition rate *were to* occur over the course of the one-year follow-up, we would still *have* a final sample of *600* teens. If *36%* of these *600 teens* are overweight or obese, which is reasonable given *the national and local norms,*[11, 13, 22] *there would be 216* overweight or obese teens *in the study. Similarly, if* 30% of the teens have elevated depressive symptoms,[11, 33, 34] *there would be 180 teens in the study for subgroup analysis of intervention effects among the higher risk teens.*

Table 8. Expected subdivision of sample *by weight category*

District	Group	School	Class[a]	Baseline BMI percentile < 85[b]	Baseline BMI percentile 85–94[b]	Baseline BMI percentile ≥= 95[b]	School Total[c]
Phoenix	Intervention	1	1–8	64	20	16	100
Union		2	9–16	64	20	16	100
	Control	3	17–24	64	20	16	100
		4	25–32	64	20	16	100
Paradise	Intervention	5	33–40	64	20	16	100
Valley		6	41–48	64	20	16	100
	Control	7	49–56	64	20	16	100
		8	57–64	64	20	16	100
Enroll Total[c]				512	160	128	800[c]
Study Total[d]				384	120	96	600[d]

[a]Typical class size in these schools is 25 students (8 × 25 = 200 students per school approached)
[b]Assuming a 50% consent rate
[c]Prior to attrition
[d]After attrition

Although all teens will be enrolled in the health class and receive the intervention curricula, participation in the research study (e.g., completing questionnaires, engaging in activity sessions) will be subject to the following criteria.

Inclusion criteria.

- Teens and parents of any gender, ethnicity/race, or socioeconomic status.
- Teens 14 to 16 years of age who are freshmen and sophomores taking a health class at one of the *8* participating high schools.
- Teens who assent to participation.
- Teens with a custodial parent who consents for themselves and their teen's participation in the study.
- Teens who can speak and read in English (educational instruction in Arizona High Schools is conducted in English)

Exclusion criteria.

- Teens who are under age 14 will be excluded because: (a) they are not likely to be enrolled in high school, and (b) they are unlikely to have sufficient cognitive development to benefit from the proposed intervention.
- Teens who are over age 16 will be excluded for two key reasons: (a) we believe that the cognitive development of and social expectations for older teens requires a more complex and flexible intervention than that proposed,[143, 144] and (b) teens need to be available for 12 month follow-up sessions (our pilot studies indicated that this becomes less likely once teens are old enough to leave/graduate from high school, emancipate from parents, and/or leave home).
- Teens who have a medical condition that would not allow them to participate in the physical activity component of the program.

Recruitment. Adolescents, aged 14–16 years, will be recruited from *8* high schools in the two participating school districts in the greater Phoenix area. Research team members will introduce the study during the first class of their 9-week health education courses. Written and verbal information about the study will be provided to the teens. Teen assent and parent consent forms will be distributed to interested students along with written information about the study for them to share with their parents (this information for the parents will be in both Spanish and English). Incentives (i.e., department store gift cards) will be provided to the teens and parents for their participation in the study. Teens will receive $10 after completing the pre-and post-intervention questionnaires and measurements, $15 after the 6-month data collection and $20 after the 12-month completion of questionnaires and measurements. Parents will receive $30 after completing both their baseline questionnaires and $30 after completing the 12 month follow-up evaluation questionnaire. In addition, we will hire a Hispanic bi-lingual Spanish-speaking research assistant (RA) to be able to address questions from predominantly Spanish speaking parents. A Spanish speaking RA also will be able to enhance recruitment of Hispanic students. The teens and parents will be informed that participation in the study is completely voluntary and there will not be any penalty if they decide not to participate or if they decide to withdraw at any point in the study. **This method of recruitment worked well in our most recent preliminary study #4 with Hispanic teens**. Teens who meet eligibility criteria, have given assent and submitted written parental consent will be able to participate in the study. *Based on our preliminary studies #4 and #6*, we estimate that we will be successful in enrolling

800 teens into the study during the project period. Teens who do not participate will remain in their health class and receive the content being delivered, but will not be involved in the study.

Retention. Because adherence is a key element of the proposed intervention, procedures will encourage full participation in all classes. Barriers to participation will be minimized by recognition of the time and effort contributed, interactive content in the intervention program, creative homework assignments that reinforce lessons, and referrals for students that need services. Intervention and data collection sessions will be held at dates and times when health class is already scheduled. Participants will be provided incentives for study participation (e.g., department store gift cards).

Study Coordination. The PI, investigators, project coordinator, and research team members will meet biweekly to discuss study progress, including recruiting, retention, intervention drift, implementation procedures, adverse events, data collection, and data entry and management. Weekly meetings will be held by interventionists to insure that fidelity documentation is up to date and to discuss challenges and solutions to consistent presentation of the manualized protocols for intervention and control groups.

Intervention Conditions (Independent Variable)

The COPE/Healthy Lifestyles TEEN Program. COPE is a manualized 15-session educational and cognitive-behavioral skills building program guided by CBT with physical activity as a component of each session (see Appendix B). It was first developed by the PI in 2002 and has been pilot tested three times with White, Hispanic and African American adolescents as a group intervention in high school settings and once with 18 and 19 year old college freshmen. COPE sessions are detailed in Table 9. Each session of COPE contains 15 to 20 minutes of physical activity (e.g., walking, dancing), not as an exercise training program, but rather to build beliefs/confidence in the teens that they can engage in and sustain some level of physical activity on a regular basis. Those healthy lifestyle intervention programs that have employed exercise interventions only have not led to sustained changes in healthy lifestyle behaviors. **Our program is designed to enhance healthy lifestyle behaviors and sustain them because life-long cognitive-behavioral skills are taught in the program.** Because the COPE TEEN program is completely manualized for the teens and instructors, it can be easily implemented by health teachers in high school settings.

Rationale for the Healthy Teens Attention Control Program. An attention control program that controls for the time spent with the adolescents in the COPE group is essential to determining the efficacy of the experimental program. The Healthy Teens program will assist in ruling out alternative explanations of the mechanism by which the intervention works. It will be standardized like the COPE program to ensure that it can be evaluated. It will be administered in a format like that of the COPE intervention program, and will include the same number and length of sessions, except for that it will not include the theoretical active components of CBT and will not include theoretical mechanisms to produce our hypothesized changes in outcomes. Teens in the attention control group also will receive the sessions in their required health class.

The difference between the two programs will lie in the content of the sessions, with the Healthy Teens program being focused on safety and common health topics/issues for teens (e.g., road safety, skin care, acne, sun safety). Workbook activities and homework assignments will focus on the topics being covered in class as well.

Table 9. COPE/Healthy Lifestyles TEEN Program Content*

Session #	Session Content	Key Constructs From the Conceptual Model and COPE Intervention
1	Introduction of the COPE Healthy Lifestyles TEEN program and goals.	
2	Healthy Lifestyles and the Thinking, Feeling, Behaving triangle.	Cognitive-behavioral skills building (CBSB)
3	Self-esteem. Positive thinking/self-talk.	CBSB
4	Goal setting. Problem solving.	CBSB
5	Stress and Coping.	CBSB
6	Emotional and behavioral regulation.	CBSB
7	Effective communication. Personality and communication styles.	CBSB
8	Barriers to goal progression and overcoming barriers. Energy balance. Ways to increase physical activity and associated benefits.	CBSB and Physical Activity Information
9	Heart rate. Stretching.	Physical Activity information
10	Food groups and a healthy body. Stoplight diet: red, yellow & green.	Nutrition information
11	Nutrients to build a healthy body. Reading labels. Effects of media and advertising on food choices.	Nutrition information
12	Portion sizes. “super size.” Influence of feelings on eating.	Nutrition information
13	Social eating. Strategies for eating during parties, holidays, and vacations.	Nutrition information
14	Snacks. Eating out.	Nutrition information
15	Integration of knowledge and skills to develop a healthy lifestyle plan. Putting it all together.	CBSB

*Fifteen to 20 minutes of physical activity also is a component of each COPE session to build beliefs/confidence in the teens that they can engage in and sustain some level of physical activity on a regular basis.

Assessment of Fidelity of the Intervention. Monitoring fidelity of the intervention program is essential to having greater confidence in the findings, being able to explain the results obtained, and in helping to ensure internal validity of the study.[145] Bellg and colleagues (2004), Sidani (1998) and Yeaton and Sechrest (1981) describe recommendations for enhancing and maintaining treatment fidelity.[146–148] Collectively, these authors suggest to: (1) develop

a detailed manualized protocol; (2) determine the dosage, duration and frequency of the intervention; (3) devise intervention strategies based on a theoretical framework; (4) account for variations in intervention dosage statistically; (5) measure participant's adherence to the intervention; (6) train the interveners to deliver the intervention consistently and as intended; (7) monitor the intervention with observation fidelity checks; (8) utilize checklists to ensure that all intervention components are included in each session; and (9) evaluate participant receipt of the intervention by building into the protocol quantitative evaluative measures, such as nutrition and activity knowledge. We will implement all of these recommendations. Meticulous record keeping will be maintained in order to evaluate the number and content of each session, and completion of homework activities. We also will have the teachers record the tasks accomplished in each intervention session, the methods used to complete the tasks, as well as time spent on each task and impressions of the flow, content and acceptance of the sessions in an intervention diary.

Evaluation of Nutrition and Activity Knowledge will be conducted by administering the Nutrition and Activity Knowledge Questionnaires to serve as a manipulation check and assess whether the teens processed the educational information that they received. Physical activity knowledge will be assessed with a 12-item questionnaire developed for our preliminary studies (e.g., Exercise helps reduce stress, Exercise can help to prevent diabetes, or Dancing is exercise). Subjects respond by answering yes, no, or don't know. The Cronbach's alpha for this scale has been above .80 in our pilot studies. Nutrition knowledge will be assessed with a 20-item questionnaire that measures knowledge regarding food nutritional information, portion sizes, eating habits, and health (e.g., Pretzels are higher in fat than potato chips, One serving size of meat should be the size of a deck of cards, People eat more when they are bored than when they are busy). Subjects respond by answering yes, no, or don't know. The Cronbach alphas for this scale were .80 and higher in our preliminary studies. Face validity was established with 10 teens and content validity was established by 8 adolescent health experts for both of these instruments. Construct validity also was supported for both of these instruments through factor analysis with 400 teens from our preliminary study. Processing of the COPE educational information will be determined by significantly higher scores on the nutrition and activity knowledge questionnaires by the COPE students versus the attention control students.

Teen Attendance Roster. Teens will be asked to sign-in/sign-out at each of the class sessions. Rosters will be used to create an attendance record for each participant. Attendance will be used to assess dose response to the intervention.

Teen Workbook/Homework Activities. Teens will be asked to complete their workbook activities as homework each week of the intervention. A log of the frequency and completeness of the teen's work will be kept. Completion of homework/workbook activities will be used to assess dose response to the intervention.

Task/time/method report of intervention with teens. *Teachers who are delivering the intervention will be asked to record tasks accomplished in each intervention session, method used to complete the task,*

and time spent on each task. This documentation will be used to evaluate the fidelity of the implementation of the manualized COPE intervention and attention control conditions. In addition, 4 randomly selected sessions (25%) of each of the experimental intervention programs will have a study team member attend the teacher's class in order to validate the fidelity of the delivery of the intervention content.

Measures (See Appendix C)

Rationale for the Study Instruments. Tables 10 and 11 on the next page summarize the instruments that will be used with the teens as well as their parents and indicate the time at which each measure will be administered. Instruments fall into four categories, including those administered: (a) to identify potential covariates/moderators, (b) to define outcomes, (c) to quantify proposed mediators, and (d) to evaluate the experimental process. Teens who participate in the program will complete outcome instruments on four occasions (Weeks 0, 9, 34, and 58). Outcome and mediator instruments were chosen because they measure key components of the theoretical framework on which the intervention is based. Process instruments will be used to inform the design of future research and dissemination studies.

Demographic questionnaire: Teens. Demographic data will be collected with a questionnaire. Examples of the items for the teens will include: (a) age, (b) gender, (c) race/ethnicity, (d) perceived social support, and (e) perceived environmental barriers to activity. These variables will serve as potential covariates and moderators in the analyses.

Acculturation (potential moderating variable). Acculturation is a complex construct that may be related to mental and physical health behaviors and outcomes. The Acculturation, Habits, and Interests Multicultural Scale for Adolescents (AHIMSA) is a valid and reliable tool for measuring acculturation in diverse urban school settings.[149] Key attributes of the scale include brevity, age-appropriateness, multicultural relevance, and assessment of multiple components of acculturation. The measure includes 8-items related to a wide range of attitudes and preferences for the U.S. culture across several life domains (e.g., friends, media preferences, celebration of holidays, ways of thinking, favorite foods). Youth respond individually as to whether each statement represents: "the U.S." (indicating assimilation), "the country my family is from" (indicating separation), "both" (indicating integration), and "neither" (indicating marginalization). Scores for each of these four orientations range from 0 to 8. By examining adolescents' preferences across more than just one dimension (e.g., language spoken), the AHIMSA may provide a more accurate picture of the acculturation strategies adopted by adolescents. We will use the U.S. orientation as our measure of acculturation where a score of 0 will indicate that the participant answered something other than the U.S. for all items and 8 will indicate the participant answered US to all 8 items. We will assess acculturation as a potential moderator of intervention effects.

Healthy Lifestyle Behaviors (primary outcome). Healthy lifestyle behaviors will be measured with the Healthy Lifestyle Behaviors Scale developed for use in our preliminary studies. Subjects respond to each of the 16 items (e.g., I exercised regularly; I talked about my worries or stressors, I made choices that lead to a healthy lifestyle) on a 4-point Likert scale that ranges

from 0 *rarely or none of the time- 1 day or less* to 3 *most or all of the time- 5 to 7 days*. Face validity was established with 10 teens and 8 adolescent health experts established content validity. Cronbach alphas with teens in our prior pilot studies have been .80 and above. *Construct validity has been supported through factor analysis from data obtained in our recent preliminary study #6.*

Table 10. Data Collection Summary for Teens

Variable from our theoretical framework	Instrument/ Source of data	Data Collection Times				Measure used in statistical analysis
		Pre	Post	6 month	12 month	
Demographics (potential covariates/ moderators)	Demographic questionnaire	X				Item ratings/ answers
Acculturation (moderator)	The AHIMSA Scale	X				Total score
Healthy Lifestyle	Healthy Lifestyle					Total score on the Healthy Lifestyle
Behaviors (primary outcome)	Behaviors Scale and Pedometer Steps	X	X	X	X	Behaviors Scale and Total Number of Pedometer Steps
Depressive symptoms (primary outcome)	Beck Youth Inventory II	X	X	X	X	Total score
Weight (secondary outcome)	BMI%	X		X	X	BMI%
Cognitive beliefs about a healthy lifestyle (mediator)	Healthy Lifestyle-Beliefs Scale	X	X	X		Total score
Perceived difficulty in leading a healthy lifestyle (mediator)	Perceived Difficulty Scale	X	X	X		Total score

Table 11. Data Collection Summary for Parents

Variable	Instrument	Data Collection Times	Measure used in statistical analysis
Demographics (covariates)	Demographic questionnaire	Week 0	Item ratings/answers
Cognitive beliefs about a healthy lifestyle (moderator)	Healthy Lifestyle Beliefs Scale	Week 0	Total score
Healthy lifestyle behaviors (moderator)	Healthy Lifestyle Behaviors Scale	Week 0	Total score
Satisfaction with the study (process)	Exit questionnaire	Week 58	Item ratings/answers

Physical Activity (Objective Measure of Healthy Lifestyle Behaviors: primary outcome). Given the limitations with self-reported physical activity, we also will employ pedometers to objectively quantify activity. Teens will be trained by research personnel in the use of the pedometer. Pedometers provide a valid and reliable means to measure habitual physical activity in youth.[150] Step counts will be recorded by the teens for 7 days at baseline, immediately following the intervention for 7 days, and again at 6 and 12 months for 7 days each. The advantage of using pedometers to assess physical activity is that they can be used as a tool throughout the intervention in order to encourage and reinforce the physical activity education component of the COPE program. Pedometer-based guidelines have been established in reference to obesity and health in both adults and children. It is recommended that adults achieve 10,000 steps per day and children achieve 12000–15000 steps/day.[151] Given the likelihood that our population will be relatively sedentary, it has been suggested that activity programs should be developed to promote incremental improvements in step counts relative to individual baseline values.[151] Therefore, COPE will encourage youth to increase their step counts by 10% each week regardless of baseline levels. Pedometers were successfully used with the teens in our prior preliminary studies.

The New Lifestyles SW-200 Digi-Walker Pedometer step counter will be provided the teens in both the COPE and attention control groups at the beginning of the study. This is a simple, easy to use step counter that tracks the number of steps taken each day. This model is approximately 2″ × 1 1/2″ × 3/4″ and weighs less than 3/4 ounce. We established the feasibility of using pedometers with the teens in our preliminary study #4.

The mean number of pedometer steps per day over 7 days will be used as a second measure of healthy lifestyle behaviors (a primary outcome in the study) in addition to the adolescent healthy lifestyle behavior scale.

Beck Youth Inventory (2nd edition; BYI- II) (primary outcome). This 100-item instrument for youth 7 to 18 years of age is the most recent version of the BYI.[152, 153] It is a commercial product (Harcourt Assessment) widely used in research and clinical settings that has well-established reliability, validity, and age, gender, and diagnostic-adjusted norms. It measures five constructs: (a) depressive symptoms, (b) anxiety symptoms, (c) anger, (d) disruptive behavior, and (e) self-concept. The five sub-scales of the BYI-II each contain 20 statements about thoughts, feelings and behaviors related to emotional and social impairment. In this study, only the depression scale will be used. The inventory assesses depression using DSM-IV criteria. Scores on the individual sub-scales are calculated as the sum of the 20 items and standardized to t scores with a mean of 50 and a standard deviation of 10. The higher the youth's t score, the higher the distress the youth is experiencing. For example, norms for the depression sub-scale are: a score <55 is average; 55–59 is mildly elevated; 60–69 is moderately elevated; and 70+ is extremely elevated.

Healthy Lifestyle Beliefs Scale (HLBS) (proposed mediator). The HLBS is a 16-item instrument that was adapted from other Beliefs scales used by the PI in multiple prior studies.[49, 154, 155] This scale taps beliefs about various facets of maintaining a healthy lifestyle (e.g., "I believe that I can be more active" and "I am sure that I will do what is best to lead a healthy life").

Subjects respond to each item on a Likert scale that ranges from 1 *strongly disagree* to 5 *strongly agree*. Face validity was established with 10 teens. Content validity was established by 8 adolescent specialists. Cronbach alphas in our preliminary studies have consistently been above .87. Construct validity of the scale was supported through factor analysis with over 400 high school adolescents.

Perceived Difficulty Scale (proposed mediator). This instrument is a 12-item questionnaire that measures one's perceived difficulty in living a healthy lifestyle. Teens respond to each item on the 5-point Likert scale that ranges from 1 *very hard to do* to 5 *very easy to do* (e.g., eat healthy, exercise regularly, cope/deal with stress). The scale was adapted from another similar scale used with teens in a HIV-preventive intervention study.[156, 157] Cronbach alphas in our preliminary studies have been above .80 and construct validity was supported through factor analysis with 400 high school students.

Anthropometric Measures. Heights and weights in order to determine **BMI% (secondary outcome)** on the teens will be taken in a private area. Height will be measured with a stadiometer. Weight will be measured with a Tanita scale.

Exit questionnaire for the Teens. As participants leave the study (whether early or at end of study), they will be asked a series of questions to which they will write written responses. For example, questions will include: a) Was the program helpful (if yes or no, describe how it was or was not helpful)? b) Would you recommend participation to a friend? c) How could participation have been made easier for you? d) Would you be interested in participating in future studies like this one? e) Why are you leaving the study? Information from this exit questionnaire will be used to inform the design of future studies and to obtain open ended responses on the helpfulness or non-helpfulness of the program that the teens received.

Parent Demographic Questionnaire and Measures. Demographic data will be collected via a questionnaire. Examples include: (a) age, (b) gender, (c) race/ethnicity, (d) marital status; (e) family structure (e.g., one versus two-parent household), (f) highest level of educational achievement, (g) perceived social support, (j) stressful life events, (j) mental health diagnoses and treatment, and (k) chronic illnesses. Parents' income and employment status will be assessed by the Hollingshead's system. In addition, parents will complete the Healthy Lifestyle Beliefs Scale and Healthy Lifestyle Behaviors Scale at baseline so these variables can be assessed as **potential moderators** of the effects of the COPE TEEN program.

Procedure

Teacher Training on the Interventions. Teachers who will be delivering the interventions will receive a full 8 hour day of training. The training will include: (a) background on the theoretical framework and CBSB, (b) review of each of the COPE sessions with accompanying homework activities, (c) role plays for skill building with the teens, and (d) review of documentation to complete in the intervention diary after each classroom session. We have found that one full day

of training on the intervention in our pilot studies was sufficient for the interventionists. Teachers will be compensated for their attendance, provided with lunch and snacks, as well as free parking. The teachers delivering the healthy teen attention control program also will receive a similar 8 hour day of training on their program.

First Study Contact (Week 0). All 14 to 16 year old adolescents who are freshmen and sophomores taking required health education classes in one of the 4 high schools participating in the project will be informed of the study during their first class session of their heath course. The study will be explained verbally and with written materials by one of the members of the research team. Those teens who are interested in participating in the study will be given adolescent assent and parent consent forms along with written information about the study to share with their parents. Information to the parents will include contact information for the study team so that the parents can call and ask questions about the study and receive more information as needed. Teens will be asked to bring back the signed assent and parent consent forms to their next regularly scheduled health class. This protocol worked well in our preliminary studies #4 and #6.

Week 0–1. For those adolescents who assent and their parents consent, baseline demographic and study questionnaires will be gathered at the beginning of the next class session. Height and weight also will be obtained at this time. In addition, for those parents who give their consent, the first packet of baseline study questionnaires for them to complete will be mailed to them, with a self-addressed stamped envelope to return the completed questionnaires to the study office. For those packets not received, follow-up reminder calls will be made to the parents asking them to complete the study questionnaires.

Weeks 1 through 9. Program content (i.e., COPE or Healthy Teens) will be delivered in the classroom setting by teachers trained on the intervention. Content of the 15-session intervention programs will be delivered two times per week over an 8 week period of time.

Post-intervention Assessment (Week 9). The week following the 15th session intervention, a research team member will administer the post-intervention follow-up study questionnaires and conduct assessments.

Follow-up Assessments #1 and #2 (Weeks 34 and 58). Approximately 2 weeks prior to the 6 and 12 month follow-up time points, research team members will contact the teens to encourage continued participation in the study and to establish an appointment with the teens to collect the follow-up assessment measures. Study procedures for both groups will be identical except for the experimental interventions. Both groups will have identical assessments. Immediately following the completion of the teen questionnaires at the post-intervention contact (Week 1 and Week 9) and follow-up assessments at weeks 34 and 58, the research team members will score the depression measure. Parents of any teen in the COPE or attention control groups who scores in the severe/clinically significant cut-off range on the depression scales that are completed at the specified times throughout the study will be called and the teen referred immediately to his or her primary care provider for further evaluation.

Data Management. As questionnaire data are collected, they will be reviewed for missing data and participants will be given an opportunity to: (a) complete questions or pages of the instruments that they overlooked or (b) indicate that they would prefer not to answer. The reason for missing data will be coded on the form. Data will be collected on paper forms and stored in locked file cabinets in a locked room in a secure building. In order to protect confidentiality, the face sheet on the instrument (which contains participant identification information) will be removed and kept in a locked, secure location with the electronic copy of the database that links the name with the identification number. Data will be entered into a computer database within one week of collection. The PI will independently verify accuracy of data entry. Computer files will be backed up following each use. Analytical files will be built using self-documenting systems (e.g., SPSS *and SAS* software), so that codebooks will be readily available. Analytical output files for key analyses will be documented, printed and archived for audit, as necessary. The database will be maintained on a dedicated computer that is not linked to public access servers and is stored in a locked office in a secure building. Access will be password protected and maintained behind Enterprise level firewalls and antivirus barriers. Written standard operating procedures will be used to protect data from error, negligence, misconduct, conflict of interest, malicious acts, and catastrophe. Published accounts of the results of the study will protect the anonymity of the participants by publishing only aggregate data. The university's institutional review board will monitor the conduct and progress of the study at least annually and may audit data collection and management procedures without notice.

Missing Data. All data analyses will be completed as intention to treat analyses (i.e., individuals will be analyzed by group, according to original random assignment, without regard to their adherence to the experimental protocol). This procedure more closely approximates the mixed levels of adherence likely to be seen in clinical practice.[158] *Missing data will be imputed using multiple imputation.[4, 9] Methods described by Horton and colleagues[159, 160] and recently adapted by Taljaard and colleagues for cluster randomized trials[2] will be implemented using SAS v9 PROC MI[9, 160, 161] or SPSS v17 Missing Values,[162] depending on the presumed cause of the missing data, the type of distributions seen in the data,[3–10] and ease of use.*

Overview of Analysis Plan. Statistical analysis of data from this first full-scale test must serve several purposes beyond simply demonstrating the efficacy of COPE; for example, estimating effect sizes, mapping the trajectory of group differences over time, and identifying subgroup differences. Analysis will begin with careful characterization of the sample with descriptive statistics that identify (a) potential problems due to skewed sampling, (b) differences between intervention and control groups that are evident at baseline despite randomization, and (c) differences between groups that appear at follow-up due to differential attrition.

The second phase of the analysis will use linear hierarchical models (also referred to as random coefficient and mixed models) to explore the effect of the intervention over time because these models incorporate random effects to reflect the correlation among observations from members of the same group.[163, 164] For example, when district, school, and class are treated as random factors in a nested design.[165–167] These preliminary analyses will assess clustering directly and suggest ways in which clustering should be accounted for in subsequent analyses.[52, 168–171] The linear hierarchical modeling technique characterizes

both group-level and individual-level effects, giving a more comprehensive understanding of the phenomena of interest.[172] *The basic statistical model is as follows:*

$$Y_{ij} = \beta_{0j}^{*} + \beta_{1j}^{*} X_i + \beta_2 W_j + \beta_3 X_i W_{ij} + \varepsilon_{ij}$$
$$\beta_{0j}^{*} = \beta_0 + \gamma_j$$
$$\beta_{1j}^{*} = \beta_1 + \eta_j$$

Where, Y_{ij} is healthy lifestyle behaviors as measured by either the healthy lifestyle behaviors scale or pedometer steps , X_{ij} is the data collection time point, W_{ij} is the indicator of group membership (COPE and the attention control group), γ_j is the error in the random intercept and ηj is the error in the random slope. The slope for the interaction between treatment groups and time, β_3, is the parameter of interest in the proposed study.

The next phase of analysis will focus on conventional tests of the efficacy of COPE guided by the **a priori** hypotheses. It will continue with gross assessment of hierarchical inter-relationships among outcome variables and repeated measures, and end with exploratory analyses of the fit of data to the proposed conceptual model.

Analysis plan for Aim 1. The intervention's efficacy will be evaluated using a mixed model ANOVA comparing the two groups over four repeated measures. The four repeated measures will be: baseline (0 weeks), post-intervention (9 weeks), 6 month follow-up (34 weeks), and 12 months follow-up (58 weeks). The test of interest in this analysis is the Groups × Time interaction because national surveillance data and the COPE model predict that there will be deterioration over time in the control group and maintenance or improvement over time in the intervention group. *Analyses will include adjustment for clustering as dictated by preliminary analyses.* This analysis will be repeated for *each of the two* outcome variables specified in **Hypothesis 1a.** A statistically significant interaction will be followed by pairwise comparisons of groups at each time point and pairwise comparisons of change over time within each group. Tukey's method, which is designed for controlling alpha when all possible pairwise comparisons need to be made, will be used to control the error rate at the level of analysis. *That is, in the Groups × Time analysis there will be eight means (2 groups × 4 time points) with a possible 28 comparisons to be made.*

The COPE model also predicts **(Hypothesis *1b)*** that the intervention will be most effective for those participants at highest risk (those with elevated *depression symptom scores*). A test of this hypothesis will be made using a *2 × 2 × 4* ANOVA (Risk Subgroups × Treatment Groups × Time). That is, participants will be divided into *two subgroups (1 = mildly elevated and 2 = moderately elevated)*. A statistically significant three-way interaction will be followed by *pairwise comparisons within the interaction using a Tukey test*.

A similar analysis will be used to evaluate **Hypothesis *1c*.** A 2 × 2 × 4 ANOVA (Weight Subgroups × Treatment Groups × Time) *of weight gain will be used*. That is, participants will be divided into two subgroups (1 = overweight teens and 2 = normal weight teens). *A statistically significant three-way interaction will be followed by pairwise comparisons within the interaction using a Tukey test*.

The differential incidence hypothesis (**Hypothesis *1d***) will be evaluated using a Kaplan-Meier time to event (survival analysis) procedure with those subjects *who were normal weight at baseline* divided into two groups (intervention versus control) and sampled at four time points.

Statistical power for analysis of Aim 1. An estimate of effect size for the *key* outcome measures can be straightforwardly based on clinical norms, published research, or pilot data,.[151–155, 173–175] As a result, **sample size for the study** was based on a power analysis using standardized estimates of effect size *and* hypothetical scenarios congruent with predicted outcomes. Sample size was based on power calculations for teen outcomes, rather than parent outcomes, because change in teen outcomes is the major determinant of the efficacy of the intervention. *Two types of power analyses were run. The first looked at power needed for omnibus ANOVA tests assuming that all ICC were zero. The second looked at the* ***a priori*** *comparison of between group differences at each time point adjusted for the class ICC, the most likely cluster variable to have a meaningful ICC and the simplest test of outcomes.* Power analyses were conducted using PASS 2005 software (NCSS, Inc.).

Power for the *Groups* × *Time* interaction test was ≥0.80 in each of the scenarios tested with 20 participants per group. This sample size was doubled (40/group), so that the effect of gender could be evaluated in separate analyses. The sample size was further increased by 25% to allow for losses to follow-up (50/group). Finally, sample size was doubled again (100/group) so that subgroup analyses could be conducted *(e.g., by weight category). Thus, each school in the study will provide 100 participants. Table 12 provides an example of the effect size estimates and trajectories of change over time used in doing power analyses, as well as the impact on power of the estimated ICC for classes. Power will be adequate for the primary outcomes (depressive symptoms and healthy lifestyle behaviors) at all time points, if the ICC is low. It will be more than adequate for follow-up comparisons, even if the ICC is more substantial. Power for the secondary outcome of weight gain will be adequate for follow-up comparisons.*

Analysis plan for Aim 2/Hypothesis 2. Structural equation modeling (SEM) will be used to examine the role of cognitive beliefs and perceived difficulty in leading a healthy lifestyle in mediating the effects of the COPE program on healthy lifestyle behaviors as well as depressive symptoms in 14 to 16 year old adolescents. Change over time in the outcomes will be modeled with a latent growth model with the intervention and mediators added to the model as predictors of the intercept and slope of the growth model. While mediated relationships could be tested using the procedures of Baron and Kenny,[176–178] SEM tests all relationships simultaneously and gives an overall test of model fit. The Chi-square for the model, root-mean-square error, Bollen's non-normed fit index, and Bentler's comparative fit index will be reviewed to assess the model fit.[179, 180] Standard errors for the coefficients will be reviewed to make sure that there are no estimation problems before testing path coefficients. If for the overall model the root-mean-square is greater than .08 or the non normed fit index or Bentler's comparative fit index is less than .90 or the absolute values of the t statistics for the path coefficient are less than 1.96, the Wald test and Lagrange Multiplier test will be used to explore a better fitting model. Any modification will be examined for theoretical meaningfulness before proceeding.[177]

Statistical power for analysis of Aim 2. For testing the proposed mediation model in Figure 1, power is defined as the ability to detect the difference between a good fitting model, i.e., a model evaluated using the fit statistic Root Mean Square Error of Approximation (RMSEA), where a good fit is defined as a value <.05, and a close fitting model where the value of RMSEA is < .09.[181, 182] Under the null hypothesis of close fit (i.e., RMSEA < .05 the value of the RMSEA test statistic is approximately asymptotically noncentral $\chi 2$ with d degrees of freedom and noncentrality parameter lo = (N − 1) deo2 and under the alternative hypothesis of not close fit

(i.e., RMSEA >.09), RMSEA is also approximately asymptotically noncentral $\chi 2$ with d degrees of freedom and noncentrality parameter l1 = (N – 1) de12. At alpha = .05, substituting the relevant values for e, that is, the parameters to be estimated in the proposed model and degrees of freedom into a SAS program included in the MacCallum, Browne and Sugawara article,[181] we can compute power for a given sample size. For the proposed model with 13 degrees of freedom, the minimum sample size needed would be 373 for a power of .80.

Table 12. Power Analysis (*after attrition)*

		Estimated Mean (SD) at baseline	Estimated Mean (SD) at 9 weeks	Estimated Mean (SD) at 34 weeks	Estimated Mean (SD) at 58 weeks
Depression Subscale of BYI-II*	Intervention	50 (10)	48 (10)	45 (10)	46 (10)
	Control	50 (10)	50 (10)	51 (10)	52 (10)
	Effect size		–0.2	–0.6	–0.6
	Power when ICC = 0.01		0.77	0.99	0.99
	Power when ICC = 0.05		0.67	0.99	0.99
	Power when ICC = 0.10		0.57	0.99	0.99
Healthy Lifestyle Behaviors*	Intervention	53 (11)	55.5 (11)	58 (11)	59 (11)
	Control	53 (11)	53 (11)	54 (11)	54 (11)
	Effect size		0.23	0.36	0.45
	Power when ICC = 0.01		0.86	0.99	0.99
	Power when ICC = 0.05		0.76	0.98	0.99
	Power when ICC = 0.10		0.66	0.95	0.95
Weight (in pounds) among overweight teens**	Intervention	165 (25)	168 (25)	170 (25)	172 (25)
	Control	165 (25)	171 (25)	180 (25)	190 (25)
	Effect size		–0.12	–0.40	–0.72
	Power when ICC = 0.01		0.24	0.93	0.99
	Power when ICC = 0.05		0.23	0.90	0.99
	Power when ICC = 0.10		0.21	0.87	0.99

*comparison of two groups, assuming 32 clusters per group and 9–10 participants per cluster, $\alpha = 0.05$
**comparison of two groups, assuming 32 clusters per group and 3–4 participants per cluster, $\alpha = 0.05$

Analysis plan for Aim 3. The theoretical framework underlying the COPE intervention suggests that specific moderators may impact the effectiveness of the intervention. Procedures described for Aim 2 (SEM and multiple regression) will be used to explore the impact of these moderators and generate testable hypotheses for future investigations.

Project Timeline. Table 13 lists each of the key tasks involved in completing the study and indicates when each task will start and finish.

Table 13. Project Timeline

Tasks	1–7 Months	8–30 Months	31–42 Months	43–48 Months
Hire and train staff	X			
Prepare tracking databases	X			
Prepare analysis databases	X			
Site Coordination	X			
Training of Teachers	X			
Formation of Community Advisory Board	X			
Screen/enroll participants		X		
Conduct baseline testing		X		
Conduct post-intervention testing		X	X	
Conduct follow-up testing		X	X	
Enter and audit data		X	X	
Analyze data		X	X	X
Prepare manuscripts			X	X

Strengths and Innovation. This study will be the first theory-based full-scale randomized clinical trial to test the efficacy of a novel reproducible healthy lifestyles educational and CBSB intervention (i.e., the COPE Healthy Lifestyles TEEN program) for culturally diverse adolescents on healthy lifestyle behaviors, depressive symptoms and weight. *In addition, the study is powered so that analyses of sub groups of teens can be conducted to determine if the intervention has positive effects on: a) the prevention of overweight in normal weight teens, b) reduction in weight gain in overweight teens, and c) reduction in depressive symptoms in teens who report mild to moderate depression at baseline assessment.* The rigorously designed trial has strong internal validity and will extend the science by testing variables that may mediate and moderate the effects of the intervention on adolescent outcomes. Power calculations were made on key variables and sample size was *calculated* so that within district and within school comparisons could be made *and clustering by class could be included in the* analysis *with adequate power*. This method provides the opportunity to: (a) conduct critical subgroup analyses, (b) begin testing the fit of the theoretical model, (c) minimize the impact of the group randomized design, and (d) take advantage of the reduced risk of cross-contamination. The team of investigators is comprised of seasoned researchers and interdisciplinary professionals with expertise in conducting interventions with culturally diverse adolescents in school-based settings. Six prior pilot studies with culturally diverse teens support feasibility and need to conduct this RCT.

Limitations with Alternative Approaches. Attrition is always a challenge in longitudinal studies. However, the need to define the trajectory of the effect requires that long-term follow-up

be conducted. Close tracking of study participants and follow-up/reminder calls in addition to the offering of incentives will help in reducing attrition. A community advisory board will be formed to assure that the approaches used in the study are trust building and culturally sensitive. Dr. Flavio Marsiglia has trained teachers in 65 schools in Arizona to deliver his substance abuse prevention intervention to children over the past 13 years, which has been highly successful. Strategies he has used successfully in his work will be used in this study.

6. PROTECTION OF HUMAN SUBJECTS

1. Risks to the Subjects

a. Human Subjects Involvement and Characteristics

A total of *800* adolescents, ages 14 to 16 years, who are high school freshmen or sophomores and one of their parents/legal guardians, will participate in the proposed study. The sample will be ethnically diverse.

Adolescents and their parents will be recruited from *8 high schools* located in the greater Phoenix metropolitan area, *4 high schools in the Paradise Valley Unified District and 4 high schools in the Phoenix Union School District.* Paradise Valley Unified Districts has a wide range of socioeconomic status with schools that are predominantly either Caucasian or Latino. As a whole, district demographics include Caucasian 70.6%, Latino 21.5%, Black 3.4%, Asian 3.2%, and Native American 1.2%. Phoenix Union High School District demographics include Latino 77%, Black 9.8%, White 8.2%, Native American 3.5%, and Asian 1.4%.

Rationale for Inclusion/Exclusion Criteria

The sample will include teens, age 14 to 16 years, as this period of middle adolescence is aligned with the cognitive level to benefit from the proposed intervention, and middle adolescents are capable of being agents of self change. Younger teens are not likely to be enrolled in high school. Teens older than 16 years are more cognitively developed and require a more complex and flexible intervention than that proposed.[143, 144]

Additionally, teens need to be available for a 58-week follow-up data collection. Our pilot studies indicated that this becomes less likely once teens are old enough to leave/graduate from high school, emancipate from parents, and/or leave home. All teens (any gender, ethnicity/race, or socioeconomic status) will be included with assent and parent consent except for students who have a medical condition that would not allow them to participate in the physical activity component of the program.

School sites/Roles of sites

Two school districts in Maricopa County, Phoenix, Arizona have given permission to have the intervention be conducted in health classes for freshmen and sophomore students. These

districts include Phoenix Union High School District and Paradise Valley Unified School District. The role of each site is to provide classrooms in which to recruit students and conduct the intervention. *Teachers of the proposed classrooms will be approached regarding whether they would be interested in having their classes participate in the intervention and be willing to be trained to deliver the intervention. After agreement of the classroom teachers, dates of the intervention training will be provided to the teachers and scheduled.* Schools that are randomized to the experimental intervention also will provide a setting in which to complete physical activity during each intervention session. Depending on the time of year, this may be a field on the school campus or in a gymnasium.

b. Sources of Materials

Self-reported data

Self-reported data will be obtained from the adolescents through completion of questionnaires. Data include information about the subjects' health, cognitive beliefs, perceived difficulty in leading a healthy lifestyle, healthy lifestyle behaviors and level of depressive symptoms. Self-reported data from the parents will include a demographic questionnaire as well as healthy lifestyle beliefs and behaviors, along with an evaluation form about the teen's program.

Client names will not be stored with study data. The master list linking the client ID number to the client's identifying information will be maintained in a separate, locked filing cabinet in the PI's locked office. Likewise, signed consent forms will be kept in a separate, locked filing cabinet, and will only be accessible to the project investigators and the full time project coordinator. No identifying information will be stored with our questionnaire forms or within the questionnaire database. Furthermore, all questionnaire data will be kept in locked file cabinets within locked offices that are accessible only to the project investigators and staff. Access to the electronic data will be restricted to project investigators and data entry staff. Databases will be password protected to guard against unauthorized access. Project staff will receive extensive training and supervision regarding the importance of maintaining client confidentiality. The PI, Co-Investigators, and the project coordinator will oversee this training.

c. Potential Risks

Human subjects' rights will be protected as explained in the consent and assent forms used for the study. It is not anticipated that the study will present risks to the subjects other than the inconvenience of time required and possible minimal feelings of discomfort if any of the questions cause them to think about things that they perceive as unpleasant. Subjects will be informed that they may choose not to answer any of the questions on the measures as well as that they may choose to withdraw from the study at any time without negative consequences or without risking their class grade. In the event that parents do withdraw from the study, the information already provided will be kept in a confidential manner, unless the parent/legal guardian direct otherwise.

Strict confidentiality will be maintained. All subjects will be assigned code numbers so that their names will only appear on the consent form. Only the researchers or their associates will have access to the data that will be stored in locked file cabinets in the study's office. It is anticipated

that the benefits of participating in the study far exceed the risks by enhancing teen and parent mental or physical health outcomes.

2. Adequacy of Protection Against Risks

a. Recruitment and Informed Consent

All adolescents, 14 to 16 years of age, who meet the previously described study criteria, will be asked to participate in the study along with one of their parents/legal guardians. Adolescents will be recruited from 4 high schools within two participating school districts in the greater Phoenix area. Research team members will introduce the study in required health courses during the first week of the semester. Assents and parent information and consents will be distributed to interested students. A phone number will be listed in the consent for parents to call if questions arise. Teens that meet eligibility criteria, have given assent and submitted written parental consent will be able to participate in the study.

Potential subjects will be assured that: 1) their participation is voluntary; 2) they are free to withdraw from the study at any time; and 3) if they decline to participate or withdraw from the study, there will be no adverse effects on them or their grade in the class. Confidentiality of the data collected for this study will be addressed during the consent process. While we will make every effort to keep information we learn about subjects private, this cannot be guaranteed. Results of the research may be presented at meetings or in publications, but the names of subjects will not be used.

Adolescents will receive a total of $55 in department store gift cards for their participation and parents will receive a total of $60 in department store gift cards for completion of study questionnaires at baseline and at the end of the study. An additional $45 in department store gift cards will be provided to the overweight adolescents who complete blood draws at the pre as well as post-intervention and 34 week follow-up points. We believe that the level of this payment is high enough to be an incentive for subjects to participate, yet low enough so that as not to be unduly coercive.

b. Protection Against Risk

If unexpected emotional reactions should occur during study contacts or clinically significant levels of depression are reported on the depression scales at any time throughout the study, the teens' parents will be telephoned and participants will be referred to their primary care providers or appropriate agencies or services within the community. We will score the Beck Youth depression sub-scale of the teens immediately after completion of the measures at each assessment contact. Specifically, parents of teens in either experimental study group who have a T score of 70 or greater on the BYI-II will be called and referred immediately to their primary care providers for a fuller assessment of their depressive symptoms for clinically significant depression. If immediate care is needed, our PI (Dr. Bernadette Melnyk, who is a psychiatric mental health nurse practitioner) will be contacted and appropriate resources obtained. Referral information for mental health services also will be provided to participants who express interest in such information, but who are judged not to be in need of immediate mental health services.

3. Potential Benefits of the Proposed Research to the Subjects and Others

Subjects may benefit from this study, as it will afford them the opportunity to express thoughts and feelings on the questionnaires and during the exit questionnaire. Also, by participating, subjects will learn cognitive-behavioral skills and health information that may be helpful to live a mentally and physically healthy lifestyle. It is anticipated that the benefits of participation will far exceed the risks.

4. Importance of the Knowledge to be Gained

The prevention and treatment of obesity and mental health disorders in adolescence are two major public health problems in the United States (U.S.) today.[11, 12] The incidence of adolescents who are overweight or obese has increased dramatically over the past 20 years, with approximately 17.1 percent of teens now being overweight or obese.[13, 14] Key factors influencing the obesity epidemic include an increase in sedentary activities (e.g., television viewing; computer games) and changes in dietary patterns and food consumption (e.g., large portion sizes, fast foods). Being overweight predisposes adolescents to adverse health outcomes compared to their non-overweight counterparts, including Type 2 diabetes, hypertension, dyslipidemia, sleep apnea, increased asthma symptoms and a shortened life span.[15–17, 183] In addition, research findings have indicated that overweight and obese adolescents, in comparison to normal weight adolescents, have a higher incidence of school and mental health problems, including poor academic performance and self-esteem, anxiety and depressive disorders, and a greater number of reported suicide attempts.[18–23, 184]

Furthermore, although approximately 15 million children and adolescents in the United States (U.S.) have a mental health problem that is interfering with their functioning at home or at school, less than 25 percent receive treatment for these disorders. Depressive disorder among adolescents is a nationwide public health problem associated with disabling morbidity, significant mortality, and substantial healthcare costs. The prevention and treatment of this disorder is one of the major public health problems in the U.S. today. As most mental health disorders begin in adolescence, intensified efforts must be placed on preventing and treating these disorders during this critical time in development. Because so few adolescents with mental health disorders receive treatment and about one third of those referred to mental health specialists do not make contact with them over the next 6 months, there is a critical need to prevent and provide early interventions for adolescents with elevated depressive symptoms in school-based settings. Schools are an ideal setting to identify adolescents who are at high-risk for mental health problems and to provide early interventions to prevent the development of major depression and anxiety disorders.

The goal of the proposed project is to test the efficacy of the COPE (Creating Opportunities for Personal Empowerment)/Healthy Lifestyles TEEN Program, a 15 session, theory- driven, manualized cognitive behavioral skills building intervention for improving healthy lifestyle behaviors and mental health. Specific aims of the study include: (1) Use a randomized controlled trial (RCT) to test the short- and more long-term efficacy of the COPE/Healthy Lifestyles

TEEN Program to improve *healthy lifestyle behaviors and depressive symptoms* of 14 to 16 year old culturally diverse adolescents enrolled in Phoenix, Arizona high schools, (2) examine the role of cognitive beliefs and perceived difficulty in leading a healthy lifestyle in mediating the effects of the COPE program on healthy lifestyle behaviors and depressive symptoms in 14 to 16 year old adolescents, and (3) explore variables that may moderate the effects of the intervention on healthy lifestyle behaviors and depressive/anxiety symptoms (e.g., race/ethnicity, gender, SES, family composition, acculturation, structural barriers to activity, and parental healthy lifestyle beliefs and behaviors). A total of *800* adolescents and their parents/legal guardians at *eight* high schools in Maricopa County will participate in the study. A variety of valid and reliable instruments will tap key process, outcome and potential moderating variables.

The proposed study is consistent with the NIH roadmap and NIH's goals of improving people's health and preventing the onset of disease and disability, specifically the prevention of overweight as well as mental health problems in a vulnerable population of adolescents.

5. Data and Safety Management Plan

- The Nursing Advisory Committee of the ASU College of Nursing has implemented a Data and Safety Monitoring (DSM) policy. This policy creates a standing DSM Board (DSMB) to protect the health and safety of human participants and provide information relevant to participants' continuation in clinical studies. The DSMB will include the Chair of the Research Advisory Board, the Associate Dean for Research, the Principal Investigator, and other ad hoc members as needed to assure expertise in safety of human participants, including a child psychiatrist. The DSMB will meet quarterly to review progress on the project. Adverse events will be reported immediately to the Principal Investigator and within 24 hours to the DSMB Chair.
- Serious adverse events will be reported to the institutional review board within 24 hours.
- Periodic reviews of data will include discussion of early termination for harm or benefit.
- Data handling security is described in Section D and computer security is described in the Resources section. Briefly, paper forms are locked in a cabinet in a locked room in a secure building. Data analysis computers are dedicated and not linked to public access systems. Backups are made to physical media and stored in different locations under secure conditions. Only authorized personnel have access.
- The institutional review board will review progress at least annually and may do so without notice at any time.

The potential risk of our current clinical trial is considered to be minimal because of the nature of the intervention. Since this study fits in the category of Clinical Trial (Phase II) study, we have developed a plan for appropriate oversight and monitoring of the conduct of the clinical trial to ensure the safety of the participants and the validity and integrity of the data.

a. The PIs have already obtained the policies of the Arizona State University IRB specifically regarding the adverse events associated with clinical trials. The PIs will adhere to those policies, and maintain a copy of the policies in the study file.

b. The PI and Co-Investigators will meet with the research assistants through regular bi-weekly meetings during the data collection phase, and identify any risks of adverse effects resulting from the data collection process and data review.
c. The PI, Co-investigators, and consultants will make decisions about necessary protocol and operational changes based on discussion and review of data and the data collection process. Any proposed changes in the consent form or research procedures resulting from the report will be prepared/identified by the PI and submitted with the report to the IRB for approval.
d. The following policies required by our IRB and NIH will be adhered to: (1) any adverse events that are serious and unexpected and are related (possibly or probably) to the study will be reported to the IRB and NIH within 15 calendar days; (2) adverse events that are both unexpected and related that are either life-threatening or result in death will be reported to IRB and NIH immediately; and (3) for adverse events that do not meet the criteria above will be documented in the summary report submitted to the IRB and NIH annually at the time of the study's continuing review. Because the proposed study has a low risk intervention, we do not anticipate any serious adverse effects described in the first two categories from a result of participating in this study.
e. The PI and Co-Investigators will ensure that the NIH (funding Institute and Center) is informed of actions, if any, taken by the IRB as a result of its continuing review, and recommendations that emanate from the monitoring activities.
f. The PI and Co-Investigators will be responsible for reporting adverse events or unanticipated problems involving risks to subjects or others to the local IRB.
g. Confidentiality will be protected. Client names will not be stored with study data. Complete anonymity is not possible given our need to link participant questionnaire data to key chart data available only through the client's medical record. However, the master list linking the client ID number to the client's identifying information will be maintained in a separate, locked filing cabinet in PI's locked office. Likewise, signed consent forms will be kept in a separate, locked filing cabinet, and will only be accessible to the project investigators and the full time project coordinator. All data garnered from the adolescents' medical records will be transferred immediately to a separate form on which data are identified only by the participant ID number. Mandated HIPAA guidelines will be followed. As noted, no identifying information will be stored with our questionnaire forms or within the questionnaire data base. Further, all questionnaire data will be kept in locked file cabinets within locked offices that are accessible only to the project investigators and staff. Access to the electronic data will be restricted to project investigators and data entry staff. Databases will be password protected to guard again unauthorized access. Project staff will receive extensive training and supervision regarding the importance of maintaining client confidentiality and HIPAA guidelines. This training will be overseen by the PI, Co-PI, co-investigator, and project coordinator.
h. Measures of depression will be screened as they are completed and appropriate referrals will be made (see previous section). The PI and Co-Investigators will be kept informed.
i. The PI and Co-Investigators will be responsible for the monitoring of this plan throughout the life of the study.

7. INCLUSION OF WOMEN AND MINORITIES

Inclusion of Women

No adolescents or parents/legal guardians will be excluded based on gender. Based on our preliminary work, it is projected that 90% of the parents recruited will be women. This is consistent with the principal investigator's study # 3, in that all but one parent participating in the intervention was female.

Inclusion of Minorities

No individuals will be excluded because of race/ethnicity, or socioeconomic status. The research team has extensive experience in conducting research with Hispanic adolescents and will conduct cultural sensitivity training with the research assistants. We will implement strategies for retention of all of our subjects, including minorities. Based on the demographics in the participating high schools, we expect our sample to be comprised of approximately 50% ethnic and racial minorities.

TARGETED/PLANNED ENROLLMENT TABLE

This report format should NOT be used for data collection from study participants.

Study Title: COPE/Healthy Lifestyles for Teens: A School-Based RCT
Total Planned
Enrollment: 800 (teens)

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	202	202	404
Not Hispanic or Latino	198	198	396
Ethnic Category: Total of All Subjects*	400	400	800
Racial Categories			
American Indian/Alaska Native	10	10	20
Asian	9	9	18
Native Hawaiian or Other Pacific Islander	2	2	4
Black or African American	30	30	60
White	349	349	698
Racial Categories: Total of All Subjects*	400	400	800

*The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

TARGETED/PLANNED ENROLLMENT TABLE

This report format should NOT be used for data collection from study participants.

Study Title: COPE/Healthy Lifestyles for Teens: A School-Based RCT
Total Planned Enrollment: 800 (parents)

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	359	45	404
Not Hispanic or Latino	353	43	396
Ethnic Category: Total of All Subjects*	712	88	800
Racial Categories			
American Indian/Alaska Native	18	3	21
Asian	12	6	18
Native Hawaiian or Other Pacific Islander	2	2	4
Black or African American	36	17	53
White	652	52	704
Racial Categories: Total of All Subjects*	720	80	800

*The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

8. INCLUSION OF CHILDREN

Children, ages 14 to 16 years, will be included in the study. The PI is a pediatric nurse practitioner and a child-family psychiatric nurse practitioner with adolescent specialization, educator, and researcher with 20 years experience developing coping and mental health promotion interventions for children and their parents. She will be assisted by clinical researchers, physicians, and a board certified child and adolescent psychiatrist, who have many years experience of treating adolescents. The intervention materials have been tested for developmental appropriateness with White, Hispanic and African American adolescents in this age group. Children under age 14 years will be excluded because the intervention is specifically targeted for late early and middle adolescents. Children over age 17 and adults will be excluded because the intervention would need to be tailored for the specific developmental characteristics of older adolescents.

ABSTRACT

The prevention and treatment of obesity and mental health disorders in adolescence are two major public health problems in the United States (U.S.) today. The incidence of adolescents who are overweight or obese has increased dramatically over the past 20 years, with approximately 17.1 percent of teens now being overweight or obese. Furthermore, approximately 15 million children and adolescents (25 percent) in the U.S. have a mental health problem that is interfering with their functioning at home or at school, but less than 25 percent of those affected receive any treatment for these disorders. The prevalence rates of obesity and mental health problems are even higher in Hispanic teens, with studies suggesting that the two conditions often coexist in many youth. However, despite the rapidly increasing incidence of these two public health problems with their related health disparities and adverse health outcomes, there has been a paucity of theory-based intervention studies conducted with adolescents in high schools to improve their healthy lifestyle behaviors as well as their physical and mental health outcomes. Unfortunately, physical and mental health services continue to be largely separated instead of integrated in the nation's healthcare system, which often leads to inadequate identification and treatment of these significant adolescent health problems.

Therefore, the goal of the proposed randomized controlled trial is to test the efficacy of the COPE (Creating Opportunities for Personal Empowerment)/Healthy Lifestyles TEEN (Thinking, Feeling, Emotions & Exercise) Program, an educational and cognitive-behavioral skills building intervention guided by cognitive behavior theory, on the healthy lifestyle behaviors and depressive symptoms of 800 culturally diverse adolescents enrolled in Phoenix, Arizona high schools. The specific aims of the study are to: (1) Use a randomized controlled trial to test the short- and more long-term efficacy of the COPE TEEN Program on key outcomes, including healthy lifestyles behaviors, depressive symptoms and body mass index percentage, (2) examine the role of cognitive beliefs and perceived difficulty in leading a healthy lifestyle in mediating the effects of COPE on healthy lifestyle behaviors and depressive symptoms, and (3) explore variables that may moderate the effects of the intervention on healthy lifestyle behaviors and depressive symptoms, including race/ethnicity, gender, SES, acculturation, and parental healthy lifestyle beliefs and behaviors. Six prior pilot studies support the need for this full scale clinical trial and the use of cognitive-behavioral skills building in promoting healthy lifestyles beliefs, behaviors and optimal mental health in teens.

This study is consistent with the NIH roadmap and goals of improving people's health and preventing the onset of disease and disability as well as promoting the highest level of health in a vulnerable population.

PROJECT NARRATIVE

The prevention and treatment of obesity and mental health disorders in adolescence are two major public health problems in the United States today. To address the increasing incidence

and adverse health outcomes associated with both obesity and mental health problems, a theory-based 15 session intervention program entitled *COPE (Creating Opportunities for Personal Empowerment)/Healthy Lifestyles TEEN (Thinking, Feeling, Emotions & Exercise)*, will be delivered within high school health classes in order to improve the physical and mental health outcomes of 800 culturally diverse adolescents (14 to 16 years of age).

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FACILITIES AND OTHER RESOURCES

Arizona State University

Arizona State University (ASU) is one of the premier metropolitan public research universities in the nation. Enrolling more than 64,000 undergraduate, graduate, and professional students on four campuses in Fall 2007, ASU is a federation of unique colleges, schools, departments, and research institutes that comprise close-knit but diverse academic communities that are international in scope. ASU champions intellectual and cultural diversity, and welcomes students from all 50 states and more than one hundred nations across the globe.

ASU has twelve colleges: Architecture, Business, Education, Engineering and Applied Sciences, Fine Arts, Law, Liberal Arts and Sciences, Nursing & Healthcare Innovation, Public Programs, Social Work, the Barrett Honors College, and the Graduate College. The four campuses are the main campus in Tempe, ASU West, the Downtown campus in Phoenix (including the main College of Nursing & Healthcare Innovation); and ASU Polytechnic campus. The state system also includes the University of Arizona in Tucson and Northern Arizona University in Flagstaff. The faculty includes recipients of prestigious academic and professional awards, including membership in the national academies and the 2004 Noble Prize winner in economic sciences, Edward C. Prescott.

Students have an opportunity to pursue an array of high -quality academic programs, including special training and targeted programs from the baccalaureate through the doctoral degree. In Fall 2007, 66.7% of the undergraduate and 49.7% of the graduate student population were white; 25.9% of undergraduates were minorities, as were 16.3% of graduates. From 1996 to Fall 2007 at ASU, the Hispanic student population went from 690 undergraduates and graduates to 1,347 (1,154 of which were undergraduates); the American Indian student population went from 672 to 1,370. There were more female Hispanic undergraduates than male (4,154 vs. 3,157) and graduate (649 vs., 372). There were also more American Indian undergraduates than male (706 vs. 403) and more female graduate than male (154 vs. 79). One -year persistence rates for first-time, full-time Hispanic freshmen went from 70.9% in 1995 to 76.6% in 2005; for American Indians, these figures are 54.3% and 67.9% respectively.

ASU is among the top 100 research universities in the nation. In September 2006 ASU announced that it had passed a significant milestone in research expenditures by reaching $203.5 million in the fiscal year that ended June 30. Revenues from grants and contracts rose again to $219 million in FY 2007. ASU has in place the financial and asset management systems required to administer contracts such as the one described in this proposal. The Vice President for Research and Economic Affairs is the principal administrative official responsible for sponsored programs at ASU. Units reporting to the Vice President have responsibility for post-award administration for all externally funded projects. These responsibilities include cash management, financial and property reporting, deliverable monitoring, and project management assistance.

The Office for Research and Sponsored Projects Administration (ORSPA), a part of Research and Economic Affairs, assists faculty, staff, and students to secure and administer outside support for their instructional, research, and public service activities. ORSPA protects institutional eligibility of external funding by ensuring that all sponsored projects comply with ASU general research policies as well as federal, state and sponsor mandates. ORSPA is organized into three life cycle teams that manage sponsored projects activity from proposal submission through project closeout. Teams include Sponsored Projects Officers, Contract Officers and Grant & Contract Accountants who integrate the pre-award and post-award functions of each award into a single comprehensive management process.

ASU administers all sponsored funds in accordance with applicable acquisition regulations and in consideration of federally mandated cost principles and financial management guidelines as they apply to institutions of higher education. Travel, procurement, financial management, and personnel policies and procedures are in place and are documented in available manuals.

Centers, Institutes, and Programs

ASU comprises dozens of centers, institutes, and programs. Among them are the following: The *ASU Office of Clinical Partnerships* serves as a link between ASU and the *Biodesign Institute* to various industrial and clinical partners in the community; the *Department of Biomedical Informatics* ; the *School of Health Management and Policy* in the Carey School of Business; the *Center for Applied Behavioral Health Policy*, a research and training center within the College of Human Services; and the ASU partnership with the *Translational Genomics Research Institute* (*TGen*), which collaboratively pursues biomedical research and projects focusing human health to meet the genetic and molecular challenges that are transforming medicine and the life sciences. With the Barrow Neurological Institute, Mayo Clinic Arizona, Sun Health Research Institute, TGen, the University of Arizona, and the Banner Alzheimer's Institute, ASU is a member of the *Arizona Alzheimer's Consortium,* which promotes the understanding and early detection of Alzheimer's disease to find effective disease-stopping and prevention therapies.

Other units attest ASU's commitment to diversity. They include, among others, the *African and African American Studies Program*; the *American Indian Policy Institute; Asian Pacific American Studies*; *Center for Indian Education*; *Department of Chicana and Chicano Studies*; the *Hispanic Research Center*; the *North American Center for Transborder Studies*; and the *Office of Pan American Initiatives*. The *Southwest Interdisciplinary Research Center* is an NIH-funded Exploratory Center of Excellence (P20) that conducts multidisciplinary, community-based research on culturally grounded drug use prevention and services. The ASU *Southwest Borderlands Initiatives* includes two faculty appointments in the CONHI.

The *Institute for Social Science Research* provides research development and data support services across ASU in three core research areas: Survey Research and Analysis Group**,** Research Technology Services, and Geographic Information System Services. Technology at ASU is promoted by such groups as *Arizona Technology Enterprises*, which works with university inventors and

industry to transform scientific progress into products and services; and the *ASU Technopolis* program, which helps transform the metro area's knowledge economy.

Libraries

ASU has excellent library facilities and staff. The collections of the university's eight libraries comprise, in print, nearly 4.3 million monographs, including serials; approximately 7.7 million microform units; in digital format, 319 E-Journals: 32,791,and E-Books: 281,588; in 2005/2006, it added 10 E-Books: 22,743. Among the other media are government publications; cartographic materials; and CD-ROMs, DVDs, videos, and sound recordings. The *Downtown Phoenix campus library* provides access to books and other research resources focusing on materials of particular interest to majors in the anchor fields taught at the Downtown campus: *healthcare innovation*, *nursing*, public affairs, social work, tourism development and management, and other related fields. Downtown campus students also have direct access to the over 4 million volumes in the Libraries' collections. Among its resources are the Nursing Research Guide and Nursing Specialties Research Guide. The *Noble Science and Engineering Library* houses the collections in engineering, physical and life sciences, physics/astronomy/math, and mathematics. Among the most frequently used resources are ABI/Inform, Academic Search Premier (EBSCOhost), CINAHL, ERIC, JSTOR, LexisNexis Academic, Medline, PsychINFO, and Web of Science. The other University Libraries are the *Architecture and Environmental Design Library;* the *Charles Trumbull Hayden Library*, which houses materials in the humanities and social sciences, including business and education; the *Law Library*; and the *Music Library*.

Computer Infrastructure

Programming, statistical, graphics, and other applications software are provided on a university-wide network of microcomputers and Unix-based servers. These services, including university-wide electronic mail and the library's online catalog, can be accessed through a communications network from many sites and most offices on campus (including the office of the principal investigator), as well as from off-campus offices and homes via a phone connection. Communication with other research facilities is possible through the Internet. Access to other information systems around the world is available via the World Wide Web and Telnet.

ASU does not charge faculty members for the use of university computer systems; therefore, computer time for this project will be absorbed by the university. The academic statistical and research servers and servers that support electronic mail and access to the World Wide Web are available through Information Technology on the ASU campus. All the academic servers use a common file system (the Andrew File System) to enable files to be shared easily among them. Individual faculty workstations also have access to this file system. Personal computers are available in all faculty offices in the Nursing Building to allow easy access to the academic servers and the Internet. Additional workstations are available in the research offices of the ASU Community Services building located approximately one mile from the Tempe campus.

College of Nursing & Healthcare Innovation

The College of Nursing & Healthcare Innovation (CONHI) began its existence 50 years ago, when it established the Bachelor of Science in Nursing degree program for prelicensure and RN students. It began as a small program that graduated only 6 individuals in the first class in 1960 and has graduated over 7,600 students. Approximately 1,850 undergraduate, graduate, and doctoral students are now enrolled; 28.6% undergraduate students are from ethnic minority backgrounds, and 7.4% graduate students are from ethnic minority backgrounds. The Commission on Collegiate Nursing Education (CCNE) accredited the College of Nursing, effective April 2004, for the next 10 years. The baccalaureate and nurse practitioner programs are accredited by the Arizona State Board of Nursing.

The CONHI offers its programs at four locations, including new and expanded facilities at the Downtown campus in central Phoenix (to which the majority of the Tempe faculty and staff moved in August 2006) and at the ASU West, ASU Polytechnic, and Mayo Clinic campuses. Faculty and staff in the college's Academy of Continuing Education, Nurse Educator, and RN to BSN programs will remain at a Tempe annex office until 2008–2009, when they will move to the Downtown Phoenix campus, occupying a new building whose groundbreaking took place in April 2008.

The CONHI has the only BSN state-supported program in Maricopa County and is Arizona's largest provider of BSN nurses. It offers an **undergraduate program** that leads to a Bachelor of Science in Nursing (BSN). The RN-to-BSN entry option offers Registered Nurses the opportunity to complete upper-division nursing program requirements leading to a BSN. **Graduate program** offerings include (a) a Master's degree in Nursing for Community Health or Nurse Educator, (b) a Master's of Healthcare Innovation, a one-year program using a hybrid online format open to nursing and non-nursing students working and living at a distance, (c) the Doctor of Nursing Practice, to improve healthcare by facilitating a culture of best practice and providing the skills necessary to develop future advance practice nursing leaders, and (d) the PhD in Nursing & Healthcare Innovation. **Specialty concentrations** are (a) Advanced Practice Nursing: Neonates, (b) Advanced Practice Nursing: Adults, (c) Nursing Education, (d) Community Health Advanced Practice Nursing, (e) Psych/Mental Health Nurse Practitioner, (f) Pediatric Nurse Practitioner, (g) Family Nurse Practitioner, (h) Women's Health Nurse Practitioner, and (i) Child-Family Psychiatric Nurse Practitioner. Graduate certificate programs are for Child and Adolescent Mental Health Intervention Specialist, Clinical Research Management, Community and Public Health Practice, Evidence-Based Practice in Nursing, and Nurse Education in Academic and Practice Settings.

In fall 2005, the college enrolled its first cohort of students in its Doctorate of Nursing Science (DNS) program. In 2006, the college started its post-doctoral fellowship program with two research fellows. In 2007, the college transitioned from the DNS to a **PhD in Nursing & Healthcare Innovation**. The PhD is designed for persons who wish to pursue careers as leaders in nursing and healthcare innovation research and education, consistent with scientific and academic roles. It will help to address a national need for faculty and researchers who are increasingly in short supply. The PhD, intended to be the primary research degree offered by the college, is an on-site program with use of web-enhanced courses. The program has three practica: teaching, leadership, and research, with the goal of optimizing quality of life and health resources. PhD students benefit from a highly individualized program that emphasizes strong faculty mentorship.

The college also now offers the **Doctor of Nursing Practice**, which focuses on improving healthcare through facilitating a culture of best practice, and providing the additional skills necessary to develop the advance practice nursing leader for the future. Graduates of this program will be able to facilitate the application and integration of research into clinical practice using innovative approaches across multiple settings to improve healthcare, patient outcomes, and healthcare systems.

One unusual program in the CONHI is the American Indian Students United for Nursing (ASUN) Project, established in fall 1990 by a grant from the Indian Health Service to (1) recruit Native Americans into the various programs at ASU CONHI, (2) provide programs to help Native American students successfully complete their studies in nursing, (3) increase the number of Native American nurses, and (4) increase the number of nurses providing care to Native Americans. ASUN has accounted for 19% of all degrees awarded to Native American students at ASU since 1990. In addition to assisting students academically by mentoring (including through its Elder Nurse Volunteer Mentor program) and tutoring, it regularly offers social, cultural, and spiritual activities, including Talking Circles, potlucks, and events such as Blessing Day, held when students return to school.

In the spring of 2005, the college launched a 5-year strategic plan. As part of that plan, a solid research infrastructure, the **Office for Research & Scholarship**, was created; it houses an associate dean for research, an administrative assistant, a research grants coordinator, a grant's specialist, biostatisticians, a data management and analysis specialist, a business manager, and an editor.

Significant increases in financial support have contributed to and promoted growth in all aspects of the college's teaching, service, and research mission, including the following:

- Permanent allocations to the college have increased 96% from $8,371,200 in fiscal year 2005 to $16,399,800 in fiscal year 2008.
- Total university funding allocated to the college has more than doubled, with a 103% increase from $8,705,800 in fiscal year 2005 to $17,697,600 in fiscal year 2008.
- Research expenditures in fiscal year 2007 were $2,211,500.
- Capitol investments in college facilities have amounted to $22.6 million since fiscal year 2005.
- In September 2007, the college competitively obtained a $1 million grant from the Hartford Foundation along with $1 million in matching funds, including gifts from the Virginia G. Piper Foundation and Sun Health, to establish a Hartford Center of Geriatric Nursing Excellence.

Leadership

Bernadette Mazurek Melnyk, PhD, RN, CPNP/NPP, FAAN, FNAP, became Dean of the College of Nursing & Healthcare Innovation and Distinguished Foundation Professor in Nursing in January of 2005. She is a nationally/internationally recognized educator and evidence-based practice expert, pediatric and child-family psychiatric mental health nurse practitioner, and NIH-funded researcher.

Mary Killeen, PhD, RN, is Senior Associate Dean for Evaluation and Educational Excellence. Her primary areas of focus are academic program evaluation, the faculty life cycle, mentoring and faculty development. *Julie Fleury, RN, PhD, FAAN*, is Associate Dean for Research, Director of the PhD in Nursing & Healthcare Innovation (PhD) Program, Guy Hanner Professor of Nursing, and Director of the Office for Research and Scholarship. *Bonnie Gance-Cleveland, PhD, RNC, PNP, FAAN,* is the Director of the Center for Improving Health Outcomes in Children, Teens, and Families at the CONHI. *Colleen Keller, PhD, RN-C, FNP*, is Professor and Director of the John A. Hartford Center for Geriatric Nursing Excellence (HCGNE) at the college. *Carol M. Baldwin, PhD, RN, CHTP, CT, AHN-BC,* is an Associate Professor, Southwest Borderlands Scholar, and Director of the Office of International Health, Scientific and Educational Affairs. *Ellen Fineout-Overholt, PhD, RN, FAAN,* is the Director of the Center for the Advancement of Evidence-based Practice (CAEP). *David Hrabe, PhD, RN,* is Interim Associate Dean for Academic Affairs, responsible for the overall implementation and evaluation of the curriculum and standards for the baccalaureate nursing program, Master of Science in Healthcare Innovation, and Doctorate of Nursing Practice programs and five certificate programs on the Downtown campus. *Pauline Komnenich, PhD, RN* **,** is Professor and Associate Director of the PhD in Nursing & Healthcare Innovation and Project Director for the Nurse Educator Concentration and the Nurse Educator Certificate program; she has also been developing the Office for Evaluation and Educational Research. *Denise Link, DNS, RNP, FNAP*, is Clinical Associate Professor and Associate Dean for Clinical Practice and Community Partnerships. *Linda Mottle, MSM-HSA, RN, CCRP,* is Director CONHI Center for Healthcare Innovation & Clinical Trials and has over 30 years experience in the health and clinical research fields. *Nelma B. C. Shearer, PhD,* is an Associate Professor and Co-Director of the Hartford Center of Geriatric Nursing Excellence. She is an American Nurse Foundation Scholar and a John A. Hartford Foundation Institute of Geriatric Nursing Research Scholar.

College of Nursing & Healthcare Innovation Office for Research & Scholarship

Research in the College of Nursing & Healthcare Innovation is coordinated by the college's Office for Research & Scholarship (ORS), which promotes the success of faculty researchers and scholars in the conduct and dissemination of their research. The head of the center is the *Associate Dean for Research*. The staff includes *statisticians/ biostatisticians*, who provide assistance in statistical methods to the college faculty in their preparation of grant applications and conduct and advise on the analysis of faculty research data, and mentor nursing PhD students in statistical methods; a *grants coordinator*, who establishes priorities and recommend timelines and to coordinate grant editing, budgetary, and statistical support for each investigator, and assists investigators in interpreting funding agency regulations and requirements and coordinates the internal and external grant routing process with the ASU Office for Research and Sponsored Projects Administration (ORSPA); a *business manager*, who provides support for prospective and active Principal Investigators (PIs) with developing a budget that is in compliance with sponsor and ASU regulations and with performing post-award functions; a *grant writing resource specialist and editor*, who supports faculty preparing grant proposals and applications or publications, by editing, proofreading, researching, and, advising on an approach to application questions; an *administrative associate*, who coordinates and tracks ORS data, maintains the archives, and fulfills multiple administrative functions; and a *grants specialist*, who reports to the grant coordinator and assists with production and distribution of grant applications.

ORS Organizational Structure: Cores

Administration Core: *Bethany Johannessen: grants management, grants development and submissions, administration, and mock reviews.*

Conceptualization Core: *Bonnie Gance-Cleveland and Colleen Keller, with various senior research faculty: pre-proposal reviews and grant conceptualization meetings, mentorship of junior faculty, development of relationships and teams to further research efforts, and mock reviews.*

Data Management and Analysis Core: *Mary Mays and Edward Greenberg, with faculty support from Kimberly Arcoleo: the Data Lab (Edward Greenberg, Mary Mays, and Myunghan Choi), SPSS training, preliminary steps in analysis, statistics training, data lab resources, rotations of Research Assistants through the data lab.*

Dissemination Core: *Nancy Moore: editorial assistance, funding opportunities, writing lab, multimedia.*

Methods Core: *Michael Belyea, with other faculty support: research methods; experimental models; linking of questions, aims, and statistics.*

Research Mentorship and Collaboration Core: *Kathie Records, with faculty support from the ORS: faculty research mentorship and development, maintenance, and fostering of collaborations and research relationships with partner institutions and colleges across ASU and the Phoenix metro area.*

Faculty and Staff Supporting the ORS Cores

Kimberly Arcoleo, PhD, MPH, Assistant Professor, Data Management and Analysis Specialist and Associate Director of the CONHI Center for Healthcare Innovation & Clinical Trials, has her primary research interests in maternal and child health with a focus on nurse home visiting services for first-time mothers, childhood asthma, and unintentional injuries among children. **Michael Belyea, PhD**, has been a statistician and co-investigator on numerous federally funded research projects, participating in the formation of the project, preparation of the proposal, management of the science, analysis of the data, and writing of articles and presentations. He has taught courses on regression, the analysis of experimental designs, longitudinal methods and analysis, and structural equation modeling. **Myunghan Choi, PhD, MPH, RN,** was a principal analyst and an evaluator of nationally funded research projects at the Arizona Center on Aging, University of Arizona, and is currently working as a research specialist involving funded research projects by providing data management, statistical analysis, and research methods using SPSS and structural equation modeling for faculty and graduate students at ASU and CONHI. **Edward A. Greenberg, PhD**, retired in June 2008 as Associate Research Scientist, but will remain in a part-time position as the Director of the ORS Data Lab and member of the ORS Data Management and Analysis Core. **Bethany Johannessen, BA**, Grants Coordinator, as the liaison between investigators, sponsors, and ASU's ORSPA. She researches sponsor and ASU requirements to provide interpretation, advice, and guidance to researchers of grant funding policies, regulations, and procedures. **Mary Z. Mays, PhD,** Biostatistician and a member of the ORS Data Management and Analysis Core, has expertise in research design, experimental methods, bioethics, data management, statistical analysis, and scientific writing. **Nancy Moore, PhD**, Grants Manuscript Editor, supports faculty who are preparing grant proposals and publications, by editing, proofreading, researching, and, advising on approaches to application questions. **Kathie Records, PhD, RN,** Associate Professor, has

her primary research interests in maternal stress responses and their effects on health during pregnancy and the postpartum, as well as health effects for the newborn. Her main outcome measures include abuse and depression.

Two Core Centers within the College of Nursing & Healthcare Innovation

Research in the CONHI revolves around two core centers:

Center for Improving Healthy Outcomes in Aging, with John A. Hartford Center for Geriatric Nursing Excellence (HCGNE)

The Center for Improving Healthy Outcomes in Aging (ASU-CHOA) emphasizes multidisciplinary research collaboratives across a variety of clinical settings. The ASU-CHOA, partner institutions, and ASU colleges work to enhance scientific and cultural knowledge, clinical practice, leadership, education, and community services in healthy outcomes in aging in the greater Phoenix metropolitan area, across the State of Arizona, nationally, and internationally. A major focus *i*s to eliminate disparities in older person's health, improve access to health care services, and promote multidisciplinary collaborations among biomedical and social scientists, educators and clinicians.

In September 2007, the CONHI was awarded a $1 million, 5-year grant from the John A. Hartford Foundation of New York to fund a geriatric nursing center to recruit and retain geriatric nursing educators in the Southwest. The grant established the *Hartford Center of Geriatric Nursing Excellence (HCGNE)* at the college and the Southwest Consortium for Geriatric Nursing Education. The ASU CGNE also plans to place special emphasis on health disparities among Arizona's large Hispanic and Native American populations. Objectives include educating qualified doctoral and post- doctoral PhD/DNP students with a geriatric focus and commitment to academic careers over the 5-year project period; increasing the number of ethnically diverse doctorally prepared geriatric nursing faculty; and developing and implementing geriatric nursing focused doctoral coursework with two graduate interdisciplinary geriatric nursing courses which provide substantive theory-based content.

Seven colleges of nursing have joined ASU to form the Southwest Consortium for Geriatric Nursing Education as a unique contribution to the initiative. Consortium members include: the three colleges of nursing in the Arizona state system and colleges of nursing in Colorado, Nevada, New Mexico, and southwest Texas. The advisory board members are Barbara Resnick, PhD, CRNP, FAAN, Professor, Hartford Scholar Fellow, the University of Maryland; Richard Schulz , PhD, Professor of Psychiatry and Director, University Center for Social and Urban Research; Deborah Koniak-Griffin, PhD, Professor and Director, Center for Vulnerable Populations Research; University of California at Los Angeles; Lee Sechrest, PhD, Professor, Clinical Psychology, The University of Arizona; Nancy Watson, PhD, Associate Professor, University of Rochester; and Linda Phillips, PhD, FAAN, DGSA, Professor, UCLA School of Nursing.

Center for Improving Health Outcomes in Children, Teens, and Families

The Center for Improving Health Outcomes in Children, Teens, and Families focuses on multidisciplinary research to develop and test interventions that will lead to optimal health outcomes for high-risk children, teens, and families in a culturally diverse world. The center provides a structure for faculty to cluster research initiatives; obtain funding from National Institutes of Health, the Agency for Healthcare Research and Quality, and foundations; attract pre- and post-doctoral students and faculty; disseminate findings from their faculty research through publications and presentations; translate their research findings into practice to improve patient outcomes; become nationally and internationally visible in their area of expertise; consult on research development and implementation; foster skills necessary for effective action to strengthen families; develop and disseminate community resources that support the diverse functions of families; consult on policy decisions and the implications of policy decisions on family functioning; and consult on evidence-based practice issues in care of children and families.

Community Connections and Partnerships

The faculty and students of the CONHI have long been closely involved in the community. The following examples describe some of the venues in which this takes place.

- *Nurse-Managed Health Centers*
- The college operates five Nurse-Managed Health Centers (NMHCs) that provided direct health care in over 15,000 client encounters with children and adults (in clinic visits or through outreach programs) last year. The NMHCs serve as clinical sites for over 300 graduate and undergraduate nursing students and students from other ASU schools and colleges and as centers for applied research. The five centers are (1) Community Health Services, which for nearly 30 years has been offering primary care services. Approximately 50% of clients are uninsured or underinsured; many are the "working poor." (2) Breaking the Cycle Community Health Care (BTC) center, in operation since 1991; since 2001 it has been a Title X delegate agency receiving federal family planning funding through the AZ Family Planning Council and providing free or low-cost family planning and related health care. Located at the Grace Evangelical Lutheran Church, its partner, BTC is the only federally funded family planning clinic in the U.S. housed in a church. The majority (96%) of clients live below the poverty level; 67% speak only Spanish. (3) Escalante Health Partnerships, founded in 1991, an interdisciplinary practice site for multiple ASU programs that provides health care, health promotion, and social services to low-income residents, with a focus on senior activity and wellness. Approximately 90% of clients last year had no health insurance; 86% were primarily or exclusively Spanish speaking. (4) The Health Center in the North Tempe Multi-Generational Center provides services across the age continuum from preschool children to older adults. The majority of the school children are Hispanic (63%); most students (80%) are eligible for the free or reduced-price lunch program; 50% have no health insurance. (5) The ASU Health Center, in the CONHI building in Phoenix, serves the downtown ASU campus community and the public. The primary providers of care are board-certified nurse practitioners

in family health and psychiatric/mental health. Through interdepartmental and community collaborations, it provides wellness programming for students, employees, and the public.

- Among the dozens of partners of the NMHCs are the AZ Dept. of Health Services; Chicanos por la Causa, Arizona's largest Hispanic Community Development Corporation; the ASU Herberger College of the Arts; local school districts; the Sojourner Center, a domestic violence center; the Tempe Community Action Agency, a 501(c)(3) organization that serves as Tempe's primary safety net social service agency for low-income, homeless, and near-homeless families and the elderly; Tempe St. Luke's Hospital; and the City of Tempe, which provides in-kind occupancy support for Escalante and the North Tempe Community Centers.
- In May 2008, the college and the United Healthcare (UNH), a UnitedHealth Group company, announced a $700,000 grant from UNH for a health care van for a CONHI mobile health initiative bringing essential primary care health services to underserved communities throughout Arizona. The funding will also be used to start pediatric obesity and child-teen mental health programs for depression and anxiety disorders as part of a broader community health and wellness initiative by the college. The van and the other new initiatives will be staffed by ASU nurse practitioners, faculty, and nursing and related health profession students, under college direction.
- *Selected Other Venues for Community Contacts*
  - The CONHI collaborates with **Mayo Clinic** on a joint nursing program based at Mayo Clinic Hospital in northeast Phoenix/Scottsdale, started in August 2005. This program—a yearlong, 16-month program of upper-division nursing major courses taught during the summer, fall, and spring—was created to increase enrollment capacity for nursing students through the combined resources and clinical strengths of both institutions. The program's educational collaboration with Mayo Clinic Hospital supports a critical component of Mayo's mission: nurturing a scholarly environment of education, research, and mentoring.
  - **Scottsdale Healthcare** and the **Virginia Piper Cancer Center** (VPCC) collaborate with the college to develop and foster cancer research that is focused on symptom management and quality of life. This endowed research chair provides the professor the opportunity to develop and expand her program of research and assist in establishing nursing research as a priority at VPCC by expanding the presence and strength of nursing research.
  - The **Arizona Prevention Resource Center (PRC),** part of ASU's Psychology Department, was established in 1984 as an NIMH-funded center to develop, evaluate, and disseminate prevention programs for children and families in high-stress situations. Research at PRC focuses on children and families experiencing the stressors of parental divorce, poverty, bereavement, and parental job loss.
  - The CONHI also has many formal contractual agreements to advance research and evidence-based practice at such sites as Banner Health; Catholic Healthcare West (including establishment of the St. Joseph's Hospital and Medical Center and the ASU Clinical Professor); Phoenix Children's Hospital; the Univ. of Oklahoma College of Nursing; and Vanguard Health System.

College of Nursing & Healthcare Innovation Computing and Other Technical Resources

The ASU CONHI provides all faculty and support staff with up-to-date computing resources. Every faculty and staff office is equipped with a personal computer running the Windows XP

operating system. Also in the Nursing & Healthcare Innovation Building are a classroom with 22 computers, including one for the instructor, and a computing workroom containing computers, printers, and a scanner. Most conference rooms in the CONHI Building are equipped with a video projector and sound system that can be connected to a presenter's computer; several of the conference rooms also include Tandberg videoconferencing systems. All computers in the college are connected to the Internet, university computer systems, and CONHI file servers via a University-wide Ethernet network. A classroom containing 16 computers and an open lab containing 24 computers are located in the Mercado F Building on the downtown Phoenix campus. A classroom with 8 personal computers is located in the Community Services Building in Tempe. Available software includes the most current versions of Microsoft Office and SPSS for Windows and other communication and productivity tools to facilitate collaboration among faculty and access to Internet resources. All CONHI personnel have access to the university's electronic mail systems. The college employs full-time staff to develop and maintain its computing facilities and provide technical support to the faculty and staff.

The **Learning Resource Center** (LRC) is available for faculty, staff and students at the Downtown Phoenix, Polytechnic and West campuses. Each campus has a computer lab, a simulation lab, a clinical skills lab and a health assessment lab. Available resources include on-line media, NCLEX study materials, and other materials through the LRC web site accessed through ASU authentication; a computer lab utilizing pay for print is available on each campus and offers a variety of opportunities to assist students be successful in their nursing program; and Nursing software on the computers include such topics Heart Sounds and Clinical and Critical Care Skills. The simulation program provides a safe learning environment for students to practice/master nursing skills in a dynamic encounter through various settings. This lab setting gives an opportunity to practice clinical reasoning and supports students in developing reflective practice and increased self-confidence. Videotaping takes place for education, research, and guided reflection.

Office Facilities

Most of the 180 nursing faculty and staff that have moved to the downtown campus are located in a modernized four-story, 80,000 square foot building in the heart of downtown Phoenix. The downtown Learning Resource Center for student clinical practice simulations is a short walk away. The first floor of the main nursing building also houses the ASU Health Center, which provides healthcare for more than 5,000 downtown students, faculty and staff—the first time the college has been responsible for the clinical and administrative direction of campus healthcare. Construction of an adjacent second nursing building at the downtown campus began in April 2008 and is expected be completed for the 2008–2009 school year. At that time the LRC and remaining program faculty and staff in Tempe will move to the interconnected 230,000 square-foot, two-building complex.

The college has dedicated space and resources for research, including office space in the Nursing buildings for principal investigators and support staff. The college provides general office and computer supplies and telephone, fax, and copying services. In addition, the college maintains office space specifically for research in the ASU Community Services Building. The building is

used to house numerous ongoing research projects. No additional space, furniture, or telephones will be needed for this project. Other college resources include business and office management supervision and professional administrative staff with a wide range of expertise.

Sites for the Proposed Research

Paradise Valley Unified District

Paradise Valley Unified District has a wide range of socioeconomic status with schools that are predominantly either Caucasian or Latino. As a whole, district demographics include Caucasian 70.6%, Latino 21.5%, Black 3.4%, Asian 3.2%, and Native American 1.2%. Total enrollment at the five high schools is 10,616 students. Percent of students with proficient scores on the state academic test in 10th grade for the main-stream schools ranged from a low of 66, 76 and 60 on math, reading and writing and a high of 90, 92, and 79 on math, reading, and writing.

Phoenix Union High School District

Phoenix Union High School District is composed of 11 comprehensive schools, 3 alternative programs and 3 small schools with a combined student enrollment of 25,322. Phoenix Union High School District demographics include Latino 77%, Black 9.8%, White 8.2%, Native American 3.5%, and Asian 1.4%. Percent of students with proficient scores on the state academic test in 10th grade for the comprehensive schools ranged from a low of 41, 42 and 37 on math, reading and writing and a high of 53, 61, and 55 on math, reading, and writing. The district has 16.6% English language learners and primary language is 62% Spanish and 35.4% English. Attendance rates are 96.5% with a 4-year graduation rate of 72%. Annual dropout rate is 5.1%. Preliminary study #4 was conducted at Carl Hayden High School in the Phoenix Union High School District.

BUDGET JUSTIFICATION

Personnel

Bernadette Mazurek Melnyk, Principal Investigator, PhD, RN, CPNP/NPP, FAAN Dean and Distinguished Foundation Professor in Nursing Arizona State University College of Nursing & Healthcare Innovation (CONHI) 2.40 person months in all project years

Dr. Melnyk will serve as the Principal Investigator (PI) for this study. She is a seasoned pediatric nurse practitioner/child-family psychiatric nurse practitioner and a nationally recognized expert in child and adolescent mental health as well as randomized controlled trials (RCTs) and evidence-based practice. Dr. Melnyk founded the National Association of Pediatric Nurse Practitioners' (NAPNAP) KySS (Keep your children/yourself Safe and Secure) Campaign in 2001, a national initiative to improve the mental health of children and adolescents. In her role as director of this campaign, she has spearheaded major national interdisciplinary initiatives to improve child and adolescent mental health, such as: (a) conducting a 24-state survey to assess the mental

health knowledge, attitudes, and needs of teens, parents, and primary healthcare providers; (b) chairing a national mental health summit that convened over 70 leading experts in pediatrics/adolescence and mental health; (c) editing the recently published *KySS Guide to Child & Adolescent Mental Health Screening, Early Intervention and Health Promotion;* (d) implementing the KySS Institute for Primary Care and School Based Providers that assisted interdisciplinary healthcare providers in learning how to better screen and intervene early for children and teens with mental health problems, and (e) spearheading the HRSA funded KySS Fellowship Program, an on-line faculty guided child and adolescent mental health continuing education program for nurse practitioners and physicians. Dr. Melnyk has been PI for a series of 10 RCTs over the past 2 decades, including 2 NIH-funded multi-site experimental studies with oversight of large interdisciplinary research teams. She also recently served as a member of the American Academy of Pediatrics' Mental Health Task Force and is a member of the United States Preventive Services Task Force.

Dr. Melnyk will ensure the scientific quality of the proposed study and assume the lead responsibility for oversight of the planning and conduct of the project. Since her move to Arizona in January of 2005, high level University administration (i.e., the President and Provost) has been fully supportive of Dr. Melnyk continuing a rigorous program of research by providing her time and research resources, which have been instrumental in her ability to construct and provide oversight for an outstanding interdisciplinary research team that has conducted 3 pilot RCTs in the past two years testing the COPE/Healthy Lifestyles Program to improve the healthy lifestyle behaviors and mental health of high risk adolescents and college freshman (see letter of support from Dr. Elizabeth Capaldi, University Provost). Dr. Melnyk will share responsibility for the data analytic strategy and data interpretation with her Co-Investigators. She will have the primary responsibility for most reports, presentations, and manuscripts that are an outcome of the project. The NIH salary cap is being used for Dr. Melnyk.

Mary Z Mays, PhD, Co-Investigator, Associate Professor Arizona State University College of Nursing & Healthcare Innovation (CONHI) .63 person months academic year and .21 person months summer in Year 1, .90 person months academic year and .30 person months summer in Years 2–3, 1.35 person months academic year and .45 person months summer in Year 4

Mary Z. Mays, Ph.D., is a Research Associate Professor in the CONHI and a biostatistician in the Office for Research and Scholarship. She will be a Co-Investigator for the proposed study. Her extensive experience as a psychologist and seasoned biostatistician on federally-funded studies and research training grants ensure that she has in-depth knowledge and skills in conducting randomized clinical trials as well as performing complex statistical analyses. Dr. Mays has had a long-standing interest in health promotion interventions with adolescents, particularly those conducted in primary care and school-based settings. Her current research program includes community-based interventions addressing depression and substance abuse among American Indian and Hispanic adolescents. Dr. Mays will assist Dr. Melnyk with the planning, administration and management of the proposed study and take the lead in designing the data base for the study, data management and conducting the planned statistical analysis. She will be a co-author on all reports, presentations, and manuscripts that are an outcome of the project.

Flavio Marsiglia, PhD, Co-Investigator, Distinguished Foundation Professor of Cultural Diversity and Health/Center Director, Southwest Interdisciplinary Research Center, Arizona State University .90 person months academic year and .30 person months summer in all project years

Dr. Marsiglia is the Distinguished Foundation Professor of Cultural Diversity and Health at Arizona State University. He has demonstrated a sustained, high level of productivity, expertise, research accomplishments, and contributions to the field. He serves as Principal Investigator of the Southwest Interdisciplinary Center, supported by both NIH/NIDA and the Arizona Board of Regents. In addition, Dr. Marsiglia has been and is Principal Investigator and Co-PI in other NIH/NIDA and CDC funded studies. He is a recognized leader in the field of culturally-grounded prevention with expertise in minority populations and special needs populations, including his work as Professor within the School of Social Work. Dr. Marsiglia participates actively in training/mentoring future researchers. The National Hispanic Science Network recently awarded him the National Mentorship Award for his "outstanding mentorship in the area of Hispanic drug abuse research to Hispanic graduate students and new investigators." Demonstrating a consistent record of outstanding research productivity including program research funding and record of publication of scientific reports, including publication of influential research papers or seminal theoretical papers, Dr. Marsiglia's recognition as a leading scientist has been reinforced by his ability to develop and maintain a high quality environment for rigorous scientific investigations and the development of evidence-based practices throughout his areas of expertise. He has conducted numerous school-based intervention studies with Hispanic populations, including training teachers from 65 schools in Arizona to deliver his substance use prevention intervention, which will be invaluable to the proposed project. Dr. Marsiglia and Dr. Melnyk, along with their faculty researchers, have a close interdisciplinary working relationship already established from multiple collaborative research initiatives. Dr. Marsiglia will work with Dr. Melnyk and the research team to ensure that the interventions and interpretation of study findings are culturally sensitivity. He will assist in training members of the research team on cultural sensitivity and work with the team to address potential confounding variables in school-based settings. He will be a co-author on reports and publications that stem from the findings. Dr. Marsiglia also will assist in forming and spearheading the community advisory board that will be assembled to address any issues of potential distrust, particularly as part of recruitment and ethics among a historically disadvantaged population. He has a long history of working with community advisory boards in his research.

Judith O'Haver, PhD, CPNP, Investigator, Assistant Professor Arizona State University College of Nursing & Healthcare Innovation (CONHI) .90 person months academic year and .30 person months summer in all project years

Dr. O'Haver is a seasoned pediatric nurse practitioner who recently completed her PhD at the University of Arizona and assumed an Assistant Professor in the CONHI. For the past 2 years, she has been a part of Dr. Melnyk's team in conducting their latest pilot intervention study (preliminary study #4) testing the COPE program with Hispanic high school teens. In her role on preliminary study #4, she delivered the attention control intervention to the high-school teens. For the

proposed study, she will assist in training the teachers who will be delivering the attention-control interventions, monitor the integrity of the and also oversee data entry and verification.

Gabriel Q. Shaibi, PhD, PT, Co-Investigator, Assistant Professor Arizona State University College of Nursing & Healthcare Innovation (CONHI) .45 person months academic year and .15 person months summer in all project years

Dr. Shaibi is an Assistant Professor in the College of Nursing & Healthcare Innovation and Exercise Physiology at Arizona State University (ASU). He has extensive experience working with overweight minority youth in both research and clinical settings. He completed his doctoral degree in Biokinesiology and Physical Therapy at the University of Southern California with a focus on cardiorespiratory fitness, exercise, and metabolic disease risk in minority youth. Dr. Shaibi is a Certified Strength and Conditioning Specialist who has developed and assessed exercise programs for diverse populations. Additionally, he has previous research experience assessing cardiorespiratory fitness, strength, and insulin resistance in overweight youth and has published several manuscripts on the subject. Prior to graduate studies, **Dr. Shaibi was a public school teacher** in Los Angeles and has worked on several school-based research projects. Dr. Shaibi has been a member of Dr. Melnyk's research team for the past year and an integral part of a recent currently funded study that tested the efficacy of the COPE intervention delivered in the context of a 3 credit course to college freshman. He designed and monitored the physical activity component during each COPE session and will do the same for the proposed study.

Leigh Small, PhD, RN, CPNP, Co-Investigator, Assistant Professor Arizona State University College of Nursing & Healthcare Innovation (CONHI) .45 person months academic year and .15 person months summer in all project years

Dr. Small is currently an Assistant Professor in the tenure track at the Arizona State University College of Nursing & Healthcare Innovation. Dr. Small has been mentored throughout her doctoral program and early research career by Dr. Melnyk, and the two investigators are currently continuing their collaborative research projects together that are focused on theory-based interventions to improve health outcomes in high-risk children and adolescents, with a strong focus in the prevention and early treatment of overweight children and teens. Dr. Small is PI of a NIH-funded R15 grant award to pilot test the efficacy of a primary care intervention for preschoolers who are overweight or at-risk for overweight and their parents, with Dr. Melnyk as a co-investigator. Dr. Small has been a co-investigator on the preliminary studies for the proposed project, and co-author on several of Dr. Melnyk's publications. Dr. Small will specifically assist in monitoring the integrity of the COPE intervention sessions being delivered in the study and assist Dr. Melnyk in training the teachers for the study. She will be a co-author on reports and publications that are an outcome of the project.

Michael Belyea, PhD, Investigator/Statistician, Research Professor Arizona State University College of Nursing & Healthcare Innovation (CONHI) .27 person months academic year and .09 person months summer in Year 1, .45 person months academic year and .15 person months summer in Year 4

Dr. Belyea is currently a research professor at the Arizona State University College of Nursing & Healthcare Innovation. He is a nationally recognized statistician who has been a co-investigator on numerous federally-funded research projects where he has planned and conducted the statistical analyses. Dr. Belyea is an expert in structural equation modeling and hierarchical linear modeling who has taught courses on regression, the analysis of experimental designs, longitudinal methods and analysis, and structural equation modeling. Dr. Belyea has a doctorate in Sociology from North Carolina State University and a biostatistics post doc from the University of North Carolina, where he specialized in medical sociology and statistics. Before joining the College of Nursing, he taught doctoral statistical courses and consulted in the Research Support Center at School of Nursing at University of North Carolina. Dr. Belyea will assist Dr. Mays in planning and conducting the structural equation modeling and hierarchical linear modeling of study data in Years 1 and 4.

Other Personnel

Diana Jacobson, MS, RN, CPNP, Part-time Project Co-Coordinator and Investigator Arizona State University College of Nursing & Healthcare Innovation (CONHI) 6.00 person months in all project years

Diana Jacobson is a seasoned master's prepared pediatric nurse practitioner and doctoral candidate, with over 15 years of practice experience in pediatric primary care practice. She joined Dr. Melnyk's research team as project coordinator in January of 2005 and has been responsible for detailed oversight of the research assistants and detailed processes for 2 pilot randomized controlled trials that tested Dr. Melnyk's COPE/Healthy Lifestyles TEEN program with adolescents in two inner city high schools and also with a 3 credit course for college freshman tested the COPE program. She also was trained on administration of the COPE program and provided the intervention at one of the study sites. Ms. Jacobson will meet regularly with Dr. Melnyk and members of the research team, including the intervention research assistants and the data collectors. She will assume the following responsibilities: assist in the initial and ongoing training of study staff; organize the timing of the subject contact points over the course of the study; organize and track in coming data; create the majority of the databases and data code book for the study; maintain data files and records; and organize measures and materials prior to and following their completion. She also will assist with training the teachers on COPE and monitoring the integrity of the intervention as it is delivered in the high schools. Ms. Jacobson will assist in conducting the initial review of lab results from the adolescents' blood work as well as cleaning data and assisting with the conduct of preliminary analyses under the direction of Dr. Mays. Due to the size of this intervention trial, involvement of several participating classrooms at various high schools located in separate high school district, outstanding oversight and coordination is required. With the extent of data collection, it is necessary to have a full FTE of a project coordinator that will be shared between Ms. Jacobson and Ms. Kelly.

Stephanie Kelly, MS, RN, FNP, Part-time Project Co-Coordinator and Investigator Arizona State University College of Nursing & Healthcare Innovation (CONHI) 6.0 person months in all project years

Stephanie Kelly is a family nurse practitioner with a research interest in adolescent overweight/obesity and currently a doctoral student. She joined Dr. Melnyk's research team in January of 2005 during her PhD program and has been heavily involved in the pilot studies for this project. She recruited subjects and assisted in the delivery of the COPE intervention in preliminary study #4 and was involved in testing the efficacy of a lengthened version of the COPE program as a 3 credit course with college freshmen. She will assume co-coordinator responsibilities as outlined for this project with Ms Jacobson as well as provide assistance in the recruitment of subjects into the study and monitoring the integrity of the interventions. She also will assist in cleaning data and assisting with the conduct of preliminary analyses under the direction of Dr. Mays.

Due to the size of this intervention trial, involvement of several participating classrooms at various high schools located in separate high school districts, outstanding coordination and oversight of this project is required. With the extent of data collection, it is necessary to have a full FTE of a project coordinator that will be shared between Ms. Jacobson and Ms. Kelly.

TBA, Data Input Operator
7.20 person months in Years 1–3, 3.60 person months in Year 4 (6 months)

Because of the large amount of data being collected, we are requesting a data input operator who will be primarily responsible for assisting with entering the large amount of data obtained from the subjects in this study.

TBA, Research Nurses
Two (2) at 6.00 person months each in Years 1–3, 3.00 person months each in Year 4 (6 months)

These two individuals will be master's prepared nurse practitioners who will be responsible for recruiting subjects into the study and assisting with the monitoring of the integrity of the intervention at the high schools. We will recruit for at least one of these research nurses to be a Hispanic bi-lingual Spanish speaker who will be able to communicate well with the Spanish speaking parents in the study.

TBA, Data Collection Research Assistants
Two (2) at 4.50 person months each academic year and 1.50 person months each summer in Years 1–3, 2.25 person months each academic year and .75 person months each summer in Year 4 (6 months)

These individuals will be nurse practitioner, psychology, or social worker doctoral students who will be responsible for collecting the baseline, immediate post-intervention as well as 6 and 12 month follow-up assessments on all participating adolescents and parents. They also will assist with data entry and verification of the study data. Dr. Melnyk currently has 4 doctoral students working with her research team and there is an abundance of doctoral students in nursing, psychology, and social work throughout the University. The pay rate being requested is $25.00 per hour.

Supplies (Total = $52,453)

Desktop computers, desktop printers, large capacity printer & printer supplies ($11,900) - Three (3) desktop computers (Dell OptiPlex 755 Minitower Intel Core 2 Duo Processor E6750, 2.66 GHz, 4M, VT, 1333MHz FSB, Genuine Windows XP Professional, DVD player/CD burner and 19" UltraSharp 1908FP Flat Panel monitor) at a cost of $1,450 each, three (3) desktop printers (HP Deskjet 6940) at a cost of $100 each, and one (1) large capacity printer (HP Color LaserJet CP3505n) at a cost of $850 will be used by the PI and Research Assistants to enter data and print the 16 session color intervention materials for the 600 teen participants, and the four session color intervention materials for the 600 parent participants. Printer supplies in the amount of $1,600 are requested in Years 1–4.

Laptop computers ($3,500)—Two (2) laptop computers (Dell Latitude D630 notebook, Intel Core 2 Duo T7300, 2.00 GHz, 4M L2 Cache, 800 MHz Dual Core, Window XP Professional) at a cost of $1,750 each will be shared between the interventionists who will be delivering the power point presentations/interventions in every health class offered in the four high schools.

Filing cabinets ($1,750)—Two (2) locking 4-drawer lateral filing cabinets at a cost of $875 each are necessary to store and secure the 1,200 completed, confidential questionnaires from both the teens and the parents in the study office.

Office supplies ($16,108)—General office supplies will be drawn from the University's Facilities and Administrative costs. However, beyond this amount, we are requesting funding for the following designated items to be used specifically for this project:

Paper ($150 = one box = 5,000 sheets)—The paper will be utilized for printing the study materials, such as informed consents, instrument packets, and the 16 session teen intervention materials.
Hanging file folders ($720 = $30/box × 24 boxes = 800 file folders)—Each teen study participant will require coded hanging folders for completed study materials.
9 × 12 Envelopes ($150 = $50/box × 3 boxes = 800 envelopes)—Large mailing envelopes will be required to mail study questionnaires to the parent participants.
Labels ($1,200 = $80/box × 15 boxes = 60,000 labels)—Labels are required to attach a coded identification number to each page of the consent/assent forms and the questionnaires.
Teen notebooks & dividers ($12,800= $16/notebook × 800 teens)—Teen notebooks with dividers are required for the teens to store their intervention materials as they are given to them at each of the 16 intervention sessions.
Facilitator notebooks & dividers ($1,088 = $34/notebook × 32 facilitators)—Teachers will be given an entire notebook of intervention materials at the training sessions to be held at the beginning of the study.
Study Instruments ($2,955)—Research instruments will be purchased in the first year. The *Beck Youth Inventory* is only available for use through purchase at Harcourt Assessment and comes with 25 in each packet (800 teen participants/25 BYI per packet = 33 packets × $85 per packet = $2,805). The manual of the Beck Youth Inventory is required for data analysis ($150).

Physical Measurements Supplies ($1,680)— Physical measurements of weight and height will be measured on each of the 800 participants at the eight high schools. Stadiometers (8 × $130 each = $1040), and scales (8 × $80 each = $640) will be required to collect these measurements.

Pedometers ($14,560)— Pedometers (800 × ($17.95+$0.25 freight) each = $14,560) will be given to each teen participant in order to directly measure physical activity throughout the study.

Travel (Total = $28,042)

Travel for Research Team to the Study Sites for Recruitment, Monitoring Integrity of the Interventions, and Data Collection ($11,392)—Funds are needed for reimbursement for local travel costs to and from the University for: study recruitment (3 trips × 8 schools × 8 recruitments = $2,136); monitoring the integrity of the interventions (2 trips per week × 9 weeks × 8 schools = $6,408); baseline, post-intervention as well as 6 and 12 month follow-up data collection (8 trips to 8 schools × 4 data collection points = $2,848). The distance for one round-trip was estimated at 25 miles and ASU's current mileage reimbursement rate of $0.445 was used for the calculations.

Travel for Conferences ($16,650)— Funding for the PI and one Co-Investigator to attend a professional conference for the exchange of information and presentation of papers is requested for Years 1, 2, and 3 (2 trips × 3 years = $11,100). The PI and two Co-investigators will attend a professional conference in Year 4 (3 trips × 1 year = $5,550). Estimated cost of conference travel for each person is $1,850 which includes conference registration, transportation, hotel and meal expenses.

Other (Total = $108,964)

Incentives for the Teens and Parents ($92,000)—The study incentives, while minimal, will demonstrate the value of the teen's and parent's participation throughout the study.

Teen Incentives: All teens will receive incentive department store gift cards for the completion of each set of study questionnaires. Total incentives for each teen participant = $55 over the course of the project ($55 x 800 teen participants = $44,000).

Parent Incentives: All parents will receive incentive monies for the completion of their questionnaires at the beginning and end of the study. Total incentives for each parent = $60 over the course of the project. Parents will receive $30 for completing the first set of questionnaires, and $30 for an evaluation questionnaire at the end of the study on whether they think the program was helpful for their teens, and how. ($60 × 800 parent participants = $48,000).

Teacher Training Sessions ($9,700): Training for the teachers that will be delivering the intervention will take place during an intensive training session that will be offered four times during the summer prior to the beginning of the school year. We estimate that between the two school districts and 8 high schools participating in the study that 32 teachers will need to be trained in the intervention over the course of the 4 year study. Each teacher will be given a $250 incentive for their participation and training ($250 × 32 teachers = $8,000). The training day will begin early in the day and continue until late afternoon. Therefore, catered food will be ordered for breakfast and lunch during the four days of training at a cost of $425/day ($425 × 4 days = $1,700).

Postage ($7,264)—Funds for postage are requested and will be used to send out reminder postcards to the teen participants (4 postcards × 800 teen participants × $0.27 postage per postcard = $864) and to send the questionnaire packets to the parents (4 packets × 800 parents × $2.00 postage per packet = $6,400).

Improving Dementia Caregiver Sleep and the Effect on Heart Disease

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Grant # R01 AG039495-01

Funded By: NIH

1. ABSTRACT

Informal caregivers provide the majority of care for chronically ill adults, including persons with dementia. While these individuals provide a great benefit to the chronically ill relative, being a caregiver is associated with deleterious health consequences, including premature mortality and higher rates of coronary heart disease (CHD). Another common complaint among dementia caregivers is poor sleep, which has been connected to premature mortality and higher rates of CHD in noncaregiving adults. Currently no sleep therapies are empirically validated as effective for caregivers of persons with dementia (PWD), and since PWD often arise at night, improving caregiver sleep could be potentially hazardous as a sleeping caregiver cannot provide supervision during night awakenings. Our primary purpose is thus to determine whether a combined intervention is effective in improving sleep in caregivers of PWD who arise at night. The intervention consists of a night home monitoring system that provides reliable alerts to caregivers when PWD leave the bed and move through the house. While this system improved home safety for PWD, it did not affect caregiver sleep, so a more traditional sleep therapy will be added—cognitive-behavioral therapy for insomnia (CBTi). In the proposed study, experimental participants will receive the night home monitoring system + CBTi; control participants will receive only the night home monitoring system. Participants will remain in the study for 24 weeks, with 4 data collection points. We hypothesize experimental participants will have less time awake after going to bed, and improved sleep efficiency (percent time asleep while in bed). Sleep data will be collected for multiple nights using actigraphy and sleep diary. Our secondary research questions focus on the relationship between poor sleep and CHD. Both in adults and in dementia caregivers, there appears to be a

link between poor sleep and abnormal levels on coronary heart disease biomarkers, and likely an increase in CHD with poor sleep. We aim to further explore this relationship as well as determine whether levels of biomarkers improve with improved sleep from the intervention. We propose to draw blood samples at 3 data collection points and measure a set of biomarkers indicative of CHD. Our **primary expected outcome is an effective, easy-to-use treatment that can improve sleep** in dementia CGs with sleep problems. We will continue to **build the science on the relationship between sleep and CHD, and to understand mechanisms that may underlie deleterious changes in CG health**. Obtaining evidence of the relationship between sleep and CHD biomarkers, supported by preliminary data that improving sleep reverses changes in biomarker levels, would begin to **fill a critically important gap in research aiming to reduce the trend of PWD caregiver mortality and CHD as well as PWD placement in nursing homes**. A longer study would then be proposed to determine how to deliver effective sleep therapies to sustain normalization of CHD biomarkers, as well as to determine whether the actual disease process was affected.

The aim of the proposed project is to improve the sleep of informal caregivers of persons with dementia. We also will explore whether sleep affects the levels of biomarkers that indicate the presence of heart disease. This study will test the effectiveness of a combined intervention on caregiver sleep; we will use both a new night home monitoring system and cognitive-behavioral therapy for insomnia.

2. SPECIFIC AIMS

Informal caregivers (usually relatives) are an indispensable component of our healthcare system for chronically ill adults. This group provides millions of hours of care per year, valued at billions of dollars,[1] and constitutes the most crucial component for allowing chronically ill adults to live at home and avoid or delay formal long-term care placement. However, there is mounting evidence that caregiving exacts a toll on the health of the caregiver (CG). Of particular concern are consistent findings in two areas, sleep and coronary heart disease, and the potential link between the two. *Poor sleep* is a common complaint in most CGs of persons with dementia but acutely salient in the subgroup we focus on in this application (dementia CGs who must awaken at night to provide supervision and care).[2–6] CGs also have higher rates of *coronary heart disease* (CHD)[7] as well as abnormal levels of biomarkers of CHD.[8, 9] Recently, researchers have begun to establish a causal link between poor sleep and CHD in noncaregivers, so investigating this link in our subgroup and identifying interventions to improve their sleep is a critical step toward addressing escalating health risks in this vitally important group of caregivers. Thus, the **purposes of the proposed longitudinal study** are to test whether an intervention specially targeted for this CG subgroup improves sleep, and to explore relationships between sleep, sleep improvement and CHD biomarkers. **The expected long-term outcome of this program of research** is to mitigate negative health consequences of caregiving through use of empirically-tested interventions in areas such as sleep, depression, and vigilance.

Causes of poor sleep are multifactorial and include factors that both originally caused poor sleep (precipitating factors) and those that perpetuate poor sleeping patterns.[10] Important precipitating factors include being awakened to attend to the person with dementia's (PWD's) care needs and greater demands on CGs as they assume the PWD's familial roles. Perpetuating factors include depression, increased worry/anxiety, and a state of enhanced vigilance during the night.[10] Enhanced vigilance is a characteristic of CGs as they attempt to stay "on duty" through their sleep to avoid missing dangerous nighttime activity associated with PWD injuries and unattended exits from the home.[11–13]

There is growing evidence that both caregiving and poor sleep *independently* are associated with incident CHD as well as abnormal levels of a variety of CHD biomarkers.[9, 14–16] CHD is significantly increased in dementia CGs as demonstrated in both a population study,[7] and in a longitudinal study.[8] Separate from sleep pathologies (e.g., sleep apnea), poor sleep, particularly daily insomnia, is also associated with higher rates of cardiovascular disease in adults followed over approximately 16 years with doubled CHD rates in subjects with frequent insomnia.[17] The pathophysiologic mechanisms responsible for this relationship appear to be enhanced inflammation and abnormal clotting secondary to increased secretion of proinflammatory cytokines.[15] In this study we propose to test an intervention to improve CG sleep and to determine whether improving sleep alters proinflammatory cytokines and biomarkers of CHD.

While there have been a number of studies conducted to describe CG sleep, a paucity exists of studies testing interventions to improve sleep. When considering interventions for this CG subgroup, however, two critical issues must be simultaneously addressed: the need for a safe night environment for the PWD and the chronic nature of CG sleep problems. Interventions solely targeting improved CG sleep may place PWD at higher risk for unsupervised activity and its hazards.[18–20] Our group developed a night home monitoring system (NHMS) that significantly improves nighttime safety for the PWD by reliably alerting CGs when the PWD arises and moves through the home.[21] While there was high satisfaction with the device, and all CGs used it continuously, use of the system did not improve CG sleep.[11] In this study we ropose combining the NHMS and CBTi to improve CG sleep while ensuring a safe environment for the PWD. CBTi is an effective therapy for chronic sleep problems[22] with preliminary evidence of its effectiveness in dementia CGs.[23]

Aim 1: Improve sleep in CGs of PWD with nighttime activity.

1. Experimental CGs (NHMS + CBTi intervention) will have less total wake time than CGs in the comparison group (NHMS-alone).
2. Experimental CGs will have improved sleep efficiency compared to CGs in the comparison group.
3. For the PWD, there will be no significant difference in the incidence of nighttime events (injuries or unattended home exits) between the experimental group and those in the comparison group.

Aim 2: To improve understanding of the relationship between sleep and CHD biomarkers in caregivers of PWD. Secondary Research Questions:

1. Do poor sleep, high levels of depressive symptoms and high levels of vigilance, alone or together, predict abnormal levels of CHD biomarkers (tissue plasminogen activator, D-dimer, C-reactive protein, inter-cellular adhesion molecule-1 and interleukin-6) and 3 CG factors (sleep, depressive symptoms, vigilance)?
2. Is there an improvement in CHD biomarkers with a combined intervention (NMHS + CBTi) designed to improve sleep, reduce depressive symptoms and reduce vigilance?
3. Is there an improvement in CHD biomarkers with a single intervention to reduce vigilance (NHMS)?

3. RESEARCH STRATEGY

3.A. Significance

Currently, there are approximately 5.3 million Americans with dementia and 9.9 million unpaid CGs, usually female relatives,[24] who provide 8.5 million hours of care per year, valued at $94 billion. The CG role can last for a number of years; the average time from symptom onset to nursing home placement in PWD is 58 months.[25] Starting with a seminal study by Schulz et al in 1995, accumulating evidence reveals that CGs suffer from higher levels of morbidity and mortality compared to their peers, particularly when caregiving is perceived as stressful.[26, 27] In a study examining which specific disease states are increased, Lee et al studied a population-based sample of women and found higher rates of CHD at the 4-year follow-up point for women providing greater than 9 hours of care per week.[7] The very people who are the backbone of care for those with chronic illness are, themselves, becoming sufferers of chronic illness. It is critical for researchers to investigate how to interrupt the cascade physiological changes associated with the caregiving role and worsening of CG health.

CGs consistently rate their sleep quality as significantly poorer than noncaregivers.[2–4, 28] In studies of objectively measured sleep, CGs have less than recommended sleep amounts with shortened total sleep time, and prolonged wake time at sleep onset and during the night.[6, 29] While these problems improve when the CG role is temporarily suspended,[30] preliminary evidence suggests that CBTi can improve sleep even for those actively providing care.[23] Inadequate sleep has been associated with increased mortality and risk of CHD in noncaregivers. Healthy older adults with prolonged sleep onset times or poor sleep efficiencies (% of time in bed spent asleep) had 1.93–2.14 greater risk of death over mean follow-up period of 12 years.[31] Poor sleep, particularly daily insomnia, is associated with higher rates of cardiovascular disease in adults followed over time[17] and CHD-specific mortality.[32]

From a physiologic standpoint, the connection between poor sleep and CHD seems to be through the inflammatory pathway (Figure 1). Experimental sleep restriction increases release of proinflammatory cytokines from lymphocytes such as interleukin-6 (IL-6).[15] These cytokines affect both inflammation in the arterial wall, promoting atherosclerosis, and accelerate the

clotting cascade with increased clots formed in the coronary artery vessel lumen where the atherosclerosis resides. These changes are likely mediated by the hypothalamic-pituitary-adrenal axis in a manner similar to activation by chronic stress.[33] In rats, poor sleep causes changes in neuroendocrine pathways typical of those seen with chronic stress, such as alterations in the regulation of the hypothalamic-pituitary-adrenal axis. [34]

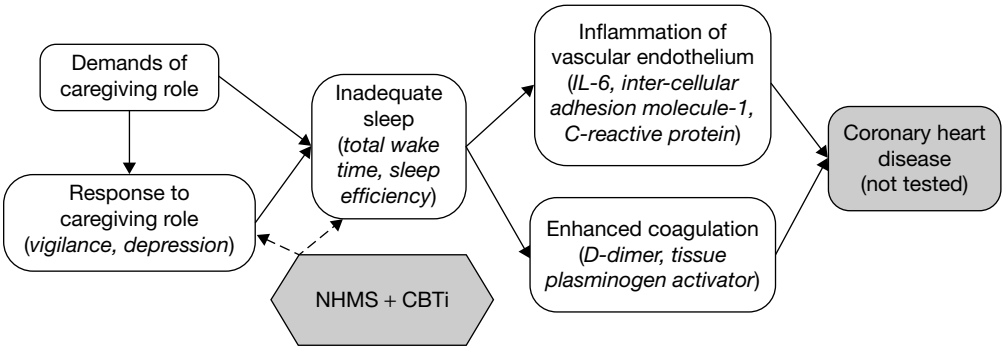


Figure 1. Theoretical framework.

If the hypotheses are supported, the **proposed research will advance the science by** providing an affordable (insurance approved), available, well-accepted therapy to improve dementia CG sleep. If primary hypotheses are not supported**, study results will provide critically important information** for building a theoretical framework to understand the physiologic impact of caregiving, a framework essential for moving forward in preventing deleterious health consequences in the millions of Americans who take on the caregiving role.

3.B. Innovation

The innovation of this study resides in three areas: the specific population, the intervention and the theoretical work of understanding the mechanisms of poorer CG health.

Zarit et al recently identified key problems that have compromised CG intervention research, including treating all CGs as a homogenous group and assuming one treatment is effective for all.[35] In this study, we are matching a specific caregiving problem with an intervention targeted to a specific subgroup of CGs with that problem. Furthermore, we are studying a problem with demonstrated clinical significance for both the CG and PWD—poor sleep. Poor sleep has negative impacts for CGs such as depression[36] and daytime fatigue,[3, 37] and for PWDs in earlier institutional placement.[38, 39]

When considering interventions for sleep complaints and sleep fragmentation of CGs of PWD who arise at night, there are basically two approaches: reduce the nighttime awakenings of the PWD or improve the sleep of the CG. Effectively reducing nighttime awakenings of the PWD has proven quite difficult due to the complex nature of sleep problems in dementia,

presence of comorbid conditions causing night awakenings, the practicality of instituting complex behavioral interventions in PWD living in the community, and the modest effects of current interventions.[40, 41] Additionally, CGs must still monitor the nighttime environment even with reduced awakenings in the PWD. Thus, we have chosen to focus on a novel intervention that combines reliable alerts to the CG whenever supervision is required, with therapy demonstrated to improve chronic sleep problems. From our previous work, we know that not all wake time during the night is associated with the need for supervision. For example, CGs took, on average, 24 minutes to fall asleep with high levels of variability in this number, meaning some nights were better andsome were much worse. It would be quite unlikely that CGs would retire when the PWD was not in a safe situation, so this is prime target for improving sleep. Additionally, this group of CGs reported high levels of vigilance through the night that can impact quality of sleep. This vigilance was reduced with use of the NHMS.[13] Finally, a combined intervention is critical because the safety of PWD at night is affected by the CG being able to respond to awakenings. Without these reliable alerts, CG sleep interventions may either not result in improved sleep (as CGs are worried about missing night awakenings), or may cause an increase in nighttime events (injuries, unattended exits) during unsupervised PWD awakenings. Thus, **a key to our innovation is in using a combined intervention employing newly developed technology designed for this group, and a common effective therapy for improving sleep**.

Third, this study aims to contribute to the body of knowledge on understanding how and why there are consequences to CG health. We propose that the sleep changes induced by the CG role, both from the demands of the caregiving role as well as the response to that role, act similar to chronic stressors activating the pro-inflammatory cytokine system. These cytokines then act on vascular endothelium, enhancing the atherosclerotic processes as well as altering the clotting system components enhancing clot formation. This combination of accelerated atherosclerosis and enhanced clotting are crucial to CHD pathology. We aim to confirm these relationships by documenting using pre-intervention data collection, and support a causal relationship by determining if they change when sleep. Depressive symptoms and/or vigilance are improved.

3.C. Approach

3.C.1. Justification and Feasibility

3.C.1.a. Review of Relevant Literature

CG Sleep: It has been difficult to fully understand CG sleep problems because no single explanation for reports of poor sleep has emerged. The best explanation to date is presented in a comprehensive review of CG sleep by McCurry and her colleagues.[10] They propose that CG sleep problems may begin with a specific source (nighttime needs of the PWD), but over time have multifactorial sources, eventually taking on characteristics associated with chronic insomnia. McCurry et al explain the complex nature using Spielman's "3P model"—predisposing, precipitating and perpetuating factors. According to this model, individuals at greatest risk for sleep problems are those with factors that predispose them to have sleep problems, particularly older age and female gender. Both factors are common characteristics

of dementia CGs.[24] When precipitating factors occur in this predisposed group, sleep problems become more prominent. The primary precipitating factor in this study's target population is nighttime awakenings in the PWD. In fact, the type of sleep disturbance most disruptive to CG sleep is the need to provide help with bathroom use and manage wandering.[42] As expected, the more times these awakenings occurred, the poorer the reported sleep quality of the CG.

When perpetuating factors are added to this situation, the sleep problem can become chronic, requiring different types of interventions to reverse. Examples of perpetuating factors include depression and mood disturbances, constant vigilance/worry, and high levels of perceived CG burden.

Depressive symptoms are closely aligned with sleep problems in CGs and older adults.[28, 29, 36, 43] For instance, depressive symptoms are worse with high numbers of night awakenings in the PWD.[42] In our study with CGs of PWD who arise at night, there were very high levels of depressive symptomatology.[11] Examining the longitudinal data (9 data points up to 1 year total) of the 26 CGs in the control group, only 3 CGs never had a score that exceeded the depression scale cutoff score of 16, while 11 (42%) CGs always had scores that exceeded the cutoff score. The 3 CGs who never scored in the depressed range only participated in the study for 2, 3, and 5 months (unpublished data). McCurry et al found that new onset of sleep problems in CGs followed for 24 months were predicted by only 2 factors: current depression and previous higher levels of objective burden.[44] Because of the prevalence of depressive symptoms and the close link between this and sleep problems, we will add a component to reduce depressive symptoms in our CBTi intervention.

CGs appropriately reported they worry considerably about the potential for negative incidents occurring in the PWD when they are awake alone at night. Potential incidents include falls/injuries [18, 19] and unattended home exits.[45] Higher levels of CG worry about unsupervised nighttime activity were associated with poorer quality and quantity of sleep due to difficulty falling asleep initially and more nighttime awakenings to assess the safety of the PWD. Additionally, this worry led to other psychological reactions such as uncertainty, fear, and rumination of negative thought, all which can affect sleep.

Although there is strong evidence that CGs consistently complain of poor sleep, and there is a sound model elucidating the causes, when CG sleep is measured objectively and subjectively, a clear pattern of deficit does not emerge. In some studies in which CG sleep was compared to age-matched controls, no difference was found in either objectively (eg, actigraphy) or subjectively (eg, sleep diary) measured sleep.[28, 46] In other studies, only some sleep variables were altered and findings were not consistent between objective and subjective sleep times. We found that CGs had significantly shorter total sleep and greater time to fall asleep than age-matched controls in the objective data.[6] However, in subjective sleep data, there were no significant group differences after controlling for depressive symptoms. Using a questionnaire to measure sleep problems, Kochar et al also found that no significant group differences in sleep between CGs and non-caregivers when clinical depression was entered as a control variable.[36]

It is clear, however, that in addition to the common and consistent complaint of poor/inadequate sleep, CGs have sleep values less than optimal, with total sleep times less than 7 hours, wake times exceeding a total of 60 minutes/night, and sleep efficiencies much less than 85%.[6, 29, 30] We recently completed a study of the specific group of CGs who provided care to PWD with nighttime activity and collected objective and subjective sleep data over 12 months. On average, it took CGs 24 minutes to fall asleep, and they were awake for 47 more minutes after falling asleep with high levels of night-to-night variability. Total sleep time averaged less than 6.5 hours. It is possible that frequent sleep complaints arise from the fact that these numbers represent less than optimal sleep and are inadequate to meet the sleep demands of CGs who, along with new caregiving duties, typically must assume many additional familial roles. This is supported by the findings of a study of CG sleep before, during and after a 2-week respite period for the PWD.[30] CG sleep significantly improved during respite and worsened with return of the PWD. Additionally, one measure of inadequate sleep is daytime fatigue,[47] and CGs consistently report high levels of fatigue.[3, 48] A recent comprehensive review of CG sleep supports the need to find evidencebased interventions to improve sleep in this vulnerable group.[44]

In summary, CG sleep problems are multifactorial with a combination of predisposing, precipitating and perpetuating factors. Additional problems common in this subgroup of CGs are depressive symptoms and worry/vigilance, which also contribute to sleep problems. As with persons with chronic insomnia, a therapy that addresses this multiplicity of factors is required for resolution of the problem. Unique to this population of CGs, an additional measure of providing a secure environment is needed to reduce the worry/vigilance needed to provide ongoing surveillance during the night. We hypothesize that this targeted solution will improve caregiver sleep and improved sleep will confer benefits in other physiologic systems such as the reducing inflammation and abnormal clotting.

Night Home Monitoring System: The NHMS provides reliable alerts to CGs regarding nighttime activity of the PWD and was developed by the PI using NIH awards.[49] A bed occupancy sensor controls whether the system is inactive (PWD in the bed) or active (PWD leaves the bed). Once the PWD leaves the bed, an alert (on-screen text, voice and alert sound) occurs at an information panel placed at the CG's bedside. Additional alerts (motion detectors and door opening sensors similar to a home security system) occur as the PWD moves through the home. These are either notification alerts (time limited) or emergency alerts (require CG response). Emergency alerts occur, for instance, when an outside door is opened, and CG must manually reset the system to stop the alert. When the PWD returns to bed, a message is provided. The prototype system was more complex to use than the current version, but we had no difficulty teaching CGs how to reliably use it in the 2–3 week period.[49] There was very high satisfaction with NHMS functions. The system is currently being produced by SR, Inc. who will supply the units for this project.

Cognitive-Behavioral Therapy—Insomnia: CBTi is a prominent, effective therapy for improving sleep and includes 4 components: relaxation, stimulus control, sleep restriction and sleep hygiene.[50–52] The basis of the therapy is directed toward components of insomnia, which include predisposing, precipitating, perpetuating and conditioned arousal factors.[53] For dementia CGs,

McCurry et al describe how the caregiving role impacts these factors[10]: predisposing factors (older age and female gender typical of CGs); precipitating factors (nighttime activity of the PWD); and perpetuating factors (ineffectual mechanisms to cope with nighttime arousals including daytime naps, increased caffeine intake or spending longer in bed). There is evidence of the fourth factor, conditioned arousal, in the qualitative study we conducted on sleep.[13] CGs reported their fear and anxiety about missing a night awakening in the PWD caused excessive vigilance and loss of sleep during the night. In a study on vigilance in dementia CGs, 59% of them reported feeling on duty 24 hours a day. Thus, a number of factors in the CG role as well as characteristics of the typical CG make CBTi an excellent therapy for this group. Additionally, it does not involve a drug, which may produce difficulty awakening or changes in balance that would put the CG at risk, or potentially lead to unattended PWD night awakenings. In general, CBT insomnia programs have been among the few types of programs that are effective with dementia CGs.[54, 55]

McCurry and colleagues successfully used CBTi to improve sleep in dementia CGs.[23] In a pilot study of 36 randomized CGs, after 4 CBT sessions, CGs showed significant sustained improvements in sleep quality, and sleep efficiency increased from a baseline score of 73% to postintervention score of 82%. There were positive improvements in wake and sleep times as well, although these did not reach significance. Recently, McCrae and colleagues utilized a modified version of McCurry and colleagues' manualized behavioral treatment to treat 4 elderly female caregivers representing diverse caregiving situations (eg, non-coresidential, non-dementia patient populations).[56] Results revealed equivalently high compliance rates and improved sleep for all 4 caregivers. Improvements in depression and anxiety were also found. CBTi has been used successfully in those providing care to persons with cancer [57] and in noncaregivers with similar age and demographic characteristics to CGs.[58]

Associations Between Caregiving, Sleep Changes and Coronary Artery Disease: Since the initial work linking caregiving with CHD, subsequent studies have begun to demonstrate that physiologic abnormalities that cause CHD (arterial inflammation, atherosclerosis, and abnormal clotting) are present in CGs of PWD. For instance, elevated levels of tissue plasminogen activator, indicating abnormal clotting processes, have been consistently associated with higher levels of CHD in middle-aged and older adults.[59] Dementia CGs were also found to have higher levels of tissue plasminogen activator as compared to noncaregivers, even when the analyses controlled for covariates that typically elevate tissue plasminogen activator.[9] D-dimer is another indicator of abnormal clotting, and this was also found to be higher in dementia CGs than in controls.[16] Some evidence that these changes are related uniquely to the CG role can be found in a study in which CGs were followed after the care recipient was placed in a nursing home. Six months after PWD placement, CG burden declined, followed by a significant lowering of D-dimer levels.[60]

While there is strong evidence of increased CHD in CGs, it is also clear that not all CGs are equally affected.[61] Poor sleep levels have been found to predict high levels of CHD biomarkers. D-dimer levels were higher in CGs who had higher amounts of wake time during the night,[16] and C-reactive protein levels were also higher in CGs with complaints of poor sleep.[14] When sleep is restricted in healthy individuals, a similar pattern emerges with

significant changes in these biomarkers favoring the development of CHD.[15] When sleep is restricted to 4 hours/night for just 5 nights, the pro-inflammatory biomarkers of IL-6 and -17 were increased. These remained elevated after 2 nights of recovery sleep and were associated with elevations in C-reactive protein and resting heart rate, both of which are associated with CHD.

Other aspects common in CGs may also be important. In a prospective study of dementia CGs, significant predictors of getting a new diagnosis of cardiovascular disease were: providing greater than 9 hours of care per day, clinical depression and care of PWD with greater behavioral symptoms.[8] In animal models, *vigilance* is a known activator of the stress response,[62] a precursor to CHD. In these CGs a state of perceived vigilance can be active as much as 24 hours/day.[12, 63]

A secondary purpose of this study is to continue to build the science on the linkages between caregiving and CHD by studying the role that sleep has on the biomarkers of CHD. We will also determine whether higher levels of vigilance, known to activate the stress response, play a role in this relationship.

3.C.1.b. Preliminary Studies

Night Home Monitoring System (NHMS): Phase I and Phase II Small Business Technology Transfer (STTR) Awards and 2 supplemental awards were used to develop the NHMS to assist CGs in managing PWD nighttime activity (41/42/43NR004952). The system reliably alerts the CG when the care recipient leaves the bed and moves through the home at night. The conclusions of the Phase I and II studies were:

- CGs easily learned and used the NHMS; the NHMS had excellent reliability.[49]
- Safety of the environment was significantly improved for the PWD.[11]
- Qualitatively, CGs had improved well-being (e.g., less worry, improved sleep and more energy).[13]
- Quantitatively, no group differences were found for total sleep time or waketime after sleep onset variables, or depressive symptom scores.[11]

Critical lessons learned from these and our other studies that guided our decisions for proposed project:

1. Significant injuries occur during the night in PWD with nighttime activity (annualized injury rate of 1 per person year, and 1 unattended exit per person.[64] Thus, before one attempts to improve CG sleep, it is critical to provide a mechanism to improve the ability for a sound-sleeping CG to be awakened when supervision is needed. This is our rationale for using the NHMS with CBTi to improve CG sleep.
2. Poor sleep in this subgroup of CGs is a significant issue: our longitudinal data revealed prolonged sleep onset latency, excessive waketime during the night, low sleep efficiencies and inadequate total sleep.[11]

3. Given the multifactorial nature of CG sleep problems, it is also not surprising that targeting only a single factor was not sufficient to produce significant sleep improvements. Hence, while providing CGs with the NHMS may be a necessary part of any treatment to improve their nighttime sleep, our study suggested it is not likely to be sufficient as a standalone treatment but probably best viewed as an important component of a multi-component treatment.[11]
4. Recruitment of CGs of PWD is a challenge that has been experienced by most groups working with this population. We have successfully recruited adequate numbers with reasonable diversity. We will build on our experience in these studies to efficiently recruit our needed subject numbers.
5. In these previous studies we were able to collect complex sleep measures on multiple nights over multiple time points. CGs were able to correctly fill out daily forms and wear an actiwatch (worn like a wristwatch to measure sleep) for multiple nights. We successfully retained our CG sample over a 12-month study. Seventy-five percent of subjects made it through the 6-month data point, a similar time frame to the proposed study. No loss was due to CGs opting to leave the study; all loss was due to the PWD leaving the home setting due to hospitalization, nursing home placement or death. We will oversample for anticipated attrition due to the unstable course of PWD.

Sleep Patterns in Older Adults: Dr. McCrae has conducted two large normative studies examining sleep patterns and sleep-related variables (health, anxiety, depression) in older adults.[65, 66] In the most recent of these studies, she and Dr. Rowe collaborated to collect 2 weeks of subjective (sleep diaries) and objective (actigraphy) sleep data from 103 community-dwelling older adults to identify factors associated with sleep complaints. We also established normative data using the same subjective and objective sleep measures we will use in this study.

Cognitive-Behavioral Therapy—Insomnia: Dr. McCrae and colleagues conducted an intervention case series in which she took a novel approach to CG insomnia by focusing on four elderly (65+ years) female CGs representing diverse caregiving situations and a continuum of caregiving stages: active, exit, recent post-exit (8 months), and enduring post-exit (6 years).[56] Each CG received manualized behavioral treatment for insomnia. Although poorer compliance was expected in the active and exit stage CGs, results revealed equivalently high compliance rates and improved sleep for all four CGs. Interestingly, improvements in depression and anxiety were also found. In another intervention study, McCrae and colleagues conducted an RCT comparing two brief behavioral interventions for insomnia in rural older adults.[67] Twenty older insomniacs (65 years+) were randomly assigned to sleep hygiene education (n=9) or multi-component behavioral treatment (n=11). Rural care providers individually administered treatment (2 in-person sessions/2 telephone follow-ups). Training involved 2-day workshop. Overall, multicomponent therapy produced greater improvement in time to fall asleep (~25 minutes vs. ~0 minutes) and sleep efficiency (~13% vs. ~6%) than sleep hygiene education, and treatment gains were well-maintained at 3 and 6-month follow-ups. Regarding clinical significance, 10 multi-component behavioral treatment participants no longer met criteria for insomnia (fall asleep 30 minutes or less and wake after sleep onset <31 minutes, or sleep efficiency >85%) at posttreatment versus only 3 sleep hygiene education participants (Fisher's exact; $p<.05$). Observed levels of improvement are consistent with levels commonly reported in

the literature.[68] This study uses "in home" ambulatory polysomnography (PSG) screening and illustrates the PI's experience with this type of assessment as well as with CBTi.

Physiologic Study Component: Maureen Groer is the director of the University of South Florida College of Nursing Biobehavioral Lab and active in the Psychoneuroimmunology Research Center. The large wet lab (over 2000 square feet) is fully equipped to allow faculty and students to perform immunological, endocrine, cell biology and genetics assays. It houses Groer's current R01, which is a study of immunity in postpartum women. Several faculty actively work in the lab on their projects, and there are 2 full-time lab technicians available to assist. Groer has many years of experience in biobehavioral research, and has a particular focus on women's health and the immune system. Another area of research is in the psychoneuroimmunology of trauma in women. She works with faculty in nursing, medicine, psychology, public health, and family mental health, and serves as a co-investigator/consultant in many current pending and funded proposals because of her expertise in immunological measurements and assays. She egularly performs all of the planned assays in the current proposal. For example, she participated in a study that demonstrated that cardiac rehabilitation led to improvements in IL-6 and C-reactive protein.[69]

3.C.2. Research Methods

3.C.2.a. Design

This study will use a true experimental design with repeated measures as diagrammed in Table 1.

Table 1. Plan for Intervention and Data Collection for Each Subject

Timeline	Study Step	Data Collected
Week 0	Potential Subject Telephone Prescreen	Screen for Inclusion/Exclusion Criteria (see 3.C.2.c.)
Week 1–2	Home Visit with Informed Consent 1 for Screen/Baseline Data Collection #1	Sleep Apnea Screening Test + Study Data*
Week 3	Home Visit with Informed Consent 2 for Intervention	
Week 3–5	NHMS installed all homes + system reliability test	NHMS reliability data
Week 6–7	Data Collection #2	Study Data*
Week 8	Randomized to CBTi Treatment or Sleep Hygiene Education Attentional Control	Treatment logs
Week 8–12	Receive Sleep/Control Intervention	
Week 13–14	Data Collection #3	Study Data*
Week 23–24	Data Collection #4	Study Data*
Week 25	Study Debriefing (Decision to keep NHMS)	

Key: * Study Data includes: 14 consecutive days of objective and subjective sleep data, 1 blood collection (at conclusion of sleep data), and 2 episodes of questionnaire data (on first and last day of sleep data collection)

Rationale for the Design: The primary outcome for this study is to determine if CBTi improves CG sleep in a setting where there is technology to support surveillance for night awakenings in the PWD (the NHMS). Even though NHMS had no effect on CG sleep in a previous study, we will control for any possible unmeasured effect by giving this system to all participants. All participants will have an equal study experience until week 8 at which point they will be randomized to either CBTi or attentional control. An attentional control is essential to account for the effect of researcher visits when the CBTi treatment is delivered. Typically, clinical trials testing the effects of CBT examine both short and longer term outcomes with 8–12 weeks post-therapy being a common end point in the initial studies of a revised therapy or new patient population.[70–72] If we have significant findings in this study, future studies can explore how long these effects are maintained and whether additional booster sessions are needed.

This design allows our secondary research questions to be answered in several ways. Using the baseline data, we can examine relationships between CHD biomarkers and sleep measured in the naturalistic setting over a 14-day period using both objective and subjective measures. Additionally, we can determine whether CHD biomarkers improve after the installation of the NHMS (and possible reduction in vigilance) and after CBTi (and possible improvement in sleep).

Data collectors at points 3 and 4 (post-sleep intervention) will be blinded regarding whether participants are receiving CBTi or the attentional control intervention. Logs will be collected by the staff delivering the sleep intervention, and data will be maintained separately until conclusion of all data collection. Randomization procedure is described below in *Procedures* but will be done by individuals outside the research team.

While participant burden is significant in terms of weekly visits to deliver the 2 treatments, we previously found CGs very receptive to both the NHMS and CBTi protocols. We will schedule visits at the CGs' convenience in their homes as well as streamline all data collection procedures. All staff will have experience in working with PWD and will be able to monitor PWD activity while CGs complete questionnaires.

3.C.2.b. Interventions

NHMS: As described in *3.c.1.b.*, NHMS is a home monitoring system that provides CGs with reliable alerts and information regarding whereabouts of the PWD during the night. The system will be installed in all homes after baseline data are collected and the second informed consent for the treatment study has been signed. The system operation is fully described in Appendix A.

Treatment Fidelity: In the NHMS, there is a log that stores the last 100 events. At each data collection point, this log will be reviewed to determine whether the system was activated each night in the previous 5–7 days. This data will be recorded. All participants will be encouraged to use the system nightly at each data collection point regardless of information in the log.

CBTi: Subjects in the combined group will receive CBTi as an intervention focused on reducing insomnia and depressive symptoms to improve sleep (reduced total wake time and improved

sleep efficiency), and on reducing depressive symptoms. We have chosen to provide the depression portion in the CBTi because our previous data (unpublished) demonstrates that this variable is unstable over time, and almost all CGs dealing with nighttime activity will score near or above the CES-D cutoff score of 16 during an 8-month period.

Table 2. Session-By-Session Overview of CBTi

Session 1 - Sleep Education, Sleep Hygiene, and Stimulus Control
Session 2 - Sleep Compression and Relaxation
Session 3 - Stress Management and Problem Solving
Session 4 - Review of Skills/Maintenance of Behavior Change

Session-by-session overview of the intervention is provided in Table 2 (see Appendix B for additional detail). All sessions will be individually administered by a trained therapist, who will be an advanced doctoral student in clinical and health psychology. A treatment credibility questionnaire will be administered at the end of the first treatment session. Similarly, the therapist will complete an expectancy for improvement scale at the end of the first treatment session for each participant. As previously stated, the proposed study is not a clinical trial intended to demonstrate the efficacy of behavioral treatment for insomnia. The pilot data presented in the Preliminary Studies section below demonstrates that our subgroup of CGs' sleep improved over the course of treatment. Our observed level of improvement was consistent with levels commonly reported in the literature.[73] Thus, we have reason to believe that similar levels of sleep improvement will be demonstrated in the proposed research.

Therapists: The GRA/therapists will be a doctoral students in clinical and health psychology at UF, trained and supervised by Dr. McCrae. The PI has previous experience as a behavioral sleep therapist in two sleep disorders centers and as director of the Insomnia & Behavioral Sleep Medicine Clinic at UF. She also has previous research experience conducting behavioral sleep trials as a PI (AG24459, AR055160, HL087831) and co-I (CA138808). Dr. McCrae will be available for consultation/supervision (by telephone) during treatment sessions and will hold 1-hour, weekly supervision meetings with therapist.

Participant Protection/Treatment Integrity: Three steps utilized by Lichstein, Riedel, and Grieve to protect participants and maintain treatment integrity will be followed.[74]

- Step 1: Treatment Delivery: The therapist will follow the treatment manual. Practice sessions with volunteers will be tape recorded. Dr. McCrae will review these tapes and determine when adequate procedural mastery has been attained. *Delivery assessment:* All treatment sessions will be taped; 50% will be randomly selected for scoring (therapists from Dr. McCrae's lab score each others' tapes) and 25% of the scored tapes will be double scored by Dr. McCrae for reliability.
- Step 2: Receipt: To ensure adequate comprehension of treatment, participants will be questioned about their experience with home practice of techniques, and procedural modifications will be adopted as necessary (eg, extending permissible amount of awake time in bed).

Receipt assessment: Participants will complete a short quiz (10 questions) to ensure they have mastered the treatmentrationale and procedures.

- Step 3: Enactment: To ensure adequate adherence to home practice assignments, the participant workbook contains written instructions for each sleep technique. The therapist will encourage faithful adherence. *Enactment assessment*: Participants will maintain daily logs of their home practice sessions (see Appendix B).

Attentional control "treatment": To control for a treatment effect of the researcher visit, the NHMS control group will also an attentional control "treatment"—sleep hygiene education. Although knowledge of sleep hygiene has been linked to sleep practices and, in turn, to overall sleep quality, few studies exist to support sleep hygiene as a single treatment.[75, 76] Sleep hygiene practices have been found to be less effective compared to sleep restriction and stimulus control interventions[77] and compared to abbreviated cognitive-behavioral interventions.[78] Sleep hygiene also makes a good control "treatment," because it is the most widely recognized and used behavioral sleep technique. Thus, it represents the standard of care for behavioral sleep techniques.

3.C.2.c. Participants

All participants will be female CGs who live in the same home and are the primary care provider for a PWD. An initial telephone screen will confirm these inclusion/exclusion criteria:

- primary female CG living with the PWD without provision for nightly respite. (Rationale for only female CGs: there is evidence of differing physiologic responses to the caregiving role between men and women,[16, 61] thus primary analyses would need to be done for males and females separately, doubling the sample size. If in this study, the hypotheses are supported, subsequent work will be done using male CGs.)
- provide care for a PWD with nighttime activity that occurs at least one night/week but is less than 4 times/night
- they meet the standard criteria for insomnia (time to fall asleep >30 min and/or time awake during the night on at least 3 nights/week over a 6-month period of time). (Rationale: This is consistent with the recommendation of Zarit and Femia[35] in the recent recommendations for research on family CGs—only those CGs that have dysfunction in the areas addressed by the intervention should be placed in the study protocol.)
- a Telephone Interview for Cognitive Status score of >25.[79]
- denies presence of chronic illness that requires frequent treatment/assessment (eg, weekly visits to a healthcare provider) and anticoagulant medication as well as a diagnosed sleep disorder such as sleep apnea or restless leg syndrome. Previous history of CHD is acceptable for several reasons: CHD is a chronic disease state and it is quite difficult to exclude all persons with this disease without extensive testing—only excluding those with a diagnosis would not suffice to exclude all those with the disease; new lesions can develop in those with previously treated CHD and thus these biomarkers would be abnormal; and previous studies on this topic have not excluded this group.[80]
- using sleep medication <3 nights/week and doesn't require aids to walk in the home at night (safety issue).

At the second contact, a home visit, participants will be consented in order to screen for sleep disorders (sleep apnea, restless leg syndrome) and to collect baseline data. Subjects who fail the screen for sleep disorders will not be invited to participate in the intervention portion of the study. All others will be invited to participate in the intervention trial.

Participant Recruiting: CGs will be recruited with procedures used in the STTR studies as well as procedures used by Lehman (co-investigator) who successfully recruited CGs of PWD. These techniques include: presentations at CG support groups, collaborations with Memory Disorder Clinics in Gainesville and Tampa FL, newspaper articles about the study, and referrals from practitioners and the Alzheimer's Associations of North Central and Gulf Coast regions. Our recruiting efforts will also be directed toward recruiting minorities (our STTR study sample contained 24% minorities). Since NHMS currently has only an English version, all participants must speak English. Because this population is particularly difficult torecruit, we will have a dedicated recruitment specialist on the study team.

Participant Retention: In our STTR study we recruited 55 caregivers with 2 caregivers not participating after signing consent (one withdrew due to family concerns and one failed post-consent screening). Otherwise, all CGs remained in the 12-month study as long as they were eligible (eg, PWD remained in the home), indicating excellent acceptance of the study and protocols. We will use the same retention methods for this study, including: conducting study investigations at CG's home, limiting data collection to less than 30 minutes/visit, using easy-to-complete instruments, acknowledging birthdays/holidays, having a consistent investigator visit a subject, and providing periodic study updates. During the first six months of the STTR study, 30% of study homes were lost due to PWD death or institutional placement. Thus, we will over-recruit by 30%.

3.C.2.d. Sample Size

Sample size estimates were calculated using the longitudinal data from the STTR study of the same population of caregivers in this study. Using the sleep diary data as recommended by experts in chronic insomnia for the treatment endpoint, the STTR sample had on average 91.3 minutes of total wake time and sleep efficiencies of ~80%. Assuming a 40% reduction (approximately the treatment effect for McCurry pilot study[23]), a sample size of 25/group would have a power of .80; a sample size of 33/group would have apower of .90. Additionally, with this sample size, there is >.80 power for total wake time and sleep efficiency measured objectively using actigraphy. Our goal, then, will be an analyzable sample of 30/group, and this requires a recruitment of approximately 42/group to account for a 30% loss.

3.C.2.e. Measurements

Primary Outcome Measures

Total Wake Time (TWT) and Sleep Efficiency (SE): Actigraphy, using the Actiwatch2, will be used to measure **objective sleep**; the device is worn on the wrist like a watch and is well

tolerated by subjects.[6] We will collect data for 14-day periods using a 30-second epoch length to accurately capture night-tonight variability.[81] (The light channel is effective for determining time to bed, get up time, and nightly out-of-bed episodes). Actigraphy is a reliable and valid measure of sleep as compared to polysomnography and has been used in previous studies involving older adults and in populations of dementia CGs.[6, 82, 83] A study comparing polysomnography to the same brand of actiwatches we are using found that values obtained using the medium threshold algorithm were in close agreement with polysomnography findings, and the total sleep time, sleep efficiency and total wake times from actigraphy were not significantly different than polysomnographic values.[84] Note that in previous research by Drs. McCrae and Rowe, 104 community-dwelling older adults wore actigraphs for 14 consecutive days with a 0% device failure rate and excellent compliance (99.001% compliance).[65, 85] Dementia CGs in the previous NHMS study had a slightly higher failure rate but still excellent compliance.[11]

Subjects will also complete a sleep diary for each day of actigraphic data collection, which will provide **subjective sleep** values of TWT and SE.[86] Data collected include bedtime, sleep start, number awakenings, minutes awake during night, wake time, out-of-bed time, minutes spent napping the previous day, and a sleep quality rating.[87] We used the same procedure in the first NHMS study and the older adult normative study. Our goal is to automate the standard paper form of the sleep diary using a PDA-type device to make diary completion easier and more accurate.

Nighttime Injuries: At each data collection point, CGs will be asked about any PWD injuries that occurred since the last data collection point. Injuries will be coded according to the American National Standards method of recording injuries.[88] The following data are collected: nature of injury; part of the body affected; object, substance, exposure, or bodily motion that caused the injury; event that directly resulted in the injury; and time and place of the injury's occurrence.[64, 89] An injury will be considered nighttime if the caregiver reported being asleep at the time the injury occurred. Caregivers will also be provided with blank data forms that can be completed at the time of the event to improve recall at the formal data collection point.

Secondary Outcome Measures

Blood will be collected by venipuncture into heparinized tubes, and centrifuged (1500 rpm) to separate the plasma, which will be aliquotted into sterile Eppendorf tubes and frozen at -80 C until batch analysis. All analyses, except D-dimer, will be done using a Luminex 200 from Millipore Corporation. The Luminex assay uses color-coded tiny beads. Each bead set is coated with a reagent specific to a particular bioassay, allowing the capture and detection of specific analytes (in this case, TPA, ICAM-1, TNF-α and IL-6) from the plasma sample. Within the Luminex analyzer, available in the University of South Florida College of Nursing Biobehavioral Lab, lasers excite the internal dyes that identify each microsphere particle, and also any reporter dye captured during the assay. Many readings are made on each bead set, further validating the results.

Alterations in Clotting Measures
D-Dimer is a marker of coagulation activation and has been associated with coronary events.[90] It has also been inversely associated with wake after sleep onset[91] as well as poor sleep quality and low sleep efficiency.[80] D-dimer is a byproduct of fibrinolysis which remains after a blood clot has been degraded. It consists of two crosslinked fragments of fibrinogen. Elevated levels of D-dimer are a marker of thrombosis, as it might occur along atherosclerotic plaques in coronary blood vessels. D-dimer will be measured by monoclonal sandwich ELISA (GenWay, CA), which measures in the 3.9–250 ng/ml range.

Tissue Plasminogen Activator is an endothelial lining protein that catalyzes the conversion of plasminogen into plasmin, which is responsible for the degradation of fibrin into soluble degradation products. Caregivers of PWD showed higher levels of TPA.[9] A meta-analysis of cardiovascular disease risk and TPA indicated that levels greater than 13.5 ng/ml increased CVD risk by 50%.[59]

Nonspecific Inflammation Measures
C-reactive protein (CRP) is a non-specific marker of inflammation shown in many studies to be elevated in AD caregivers and to be associated with poor sleep. High sensitivity CRP levels are onsistently and independently associated with increased risk of cardiovascular events.[92] HS-CRP will be measured by an ELISA (Alpco, NH).

Intercellular adhesion moledule-1 (ICAM-1) is found in leukocytes and endothelium and is involved in adhesion of leukocytes to and through the endothelium. ICAM-1 is stimulated by the proinflammatory cytokines. ICAM-1 may participate in atherogenesis by increasing monocyte transmigration into the arterial intima.

Proinflammatory Cytokines
IL-6, and TNFα: It is becoming apparent that sleep and immunity are strongly related and that impairments in sleep increase these circulating cytokine levels. Further, caregivers of Alzheimer's patients show both impaired sleep and elevated IL-6 and TNF-α . Levels of IL-6, IL-1, and TNF- α are partially controlled by sleep, and also regulate sleep and many aspects of the immune response. IL-6 and TNF-α are central mediators in the inflammatory process by regulating acute phase and coagulation protein, and inflammation plays a central role in the development and instability of atherosclerotic plaques. Theproinflammatory cytokines IL-6 and TNF-α will be measured by Luminex assays as described above. These assays are highly sensitive and can measure down to 1 pg/ml of cytokine in plasma samples.

Screening Measures
Screen for sleep disorders: The Watch-PAT is a device worn on the wrist with 2 sensors on the fingers, and measures peripheral arterial tone, oximetry, actigraphy, heart rate, body position and snoring. This is ideal for the CG population, as it is does not inhibit quickly rising at night and provides results very similar to polysomnography, the gold standard for diagnosing sleep disorders. Numerous validation studies demonstrated high degree of correlation in common measures of sleep disorders between the Watch-PAT and PSG sleep studies (ranging from R= 0.85–0.96).[93–96]

Scores for the respiratory distress index and apnea-hypopnea index are highly reproducible. The Watch-PAT device has an excellent reliability with minimal failure rate (< 2%) during data acquisition or data analysis, and minimal technician time when compared with PSG.

Telephone Interview for Cognitive Status: This 11-item screening test for assessment of cognitive function is administered over the telephone. A cutoff score of <25 distinguishes between dementia and non-dementia; sensitivity and specificity are similar to the Mini-Mental Status Exam, and test-retest reliability was high.[79]

Demographic, Clinical and Control Variables (Questionnaires available in Appendix C.)
Body Mass Index: Each subject will be asked for the height and weight and body mass index will be calculated using the standard Imperial BMI formula.

Perceived Stress of Caregiving: The Sense of Competence Questionnaire, a 27-item, 4-point Likert scale self-report measure, will be used to asses overall burden of caregiving. Higher scores indicate greater burden. Subscales measure 3 factors: satisfaction with impaired person as recipient of care, satisfaction with one's own performance as a CGs, and consequences of involvement in care for the personal life of the CG. The questionnaire has acceptable reliability and validity.[97] It has been used in CGs providing care to individuals with a variety of chronic illnesses.[97, 98]

Depressive Symptomatology: The Centers for Epidemiologic Study-Depression (CES-D) scale is a 20-item, self-report questionnaire with each item (depressive symptoms) rated on a 4-point scale from "rarely or none of the time" to "most of the time."[99] Three normative and one patient sample were used to establish parametrics, with and an approximate population mean of 9.25 (SD= 8.58). The CES-D was found to have high internal consistency and adequate test-retest reliability, as well as demonstrated validity.[100] CES-D has also been used successfully to assess prevalence of symptoms in the elderly and demonstrated excellent sensitivity/specificity with regard to detecting a high level of depressive symptoms in older adults.[100]

Overall Perceived Stress: The Perceived Stress Scale is a 14-item self-report questionnaire that measures the amount to which respondents feel their lives are unpredictable, uncontrollable and overloading in response to a life situation.[101, 102] Validity was established using construct and discriminant techniques as well as predictive techniques.[102, 103] Internal consistency is reported at 0.78.[102]

Demographic and Clinical Variables: A standard set of demographic variables will be collected as well a description of the sleeping arrangements between the CG and PWD. A list of daily and as needed medications for the caregiver will be collected, as well as all recent medical diagnoses.

3.C.2.f. Statistical Analysis Plan

Descriptive statistics for all primary and secondary outcome variables will be calculated as percentage, mean, and standard deviation, or median and percentile. Additionally, the

characteristics of demographics and outcomes between the intervention and control groups will be examined.

Analysis of covariance (ANCOVA) models will be used for the analysis of continuous primary and secondary variables using the strategy diagrammed below in Figure 2.

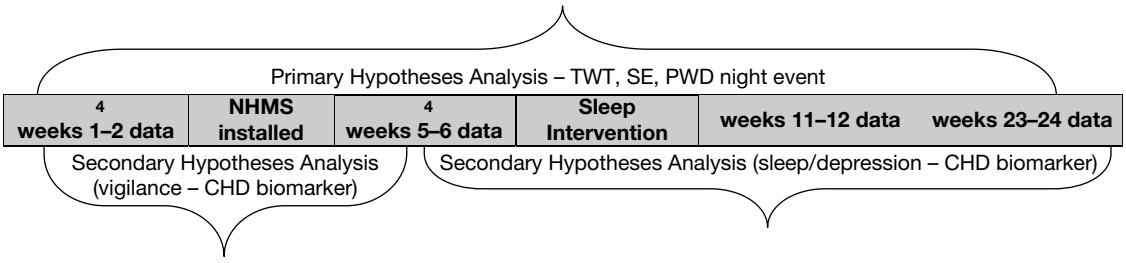


Figure 2. Analysis points for hypotheses.

Extensive secondary analysis will also be undertaken, using all available longitudinal data, (eg, study effects immediately post CBTi intervention period). Additionally, general linear mixed models will be used to explore differences between groups over the total available time frame. Analyses will be adjusted for preintervention response as well as covariates critical to the specific analyses. The fixed effect of time is of primary interest. The random effect is the caregiver. Correlation among observations from the same person will be accounted for in the covariance structure. Thus, let y_{ij} be the response of CG i at time j. Let $\mathbf{x}_{ij}$ be a vector of values for the fixed effects associated with CG i at time j, including possible covariates and the effect of time. Let $\mathbf{z}_{ij}$ be the random effect of person i at time j. Further, let β be the vector of unknown parameters associated with the fixed effects. and let $\mathbf{u}$ be the vector of unknown parameters associated with the random effects to be estimated. Finally, let e_{ij} be the error associated with person i at time j; the correlation among the e_{ij}'s resulting from having multiple measurements from the same person will be reflected in the modeled covariance structure. Then the model may be expressed in the following equation:

$$y_{\mathrm{ij}} = \mathbf{x}_{ij}\beta + \mathbf{z}_{ij}\mathrm{u} + e_{ij}$$

In the event of drop-outs, the missingness mechanism will be explored. If the assumption of Missing Completely at Random (MCAR) or the common assumption of Missing at Random (MAR) are plausible, then little change to the analysis plan is necessary. ANCOVA models with complete cases pre and postintervention will yield unbiased results, and mixed models analysis will be also be unbiased and appropriate. Study efficiency (power) will, of course, be affected by the smaller amount of available information. This is accounted for in sample size calculations. If missingness assumptions are not plausible, then Missing Not at Random (MNAR) techniques will be explored and employed;[104, 105] data analysis results will be interpreted with caution.

3.C.2.g. Procedures

Randomization will be done using a set of previously created envelopes. For both the Gainesville and Tampa site a set of envelopes will be made containing one label (either Experimental or Control). We will have 60 of each label, and these will be divided equally between the 2 sites. The envelopes will be shuffled and placed in a large envelope. Using personnel in the Office for Research Support at each school, a researcher will be given one randomly selected envelope prior to the home visit.

Using recruiting procedures detailed in Human Subjects 6.B.1., potential participants will be asked to call the project coordinator. The project coordinator will use a script to briefly describe the study and then ask a series of screening questions based on inclusion and exclusion criteria. If the screen is passed, an initial appointment will be set up in the potential participant's home. (Those failing this screen will be made aware they had an abnormal screening test for sleep problems and will be encouraged to follow up with their healthcare provider.)

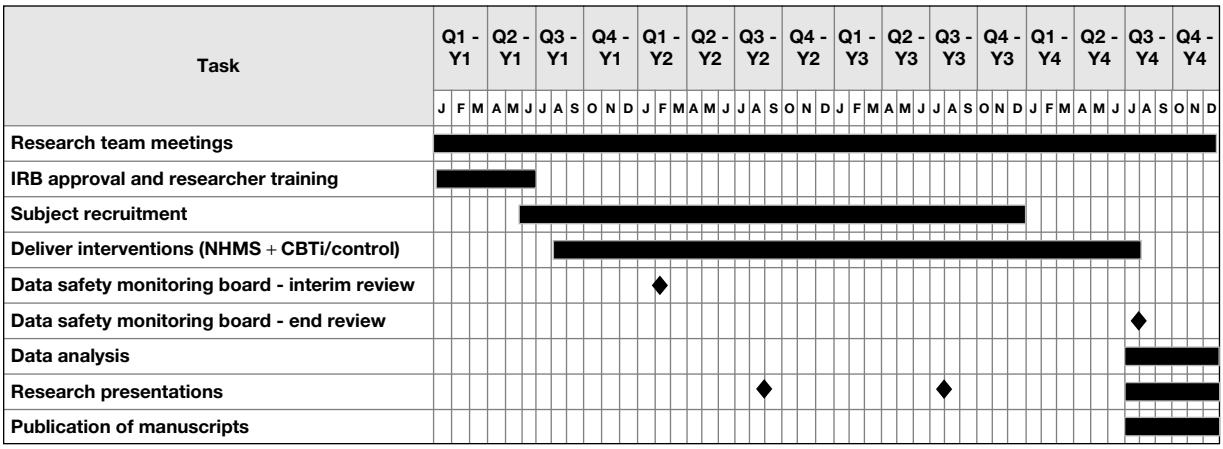
During the first visit, the study will be fully explained and caregiver informed consent will be obtained for the baseline and screening measures. If the caregiver does not have evidence of sleep apnea or restless leg syndrome and is willing to continue, she will be randomized to either the experimental or control condition. Then a second consent will be signed to participate in the full study.

Since baseline measures have already been collected, the next step is to install the NHMS. This will be installed using procedures we developed in the first NHMS study, in which there were no system failures. The system can be installed wirelessly and does not require any home modifications, such as screws, since we can use secure, but removable, 3M CommandStrips. For the next 2 weeks reliability data on system functioning will be collected using an RS232 port embedded in the NHMS that streams data into a laptop computer. That data is analyzed using procedures we perfected in the first study (see Appendix D) to ensure that all bed or home exits activate an alarm 100% of the time. When this occurs for 2 consecutive weeks, the laptop will be removed. CGs are instructed to monitor the system but not rely on it during the reliability period. This is also the period that CGs are educated about the system and tested to ensure it is properly used. Once system reliability and CG competence are established, CGs are free to use the system as it best meets their needs.

Following a second data collection period, the CBTi or sham intervention is delivered using procedures described above and in Appendix B.

At week 23–24, the final data are collected. Participants will be provided with published reports of the study, but will not be provided with any individual level data. At participant request, the NHMS will be left in the home at the conclusion of the study. We will provide support for system functioning for 6 months following their participation and will provide written instructions for system maintenance (primarily battery changes in the sensors) as we did in our first study, in which all participants kept the system and successfully maintained operation using these procedures.

3.C.2.h. Study Timeline



3.C.3. Expected Outcomes

Our primary expected outcome is an effective, easy-to-use treatment that can be used to improve sleep for dementia CGs with sleep problems. CBTi is rapidly becoming a standard treatment for chronic insomnia and should be readily available to CGs using psychologists in their area. In subsequent studies, we will test easier methods to deliver this intervention to this vulnerable group.

In addition, we will continue to build the science on the relationship between sleep and CHD, as well begin to understand mechanisms that may underlie deleterious changes in CG health. Our hope is obtain evidence of the relationship between sleep and CHD biomarkers and support this by gathering preliminary data that improving sleep reverses the changes in biomarker levels. If this occurred, a longer study would be proposed to determine how to deliver effective sleep therapies to sustain normalization of CHD biomarkers, as well as to determine whether the actual disease process was affected.

3.C.4. Potential Problems and Alternative Strategies

Table 3. Solutions to Potential Problems

Potential Problem	Alternative Strategy
Inadequate subject recruitment or minority representation	Utilize the James A. Haley Veterans Administration Hospital in Tampa, FL. Utilize a 3rd co-investigator and recruit in the Orlando area (we successfully recruited Hispanic and African-American populations here in first NHMS study)
Ineffective treatment	While all evidence suggests otherwise, if at the mid-point DSMB review, no treatment effect was seen, we would begin by interviewing previous participants regarding problems/ improvements for the CBTi. Any recurring suggestions would be reviewed by the team and adjustments made to the treatment. Final analyses would be done for the whole sample as well as the sample with revised therapy.
Excessive participant burden	If this is problematic, we have considered several ways to reduce burden: 1) reduce number of in-persons CBTi sessions as has been effectively done in other populations or pilots[5, 78, 106]; 2) reduce actigraphy/sleep diary to 7 days—mean levels are still accurate but some night-to-night variability is lost[81]; and, 3) have an interval between NHMS and CBTi interventions that can be controlled in statistical analysis of longitudinal data.

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Maintaining Abstinence and Reducing HIV Risk in Adolescent Girls

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April 27, 2006

Center for Scientific Review
National Institutes of Health
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To Whom It May Concern;

Enclosed please find six copies of an R03 application for AIDS-related research entitled "Maintaining Abstinence and Reducing HIV Risk in Adolescent Girls" for a submission date of May 1, 2006. I am requesting review by the BSPH study section and primary assignment consideration for funding from the National Institute of Nursing Research and secondary by the National Institute of Mental Health. Thank you for your thoughtful consideration.

Sincerely,

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DESCRIPTION: See instructions. State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project (i.e., relevance to the **mission of the agency**). Describe concisely the research design and methods for achieving these goals. Describe the rationale and techniques you will use to pursue these goals.

In addition, in two or three sentences, describe in plain, lay language the relevance of this research to public health, if the application is funded, this description, as is, will become public information. Therefore, do not include proprietary/confidential information. **DO NOT EXCEED THE SPACE PROVIDED**.

The face of HIV/AIDS is becoming increasingly female, African American, and young; adolescent girls, are at increasing risk for HIV infection primarily due to sexual behavior. Sexually abstinent girls represent a significant subgroup of the adolescent population, with recent data indicating that more than 50% of females ages 14–19 have never had vaginal intercourse, it is crucial to address prevention of HIV/AIDS prior to when adolescent girls become sexually active; interventions should help (a) to delay sexual initiation and (b) to prepare girls for risk reduction when they do become sexually active. Of the small number of small-group sexual risk reduction interventions developed for adolescent girls in the community, none has focused solely on sexually abstinent girls. The research proposed in this application aims to address this gap in HIV prevention science. Specifically, we will evaluate the feasibility of an intervention designed to maintain abstinence and to reduce future sexual risk behavior in sexually abstinent girls. The purposes of this proposal are to identify and clarify the specific needs of abstinent girls through formative research and then to pilot test a gender specific "abstinence-plus (*AbsPlus*)" intervention designed to maintain abstinence and reduce future risk behaviors. Specifically, we will conduct focus groups with 18 sexually abstinent girls ages 14–19 to gain insight into the context of sexual abstinence and identify potential determinants of self-protective behavior in this population; we will also determine how to tailor a group-based intervention (developed previously for use with sexually active girls) to maintain abstinence, delay onset of sexual activity, and promote self-protection at the first and subsequent sexual contact. We will then assess the feasibility of the *AbsPlus* intervention with sexually abstinent girls using a randomized, two-group (controlled) experimental design. This design will allow us to estimate the effect sizes for both the theoretical antecedents of risk behavior and actual behavioral outcomes. We will recruit 60 adolescent females aged 14 to 19 years from youth development programs and randomly assign groups to one of two conditions: (a) a sexual risk reduction intervention based on the Information-Motivation-Behavioral Skills model (Fisher & Fisher, 1992) or (b) a structurally equivalent health promotion control group (CTL). Groups will be facilitated by trained adult female leaders using a motivational enhancement style. At immediate and short-term (3-month) follow up assessments, we expect that girls enrolled in the *AbsPlus* intervention will increase their HIV-related knowledge, motivation, and behavioral skills; we also expect that girls who receive the intervention will be more likely to maintain abstinence and to decrease the frequency of related-risk behaviors relative to CTL participants. The long-term goal of this study is to develop an effective intervention to prolong abstinence and decrease future HIV risk in girls ages 14–19.

PERFORMANCE SITE(S) (organization, city, state)

University of Rochester School of Nursing
Rochester, New York

Planned Parenthood of the Rochester/Syracuse Region Inc.
Rochester, New York

The In-Control Program
Rochester, New York

A. SPECIFIC AIMS

The face of HIV/AIDS is becoming increasingly female, African American, and young. Adolescent girls, particularly those of color, are at increasing risk for HIV infection primarily due to sexual behavior.[1,2] Abstinent girls represent a significant subgroup of the adolescent population, with recent data[3,4] indicating that over half of females ages 14–19 have never had vaginal intercourse. It is crucial to address prevention of HIV/AIDS prior to adolescent girls' becoming sexually active to promote delayed sexual initiation and reduce risk behaviors when they transition to sexual activity.[5]

Despite the demographic profile of risk, there are few interventions developed specifically for adolescent girls who are not yet sexually active and wish to remain so. Such an intervention should focus on "abstinence plus" other protective behaviors and aim to maintain abstinence, as well as prepare for safer sexual behaviors including protection at first sexual experience. Our experience in an ongoing trial with sexually active girls (N = 640) and prior research[6] indicate that an HIV risk reduction intervention including both sexually-active and sexually-abstinent girls will serve neither group well.

The **purposes** of this proposal are to identify and clarify the specific needs of abstinent girls through formative research and then to pilot test a gender specific "abstinence-plus (*AbsPlus*)" intervention. **For Specific Aim I** we will conduct focus groups with 18 sexually abstinent girls ages 14–19 to gain insight into the context of sexual abstinence and identify potential determinants of HIV-preventive behavior in this population and determine what refinements in materials (e.g., intervention, measures) are needed to tailor a group-based intervention (previously used with sexually active girls) to maintain abstinence, delay onset of sexual activity, and promote protected first and subsequent sexual contact. **For Specific Aim II** we will assess the feasibility of the *AbsPlus* intervention with 60 abstinent girls using a randomized 2-group experimental design; and estimate effect sizes of theoretically-driven and behavioral outcomes. The **long-term goal** of this study is to develop an effective intervention to prolong abstinence and decrease future HIV risk in girls ages 14–19.

B. BACKGROUND AND SIGNIFICANCE OF PROPOSED RESEARCH

Protecting adolescent girls from HIV. Developing intimate relationships, including in some cases sexual intimacy, is an expected adolescent developmental achievement.[7] A majority of

girls (70%) will become sexually active by age 20[8] so the years when they are developing relationships with boys and face real-life decision making surrounding sexual choices are an opportune time to intervene. It is crucial that girls learn the benefits of, and be assisted in, delaying onset of sexual activity; however, they must also be prepared to protect themselves from HIV, STIs, and unintended pregnancy when they transition to sexual activity.[9]

The earlier girls initiate sexual activity, the greater their risk for infection.[10–12] Delaying the transition to sexual activity until late adolescence or early adulthood can reduce lifetime number of sexual partners, improve the likelihood that girls will require their partners to use condoms, and reduce the likelihood of transmission of HIV and STIs. However, adolescent girls may avoid vaginal intercourse in order to maintain "abstinence" or "virginity" yet still engage in sexual behavior that puts them at risk for acquiring HIV and other STIs.[13] Successful interventions for other adolescent subgroups have included both abstinence-focused and other HIV-risk protective behaviors.[14–17] A meta-analysis of 174 sexual risk reduction interventions also revealed that these interventions do not inadvertently increase the frequency of sexual behavior.[18]

Although studies with sexually-active girls suggest that gender-specific interventions may enhance both psychosocial and behavioral outcomes related to HIV prevention,[19,20] few all-girl interventions have been tested, and none have focused exclusively on sexually abstinent girls. The REACH study suggests that little improvement in risk behaviors will be actualized without targeted interventions.[21] Rigorous research targeting abstinent adolescent girls, particularly those from high-risk urban environments, is needed to tailor and test prevention interventions that are relevant and effective.

We are conducting a large (N = 640) randomized trial evaluating an HIV risk reduction program for sexually active adolescent girls ages 15–19. To date, we have screened almost 600 girls for this trial. Of the 300 girls who did not meet study inclusion criteria, more than 50% (N = 166) did not meet these criteria because they were sexually abstinent; an additional 20 abstinent girls could not be enrolled because they were 14 years of age. We have had numerous requests from these girls, as well as their parents, and community members (e.g., social workers, teachers, and administrators) for programs tailored to the unique concerns of these girls. Thus, we recognize that the needs of a large group of girls are not being met.

Effective HIV risk reduction in adolescents. Close to half of all new STIs, including HIV, in the US occur in persons under the age of 25.[22,23] The risk of becoming infected is greater for girls than boys because girls are physically more susceptible, may have sex partners who are older (and thus more likely to be exposed to HIV/STIs), and may experience relationship dynamics that do not support use of condoms.[24] Certain subpopulations of adolescent girls have been shown to be at greater risk of becoming infected: African-Americans, Latinas, and impoverished youth or those living in urban HIV/AIDS epicenters.[25]

There is little evidence supporting the effectiveness of programs without comprehensive risk reduction components,[26–31] and community abstinence-only interventions consistently fail to reach urban youth.[32] Abstinence only programs (e.g., virginity pledges) may inadvertently

increase the risk that a girl's first sexual contact will be unprotected[27,33,34]; moreover, such programs have not consistently demonstrated efficacy in delaying onset of sexual intercourse.[35] Girls who consider themselves abstinent may engage in other unprotected sexual behaviors, such as oral sex, which put them at risk for HIV and STIs.[13,36,37] Comprehensive sexual education is known to delay sexual onset and reduce sexual risk behaviors in various young adult and adolescent subgroups,[12,38] yet few HIV prevention interventions are specific to adolescent girls, who have been found to have different needs and responses to interventions.[20,39] In recent reviews of HIV prevention and abstinence intervention studies,[40,41] of the few targeted to girls none was developed exclusively for those who were sexually abstinent. Thus, interventions for sexually abstinent girls are notably absent from the literature, yet these girls are clearly in need of interventions tailored specifically for them. Formative work is considered essential to tailor and refine successful interventions for use with other populations[42] and our studies with sexually active adolescent girls and this proposed study will provide us with a foundation from which to develop interventions for sexually abstinent girls that are gender-specific as well as developmentally and culturally appropriate.[43–47]

Theoretical Framework

In a meta-analysis with more than 116,000 participants, greater risk reduction was noted in interventions that included more information, motivational, and skills components.[18] Many adolescent girls do not perceive themselves at risk for HIV, have a poor understanding about what situations put them at higher risk for HIV, and lack the skills to decrease their risk for HIV.[44,47,48] Without information, motivation, and behavioral skills, girls who successfully delay sexual onset will be susceptible to HIV/STI infection at the eventual onset of sexual activity. Interventions are more likely to be effective if they are guided by a theoretical model that is based on (and tested with) empirical research.[49,50] **The Information-Motivation-Behavioral Skills (IMB) Model**[42,51] combines elements from several health behavior models (e.g., Theory of Reasoned Action[52]) that propose that initiating and maintaining HIV prevention behaviors are a result of **information** about HIV prevention, **motivation** to reduce risk, and HIV prevention **behavioral skills** (see Fig. 1). The IMB model provides a parsimonious conceptual framework relevant across gender, age, sexual orientation, cultural background, and other characteristics. The theoretical links in the IMB framework, in which information and motivation are partially mediated by behavioral skills to influence HIV preventive behavior, have been supported in other populations.[53–55]

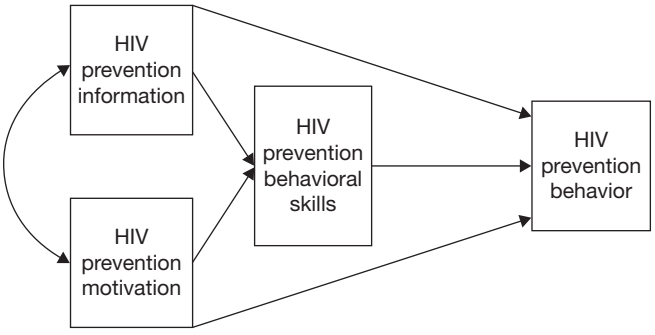

Figure 1. IMB Model (Fisher & Fisher)

In our past RCTs using the IMB to guide intervention development, we have extended information-only and information-and-skills based programs by enhancing the motivational components of an HIV risk reduction program for other adults including women and sexually active girls.[56–59] We are acutely aware of the unique gender-related challenges associated with risk reduction for females, relying on the Theory of Power and Gender to guide us as well during our formative work with the female population.[60] We included aspects of both immediate (behavior-focused) motivation and broader-based motivation related to life goals, values, and other transsituational influences.[61] These client-centered interventions were administered using a motivational enhancement approach similar to that used in treating substance abuse[62,63] and designed to increase the participant's collaboration, offering a directive style that differs from purely didactic or confrontational approaches. We propose to extend this model to sexually abstinent girls.

C. PRELIMINARY STUDIES AND RESULTS

C.1.1 Summary of Core Experiences and Skills

Our research team is well qualified and has the experience necessary to develop, implement, and disseminate the findings from this pilot HIV prevention intervention for sexually abstinent adolescent females. We will use these findings to refine and tailor the intervention for this population in preparation for a full-scale trial. We have experience with multi-site RCTs,[44,56,58,64] formative and qualitative HIV prevention work,[43,45,46,65,66] and methods planned to refine and pilot test this intervention.[65,67–69] These strengths, together with the research infrastructure at the University of Rochester and the investigators' successful working relationship with the clinical sites, demonstrate a skilled team prepared for all aspects of this proposed work (see pp. 66–69).

C.2 Pilot Work

C.2.1 Formative Qualitative Work With Urban Adolescents and Young Women

We conducted focus groups with 30 impoverished sexually-active adolescent girls[46,70] and 45 low-income, urban, minority women[71] to understand their HIV-related information, motivation, and behavioral skills and to pretest measures to reflect issues of importance to females. We refined our original manual used with adult women in an IMB-based intervention[72] for use with adolescent females by incorporating elicitation findings from focus groups,[73] maintaining the theoretical mechanisms of the intervention and incorporating relevant issues related to gender and power.[60] Group activities were designed with the language and mannerisms familiar to adolescent girls.[70,74,75] A similar process was used for the structurally equivalent control manual.[76]

C.2.2 Pilot of HIV-Prevention Intervention With Sexually Active Adolescent Girls (Health Improvement Project for Teens/HIPTeens)

We recruited an at-risk sample of 62 sexually active females (ages 15-19) to pilot test a gender-specific, HIV-prevention intervention, using a randomized 2-group experimental design with 3 month follow up. The manualized HIV and control interventions were provided by two trained

female facilitators. Following four 2-hr sessions addressing HIV-related information and behavioral skills combined with motivational enhancement strategies, we determined that girls in the intervention group improved both knowledge and motivation to reduce risk as well as 5 of 8 behavioral outcomes.[59]

C.2.3 RO1-Funded RCT With Sexually Active Adolescent Girls (Health Improvement Project for Teens/HIPTeens)

Following that successful pilot, we have presently recruited almost 1/2 of the 640 girls need to test the short- and long-term efficacy of the intervention in a full-scale trial. We expanded the pilot by adding booster sessions post intervention (3 & 6 mo.), longer-term data collection (6 & 12 mo.), and biological outcomes. Although we do not have sufficient post intervention data to evaluate at this point, this RCT has been met with great enthusiasm by the girls (high program satisfaction ratings for both groups are over 91%). Having conducted more than 350 focus group and intervention sessions with sexually active girls has given us ample opportunity to identify their major concerns within the role-playing, assertiveness training, and skills components that deal specifically with situations in which they are already sexually active. Abstinent girls will need similar skills with a focus on remaining abstinent and delaying onset of sexual activity. As noted, we receive many requests from abstinent girls to be included in a program designed for them. Our experience indicates that if we combined abstinent and sexually active groups in an intervention, the interaction would most likely be stifled if many were dealing with very dissimilar situations. Thus, the logical next step is to tailor the intervention using formative methods and conduct a pilot study to test its feasibility and document effect sizes in preparation for the sorely-needed full-scale intervention.

D. RESEARCH DESIGN AND METHODS

D.1 Design

Phase 1: Formative Work to Tailor Intervention and Refine Materials (Specific Aim I)

We will conduct 3 focus groups with a total of 18 abstinent adolescent girls ages 14–19 in order to (a) gain insight into the context of sexual abstinence and preparing for future safer sexual behaviors in this population; (b) identify potential determinants of HIV-preventive behavior; and (c) determine what refinements in materials (e.g., intervention, measures) from our current RCT are needed for use in subsequent phases of the research. The intervention, measures, and materials will be modified as needed for sexually abstinent girls. We have used focus groups successfully for these purposes with other populations and based on past experience expect to get saturation of data with that number of participants.[67,77]

Phase 2: Feasibility Trial of Abstinence-Plus *(AbsPlus)* Intervention (Specific Aim II)

A prospective, randomized two-group design including a tailored intervention and refined protocol will be conducted to provide feasibility data in preparation for a full-scale RCT. A sample

of 60 girls (none from the focus groups) from two sites will be randomized at each site into the IMB-based HIV intervention or a structurally equivalent health promotion control group (10 groups with 6 girls/group). Assessments will take place at baseline, 1 week post-intervention, and at 3 month follow-up. Trained female facilitators will provide the four-session manualized intervention. Thus, girls will meet for a total of 7 times (sessions 1, 6 and 7 for data collection and sessions 2–5 for intervention sessions). Data for the modified instruments will be collected using audio-computer assisted self interview (ACASI), which has been used very successfully with adolescents including in our prior work.[59,78–81]

We ***hypothesize*** that, as compared to those assigned to the control condition, girls assigned to the *AbsPlus* intervention will increase IMB factors as follows: (a) HIV-related ***knowledge*** and (b) ***motivation*** for engaging in HIV-preventive behaviors including remaining abstinent, and (c) ***behavioral skills*** to remain abstinent, prepare for safer future sexual activity, or reduce risk behavior at the time of onset of sexual activity and at subsequent encounters. In data analysis, we will summarize the prevalence of HIV-preventive and risk behaviors, and identify relationships between these behaviors and demographic, theoretical, and clinical correlates. We will estimate effect sizes of the modified intervention model.

D.2 Setting and Sample

The proposed study will be conducted in Rochester, NY, an area with one of highest rates of Chlamydia in adolescent girls and the second highest rate of gonorrhea nationwide.[82] Participants will be 78 healthy 14–19 year old adolescent girls recruited for focus (N = 18) and intervention (N = 60) groups through youth development programs. These programs provide after school educational support, health services, or activities (e.g., dance, drama) for high school aged and GED youth. (Attached are strong letters of support.) Our experience during the current RCT in which over 25% of potential participants have not met inclusion criteria because they were sexually abstinent increases our confidence in our ability to recruit an adequate sample. It is anticipated that the girls recruited for the proposed study will mirror in race, ethnicity, and SES those enrolled in the current RCT (greater than 70% girls of color, economically disadvantaged) but expect that, because participants will not be sexually active, the mean age may be somewhat younger than that of the sexually active study sample (17.4 years). Although HIV is found disproportionately in adolescents of color, we will recruit girls of all races since recent data suggest that white adolescent girls have higher rates of numerous risk behaviors yet lower rates of HIV testing[3,47] confirming that they also need to be included in such interventions.

D.2.1 Inclusion Criteria

A total of 78 girls ages 14–19 will be recruited – 18 girls for the focus groups and 60 girls for the pilot intervention study. The inclusion criteria include: age 14–19, unmarried, with no experience of vaginal or anal intercourse. We choose to enroll girls who have had oral sex because of its high prevalence even in girls who have not had penetrative sex.[13] They must be able to attend groups with 3-month follow-up, and participate in an English-speaking intervention (in the

ongoing RCT, fewer than 1% did not meet the language criterion). If we find a girl who does not meet the language criterion, although she cannot participate in our study, she will be referred to a bilingual health educator on site, or to services in her primary language).

D.2.2 Determination of Sample Size (Power Calculations)

The proposed study will examine the effect of an IMB-based *AbsPlus* intervention on maintaining abstinence for adolescent girls. We will estimate effect sizes that can be detected at post-intervention and 3 month follow-up. These effect sizes will provide information for power and sample size estimation for a full-scale trial. As a feasibility pilot study we do not expect to be sufficiently powered for inferential analyses of intervention efficacy.

D.3 Methods

D.3.1 Recruitment and Tracking

Recruitment/Assessment Team: This team will consist of Dr. Morrison-Beedy and the Project Coordinator (PC), and an Assessor/Recruiter. All team members will receive training regarding the need to be sensitive to age, cultural, and racial issues when working with potential participants. The Assessor will ***not*** conduct the interventions, in order to minimize self-report biases caused by wanting to please one's interventionist.

Training, Supervision, and Quality Assurance: Time is allocated for Assessor training in consent administration, ACASI assessment measures, and protection of human subjects. The PI and PC will provide modeling, rehearsal, and feedback, and hold regular supervisory meetings to review study procedures. Once the Assessor has established her competence during mock sessions, she will be allowed to begin recruitment.

Recruitment will take place at two youth development sites in Rochester NY and will rely on study advertisements posted at the sites, word of mouth, and active outreach by research team. All girls ages 14–19 attending those sites/activities will serve as the recruitment pool.

Screening: The Assessor will speak with girls after they have registered for activities. Girls who express interest in the study will be screened briefly to determine if they meet initial criteria (ages 14–19, unmarried, English speaking). Girls not eligible for the proposed study because they are sexually active (and meet the RCT inclusion criteria) will be invited to join our ongoing RCT for sexually active girls. Girls who are interested will meet privately with the Assessor to be screened for remaining inclusion criteria. If met, the Assessor will review the details of the study verbally and in writing.

Consent. After all questions have been answered, potential participants will be asked to read and sign an assent (consent for those 18 and older) that explains the study, potential risks, expected benefits, and manner in which confidentiality will be maintained; it also offers assurances that participants can terminate participation at any time without penalty. Girls will be allowed to participate even if they do not agree to have their sessions taped. In our previous

RCT experience,[56,57,83] when we clearly explained why the sessions were being taped, that girls could use fictitious names, and that we would protect their identities, their fears were allayed and none refused to be taped. Underage participants will receive a copy of the study consent and a stamped, addressed envelope to give to their parents. We will contact a parent by phone within one week of assent to review study procedures and request that the signed consent be mailed to us. It is our experience that many of these parents do not have the time or means to come in for a consent visit yet do not want their girls to miss out on opportunities. Confidential tracking cards for participants will also be completed. We will then schedule girls who have completed full assents/consents for the data collection (starting session 1, also sessions 6 and 7) and intervention groups (sessions 2–5).

D.3.2 Data Collection Procedures

PHASE I Focus Group Methods

These carefully planned discussions will be designed to understand the context and obtain information regarding HIV-related knowledge, motivation, and behavioral skills for abstinence and risk avoidance to tailor the intervention components to sexually abstinent girls. Detailed descriptions of experiences, opinions, and responses will be elicited. Potential questions might include: "What reasons do you have for remaining abstinent; which is the most important?" "What are the difficulties of becoming sexually active or remaining abstinent?" "What helps you to resist the pressure to have sex; what makes it difficult to remain abstinent?" "How do your friends or parents make it easier or harder to remain so?" Strategies with proven effectiveness such as 6–8 participants per group, a trained moderator, audio-taping and transcription for later analysis, and field notes will be used. Data analysis of transcripts will include both within-group and between-group content analysis of common responses and intervention preferences.[65] Based on these data, the intervention, measures, and materials from the current RCT will be refined as needed for sexually abstinent girls prior to Phase 2.

Phase II: Pilot Intervention Randomization, Data Collection and Retention

Randomization procedures: Subjects who meet inclusion criteria will be assigned to either the *AbsPlus* intervention or a structurally equivalent health promotion control group (a total of 10 groups with 6 girls/group). Given the relatively small number of groups for the study, we will randomize groups using a permuted block randomization procedure so that we can have a balanced mix of intervention and control groups. A card and envelope system will, keep the assignment concealed until the participant is enrolled. Girls will not know their group assignment until they attend their first session.

Assessments: Participants will be asked to complete three self-report assessments using ACASI. Assessments will take place in private areas with computer stations at each recruitment site during session 1 (data collection group meeting) and sessions 5 and 6 following the four intervention sessions. ACASI allows participants to listen with headphones to spoken questions recorded and stored on a computer; they may also respond to the visual presentation of the questions on the computer monitor at their own pace.

An Assessor will start the computer program, ascertain if participants are comfortable using a computer by having them do a few "warm-up" questions, and be available for questions as they complete the program. There will be visual barriers and adequate space between computers so participants cannot see one another. Assessments take about 30 minutes to complete. Several additional techniques will be employed to promote candid reporting: (1) asking each girl to generate a personal identification code to be used to match her data throughout the study,[84] (2) assuring them that their responses are confidential,[85] (3) emphasizing the importance of honest answers and their unique opportunity to contribute to the health and well-being of fellow adolescent girls,[56,86] and (4) using different personnel for assessments and intervention groups. The Assessor will insure the data are saved before the girls leave, and then save data to a removable hard drive.

Retention Strategies: We will use several ways to maximize the number of girls who complete the sessions. Groups will be held during convenient, after-school hours at sites that offer specific services and hours for teens. Each site is on a major bus route. Our present work shows that the groups are engaging, developmentally and culturally appropriate as well as gender specific and consonant with their everyday life experiences. We have high satisfaction ratings from girls in the other RCT (>90% highly interested/satisfied). By using key informants' opinions to develop recruitment, retention, and intervention strategies,[70,74,75] we developed participant-centered methods that should help decrease attrition.[87] We give participants a personal calendar marked with the dates and times of appointments and sessions plus our contact number and email address. Refreshments are served during the sessions. The Assessor will telephone or email participants prior to their visits; we also obtain collateral contact numbers and send cards to participants and telephone them on a regular basis as an in-between assessment contact.[88] Our diligent tracking system includes attempting multiple contacts with any participants who do not return for their follow-up appointments. Finally, we will provide financial incentives to participants. Of course, all participants have the right to withdraw from the study without penalty. If this occurs, we will try to determine the reason and record it.

Participant Payment: To avoid attrition due to transportation costs, lost wages, and other logistical issues, participants will be paid $20 for each intervention session. Because assessments are conducted for scientific reasons and do not provide participants with any direct benefit, they will also be compensated $20 for each of three assessments. Payments for the full study total $140. Previous adolescent participants strongly encouraged cash payments vs. gifts (e.g., CDs) because of diverse individual needs/desires.

D.3.3 Procedures for Intervention and Control Conditions

Intervention Team: This team will consist of Drs. Morrison-Beedy and Carey, the Project Coordinator, and four part-time interventionists. All groups will be conducted by a pair of women thoroughly trained by the Pls in both the *AbsPlus* and CTL intervention. These teams will be assigned to work in any combination and at all sites to avoid a "paired-facilitator" effect. Our interventionists will ***not*** conduct assessments to avoid demand biases and other difficulties that can arise when an assessor has a dual relationship.

Manuals: The abstinence plus intervention will be guided by a previously evaluated manual[72] modified to meet the unique needs of abstinent adolescent females.[73] Phase I will yield information that will be used to tailor our existing manual for abstinent girls. The health promotion control group will be guided by a manual that mirrors the time allotted for and activity strategies in the intervention manual.[89] These manuals specify step-by-step information to be presented by the interventionists, prompts, instructions for conducting intervention strategies, and motivational techniques that can be used throughout the sessions to promote behavioral change (see Appendices B and C for the manuals).

Training, Supervision, and Fidelity: All personnel will receive orientation, monitoring, and evaluation[90] including review of related literature, manuals, and motivational training videos[91] as well as role-playing, modeling, feedback, and periodic reviews of manualized intervention procedures. All will complete training on protection of human subjects, interpersonal violence, sexual abuse, mandated reporting, duty to warn, and related ethical/clinical issues. All facilitators in various combinations will provide the *AbsPlus* and CTL interventions at both sites to prevent confounding of individual interventionists with treatment condition or site.

Fidelity of the intervention will be facilitated by: 1) extensive training of facilitators, 2) random observation of groups by the PI, 3) random review of audiotapes from group sessions (all will be audiotaped), 4) weekly meetings between interventionists and PI, 5) monthly team meetings, 6) self-evaluation forms completed by interventionists directly after every session regarding meeting session goals and girls' participation, 7) group guidelines of confidentiality to prevent cross-contamination, and 8) control manual guidelines pertaining to appropriate responses if girls ask about abstinence-plus topics during control intervention.

Overview of Interventions: Groups will take place in four weekly 120-minute sessions. Small groups (6 girls/group) will be used to provide each girl with time to role play, practice skills and receive feedback. We will employ these tested strategies: (a) same-sex, small group format; (b) a variety of learning modalities (e.g., verbal, visual, experiential); (c) repeated exposure to important constructs; (d) explicit and concrete terms and guidelines; and (e) argot, colloquial language, and mannerisms familiar to adolescent girls. Each session includes take-home activities to complete for the next session; some may be done with parents or friends.

The intervention design will be informed by previous work with sexually active adolescent girls and the focus groups in Phase I. The *AbsPlus* and CTL sessions will be similar in process but differ on specific knowledge, appropriate role-play scenarios, and targeted behaviors. Both interventions are guided by the assumptions that behavior change occurs along a continuum, girls will be at varying levels of readiness to change or maintain targeted behaviors,[92] and some reduction in risk behavior is better than none (cf. harm reduction philosophy[93]).

Our motivational exercises will be tailored to girls' unique motives: e.g., their interest in remaining abstinent. We will address gender-based ideologies and sexual scripts as they relate to

abstinence and risk behavior. Skills exercises will include female-specific needs to negotiate abstinence and lower risk behaviors with a reluctant partner, to avoid situations where they may be vulnerable to coercive sex, and to better manage moods sometimes associated with poor sexual decision-making. We place skill exercises in a developmentally appropriate context. For example, potential risk situations are constructed within a neighborhood or home setting, whereas in an adult intervention, they might be in a bar or other adult setting.

To enhance confidentiality, we will strongly encourage participants to "keep what is said within the group," but it is possible that some cross-session discussion may occur outside the groups. Based on our experience, we expect this discussion to be very limited, in addition, we believe the magnitude of the information, motivation, and behavioral skills presented in the intervention cannot be acquired through casual conversation but requires intensive facilitator-led, theoretically-driven activities, thus reducing the potential for contamination.

Abstinence-Plus (AbsPlus) Intervention

Following the IMB Model,[42] the abstinence-plus intervention is designed to (a) provide correct, current HIV information necessary to appraise risk, (b) promote abstinence and readiness to avoid or change risk behaviors (motivation), and (c) offer behavioral skills that are ultimately necessary to maintain abstinence and reduce risk. The informational component provides current information on HIV transmission, prevention, and consequences of infection. The motivational component helps participants understand why maintaining their safer behaviors is desirable and build their commitment. Concerns that influence both immediate (behavior-focused) and broader-based motivation related to gender-specific life goals, personal and community values, and other trans-situational influences are presented. The behavioral skills component focuses on assertiveness skills, improving self-efficacy, negotiating abstinence, condom use or other risk reduction practices with partners, and identifying high-risk situations; it will also prepare girls to buy and use condoms and counter negative attitudes about abstinence and condoms.

These sessions include opportunities for role-playing and receiving positive reinforcement and feedback from facilitators and other participants, which helps to modify social norms and generate other risk reduction options. Developmentally appropriate strategies such as games and interactive group activities are integrated throughout the sessions. The manual used for sexually active girls' intervention, will be modified in Phase 1 of this project, is provided in Appendix A. The sessions will include:

Session 1—Provide rationale for motivational approach, develop future time perspective; summarize girls' concerns regarding HIV, encourage risk sensitization, summarize concerns and motivational statements. Provide personalized feedback on HIV risk and reactions; develop discrepancy between perceptions of invulnerability and potential risk; educate regarding HIV risks, transmission, prevention and AIDS. Provide personalized feedback about HIV based on the sample's HIV knowledge responses and those of previous studies.[56,57] Define and role-play assertive communication; summarize discussion.

Session 2—Review session 1. Group activity to encourage risk sensitization; use participants' knowledge of safer sex behaviors to develop menu of healthy choices including abstinence; discuss pros and cons of abstinence/HIV risk reduction and develop action plans to reduce risk. Discuss risk situations, elicit feedback, summarize. Role play assertive statements using video clips; game that addresses gender-based ideologies and sexual scripts.[94] Discuss action plans, summarize session, affirm girls' commitment to change.

Session 3—Review prior sessions. Introduce behavioral skills training on correct condom use/purchase. Identify triggers to risk behaviors (e.g., alcohol). Role play assertive responses to rationalizations for sex. Culturally sensitive video presents motivation and behavioral skills to avoid sex, reduce risk, reactions discussed. Discuss and summarize session, affirm progress in behavioral change.

Session 4—Review previous sessions, address questions/concerns. Extensive role-playing and rehearsal with video clips and actual situations to enhance communication and interpersonal skills for abstinence/HIV risk reduction. Media presentation to encourage abstinence and motivation for behavioral change; game to review and reinforce HIV-related information. Review motivational statement/commitment to change and congratulate on progress, support self-efficacy, and address concerns.

The Health Promotion Intervention Control Group (CTL)

Our structurally equivalent CTL intervention controls for effects of professional attention, time, and group support. To contrast with the intervention, we offer an alternative program addressing three topics (anger management, breast health, and nutrition); these have direct health benefits and were previously identified by girls as important and of interest. Like the intervention, it consists of four weekly 120-minute sessions, was pilot tested with adolescent females, and is the control condition in the current RCT (see Appendix B).

D.3.4 Maintaining an Adequate Control Condition

The control group is structurally equivalent to the intervention group in contact time, therapeutic processes, and intervention activities (e.g., games, skits). The same facilitators will implement both the CTL and AbsPlus sessions. There will be no sexual skills training in the control group. If the participants bring up sexual situations, the facilitators will not focus on sexual content but, for example, will process role-play scenarios focusing on the anger management aspect of sexual encounters. A random selection of control sessions will be routinely reviewed for adherence to the goals of the project and the manual. In our experience with the sexually-active RCT we have not experienced differential attrition, and participant satisfaction ratings are equivalent between groups.

D.4 Measures

Measures (Table 1) will be used to: (a) describe the sample, and (b) determine effect sizes of the intervention on the proposed predictors of behavior (knowledge, motivation, skills) and on

the behavioral outcomes (abstinence/sexual behaviors, communication with parents and boyfriends, and substance use). We will include both abstinence-related and sexual behavior outcomes because few girls will become sexually active during the pilot 3-month follow up period. All measures will be given via ACASI to all girls at pre, post and 3-month follow up. Based on feedback for similar measures we have used in the past (see Battery of Measures App C), these measures are sensitive to change, easy to administer with adequate comprehension by participants and require no more than a 5th grade reading level; the initial assessment takes approximately 30 minutes to complete.

D.4.1 Descriptive Measures

Appendix C is the battery of measures used for our present RCT with sexually active girls. We plan to modify many of these measures drawing from our focus group, theoretical, and empirical work to be relevant for abstinent girls. We were highly selective in our choice of measures to maximize scientific yield while minimizing burden to participants using measures which map on to the theoretical constructs of the IMB model:

Demographics: Data will be obtained on participant's age, date of birth, housing environment, with whom the participant lives, employment status, socioeconomic status, race/ethnicity, and education.

Sexual History: Although ail participants will have been recruited because they are not sexually active, we will collect information on lifetime sexual and intimate activity (onset, frequency, and number of partners), STI history, condom use, pregnancy history, and contraceptive use to confirm their abstinence pattern. We will include girls who have engaged in oral sex and other non-penetrative intimate behaviors.

D.4.2 Antecedent Variables

Information will be assessed using the *HIV Knowledge Questionnaire (HIVKQ)*.[95] These 45 items elicit "true-false-I don't know" responses. This measure is internally consistent (alpha = .91) and is stable over 2-week (r = .91) and 12-week (r = .90) intervals. Factor analyses with diverse samples indicate the measure contains a single factor. Both content and construct validity for the measure has been assembled.[95]

Motivation to engage in abstinence and safer sex practices[42,96] will be assessed using three measures of attitudes and intentions toward abstinence/preventive acts and subjective norms of what significant others think should be done (behavior-focused motivation).

Social Norms*:* Perception of boyfriend's, parents', and peers' attitudes towards abstinence and risk reduction behaviors will be measured by three 8-item scales. These items will be rated on a scale ranging from 1 = "strongly disagree" to 5 = "strongly agree," with possible total scores on each ranging from 8–40. Sample items include "Your boyfriend(s) think it is OK for teenagers to have sex if they protect themselves by using condoms" and "Your friends think having sex is a

normal part of growing up for teenagers." Cronbach's alpha for this scale in previous work with adolescents was .80 and construct validity has been established.[97]

Condom Attitude Scale: Adolescent version (CAS-A[98]): The CAS-A is a 23-item measure of attitudes toward condoms with six subscales: relationship safety, perceived risk, interpersonal impact, safety, effect of sexual experience; and promiscuity. Responses are in a 7-point Likert format ranging from "strongly disagree" (1) to "strongly agree" (7). Scores on the six subscales are summed to create an overall attitude toward condoms score. This instrument has been used with 14-18 year olds and has an internal consistency of .80 and brief (1 month) test-retest reliability (r = .84); evidence of construct validity has also been established.[98]

D.4.3 Behavioral Skills

Relevant to implementing HIV-preventive and abstinence behaviors will be assessed. We considered direct assessment (i.e., behavioral simulations) but decided against them because (a) indirect measures of this construct have been used by Fisher and Fisher[53,54] and are considered reasonable proxy measures, and (b) an intensive skill assessment would require additional time, reduce privacy, and likely reduce participation rates. Thus, we chose *three* previously tested, self-report measures:

Condom Use Confidence: Five items will rate how confident girls would be using condoms every time they had sex and five items will measure confidence to remain abstinent. Responses to s such as "When you have been using alcohol or drugs" and "When you think your boyfriend will get angry" are rated on a five-point Likert scale ranging from "1 = not at all confident" to "5 = extremely confident." This measure is both reliable (alphas .82 to .87) and valid in studies focusing on condom use.[99]

Perceived Difficulty of Performing AIDS Preventive Behaviors: Seven items will be used to assess perceived difficulty of performing AIDS preventive behaviors. Adapted from items previously published,[100] these 4-point Likert scale items include, for example, "perceived difficulty in discussing safer behaviors with a new partner" and "engaging in alternative safer sexual behaviors with a new partner if a condom is not available." These items are scored "1 = very hard" to "4 = very easy." Cronbach's alpha was .65 in previous work with adolescents[101] and significant associations have been shown between self-reports and independent assessments of behavioral skill enactment.[102]

Sexual Assertiveness: We will use two subscales of the Sexual Assertiveness Scale (SAS)[103] measuring women's assertiveness in refusal and pregnancy/STD prevention in sexual situations. Each subscale consists of six items with answer choices ranging from "disagree strongly" to "agree strongly." Sample items include "I don't have sex if I don't want to, even if my partner wants to" (refusal), and "I (would) insist on using a condom or latex barrier if I want to, even if my partner doesn't like them" (pregnancy/STD prevention). The measure of internal consistency for the total scale was .84, with test-retest correlations of .74-.69 over 6- and 12-month time periods; construct validity has been established.

D.4.4 Outcome Variables

Sexual Risk Behaviors: The frequency of unprotected and protected vaginal, oral, and anal intercourse and other intimate behaviors (e.g., breast touching, genital touching) in the past ***three*** months will be assessed using an open-ended count format. Number, age, and type of intimate partner(s) will also be assessed (i.e., steady vs. nonsteady partner).

Sexual Communication: In three items using open-ended count format girls will be asked if they have (a) talked with a sexual partner about abstaining from sex or lower risk sexual behaviors, (b) talked with a partner about getting tested for HIV, and (c) refused to have sex with a partner. Previous work has indicated that this scale has achieved adequate levels of reliability (.62 to .83).[56]

Substance Use: Previous studies suggest that substance use before sexual activity may increase the likelihood of high-risk sexual behaviors,[104,105] so six items using open-ended count format will be used to determine the number of times participants had used drugs and alcohol (a) during the past month, (b) before dating or intimate activity in the past month and (c) intentionally drank less or used drugs ***less*** before dating or intimate activity during the past month.

Table 1. Measures and Variables

Construct	Content	# Items	Alpha	T1 pre	T2 post	T3 3mo	Prediction
	Demographics, sexual history			X			*
Information	HIV knowledge	45	.89	X	X	X	AbsPlus >CTL
Motivation	Social norms	8	.80	X	X	X	AbsPlus >CTL
	Abstinence/Condom Attitudes Scale	23	.80	X	X	X	AbsPlus >CTL
	Behavioral Intentions	9	.79	X	X	X	AbsPlus >CTL
Skills	Sexual Assertiveness	18	.84	X	X	X	AbsPlus >CTL
	Confidence (abstinence/condom use)	5	.82	X	X	X	AbsPlus >CTL
	Perceived Difficulty	7	.65	X	X	X	AbsPlus <CTL
Behavior	Abstinence/protective behaviors, Communication, substance use	15	N/A	X		X	AbsPlus >CTL

Database Management All records for this study will be kept in locked file cabinets in the office of Dr. Morrison-Beedy The databases will be created using a relational database system and only authorized staff will use these files (Dr. Morrison-Beedy, PC). Codes and identification numbers will be created for each study subject so that confidentiality will be maintained in data entry. ACASI allows direct data entry by the participant to minimize errors. The randomization system will be maintained by the study coordinator and will include subject enrollment data, treatment condition and visit schedules to track patient accrual.

Data Analysis

The primary objective of the study is to estimate intervention effect sizes but we will also explore other influences on outcomes of interest. For the latter, all statistical tests will be two-sided with alpha = 0.05. Baseline data will be analyzed to ensure equivalence of treatment and control groups. Categorical variables will be compared using Chi-square analysis (or Fisher's exact test where feasible). Linear regression models will be used for continuous variables. Potential confounders identified in the comparability analyses will be included in the analytic models described below.

The principal analyses focus on changes from baseline to post-intervention and 3 month follow-up. The main independent variable will be the treatment condition (AbsPlus intervention vs. control condition). Since the group-based longitudinal study design gives rise to two-level clustered data, we will model the data using the generalized estimating equations (GEE) and mixed-effects model approach (MM). For GEE, we will assess the missing completely at random (MCAR) assumption by modeling the missingness of the responses and use weighted generalized estimating equations (WGEE) for inference if MCAR is deemed inappropriate.

We will estimate effect sizes of the intervention by modeling the between group difference over time for each of the primary outcomes (HIV-related knowledge, motivation for engaging in HIV-preventive behaviors and behavioral skills to remain abstinent). To account for different changes over time we will include a time by group interaction. We will use the mode to estimate between-group effect size at post-treatment and 3 month follow-up. Some behavioral outcomes such as substance use typically have an excessive amount of zeros beyond the expected frequency of 0 as modeled by the Poisson distribution. We will use zero-inflated Poisson models to model such count responses. All analyses will be conducted using the latest version of SAS.

Table 2. Proposed Time Table

	Year 1				Year 2			
	0–3	**4–6**	**7–9**	**10–12**	**0–3**	**4–6**	**7–9**	**10–12**
Hiring and training, Focus group recruitment	X							
Focus group data collection and analysis		X						
Materials modification			X					
Phase II recruitment				X	X	X		
Conduct of Intervention & control groups				X	X	X	X	
Analysis and report writing							X	X

We will recruit and conduct one *AbsPlus* or CTL group approximately every 3–4 weeks for a total of 10 groups.

E. HUMAN SUBJECTS RESEARCH

This Human Subjects Research meets the definition of a Phase I clinical trial.

Protection of Human Subjects

1. Risks to the Subjects

Human Subjects Involvement and Characteristics: Participants will be 78 healthy 14–19 year old adolescent females recruited from two youth development sites in Rochester, New York. The NIH Consensus Statement on HIV Prevention[106] identified inner-city health programs that reach disenfranchised high-risk adolescents as a high priority for HIV-risk reduction and prevention research. In-Control is a youth development program with two sites and is affiliated with Planned Parenthood of Rochester and Syracuse Region Inc. These programs provide services such as after school educational support, mentoring, activities and social networking to predominantly impoverished, minority, inner-city youth. Eligibility for the focus groups and pilot intervention will be limited to participants who are: (a) female, (b) 14–19 years of age at the time of enrollment, (c) report never having had vaginal or anal intercourse, (d) not married, and (e) English-speaking. All 14–17 year old participants will be required to provide written informed assent and parental consent prior to enrolling in the study. All 18–19 year old participants will be required to provide written consent.

Sources of Materials: The subjects will be the primary source of information used in this study. They will participate in focus group discussions, which will be taped, or will complete audio-computer assisted self interviews and participate in intervention sessions that will be taped. These data/research materials will be used specifically for research purposes.

Potential Risks: Because of the sensitive nature of the data being collected, a breach in confidentiality concerning study participation or disclosure of confidential patient information represents a primary risk associated with study participation. We will follow required Confidentiality of Records and HIPAA Authorization guidelines. In addition to the potential risks associated with a breach of confidentiality, it is also conceivable that completion of questionnaires or participation in the intervention could cause distress as a result of disclosing sensitive information about sexual behavior, or other private material. This discomfort is expected to be relatively minimal as they will have been informed of the types of questions that they will be asked to answer and will have the option of refusing to answer specific questions that they feel are too personal. Girls who do not want their intervention sessions taped will still be allowed to participate in the study. Our experience with similar studies with adolescent girls was that when we clearly explain why the sessions are being taped, that participants can use fictitious names, and that we would protect their identities during tape review, analysis, and write-ups, their fears were allayed and none have refused to be taped.

2. Adequacy of Protection Against Risks

Recruitment and Informed Consent: Trained assessors will work in collaboration with the PI and PC to recruit clients at the youth development sites. Recruitment will rely on study advertisements posted at the youth development sites, word of mouth, PPRSR contacts who do not qualify for the sexually active RCT underway, and active outreach by the assessors. All English-speaking girls ages 15–19 who attend the youth development sites will serve as the recruitment pool. An Assessor will speak with clients after they have registered for youth service activities. Adolescents who express interest in the study will be screened briefly to determine if they meet the initial criteria of being ages 14–19 and unmarried. If eligible and interested, each girl will meet individually with an Assessor in a private area to be screened for full study inclusion criteria. If she meets the inclusion criteria the assessor will then review the details of the study verbally and in writing; the assent/consent form will be presented and discussed. After all potential participant's questions have been answered, and if the client remains interested, she will be asked to read and sign the assent/consent. The assent/consent form will explain the study, potential risks, expected benefits, and manner in which confidentiality will be maintained; the assent/consent form offers assurances that participants can terminate participation at any time without penalty. Girls who are 18 and 19 years old will complete the informed consent form. For girls younger than 18, informed assent will be obtained and informed consent will be requested from a parent or guardian. Underage participants will receive a copy of the parental study consent and a stamped and addressed envelope to give to their parents. We will contact a parent by phone within one week of assent to review study procedures and request that the signed consent be mailed to us. It is our experience that many of these parents do not have the time or means to come in for a consent visit yet do not want their girls to miss out on such opportunities.

Protection Against Risk:

Confidentiality. The following steps will be taken to insure that all client data remain confidential and have been used successfully in our prior work with adolescent and adult women.

(a) ***Use of numeric identifiers:*** To ensure confidentiality, study questionnaires and tapes and electronically stored data will be identified only by a numeric participant ID number. Client names will ***not*** be stored with study data. The master list linking the client ID number to the client's identifying information will be maintained in a separate, locked filing cabinet in PI's locked office, and will be destroyed at the conclusion of the study. Likewise, signed consent forms will be kept in a separate, locked filing cabinet, and will only be accessible to the project investigators and the full time project coordinator. We will follow mandated HIPAA requirements.

(b) ***Data storage***: As noted, no identifying information will be stored with our questionnaire forms or within the questionnaire data base. Further, all focus group or questionnaire data will be kept in locked file cabinets within locked offices that are accessible only to the project investigators and PC. Access to the electronic data will be restricted to project investigators, PC and data entry staff. Databases will be password protected to guard again unauthorized access.

(c) ***Staff training***: All project staff will receive extensive training and supervision regarding the importance of maintaining client confidentiality and protection of human subjects. This training will be overseen by Dr. Morrison-Beedy, a licensed women's health Nurse Practitioner with more than 20 years of clinical and research training and experience in OB/GYN nursing, including HIV and STD counseling; and by Dr. Carey, a licensed clinical psychologist with 15 years of postdoctoral experience in sexual health. Training will emphasize mastery of study procedures established to maintain strict client confidentiality, including procedures outlined above for separating data forms from identifying information. Training will also emphasize that discussion or disclosure of ***any*** information obtained from research participants during the course of questionnaire administration is strictly prohibited. Thus, prior to having any direct contact with research participants, all Assessors will receive extensive training in recruitment and assessment procedures, and will participate in a series of training sessions designed to increase awareness of the importance of client confidentiality and the need for clinical sensitivity in working with adolescent females. All Assessors will be required to demonstrate competence with regard to the study protocol by participating in mock recruitment and assessment sessions with Dr. Morrison-Beedy. All project staff will also, complete formal training in research ethics, as required by the University of Rochester and Syracuse University. This training will be documented, and renewed annually.

(d) ***Handling of published data and reports***: Published data derived from this study will consist of statistical analyses collapsed across participants. Under no circumstances will data from individual participants be identifiable in reports or published manuscripts.

Minimizing the Risk of Adverse Effects to the Subjects

Several steps will be taken to minimize the likelihood of adverse reactions to study participation. First, our consent forms will describe clearly the types of questions that will be asked of participants, and the nature of the focus or intervention groups. Thus, individuals who are uncomfortable with participation in sexual health research will likely choose not to participate in the study. Second, although some may experience some distress when answering sensitive questions or participating in an intervention group, we anticipate that many participants will experience benefits from completing questionnaires and participating in a supportive group intervention. Finally, we plan to provide printed information to all participants concerning referral sources for mental health counseling and specific HIV- and STD-related community services. In the unlikely event that a participant experiences a high degree of distress during the course of participating in the study, research team members and other staff will be instructed to immediately inform a treatment provider available on a 24 hour hotline at PPRSR and contact the study PI. Because PPRSR already has an existing protocol in place for initiating referrals this protocol will be maintained for the current study. That is, a judgment will be rendered by the attending physician or nurse practitioner as to the need for on-site psychiatric, psychological, or social work consultation. If such a consultation is needed, the clinic staff will provide information on an "as-needed" basis the attending physician or nurse practitioner as to the need for on-site psychiatric, psychological, or social work consultation. If such a consultation is needed, the clinic staff will

provide information on an "as-needed" basis about specific symptoms experienced by the client. However, clinic staff members will not provide specific information to a mental health provider about study involvement nor about a participant's responses to individual questionnaire items. Referral information for mental health services will also be provided to participants who express interest in such information, but who are judged not to be in need of immediate mental health services.

3. Potential Benefits of the Proposed Research to the Subjects and Others

We expect that the overall cost/benefit ratio to be quite favorable for participants. Our previous experience in conducting survey and intervention work with this population suggests that most participants find the experience to be rewarding as well as enjoyable. All participants will have the opportunity to learn from a close examination of their own health-related behaviors in the context of completing the assessments. Further, those participating in the AbsPlus and control interventions may experience tangible benefits in terms of knowledge gained and reduced risk behavior. The costs associated with participating in this research will be minimized through our use of clearly written consent procedures and our close attention to the need to maintain strict confidentiality.

4. Importance of the Knowledge to be Gained

The larger benefits of this research are that it will help us to develop and refine effective interventions to maintain abstinence and reduce HIV risk in adolescent girls ages 14–19 who are not presently sexually active. We believe that such interventions can reduce the potential future risk of HIV infection in this population.

Inclusion of Women and Minorities

Inclusion of Women. Study participation will be restricted to females. Interventions specifically targeted to and tailored for adolescent females are needed. Such gender-specific and developmentally-tailored interventions need to address the increased biological and psychosocial vulnerability of these persons. As described in the Background and Significance section, there have been very few programs developed specifically for adolescent girls despite their increased vulnerability (relative to adult females, and adolescent and adult males) to infection with HIV and other STDs. Rochester ranks 4th nationwide in gonorrhea rates per 100,000 population and girls ages 15–19 years also have one of the highest rates of gonorrhea and chlamydia in the nation exceeding comparable values in the US by 111 %.[107,108] Last year PPRSR provided services to over 1500 girls ages 15–19 at the Rochester site and In-Control provided youth development services for more than 300 adolescent girls; these numbers reflect total individual clients and are not duplicate client visits. We estimate based on number of abstinent girls who have not qualified for our sexually active RCT (N = 150) and approximately one-third of In-Control clients meeting abstinent criteria that we will have sufficient numbers to recruit for this feasibility study; these numbers do not include those girls that may be recruited by word-of-mouth and poster recruitment.

Inclusion of Minorities. The clientele at the PPRSR includes a significant percentage of minority adolescents; data from the most recent service year (2000) indicates that over one-third of adolescent female clients at the Rochester site are African-American and 8% are other minorities. Clients utilizing In-Control are almost all African American or Hispanic with the majority being economically disadvantaged or impoverished. Overall, based on these data, we anticipate approximately 70–75% of our participants will be racial or ethnic minorities. These numbers reflect a much larger percentage of minorities than the general populations of either of these cities yet represent the current trend in HIV infection rates. Previous work has helped us develop racially/ethnically sensitive recruitment materials to facilitate involvement of minorities. In our present work we have successfully recruited minority participants at rates far higher than the region's racial demographics. Our staff is racially diverse and we are keenly aware of the importance of working within the community and hiring and training racially diverse facilitators and Assessors.

Targeted/Planned Enrollment Table

Study Title: Maintaining Abstinence and Reducing HIV Risk in Adolescent Girls

Total Planned Enrollment: 78

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	8	0	8
Not Hispanic or Latino	70	0	70
Ethnic Category: Total of All Subjects*	78	0	78
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	2	0	2
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	56	0	56
White	20	0	20
Racial Categories: Total of All Subjects*	78	0	78

*The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories; Total of All Subjects."

Inclusion of Children. All of our participants will be between the ages of 14–19 at the time of study recruitment and enrollment. Thus, we will be including children, as defined on page 25 of the USHHS PHS 398 grant application instructions, in the proposed research. The majority of clients at In-Control as well as PPRSR are adolescent and young women who will meet the age criteria established for this study. The participants will be required to give written assent

(ages 14–17) or consent (ages 18–19) for the study (described in more detail below). We will also require parental consent for girls ages 14–17 and provide those ages 18–19 with a copy of the consent to take home to their parents should they decide to do so. These consents review study procedures, benefits, risks, and how confidentiality is maintained. We will strongly encourage each 18–19 year old participant to provide these forms to their parent(s) or guardians.

We will not include adults aged 20 and older in the proposed research. The rationale for this exclusion is the need to develop and evaluate HIV-risk reduction programs that are developmentally sensitive and appropriate to the needs of adolescents, as described in the Background and Significance section of this application. This age group faces an ever-increasing risk for HIV yet few gender specific community interventions have been developed for girls and none for sexually abstinent girls. Dr. Morrison-Beedy has extensive clinical experience working with this age group as a nurse practitioner, HIV counselor, and PI on an adolescent intervention. Dr. Carey, a licensed clinical psychologist, also has extensive experience in the area of HIV prevention in female adolescents. Research team members will be provided with extensive training in preparation for working with this age group.

Data and Safety Monitoring Plan

In accordance with the National Institutes' of Health requirement, the oversight and monitoring of this study to ensure the safety of participants and the validity and integrity of the data will occur through the establishment of a Data and Safety Monitoring Plan (DSMP). Although a DSMP and Board required at the level of a Phase III trial would not be required for this feasibility pilot Phase I study, we plan to utilize the DSMB in place for our sexually active RCT (NR 008194) and to follow the general protocol we have established because we are working with a vulnerable population.

Membership

The Data and Safety Monitoring Board (DSMB) will be comprised of three (3) voting members who will be selected by the PIs. In turn, these members will be reviewed and approved by the NIH Project Officer. The members will be chosen based upon their knowledge of clinical trial methodology and their clinical or research-related experience. They may be from within or outside of the institution but a majority will not be affiliated with the institution; they should also have an absence of other conflicts of interest. They should view themselves as representing the interest of the participants, not the institution. They will be appointed for the life of the project. The Chair of the DSMB will be selected from among the DSMB members. The NIH Project Officer will serve as an ex-officio member of the DSMB.

Responsibilities of the DSMB Members

1. Maintain confidentiality of the data and the results of the monitoring.
2. Review the research protocol and plans for data and safety monitoring.

3. Review on a yearly basis and as needed basis the quality of outcome data at all sites; participant recruitment, randomization and retention; risk versus benefit ratio for participants including unanticipated adverse effects; and other factors that may affect outcome.
4. Determine whether the trial should continue as designed, should be changed, or should be terminated based on the data and make recommendations to the NIH, Institutional Review Boards at each site, and site investigators considering conclusion or continuation of the study.
5. Monitor reports of related studies to determine whether the current study needs to be changed or terminated.
6. Following DSMB meetings, provide appropriate NÍH staff and the PIs with written information concerning their findings.
7. Submit summary reports of discussions regarding unexpected adverse effects or unanticipated problems involving risks to participants or others. These reports should include a review of data and outcomes across all sites, summary of the review of these events, and any recommendations for modification of the study protocol.
8. Oversee that reports are relayed to the IRB and to the Office of Human Research Protections (OHRP).
9. Review proposed modifications to the study prior to their implementation.

Reporting Adverse Events

All project personnel will be trained to immediately report any adverse events to the PI and determine the appropriate manner in which to proceed. A written report will be submitted describing the adverse event within 72 hours to the DSMB and PIs as well as the university IRB and NIH project officer. Potential adverse events that could occur as a result of study participation include: (1) adverse psychological reactions such as feeling upset, embarrassed, or uncomfortable responding to any assessment questions or participation in the intervention group sessions; and (2) loss of confidentiality related to self-reports regarding sexual or substance use behaviors. The study statistician will also conduct preliminary analyses every 6 months to determine if any adverse (or statistically positive) results are occurring within the study groups and will report such findings to the PIs.

Meetings

DSMB meetings will be held annually (or more often if needed) starting Year 1 of the study. The Chair of the DSMB or the PIs can call a meeting as needed. Serious adverse events will be reported to the Chair of the DSMB as soon as they occur. The Chair of the DSMB will determine whether an in-person meeting or teleconference is needed. Prior to the meetings, a written report containing any outcome data will be sent to DSMB members by the statistician. Each meeting will be divided into three parts. First, there will be an open session in which the PIs and co-investigators may be present to review the conduct of the study and to answer questions from members of the DSMB. Outcome results from the study cannot be discussed during this session. Next, a closed session involving the DSMB members and the study statistician will be

held during which outcome results will be discussed. Third, a final session involving only the DSMB members will be held to allow DSMB members to discuss the conduct of the study and outcome results. This includes any serious and unexpected adverse events, as well as unanticipated risks to participants or others, to the local IRB and DSMB members, to develop recommendations, and to vote as necessary. These adverse effects may be identified through the close monitoring of participants or assessed through statistical comparisons between groups.

Recommendations

The DSMB recommendations will be given to the PIs with a copy given to the NIH Project Officer. If the DSMB recommends a change to the study or that the study be closed, the PIs will act as quickly as possible upon those recommendations. If the PIs do not agree with the DSMB, the NIH Project Officer will be notified of the reason for disagreement and all parties will reach a mutually acceptable decision. Confidentiality must be maintained throughout this process unless relevant data need to be shared to facilitate reaching **a** mutually acceptable decision.

Release of Outcome Data

Outcome data will not be released to individuals outside of the DSMB. Each member of the DSMB will sign a statement of confidentiality.

Conflict of Interest

Members of the DSMB will disclose any potential conflicts of interest, either pre-existing or those that develop during their tenure, to the PIs and the NIH Project Officer.

F. VERTEBRATE ANIMALS

There are no vertebrate animals involved in the proposed research.

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A Pilot Study of a Strength and Balance Training Program for Persons With Oxaliplatin Induced Peripheral Neuropathy

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Grant #: No Number

Funding Source: Oncology Nursing Society Foundation 2012 Small Grants Program

INNOVATION

There is a dire need for interventions to support cancer survivors dealing with the long-term sequelae of cancer treatments and effective treatments for chemotherapy induced peripheral neuropathy are virtually non-existent. While taxane induced neuropathies gradually improve after completion of chemotherapy, oxaliplatin induced neuropathies may be more persistent, leading to long-term disabilities and emotional distress. The proposed study is innovative because it focuses on a unique but large and growing population of patients who may feel guilty for acknowledging problems with neuropathy, when they get the message that "it is something they are going to have to live with" and "they should feel lucky to be alive," as colorectal cancer survivors in our previous studies have described. Delivering an exercise intervention to this specific group of patients, colorectal cancer survivors with oxaliplatin induced peripheral neuropathy is also an innovative approach because the vast majority of studies of oxaliplatin induced peripheral neuropathy have evaluated pharmacological interventions such as calcium and magnesium infusions for prevention of neuropathy but few have focused on treatment using non-pharmacological interventions like strength and balance training or alleviating symptoms of neuropathy once they have occurred.

BACKGROUND AND SPECIFIC AIMS

In a single-group pilot study we will test the feasibility, tolerability and determine the effect size of a 12 week, bi-weekly strength and balance training program among 20 colorectal cancer survivors with oxaliplatin induced peripheral neuropathy. The risk of mortality from colorectal cancer has declined over the last twenty years because of early detection and new treatment alternatives like oxaliplatin.[1] Oxaliplatin was approved for first-line adjuvant

treatment of stage III colorectal cancer in 2004[2] and is now considered the standard of care for persons with colorectal cancer for whom chemotherapy is recommended.[3,4] Peripheral neuropathy is a common, dose-limiting side effect of oxaliplatin that can persist for years following completion of oxaliplatin-based chemotherapy.[2,5,6] At least 48% of patients who receive oxaliplatin develop peripheral neuropathy during treatment,[7] or soon after cessation of treatment, known as "coasting."[8,9] and approximately 20% of patients will develop irreversible peripheral neuropathy[5,10] Peripheral neuropathy interferes with every aspect of daily living,[11–13] leads to impaired gait and balance, and increases the risk for falls and injuries, resulting in significant morbidity.[14] Physical activity, specifically strength and balance training, may improve balance and decrease neuropathic symptoms. Strength and balance training increases blood supply to nerves and muscles of the lower extremities and strengthens the muscles involved in maintaining balance. Animal studies of structured exercise demonstrated the generation and production of new nerve cells potentially reversing neuropathy.[15,16]

There are currently no evidence-based interventions for chemotherapy-induced peripheral neuropathy (CIPN).[17] Non-pharmacologic interventions for oxaliplatin-induced peripheral neuropathy are rare despite the common use of oxaliplatin and more prolonged or permanent neuropathies that result. Application of data from elderly patients and those with diabetic neuropathy suggest that referrals to physical therapy can improve strength and balance.[16,18–22] However, randomized, controlled trials of specific interventions designed to increase strength and improve balance in individuals affected by CIPN are sorely needed. Therefore the purpose of this study is to evaluate the effects of a 12-week strength and balance training program in persons with oxaliplatin-induced peripheral neuropathy with the following specific aims:

Specific Aim 1: To evaluate the feasibility and tolerability of a 12-week strength and balance training program among colorectal cancer survivors with oxaliplatin induced peripheral neuropathy.

Specific Aim 2: To determine the level and magnitude (i.e. effect size) of a 12-week strength and balance training program on (a) strength (measured using isokinetic dynamometry) (b) balance (Modified Clinical Test for Sensory Interaction in Balance, Berg Balance test, Timed Up and Go, unipedal stance time) and (c) peripheral neuropathy (Chemotherapy Induced Peripheral Neuropathy Assessment Tool and Modified Total Neuropathy Score-short form).

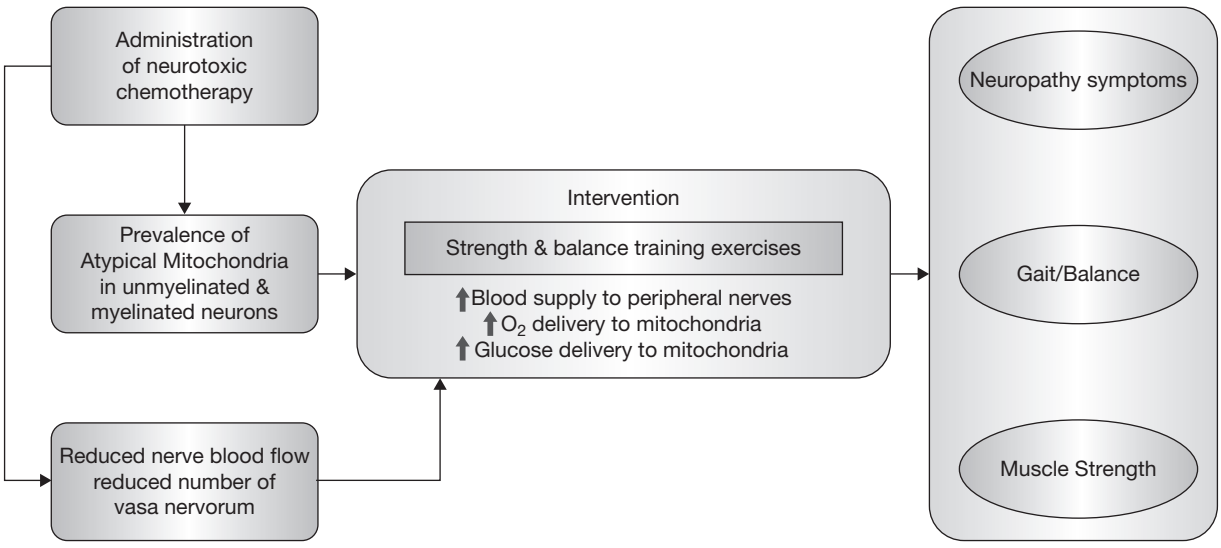
SIGNIFICANCE

CIPN poses significant risk for falls and injury: Peripheral neuropathy is a major risk factor associated with falls in the elderly, diabetics, and persons receiving neurotoxic chemotherapy such as oxaliplatin.[21,23–25] Reduced lower extremity muscle strength, impaired position sense, and diminished sensation and motor changes may all contribute to increased risk of falls in persons with peripheral neuropathy.[24] Occurrence of falls in persons with peripheral

neuropathy may be as high as 39%.[26] Increased age and polypharmacy are additional risk factors for falls commonly seen in patients undergoing neurotoxic chemotherapy that may further increase their risk of falls. **Evidence supports strength and balance training for neuropathy.** Studies involving diabetics and others with various types of neuropathy, have demonstrated consistent improvements in balance, strength, and fear of falling.[27–31] Improvement in balance measures of balance (unipedal stance time, functional reach, tandem stance time) have been demonstrated in as little as 3 weeks.[30] **This study addresses two important ONS Research Priorities, neuropathy and functional impairment.**[32] Oncology nursing needs evidence-based interventions that can be recommend to patients to ameliorate the neurotoxic side-effects of cancer treatments. The proposed study will provide ***the first*** data to test the feasibility, tolerability and efficacy of strength and balance training for CIPN, and will lay the foundation for a large-scale clinical trial.

THEORETICAL FRAMEWORK

A modified conceptual model, originally developed by Dr. Visovsky, depicts the relationships between neurotoxic chemotherapy and nervous system damage that can be ameliorated through a strength and balance training program. Neurotoxic chemotherapeutic agents induce sensory and motor neuropathy by inducing mitochondrial and vascular dysfunction.[33–36] These metabolic and vascular dysfunctions lead to sensory loss and reduced muscle strength, functions that depend upon cellular mitochondria to generate energy. Strength and balance training may increase the supply of blood, oxygen, and glucose to mitochondria, allowing the mitochondria to function produce energy in a more efficient manner.[37,38] Increasing mitochondrial energy production and blood flow to peripheral nerves may result in fewer neuropathic symptoms, increased strength and better balance.



LITERATURE REVIEW

A great deal of literature exists to support the use of exercise to improve strength and balance in older adults with postural instability or high risk for falls and a growing body of literature indicates that persons with peripheral neuropathy also may benefit.[19,27–29,39–46] strength and balance training exercises can easily be provided by a physical therapist and there is a great deal of data that supports physical therapist led exercise interventions that include specific exercises to strengthen the lower extremities and improve balance.[19,27–29,39–46] Participation in exercise programs focused on improving lower extremity strength and balance has been repeatedly demonstrated as safe, even among people with a very high risk of falls.[40–42]

There is a great need for additional research exploring the benefits and limitations of strength and balance training in oncology populations. The studies in our review indicate that while patients may be more likely to adhere to a home based strength and balance training program, supervised programs may offer better results, probably because of the inherent challenges of monitoring adherence in a home setting.[41] Thus, we elected a supervised program for this study. The amount of exercise (dose) needed to achieve the desired improvements in strength and balance and reduction in falls has not been determined. Previous studies of strength and balance interventions show variation in duration (10–60 min),[31,47] frequency (twice a day to twice a week[29,45,48,49] and length (3 weeks–12 months).[30,42,50] Therefore, even though strength and balance training exercises can be recommended, the optimal frequency and duration with which they should be prescribed is not known. Exercise programs that include strength and balance training increase physical performance, independence and have positive effects on health related quality of life.

Our bi-weekly, one-hour, 12-week long intervention was chosen based upon the reviewed literature and in consultation with Meredith Wampler, DPTSc, PT and Kerry Courneya, PhD, experts in cancer-exercise behavior and consultants on this pilot study. We chose the conservative approach of 5 participants per 1 physical therapist previously demonstrated by researchers at the Patient Safety Center, James A. Haley VA Hospital as safe for community dwelling older adults at risk for falls.[31] Although not the primary goal of this study, we will evaluate results over time in order to determine the minimum dose requirements needed to achieve a significant effect. As a secondary outcome of this study, we will also evaluate effects of our intervention on common neuropathic symptoms such as pain and numbness (both measured with the CIPNAT) and functional status, an important indicator or health related quality of life in persons with cancer. This proposed study addresses an important issue in cancer survivorship, chemotherapy-induced peripheral neuropathy, uses an innovative approach to the treatment and assessment of neuropathic parameters and may provide critical information concerning dose of strength and balance training needed for future interventions.

PRELIMINARY FINDINGS

Dr. Tofthagen and Dr. Visovsky have both published numerous studies on chemotherapy induced peripheral neuropathy.[14,17,51–61] Dr. visovsky was Dr. Tofthagen's mentor on an ONS research

fellowship that is now nearing completion.[56] Dr. Tofthagen recently completed data collection for a descriptive study evaluating relationships between CIPN, quality of life, depression, and sleep in colorectal cancer survivors.[62] Preliminary data from the 111 participants demonstrated that colon cancer survivors continue to have significant problems with numbness and tingling in the feet (n = 78, 70.3%), leg weakness (n = 49, 44.1%) and loss of balance (n = 48, 43.2%) for many years post-treatment. Participants reported moderate severity of numbness/tingling (mean of 6.2 on a 0–10 scale), muscle weakness (mean of 5.0 on a 0–10 scale) and loss of balance (mean 4.3 on a 0–10 scale). Higher CIPN symptom scores were significantly correlated with depressive symptoms ($r = .38$, $p<.001$) and sleep disturbance ($r = .35$, $p<.001$) and negatively correlated with physical functioning ($r = .21$, $p = .037$).

METHODS AND DESIGN

Design: A single-group longitudinal design will be used for this pilot study. While a traditional RCT is the preferred design, this study represents a first step in testing the feasibility, tolerability and effect size and a single group design will achieve these aims at a lower cost while having adequate power to guide future studies.

Sample and Setting: 20 colorectal cancer survivors who screen positive for oxaliplatin-induced peripheral neuropathy, previously treated at Moffitt Cancer Center, who live within driving distance of the University of South Florida will be recruited for this study.

Inclusion and Exclusion Criteria: Participants must meet the following criteria to enroll in the study: 1) Prior history of colorectal cancer 2) completed oxaliplatin-based chemotherapy at least 6 months prior to enrollment (to account for coasting effect) 3) Numbness, tingling, or pain of the lower extremities 4 by CIPN Visual Analog Rating (Appendix A). 4) Karnofsky performance status of at least 60% (5) Able to read, write, and understand English. Patients will be excluded from the study if they are currently undergoing chemotherapy or radiation therapy, or if they regularly (at least once a week) participate in strength or balance training exercises.

Experimental Variables and Instruments: The following outcomes will be evaluated upon enrollment in the study (T1), after 4 weeks (T2) of strength and balance training, 8 weeks of the strength and balance training (T3) and upon completion of the 12-week strength and balance training intervention (T4). 1) ***Feasibility*** To evaluate feasibility, the percentage of patients screened to percentage enrolled in the study and the percentage enrolled to percentage who complete the study will be calculated. The number of sessions attended will also be recorded. Subjects who do not complete the study will be contacted to determine the cause for drop-out, and be considered in the final analysis. At the 12-week data collection point, open-ended questions will be asked about satisfaction with the program in order to refine the intervention; 2) ***Tolerability*** To evaluate tolerability, at each session, data regarding reasons for inability to complete the session will be recorded. Side effects of the strength and balance intervention will also be collected. The level of exercise performed at each session will be collected (too easy,

just right, too challenging). 3) ***Treatment effect size*** will be evaluated by means of changes in a) lower extremity muscle strength, b) balance, and c) neuropathy from the beginning to completion of the study. Outcome measures of lower extremity muscle strength, balance, and peripheral neuropathy will be assessed at 4 time points: Prior to the intervention (baseline, T1), four weeks (T2), eight weeks (T3), and twelve weeks (T4; end of intervention) into the intervention. These data collection points were chosen based upon reviewed literature and expected physiologic changes in the outcome variables over time.

a. **Lower Extremity Muscle Strength**
Isokinetic dynamometry (Biodex 3.0)[63] Hip flexors, hip abductors, and ankle dorsiflexors will be tested. A composite strength score for the lower extremity will be calculated by adding together strength values for hip flexion, hip abduction, and ankle dorsiflexion for each extremity.

b. ***Balance*** Four measures of balance will be assessed at T1, T2, T3, and T4. In addition, unipedal stance time and the Timed Up and Go will be assessed on a weekly basis. All of these measures have been validated for use in persons with postural instability.

i. ***Unipedal Stance Time*** Participants will be asked to stand on one foot for as long as they can. The longest of three tries will be recorded.

ii. ***Timed Up and Go*** The Timed Up and Go is a well validated measure of performance status, balance, and fall risk.[64,65] The test begins with the participant sitting in a chair with arms with the subject's back should resting on the back of the chair. A piece of tape will be placed on the floor 3 meters away from the chair so that it is easily seen. Each participant will be prompted to stand up, walk to the line on the floor, turn around and walk back to the chair and sit back down, walking at their regular pace. Participants will be given a practice trial that is not timed before testing. They will be given three trials and the times will be averaged for their final score. Scores under 10 seconds indicate good balance and physical function and low fall risk. A score of greater than 14 seconds indicated a high risk of falls.

iii. ***Modified Clinical Test for Sensory Interaction in Balance (mCTSIB).*** The mCTSIB consists of four balance activities performed in an upright position.[66] The activities are 1) firm surface with eyes open 2) firm surface with eyes closed 3) foam surface with eyes open 4) foam surface with eyes closed. The time participants are able to maintain their balance (up to 30 seconds) in each condition is recorded. Lower scores indicate decreased balance.

iv. ***Berg Balance Test.*** The Berg Balance Scale (Appendix B) is a widely used measure of balance consisting of 14 balance activities.[67] It takes approximately 15 minutes to complete. All items are scored on a 5 point scale from 0–4 with a maximum total score of 56. Lower scores indicate decreased balance. Scores from 0–20 indicate a high risk of falls.

c. ***Neuropathy***

i. ***Chemotherapy Induced Peripheral Neuropathy Assessment Tool:*** Neuropathic symptoms, functional status will be measured using the Chemotherapy Induced Peripheral Neuropathy Assessment Tool (CIPNAT) (Appendix C).[54] The CIPNAT is a fifty-item instrument that contains two sets of items; symptom experience items

and interference items. The 36 symptom experience items measure severity, distress, and frequency of nine neuropathic symptoms. The symptom experience item set is scored by adding the number of symptoms reported with the severity, distress, and frequency scores for each reported symptom. Scores range from 0–279 with higher scores corresponding with higher levels of CIPN. The 14 interference items assess neuropathic interference with usual activities (functional status). A scale of 0 (not at all interfering) to 10 (completely interfering) is used. Scores on the interference item set are calculated by adding scores and range from 0–140. Higher scores on the interference item set correspond with greater neuropathic interference with usual activities (poorer functional status). Correlations with a measure of the same or similar concept ($r = .83$, $p<.001$) and differences between contrasting groups ($t = 7.66$, $p<.001$) provided evidence of construct validity. High test-retest correlations ($r = .921$, $p<.001$) and Cronbach's alpha (alpha = .927) provided evidence of reliability.

ii. ***Modified Total Neuropathy Score-short form*** In addition to the CIPNAT, a self-report measure, neuropathy will be clinically evaluated using a modified version of the Total Neuropathy Score (TNSr).[68] The TNSr grades symptom extension, pin sensibility, vibratory sensibility, strength, and deep tendon reflexes on scales of 0 (normal) to 4 (severe neuropathy). The TNSr has demonstrated reliability and validity for use in CIPN and registered nurses or nurse practitioners can be trained to use it.[69] See Appendix D for detailed scoring and Appendix E for detailed instructions.

Data Collection Schedule and Procedures: IRB approval has already been obtained from The University of South Florida IRB. Contact information for patients who completed oxaliplatin-based chemotherapy from 2002–2011 will be obtained from the Moffitt Cancer Center Cancer Data Registry. Potential participants will be sent postcards asking them to contact the primary investigator if they have numbness or tingling in the lower extremities and wish to participate in a strength and balance training study. The purpose, benefits, and risks of participation, as well as study requirements will be explained in detail by the PI over the phone and time will be allotted to answer any questions or concerns that arise. The PI will use a commonly used visual analog scale (see Appendix A) to screen for the presence of CIPN. Eligible participants will be asked to obtain written permission from the oncologist to engage in the strength and balance program. Informed consent will be obtained at the first meeting at which the intervention will be conducted at the USF School of Physical Therapy and Rehabilitation Science, located in close proximity to the Cancer Center. At that time, a demographic questionnaire including age, gender, race/ethnicity, income, education, marital status, income, years of formal education, employment status, current medications and treatments used to control neuropathic symptoms will be obtained. Participants will each be paid $240 for completing the study and prorated at $10 per intervention visit, for those who do not complete the study.

Intervention: The strength and balance training intervention was designed by the PI in collaboration with Meredith Wampler, DPTSc, Kerry Courneya, PhD, and Constance Visovsky, PhD, RN. This exercise intervention is designed to target the systems involved with balance and postural control that may be impaired secondary to CIPN (i.e., somatosensory,

vestibular, visual, and motor). The balance exercises are designed to vary the sensory information (static and dynamic tasks with eyes open/closed for visual system), head steady or with head turns (vestibular), on firm surface/on foam (somatosensory). Balance will be challenged by varying the base of support. Potential motor neuropathy is addressed by adding a strengthening component to the intervention. As muscle strength and power are associated with falls[70,71] we have included both slow and fast performing exercises to address this issue. Finally, stretching was included to address range of motion limitations that may affect balance and postural stability. A total of 4 groups consisting of 5 patients/group (n = 20) will be established to allow close supervision by the intervention physical therapist and to provide schedule flexibility. Each group of 5 colorectal cancer survivors will meet twice weekly for a one hour session.

STRENGTH AND BALANCE INTERVENTION PROTOCOL

Exercises and Instructions
Balance Each balance exercise will be performed up to 30 seconds for 2–3 trials, holding onto a chair for support. Instructions will be given to remain steady for up to 30 seconds. Once safely completed, progression to the next level of difficulty (Beginner **(B)**→Intermediate **(I)**→Advanced(**A**)).
#1 Static Standing. **B**: With *feet together, eyes open* and arms at sides or across chest, look straight ahead at stationary object.[a,b]
#2 Standing Partial Tandem. **B:** Stand with right foot partially in front of the left, eyes open and arms at side or across chest. Look straight ahead at a stationary object. Repeat with left foot in front.[a,b]
#3 Standing Heel to Toe. **B:** With *right foot directly in front of left foot, eyes open,* arms at side or across chest. Look straight ahead at stationary object. Repeat with left foot in front.[a,b]
#4 Standing with Head Turns. **B:** Stand with *feet apart*. Focus on a stationary object in from to you. Move head slowly up and down, then side to side, then diagonally. Repeat moving head quickly. **I:** Repeat with *feet together.* **A:** Repeat with *feet partial heel to toe.*
5 Single Leg Stance. **B:** While *standing on firm surface holding onto support*, lift right leg up while maintaining balance over single leg. Repeat on the left leg. **I:** *Repeat without using support.* **A:** Repeat while *standing on foam* with support, then without support.
#6 Marching in Place. **B:** March in place slowly lifting knees toward ceiling *holding onto chair.* **I:** Repeat *without chair support.*[b]
#7 Turning in Place. **B:** Standing on *firm surface*, lead with head and turn slowly making quarter turns, then half turns, then full turns. Repeat quickly.[b]
Strength Theraband Exercises Participants will perform 2 sets of 10 repetitions of each exercise, the first at a slow pace and the second at a fast pace. All participants will begin with yellow Theraband (the easiest resistance) and the 'beginner' level of the exercise. Once they are able to perform 2 sets of 10 repetitions, they will be instructed to progress to the next higher level of resistance (yellow→red→green→blue). Once they can perform 2 sets of 10 repetitions with the blue Theraband, then they will be instructed to perform the next level of difficulty of the exercise (beginner (B)→intermediate (I)→advanced(A))

#1 Hip Abduction. **B:** Lie on side with knees bent, Tie Theraband around thighs just above knees. Raise top leg, keeping knee bent. Repeat on opposite side. **I:** Lie on side, tie Theraband around ankles. Raise top leg keeping knee straight. Repeat on opposite side. **A:** Tie Theraband in a loop around chair leg. Insert foot into loop. Raise leg out to the side (hip abduction). Repeat on opposite side.
#2 Leg Press. **B-A:** Lie down on back, and bend knee towards chest to loop Theraband around one foot. Hold onto each end of the Theraband while pushing the knee straight. Return to starting position.
#3 Leg curl. **B-A:** Anchor the Theraband to the leg of the chair. Stand facing the chair and put the loop around your right ankle. Bend same knee forward toward buttock. Repeat with the left leg.
#4 Resisted Ankle Dorsiflexion. **B-A:** Sit in a chair. Tie Theraband tightly around both feet. Move both feet upward and outward.
#5 Resisted Ankle Plantarflexion. **B:** Sit in a chair. Loop Theraband around ball of foot of straight leg. Hold onto the ends with your hands. Leg straight, point toes downward. **I:** Using support, gently rise up on toes and rock back on heels. **A:** Without support, gently rise up on toes and rock back on heels.
Stretches Participants will be instructed to hold each stretch for 10–15 seconds and repeat x 2 trials for each stretch. Stretches will be performed for both right and left side. Stretches will not be progressed during the 12-week intervention.
#1 Seated Hamstring. From sitting position, place right heel on a stool or foam pad and lean forward leading with your chest (keep back straight) until a stretch is felt in back of thigh.
#2 Standing Quadriceps. Supporting yourself with one hand on chair, standing on right leg, pull left heel toward buttock until stretch is felt in front of thigh.
#3 Gastroc Stretch. Facing a wall, stand with right foot back, leg straight, forward leg bent. Keeping heel on floor, turn slightly out, lean into wall until stretch is felt in calf.
#4 Soleus Stretch. Facing a wall, stand with right foot back, both knees bent. Keeping heel on floor. Turned slightly out, lean into wall until stretch is felt in lower calf.
Functional Balance Activities To be initiated in week 9. All participants will be individually guarded by the exercise leader during the task. Other participants will be performing their stretches as they wait for their turn to practice the functional activities.
#1 Functional Activity **B:** While standing, step forward with the right foot. Slowly shift weight forward over right leg then shift weight back to left foot. Repeat this 10 times and then perform with the left leg in front. **I:** Place feet closer together than normal stance width and walk while maintaining a straight path. **A:** walk backward with eyes open or closed. Turn and walk backward to starting place.
#2 Walking with Side to Side head motion **A:** Walking on solid surface with head and eyes positioned straight ahead. Begin walking while turning head right and left, keeping eyes focused on target.
#3 Walking with Up/Down Head Motion **A:** Walking on solid surface with head and eyes positioned straight ahead. Begin walking while turning head up and down, keeping eyes focused on target.

[a]**Intermediate:** Repeat with ***eyes closed*** [b] **Advanced:** Repeat on *foam with eyes open.*

Each intervention will consist of approximately 20 minutes of strength training, 20 minutes of balance training and 10 minutes of stretching. During the last 4 weeks of the intervention, 10 minutes of functional balance training will be added. Ellen Eckelman, MA, PT, a licensed physical therapist with extensive clinical experience treating persons with postural instability, will conduct the strength and balance training intervention and collect the data. The PI will

train the licensed physical therapist conducting the intervention on all intervention related procedures and data collection and ensure intra-rater reliability. The PI will also be present at each session of the intervention to ensure intervention fidelity.

Data analysis and interpretation: All data will be stored and analyzed using the most recent version of Statistical Software for the Social Sciences (SPSS). Descriptive statistics will be used to evaluate feasibility and tolerability. The primary inferential test to be used will be one-way repeated measures contrast (i.e., F-test comparison of mean values for effect size outcomes across all 4 assessment intervals assuming an ordered effect). **Feasibility-** The percentage of potential participants screened to percentage enrolled in the study will be calculated. The mean number of intervention sessions attended and percentage of participants attending each session, the reasons for incomplete sessions will be calculated. Descriptive statistics will be based on multiple indicators including proportion of potential participants screened who were enrolled (categorical yes/no variable), number of intervention sessions attended (continuous variable), and proportion of participants who attended each session (categorical yes/no variable). For the continuous indicator, the mean, median, and interquartile range will be calculated. In addition, a 95% confidence for each mean value will be calculated. For proportions, a 95% confidence interval will be calculated. **Tolerability-**The percentage of participants who rate the exercise intervention as a) too easy, b) just right, and c) too challenging, will be calculated. Percentage of participants reporting side effects or unable to complete an intervention session will be calculated. This data will be used to inform any necessary changes in difficulty or intensity of the intervention in preparation for a larger, randomized, controlled trial. Categorical indicators will be used including proportions of participants who rate the exercise intervention as (i) too easy, (ii) just right, or (iii) too challenging, proportion of subjects who report side effects (yes/no), and proportion of subjects unable to complete intervention sessions (yes/no). For these measures (proportions), a 95% confidence interval will be calculated. **Effect size** - 1) Results of brief balance measures (unipedal stance time and Timed Up and Go) and detailed outcome measures from T1, T2, T3, and T4 will be compared, in order to estimate rate of improvement over time. This may inform us as to whether a 12 week program is necessary or whether the length of the intervention could be reduced without compromising efficacy. 2) Changes in the more detailed assessments of balance, as well as measures of strength and neuropathy, measured at T1, T2, T3, and T4 will be compared with weekly brief assessments of strength to determine if the weekly brief assessments can be substituted for some intermittent in depth assessments (T2, T3) in future studies. For effect size indicators, a one way repeated measures contrast will be used to estimate the extent (effect size) to which the intervention results in improvements in muscle strength, measures of balance, and measures of neuropathy (all continuous variables). Although limited to a pilot study, each subject will have up to 4 measurements for each outcome variable. In addition, the within-subject design is generally more sensitive to detect changes in physical and functional status compared to a between-subjects design. Specifically, with a proposed sample size of 20 subjects, the study will provide 80% power (2-sided type I error rate of 0.05) to detect medium effect sizes of 0.57 and 0.46 with either 3 or 4 measurements per subject, respectively, assuming within-person correlation of 0.30.

Timetable

Months of Study	Activities
Month 1	Hire and train research staff
Months 2–3	Recruit participants
Months 4–6	Intervention and data collection
Months 7–9	Conduct analysis and write publications
Months 10–12	Write and submit proposal for R01 study

WOMEN AND MINORITY INCLUSION IN CLINICAL RESEARCH

Every attempt to include women and minorities will be made. We expect that approximately 50% of participants will be female and 8–10% will be ethnic or racial minorities, based on previous studies of patients conducted with patients from Moffitt Cancer Center.

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ONCOLOGY NURSING SOCIETY FOUNDATION

2012 Small Grants Program

LETTER OF INTENT FORM

Please review application instructions for specific requirements.

Note: Applications without a prior letter of intent form will not be considered for funding.

Principal Investigator: (Name, credentials, institutional affiliation and previous funding experience and amount of funding)
Name & Credentials: Cindy Tofthagen, PhD, ARNP, AOCNP
Institution: University of South Florida

Previous Funding Experience:

Current Research Support

ONS Research Fellowship Tofthagen (PI) 9/30/10–9/30/11 $20,000
Oncology Nursing Society
Major Goal: To develop a program of interventional research in chemotherapy-induced peripheral neuropathy

1R01 NR010751-01A1 McMillan (PI) 12/1/08–11/30/12 $2.5 million
NINR/NCI
Managing Medication-induced Constipation in Cancer: A Clinical Trial
Major Goal: To assess the incidence and trajectory of medication-induced constipation in persons with cancer and to test an intervention to treat it.
Role: Co-investigator

Completed Research Support

No Number Tofthagen (PI) 03/01/09– 2/28/11 $7500
USF Nursing Faculty in Pilot Research Project
Neuropathic Symptoms and Their Relationship to Depressive Symptoms, Quality of Life, and Sleep Quality in Colorectal Cancer Survivors
Major Goal: To evaluate the characteristics of chemotherapy induced peripheral neuropathy in survivors of colon cancer who were treated with oxaliplatin and to examine how chemotherapy induced peripheral neuropathy affects depressive symptoms, quality of life, and sleep quality in this population.
Role: PI

DSCN-08-205-01 Tofthagen (PI) 8/1/08–7/31/09 $15,000
American Cancer Society
Chemotherapy Induced Peripheral Neuropathy
Major Goal: to develop and evaluate a new self report tool designed to measure chemotherapy induced peripheral neuropathy. Doctoral dissertation.
Role: PI

R01 NR008270-04 McMillan (PI) 8/1/06–5/30/08 1.8 million
NINR
Caregivers of Cancer Pain Patients: Coping Intervention
Major Goal: To provide a coping intervention for caregivers of actively treated cancer patients that will assist them in managing pain.
Role: Research Assistant

Title of the Project

A Pilot Study of a Strength and Balance Training Program for Persons with Oxaliplatin Induced Peripheral Neuropathy

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Brief Statement Describing the Proposed Study, Including the Following Areas: (Please limit the description to 30 lines)

Purpose/Background: Oxaliplatin based chemotherapy is first line adjuvant treatment for persons with colorectal cancer. 85–100% of people receiving oxaliplatin will develop neuropathy as a result of treatment. Effective treatments for oxaliplatin induced peripheral neuropathy are urgently needed. Exercise programs that focus on building strength and improving balance may help alleviate neuropathic symptoms, improve strength and balance, and enhance physical performance. Although data are limited, several small studies have demonstrated that patients with peripheral neuropathy may show improvement after participating in therapeutic exercise programs that incorporate strength and balance training. This pilot study will be the first to evaluate a therapeutic exercise intervention focused on improving lower extremity strength and balance for colorectal cancer survivors with chronic peripheral neuropathy caused by oxaliplatin

Aims: To evaluate feasibility, tolerability, and effect size of a bi-weekly 12-week strength and balance training program in a group of cancer survivors with oxaliplatin induced peripheral neuropathy.

Methods (Design/Sample/Setting/Procedure): Design: Single group, pilot intervention study with longitudinal outcome measures. Sample and setting: 20 colon cancer survivors from Moffitt Cancer Center with oxaliplatin induced peripheral neuropathy will be recruited to participate in a small group strength and balance training program conducted by a physical therapist on the University of South Florida campus. Procedure: After providing informed consent, small groups with a maximum of 5 participants will be established. Each intervention will consist of approximately 20 minutes of strength training, 20 minutes of balance training and

10 minutes of stretching. During the last 4 weeks of the intervention, 10 minutes of functional balance training will be added.

Outcome measures of lower extremity muscle strength, balance, and peripheral neuropathy will be assessed at 4 time points: Prior to the intervention (baseline, T1), four weeks (T2), eight weeks (T3), and twelve weeks (T4; end of intervention) into the intervention. Muscle strength will be measured using isokinetic dynamometry (Biodex 3.0). Balance will be measured using the Modified Clinical Test for Sensory Interaction in Balance and Berg Balance Test. Peripheral neuropathy will be measured using the Chemotherapy Induced Peripheral Neuropathy Assessment Tool (subjective), and the Modified Total Neuropathy Score-short (objective). A brief balance evaluation (unipedal stance time and the Timed Up and Go) lasting less than 5 minutes, will be conducted on a weekly basis.

Research Team: (names, credentials, institutional affiliations, role on the team, previous funding experience and amount of funding)

Constance Visovsky (Co-I)
2008–2009 Heading Off Peripheral Neuropathy with Exercise (HOPE), UNMC College of Nursing Dean's Cancer Initiative for Cancer Research, $23, 5000. Visovsky, C, Principal Investigator

2005–2008 Diabetes in Older Cancer Patients: Impact of a Common Multiple Morbidity. UNMC College of Nursing/Eppley Cancer Center Grant, $12,000. Visovsky, C, Principal Investigator

2004–2007 Strength Training for Therapy-Induced Muscle Weakness, The National Cancer Institute, 5R03CA103488-02. ($100,000). Visovsky, C., Principal Investigator

2004–2006 Impact of Treatment with Taxane or Platinum-Containing Regiments on Peripheral Nerve Functioning in Older Cancer Patients with Diabetes, Aging–Cancer Research Program Development at Case Western Reserve University and the Comprehensive Cancer Center (National Cancer Institute P20 CA103736. (N. Berger, PI).
Funded Pilot grant, $150,000. Visovsky, C., Principal Investigator

2004 Refining Clinical Measures for Research, Oncology Nursing Society, $20,000.
Visovsky, C., Principal Investigator

2003–2004 Strength Training for Biotherapy-induced Muscle Weakness, Translational Research Oncology Training Grant, $10,000. Visovsky, C., Principal Investigator

2002–2004 Translational Research Oncology Grant (TROTG NIH K-12 CA 76917-05), NCI/NIH, Post-doctoral training grant providing 90 % salary support and $30,000/year research support. Case Western Reserve University, Cleveland, OH.
Visovsky, C., Post-doctoral Fellow

2000–2001 Characterization of Biotherapy-induced Peripheral Neuropathy, Oncology Nursing Foundation/Shering Oncology Biotech Grant, $50,000.
Visovsky, C., Principal Investigator

List of Potential Research Sites, if Applicable:
Moffitt Cancer Center and Research Institute

A Pilot Study of a Strength and Balance Training Program for Persons with Oxaliplatin Induced Peripheral Neuropathy
Cindy Tofthagen, PhD, ARNP, AOCNP
University of South Florida (USF)
Pilot Study

Purpose/Specific Aims: The purpose of this study is to evaluate a strength and balance training intervention focused on improving lower extremity strength and balance for colorectal cancer survivors with oxaliplatin induced peripheral neuropathy (PN). The aims of this study are to:

1. To evaluate the feasibility and tolerability of a 12-week, bi-weekly strength and balance training program among colorectal cancer survivors with oxaliplatin induced PN.
2. To determine the level and magnitude (i.e. effect size) of a 12-week strength and balance training program on (a) strength (b) balance and (c) peripheral neuropathy.

Rationale/Significance: At least 48% of people receiving oxaliplatin will develop neuropathy as a result of treatment. Effective treatments for oxaliplatin induced peripheral neuropathy (PN) are urgently needed. Exercise programs that focus on building strength and improving balance may help alleviate neuropathic symptoms, improve strength and balance, and enhance physical performance.

Theoretical Framework: Neurotoxic chemotherapeutic agents induce sensory and motor neuropathy by inducing mitochondrial and vascular dysfunction. Exercise, including strength and balance training, may increase the supply of blood, oxygen, and glucose to mitochondria, allowing the mitochondria to function produce energy in a more efficient manner and reducing symptoms of PN.

Main Research Variables: To evaluate ***feasibility***, the percentage of patients screened to percentage enrolled in the study and the percentage enrolled to percentage that completes the study will be calculated. Patients who do not complete the study will be contacted to determine why they were unable to complete the study and the reasons will be recorded. How many sessions were attended will also be recorded. To evaluate ***tolerability***, at each session, data regarding any participant who was unable to complete the entire session will be recorded along with any side effects that participants report. Participants will also be asked to rate the level of exercise they perform at each session as either a) too easy b) just right c) too challenging. To evaluate ***effect size***, lower extremity muscle strength, balance, and PN will be assessed at 4 time points: Prior to the intervention (baseline, T1), four weeks (T2), eight weeks (T3), and twelve weeks (T4) into the intervention. Muscle strength will be measured using isokinetic dynamometry (Biodex 3.0). Balance will be measured using the Modified Clinical Test for Sensory Interaction in Balance and Berg Balance Test. PN will be measured using the Chemotherapy Induced Peripheral Neuropathy Assessment Tool (subjective), and the Modified Total Neuropathy Score-short (objective). Brief balance evaluations (unipedal stance time and the Timed Up and Go) will also be conducted on a weekly basis.

Design: Single group, pilot intervention study

Setting: This study will take place in an outpatient setting on the USF campus.

Sample: 20 colorectal cancer survivors from Moffitt Cancer Center with oxaliplatin induced PN will be recruited to participate.

Methods: A 50–60 minute group strength and balance training program will be conducted twice a week for 12 weeks by a physical therapist.

IMPLICATIONS FOR PRACTICE

The proposed study may provide beginning evidence to support physical therapy for strength and balance training for patients with oxaliplatin induced peripheral neuropathy affecting the lower extremities.

Word count 496 excluding headings, title, author, affiliation and type of study

HUMAN SUBJECTS PROTECTION

The study has been already received approval by the Moffitt Cancer Scientific Review Committee and the University of South Florida IRB. Each session will be conducted with participants positioned in a large circle with the interventionalist in the middle of the circle so

that she has good visualization and proximity to every participant and can ensure the safety of each participant. In addition, the PI will act as a circulating "spotter" to further reduce the risk of imbalance or the risk of fall during the intervention sessions. Each participant will be provided with a foam balance pad for the balance exercises. Participants will be instructed at each session to go at their own pace, rest if they become tired, and not to attempt any exercises that they do not feel confident in performing. Water and healthy snacks will be available and a firm, steady surface that participants can hold onto to catch or maintain their balance, such as a sturdy chair, will be available for each participant. Participants will be encouraged to use one hand to steady themselves until they feel comfortable that they have mastered the exercise and then to use no hands unless they lose their balance. Theraband progressive resistance bands will be used for the strength training component of the intervention. Yellow (beginner), red (intermediate), green (advanced) and blue (very advanced). Therabands will be provided for each participant. Yoga mats and pillows for support and comfort will be provided for floor exercises. Participants will be taught at the first meeting how to safely go from standing to lying down and then from lying down to standing. In addition, to ensure participant safety during functional activity training, each participant will be individually guarded by the exercise leader, while the rest of the group is stretching. Foam pads, pillows, yoga mats, and Therabands will be cleaned with antibacterial disinfectant and stored in a closed, airtight container after each session.

IMPLICATIONS FOR PRACTICE AND RESEARCH

We anticipate that the proposed study will impact clinical practice by providing beginning evidence to support physical therapy for strength and balance training for patients with oxaliplatin induced peripheral neuropathy affecting the lower extremities. To date, even though physical therapy may be consulted when balance or gait are negatively affected, data to support its use has not included persons with cancer or chemotherapy induced peripheral neuropathy. As oncology nurses, we want to recommend interventions for our patients that are supported by empirical data. While the goals of the proposed study are limited to evaluating feasibility, tolerability, and effect size, our team anticipates that the results will provide preliminary evidence supporting the efficacy of strength and balance training as well as providing preliminary data for a randomized, controlled trial that, if we hypothesize correctly, will support the use of strength and balance training to improve strength and balance, reduce falls and fall risk, and improve symptoms of neuropathy.

There is a growing interest in chemotherapy induced peripheral neuropathy research but limited studies that include non-pharmacologic interventions. Both pharmacologic and non-pharmacologic interventions are needed. Both Dr. Tofthagen and Dr. Visovsky plan to continue to develop programs of research in this area. Extramural funding (R01) will be sought using the data from this study as preliminary data. Future studies will include development and evaluation of an electronic self-management program for persons with chemotherapy induced peripheral neuropathy. Results of this study will be submitted for publication in the Oncology Nursing Forum.

Effectiveness and Benefit of Two STI Prevention Delivery Methods for Military Women

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Tri-Service Project #HU0001-11-TS05

Funding—Tri-Service Nursing Research Program

1. ABSTRACT

Purpose: Military women are at higher risk for sexually transmitted infections (STIs) than civilian women. This multidisciplinary, tri-service study is designed to promote safer sexual behaviors and decrease exposure to STIs among military women with the Sexual Awareness Kit (SAK), a theory- and evidence-based self-administered intervention, consisting of the Sexual Health Information Guide©, Sexual Health Calculator©, and an electronic Virtual Date© game. Specific Aims: 1) using a mixed-methods explanatory approach, evaluate and compare the effectiveness and benefit of the SAK-P (paper version); 2) Validate the theoretical consistency of the SAK-P Design: An integrated mixed-method explanatory methodology and non-equivalent two-group repeated measures design will be used to evaluate the effectiveness and benefit of the SAK-P. Sample: To recruit a sample size of 267 women, a DOD Survey Control Number will generate e-mails linked to the SAK Study Website to all military women. Procedure: Participants will complete safer sexual behavior questionnaires at baseline and at 3- and 6-months, with a final evaluation at 8 months. Analysis: A generalized linear mixed effects model will be used to measure change over times and between group effects of the quantitative data. These data will be analyzed for patterns and inconsistencies, which will inform the questions to be asked in the explanatory and evaluation phase of the study. A systematic content analysis method and QDA Miner® software will be used to analyze qualitative data, which will be electronically integrated and analyzed for further insights into the value of the SAK.

A. SPECIFIC AIMS

A single sexual encounter can have devastating and lifelong effects. Sexually transmitted infections (STI) are at pandemic proportions among young women,[1] and STI rates are up to seven times higher in military personnel than among civilians.[2] Most young women have had limited exposure to information about STIs and ways to prevent transmission of them. Currently the best method to prevent STIs is either through abstinence or the use of a condom.[1] Many women are reluctant to use condoms because they believe that their partner is safe, it violates trust in their relationship, and women tend to defer to male partners who object to condoms.[3–5] To meet the military's need for "a and ready force" by minimizing military women's exposure to STIs, our research team designed the Sexual Awareness Kit© (SAK), an innovative, self-administered, theoretically- and empirically-based decisional support system that provides women with the information and skills they need to identify personal sexual risk patterns, personal sexual health goals and values, and to negotiate condom use or sexual refusal in sexual encounters. This proposed study is a multidisciplinary clinical trial involving Nursing, Fine Arts (digital animation and interactive media), Computer Science, and Statistics.

The SAK consists of a Sexual Health Calculator© and a Sexual Health Information Guide© developed by the investigators. The Sexual Health Calculator© is an innovative tool that allows women to "practice" calculating their STI risk score by specifying the personal, partner, and contextual circumstances of a potential sexual encounter. The women's potential for exposure to STIs is indicated by a *risk score* (0 to 14) that corresponds to a color-coded *visual risk level* (green = low risk, yellow = caution, red = high risk). The companion Sexual Health Information Guide© consists of detailed, easy-to-read information and color photographs describing safer sex, STIs, birth control, and color-coded risk-level *prescriptions* for protecting oneself in sexual encounters of varying intensity and risk. The prescriptions include suggested language for negotiating condom use or sexual refusal in high-risk situations. In this study, the SAK will be administered to military women by two methods—a paper (SAK-P) version, and an electronic (SAK-E) version enhanced with an interactive *Virtual Date*© game that simulates sexual encounters with varying levels of risk and intensity. Women must make decisions at each phase of an encounter that may or may not decrease their risk for STIs. To evaluate the effectiveness and benefit of the SAK, we will use an integrated mixed-method explanatory approach that yields quantitative and qualitative data.[6] *Effectiveness* is defined as positive changes in women's sexual risk patterns, goals and values, and exposure to STIs, as measured by a battery of reliable and valid sexual health and behavior questionnaires. *Benefit* is defined as women's perceptions of the usefulness of the SAK to them, i.e. important information, convenience, ease of use, long-term effect on their sexual behaviors, and recommendations for improvement of the SAK.

Specific Aims

1. Evaluate and compare the effectiveness and benefit to military women of paper and electronic versions of the Sexual Awareness Kit (SAK).
2. Validate the theoretical consistency of the electronic version of the SAK by evaluating *metadata* that reveal the frequency and sequence with which women access components of the SAK.

The SAK intervention is novel in that: 1) it is a decision aid that takes women through an autonomous, decision-making process tailored to their individual sexual health goals, values, and potential sexual encounters; 2) it does not rely on a practitioner or trained facilitator to deliver this type of information; 3) the decision-making process and evidence-based information is delivered in an interactive, virtual and private format that women prefer[7]; and, 4) the paper and electronic versions can be used multiple times for a knowledge and skills "dosing" effect. Military nurses who care for women can recommend the SAK to military women, keep paper versions of the SAK in their offices, and add the electronic version of the SAK to computers that are available to women in waiting rooms and examination rooms. This research will contribute to the body of science in the TSNRP Women's Health Research Interest Group.[8]

B. BACKGROUND AND SIGNIFICANCE

B.1. Sexually Transmitted Infections (STI)

An estimated 19 million new STI infections are reported annually,[1] costing the United States health care system $16.4 billion per year. Most STIs in women manifest few signs or symptoms, thus many women are undiagnosed, and untreated until serious consequences occur.[1] Roughly one-third of women with untreated STIs will develop pelvic inflammatory disease, infertility, painful chronic genital lesions, and, in the case of AIDS, a lifelong chronic illness and a premature death.[1] The primary route of transmission for women is unprotected heterosexual intercourse (oral, vaginal and/or anal). Adolescent and young-adult women, regardless of race are at increased risk for STIs compared to other adults; however, STI rates are nearly 20 times higher in African American women than White women.[1] Unless they obtain correct information from their families, most individuals are never exposed to accurate information that promotes sexual health and safer sex. Only 35 states mandate that STI/HIV education be required in school, and only 15 states require that STI/HIV education be medically accurate and have factual information.[9] Further compounding the public's lack of knowledge many practitioners are not comfortable with these topics and do not discuss them with their patients.[10] Thus, the vast majority of the public, especially young adults, are not well-educated about sexual health, and it is imperative that new, effective interventions be developed to minimize women's exposure to STIs.

B.2. Prevention of STIs

Abstinence, or sexual refusal, is the best way to prevent transmission of STIs.[1] However, sexual relationships are a normal part of human development, especially in young women. Biological approaches to prevent transmission (e.g., HIV gel) have not been fully developed.[11] The only vaccine available is infection specific (e.g., Human Papillomavirus) and does not protect individuals from other types of STIs. After abstinence, the next best way to prevent transmission of STIs is through the use of condoms when they are used properly.[1] Behavioral interventions to promote condom use are essential if we are to reduce the infection rate in populations of young women who are high risk for STIs. The purpose of behavioral interventions is to persuade a target population to adhere to a desired health behavior in order to reduce risk of

infection or disease.[12] The purpose of the intervention in this proposal is to provide women with the motivation, information, and skills to negotiate condom use or sexual refusal to prevent transmission of STIs. However, these behaviors pose unique challenges for women. Most women are not socialized to take control of negotiating sex, or using condoms with sexual partners.[13–15] Men have been socialized to control condom use and report that they are more likely to do so compared to their female partners in sexual relationships.[13] Women typically defer to men with regard to using condoms and will change their intentions to use condoms based upon their partners' desires.[16–17] Successful negotiation of condom use in women is associated with increased knowledge of STIs and HIV, self-efficacy for condom use, and positive attitudes toward condoms.[16] However, women significantly underestimate their partner's desires to use condoms, use condoms less frequently when other forms of birth control are being used, and will allow their perceptions of their partner's desires to dominate their own.[17] Thus, women must be "resocialized" to sexual negotiation and use of condoms.

B.3. Electronic Interventions to Prevent STIs

The most effective interventions are based upon a behavioral change theory and are targeted toward characteristics of the learner. However, the behavioral effects of these interventions often fade within a year.[18] Electronic interventions offer a solution to this. Computer-based, electronic interventions have an advantage in that they are more cost-effective, have greater intervention fidelity, greater flexibility in dissemination, and the knowledge and skills can be "dosed" longitudinally.[19–20] In a meta-analysis of technology-based HIV prevention interventions there were statistically significant effect sizes for increased condom use and reduction of number of sexual partners, frequency of sexual behaviors, and incident of STIs up to 9 months.[21] These effect sizes are comparable to interventions delivered by human facilitators. Similar to human-facilitated interventions, computerized interventions that were targeted to demographic characteristics of the learner were significantly more efficacious.[21] A non-significant trend was that studies with longer follow-up had smaller effect sizes, suggesting that beneficial effects may wane after a year. This may be due to limited "dosing" of the intervention, lack of skills training, and non-tailoring of the intervention. So, although electronic interventions are efficacious in promoting condom use in the short term, there are gaps in the method of delivery that can be improved upon to improve sexual health outcomes.

C. THEORETICAL FRAMEWORK

The SAK-E is based upon Decision Theory, which will guide the process that women use to make decisions about their short- and long-term sexual health, and on Social Cognitive Theory which explains the mechanisms of learning and motivation within the intervention. The *Decision-Making Context* refers to influences on decision making from the broader context of an individual's life.[22–23] In the case of sexual risk, these aspects include, but are not limited to, partner characteristics and preferences, availability of condoms, and sociocultural factors (i.e., ethnic variations, values toward sexuality). *Information* refers to decision-relevant data

used to make decisions. Information in this case, refers to data about STIs, personal risk assessment, risks and benefits of making a decision, and lifestyle changes such as the use of safer sexual practices. *Values* represent the importance individuals place on information and the attractiveness of desired health states (absence of STIs, promotion of sexual health). The strength of these values can significantly impact preferences for preventative measures to reduce exposure to STIs. *Preferences* refer to a greater liking of one alternative as compared to others. The major individual-level variables involved in the decision making context are: information, values, preferences, decision, behavior, and outcomes. *Decisions* are the choices shaped by preferences. Women decide to either use or not use safer sexual practices to avoid acquiring STIs. *Behavior* is the implementation of decisions, in this case, use of safer sexual practices. *Outcomes* are the end result of behavior. The ultimate goal both for the individual and on a greater system level is optimal sexual health by avoiding short-term (e.g., STIs, asserting one's self in sexual relationships) and long-term (e.g., complications from infections such as pelvic inflammatory disease and cervical cancer, healthy sexual relationships) health concerns. Constructs from social cognitive theory are embedded in the SAK intervention.[24–25] *Reciprocal Determinism* is the way in which an individual can influence their environment to regulate her own behavior. *Outcome Expectations* are beliefs about the likelihood and value of the behavioral change. *Self-efficacy* refers to the individual's beliefs about being able to perform a behavior to bring about an expected outcome. *Observational Learning* is the learning of a new behavior through exposure to them or by peer modeling. *Incentive Motivation* is the use and misuse of rewards and punishments to modify behavior. *Facilitation* provides the tools and resources to make new behaviors easier to perform. *Self-regulation* is controlling oneself through self-monitoring, goal-setting, feedback, and self-instruction. *Moral Disengagement* refers to thinking about harmful behavior and the individuals who are affected by that behavior.

D. PRELIMINARY STUDIES

The Principal Investigator, Dr. Nancy Ryan-Wenger, has an established program of research in military women's health since 1996. The first project funded by TSNRP (N96-029) described the scope of the problem related to gynecologic infections experienced by military women, and to demonstrate the need for an alternative to current health care resources in austere environments. Military women from 88 Army and Navy units completed an anonymous survey (N = 1537). Overall, the survey findings indicated that military women are deployed with pre-existing risk factors for vaginitis and UTI, many factors unique to deployment are likely to increase their risk, their comfort with going to a health care provider (HCP) with these symptoms during deployment is lower than at the home duty station, and fully one-fourth of the women would not even seek care from a medic during deployment. A second component of this project was to test a prototype of an investigator-developed Self-Diagnosis kit and decision-making guide for vaginitis and UTI. In general, this prototype distinguished BV/TV from CV, with sensitivity ranging from 84%–91.3%, and specificity from 81.5%–82.8% compared to an advanced practice nurse's clinical diagnosis. The findings from this study were published in *Women's Health Issues*,[26] *Military Medicine*,[27] *and Clinical Nursing Research.*[28] We were subsequently funded by NIH NINR (1-RO1-NR07662-01A1) to evaluate the self-diagnosis Kit with 715 military women

with vaginal and/or urinary symptoms, by comparing their self-diagnostic results to laboratory gold standards (DNA for BV, CV, TV, and urine culture for UTI). Publications from this study appear in *Obstetrics & Gynecology*,[29] and *Nursing Research*.[30] In our current TSNRP-funded study (HU0001-08-1-TS07), we are simultaneously measuring: 1) whether or not women can accurately conduct the tests included in the Kit, 2) which level and intensity of training in the use of the Kit is required to yield the most accurate results, and 3) which combination of Kit components and diagnostic algorithms yield the most accurate results, compared to standardized specimens.

The Co-Investigator, Dr. Victoria von Sadovszky's research program focuses on sexual health in women. Her primary goal is to develop an educational intervention, based on Decision theory and Bandura's Social Cognitive Theory, to tailor evidence-based information to the unique sexual health needs of military women. Many studies have contributed to her knowledge and development of this intervention.

Study 1: ***Contextual factors and perceptions of sexual encounters among college students.*** (Funded: Sigma Theta Tau, Int. Small Grant; Beta Eta-at-Large). This dissertation study was the first step in developing the intervention for young women. **Purposes:** 1) to determine the characteristics involved in safer and risky sexual encounters, and 2) to describe perceptions of safer sexual practices among college students. The sample consisted of 85 young women (68%) and men, ages 18 to 21. **Findings:** Participants provided detailed information about themselves, the partner, the place of the encounter, thoughts and emotions about the sexual encounter and perceptions of safer and risky sexual behaviors. **Implications for this proposal:** The major findings will be used as "triggers" in the video game called the *Virtual Date.© Results are published in her dissertation, Journal of Obstetric, Gynecologic, and Neonatal Nursing (JOGNN), Journal of Nursing Scholarship*.[31–33]

Study 2: ***Context, temperament, and sexual behaviors***. (Funded: Sigma Theta Tau, Int. Small Grant as part of Study 1). **Purpose**: The purpose of this study was to examine the effect of temperament on sexual risk behavior among young adults. **Findings**: Temperament was not related to safer or risky sexual encounters (R^2 = 0.03 to 0.04; hence, heritable traits of emotion did not influence sexual risk behavior in this sample. **Implications from this study:** Since emotions involved in sexual encounters are not affected by heritable traits, thus, emotions can be regulated and changed, an important aspect of Self-Regulation based upon Bandura's theory. Results were presented at MNRS,[34] and published in the Journal of Nursing Research and Practice.[35]

Studies 3 & 4: ***A unique kit for prevention of STIs and pregnancy during deployment.*** (Funded: TriService Nursing Research Program, with Co-I Nancy Ryan-Wenger). **Study 3: Purpose:** To assess sexual health information needs of military women and establish validity for a new intervention designed to promote safer sexual behaviors in this population based on the women's preferences for sexual health information, and replicated an earlier study. **Results:** Military women desired information about sexual health, prevention of STDs, and sexual violence in non-deployment and deployment situations. **Implications for this proposal:** Results were used to develop the Sexual Awareness Kit© (SAK). **Study 4: Purpose:** To assess validity of a self-administered intervention designed to promote safer sexual behaviors among military women and replicated an earlier study. **Findings:** Military women endorsed the intervention and either

use the intervention or recommend its use to other women. Based upon these results the intervention was modified to highlight certain aspects of interest and change undesirable qualities (i.e., the color of the intervention). **Implications for this proposal:** This is the paper version of the Sexual Awareness Kit© (SAK-P). Results are published in *JOGNN, Women's Health Issues*, and *Travel Medicine and Infectious Disease*, *American Journal of Maternal Child Nursing*.[36–39]

Study 5: ***Women's Use of Information Technology for Health Related Messages*** (Funded: College of Nursing.)[7] **Purpose:** to assess women's use of computers and handheld devices (i.e., cell phones, PDAs) for accessing sexual health information, preference for type of technology, and desire to learn the information in a game format. **Findings:** Women in this study primarily used computers, all accessed the internet for health related information, including sexual health. Women preferred computers over other technology for accessing information because their computers are faster and perceived as more private. Over half of the women used the computer for games and would consider using a sexual health game. **Implications for this proposal:** Demonstrates that women are interested in using their computers for health related information, including the use of a game for sexual health promotion.

E. RESEARCH DESIGN AND METHODS

E.1. Design

The Explanatory Design: Follow-up Explanations Model (EDFE Model) is a mixed-methods design that will be used in this study.[6] Quantitative data are collected, analyzed and results are reviewed to identify areas that require further explanation, such as unexpected results or inconsistencies. Then, qualitative, open-ended questions are formulated and submitted to the participants. Those data are analyzed with a systematic content analysis methodology. In the final step, quantitative and qualitative data are integrated to yield a clearer understanding of observed relationships and differences in outcomes over time and between groups. A non-equivalent two-group repeated measures design will be used to evaluate and compare the effectiveness and benefit of the two delivery methods of the SAK intervention. Women will serve as their own controls to evaluate changes in their sexual risk patterns, goals and values, and exposure to STIs, as shown below (O_1 = baseline sexual health knowledge, values, and behavior; X = paper or electronic version of the SAK intervention; O_2 and O_3 = sexual health knowledge, values, behavior, and exposure to STIs (quantitative); O_4 = qualitative evaluation of the SAK intervention).

O_1 X = SAK-P O_2 O_3 O_4
O_1 X = SAK-E O_2 O_3 O_4

E.2. Sample

Women from the active, reserve, and guard components of the Army, Navy, and Air Force will be the participants in this study. Consistent with the demographics of active duty military,

we expect that the majority will be between 18 and 28 years old, with decreasing numbers of women as age increases. To maximize representativeness of the sample, all women, including those who are deployed, are eligible to participate. Exclusion criteria are those who choose not to respond to invitations to participate, and to ensure independent observations across groups, women who participated in the SAK-P phase of the study will not be eligible to participate in the SAK-E phase.

E.3. Sample Size Justification

Our statistician performed a power analysis assuming that the key effect of interest is the *within-subjects* pre-intervention to post-intervention effects. This component of the modeling can be represented in a simplified way by a paired t-test, which was used for power calculations. We set Type I Error rate at 0.05 and our power at 80%. For most instruments, test-retest correlation from previous studies was available for estimating within-subject correlation. When test-retest correlation was not available, we assumed a level of 0.70. *Between-subjects* standard deviations of scores were not available from previous studies, so a worst-case scenario (scores uniformly distributed across the range of possible values) was used. The scale requiring the most subjects represents the required sample size for our study. As a result, we will need a total of N = 178 subjects (n = 89 per group). To account for the potential attrition of 50% of the subjects in this longitudinal study, we will oversample to achieve a *total sample size of 267.*

E.4. Participant Recruitment

We will obtain IRB approval from The Ohio State University immediately after submission of this proposal to minimize delays in subject recruitment. LTC Lori Trego (Army Consultant) will serve as our Lead Agent by assisting us with obtaining IRB approval at her duty station, and then sponsor our application for a *DOD Survey Control Number*. When this is approved, the Navy and Army are invited by the Army IRB to participate in this study. When all approvals are in order, a description of the study and a web-link to our SAK Study website are sent by the DOD survey office to the targeted population (military women) via their official military e-mail addresses. A limitation of this method is that women who do not have access to, or use their military e-mail address will not be informed of the study. Deployed women may participate if they choose. This convenience sample may not adequately represent the target population, but this is true of most human subject research. At the website, women who are interested in participating will be instructed to contact the SAK Study e-mail address. Women will be asked to provide an e-mail address that they prefer to use during the study (e.g., personal e-mail provider), and for women in the SAK-P group, we will ask for a mailing address. Upon their reply, the military e-mail addresses will be deleted from the server. We will reply to their preferred e-mail address, with a link to the SAK Study Website, where secure and encrypted on-line access will be granted. Potential participants will review an on-line informed consent document (Appendix I). If she electronically signs the informed consent to participate she will be granted access to a screen where she will register with the study and make a username

and password prior to accessing the demographic data form, and for the SAK-E group, the baseline questionnaires. Baseline questionnaires will be mailed to the SAK-P group with return mail envelopes. Upon completion of baseline questionnaires, participants will be sent the SAK materials either by mail or on-line link from the SAK Study Website. Periodic reminder and encouragement e-mails will be sent to all participants throughout the study. Women who choose not to sign the on-line informed consent will be taken to a screen where they will be thanked for their time with an assurance that their e-mail addresses will be deleted from the server and that their decline of participation will have no bearing on their relationship with the military. Women may discontinue their participation at any time without repercussions. The investigators will use ID numbers rather than names or other identifying information in the dataset. Only group data will be reported. All data will be kept on a secure server (see Section K. below for Electronic Data Safety Plan). At 3 and 6 months from baseline, women will be sent an e-mail reminding them to access the website to complete the study questionnaires.

E.5. The SAK Intervention

The Sexual Health Information Guide© developed by the investigators consists of detailed, easy-to-read information (7th grade reading level) and color photographs describing safer sex, STIs, birth control, and prescriptions for protecting oneself in sexual encounters of varying intensity and risk (see prototype in Appendix II). The Sexual Health Calculator© is an innovative tool developed by the investigators that allows women to "practice" calculating their risk for exposure to STIs by specifying the personal, partner, and contextual circumstances of a potential sexual encounter (see prototype in Appendix III). The women's responses translate into an STI risk *score* (0 to 14), and a *visual risk level* by the background color that corresponds to their responses, i.e., *green* (not at risk), *yellow* (proceed with caution), and *red* (high risk-take precautions). *Prescriptions* in Sexual Health Information Guide© correspond to risk scores and color-coded risk levels found in the Sexual Health Calculator© and include suggested language for negotiating condom use or sexual refusal in high-risk situations. Figure 1 illustrates the theory- and evidence-based "workflow" sequence of decision-making and the Guide contents.

Paper Version (SAK-P). Encompass Media, a communications design firm will design and produce the SAK in attractive, easy-to-use products. The SAK-P Sexual Health Calculator© will be a 9 × 4.5 inch cardboard "envelope" with cut out "windows" and three 2 × 4.5 inch response cards that slide up and down behind the windows (Appendix III). The windows reveal the women's STI risk by their *score* as well as by the *background color of their responses* that show through the windows, i.e., *green*, *yellow*, and *red*. The companion Sexual Health Information Guide© (Appendix II) will be packaged as a 7 × 5 inch, spiral-bound pocket guide.

Enhanced Electronic Version (SAK-E). Experts from The Ohio State University Advanced Computing Center for the Arts and Design (ACCAD), consisting of faculty and research assistants from Fine Arts (digital animation and interactive media) and Computer Science, will design, test, and launch the SAK-E in an interactive, website format. The same workflow structure shown in Figure 1 will be re-created. In addition, the SAK-E will be enhanced by

the addition of an investigator-developed interactive game, called the *Virtual Date*© game that simulates sexual encounters with varying levels of risk and intensity. Women must make decisions at each phase of an encounter that may or may not decrease their risk for STIs.

E.6. Timeline

The timeline below illustrates the sequence and overlap of events that will occur over a three-year period. We will seek IRB approval from the University immediately after submission of this application to minimize delays in start-up. Procedures for evaluating the effectiveness and benefit of the SAK will be described first, followed by procedures for development of the electronic version of the SAK.

Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun
YEAR 1 2011						2012					
Start-up; refine and print SAK-P intervention materials			Recruit for SAK-P; collect baseline data			Begin SAK-P intervention		Collect SAK-P quantitative data X 2			
Create the web-based electronic version of the SAK-E						→	→	→ →	→	→ →	→
YEAR 2 2012						2013					
Analyze SAK-P data & plan qualitative evaluation		Collect SAK-P qualitative data			Analyze & integrate SAK-P quantitative and qualitative data						
Start-up SAK-E intervention			Recruit for SAK-E; collect baseline data			Begin SAK-E intervention		Collect SAK-E quantitative data X 2			
YEAR 3 2013						2014					
Analyze SAK-E data & plan qualitative evaluation		Collect SAK-E qualitative data			Analyze & integrate quantitative & qualitative data				Write reports, abstracts, manuscript		

E.7. Procedure for Evaluating the Effectiveness and Benefit of the SAK

1. Collect demographics and quantitative baseline questionnaire data.
2. Send women their version of the SAK by mail or electronically.
3. Send e-mail reminders about the SAK Study periodically.
4. Allow a 2-month period for women to use the SAK intervention.
5. At the 3rd and 6th month, collect quantitative outcome questionnaire data by mail or electronically.
6. The investigators will analyze the quantitative data and design qualitative questions for follow-up and evaluation of the SAK.
7. At the 8th month, collect qualitative follow-up and evaluation data by mail or electronically.
8. Analyze and integrate the data, evaluate changes in effectiveness and benefit over time (outcomes) and compare outcomes between the paper version and electronic versions.

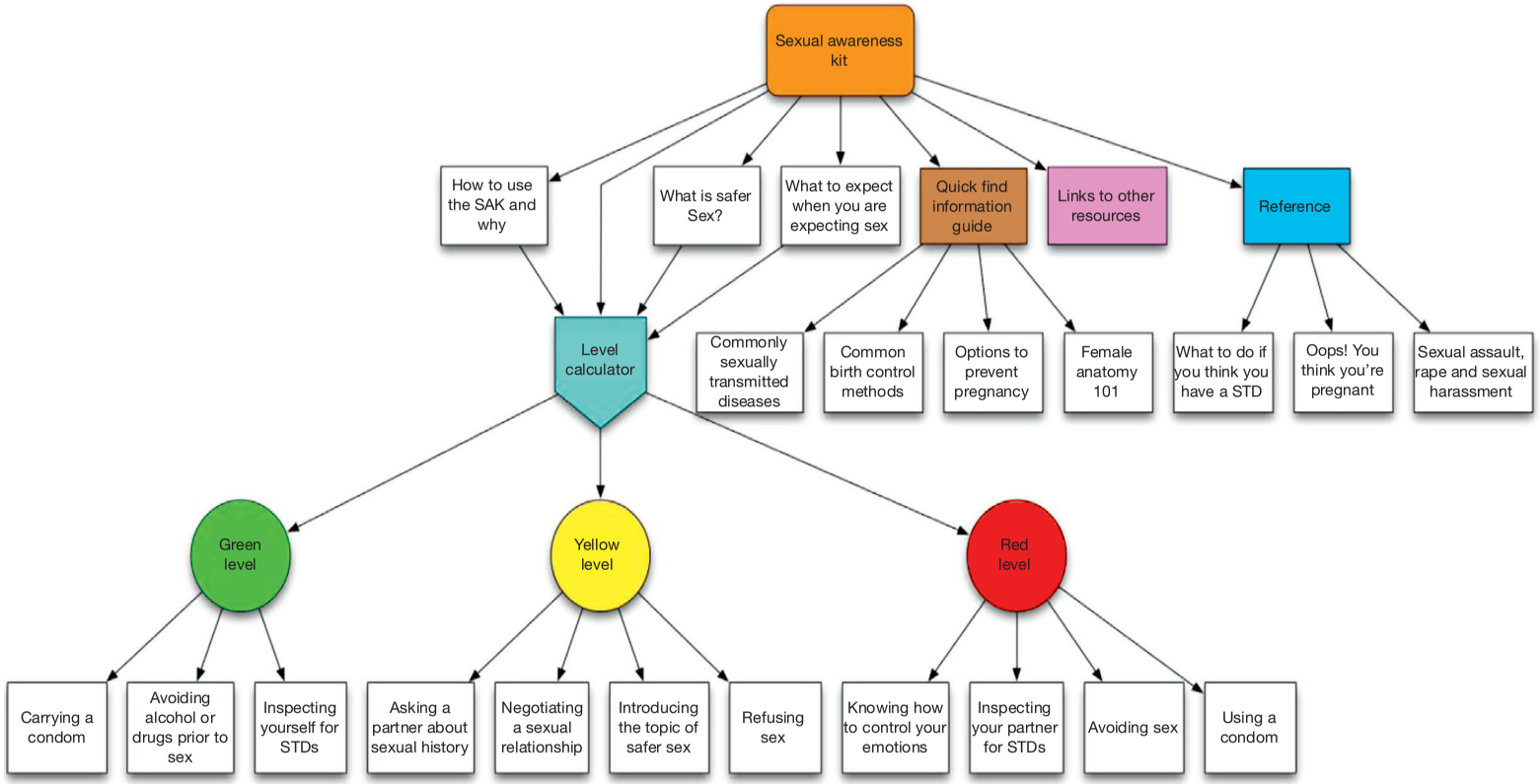

Figure 1. Workflow sequence.

E.8. Instruments to Measure SAK Effectiveness and Benefit (Appendix IV)

Demographic data will be collected at baseline to describe the sample. A total of 10 instruments will be used in this study, presented as a continuous battery of 184 forced-choice questions that measure effectiveness and benefit of the SAK. This battery requires up to 30 minutes to complete. *Effectiveness* is defined as positive changes in women's sexual risk patterns, goals and values, and exposure to STIs. *Benefit* is defined as women's perceptions of the usefulness of the SAK to them, i.e., important information, convenience, ease of use, long-term effect on their sexual behaviors, and recommendations for improvement of the SAK. The instruments will be administered at baseline, and twice to measure outcomes (change from baseline). The purpose and psychometric properties of each instrument are described in the table below.

Instrument Title	Purpose	# of Items	Scoring	Alpha/ Retest	Validity
Condom Use Self-Efficacy Scale (CUSES)[40]	Assess perception of ability to use condoms	28	Summed score Range: 0–112	.94	Higher scores in those who consistently use condoms vs not ($p < .05$)
STD Knowledge Questionnaire (STD-KQ)[41]	Assess knowledge of STDs	27	Percent correct Range: 0–100	.86 .88	r = 0.64 with HIV Knowledge Questionnaire
Safer Sex Behavior Questionnaire (SSBQ)[42]	Evaluate women's sexual risk behavior	30	Summed score Range: 24–96	.83 .83	r = 0.91 with Self-Expression Scale, r = 0.89 with Risk-Taking Questionnaire
Decisional Conflict Scale[43]	Assess level of difficulty in making a decision	16	(Summed score/16) x 25; Range: 0–100	>.78	Discriminates between those who make vs delay decisions (ES = 0.4–0.8)
Decisional Self-Efficacy Scale[44]	Assess level of confidence in making a decision	11	(Summed score/11) x 25; Range: 0–100	.92	Correlates with Decisional Conflict subscales of feeling informed (r = .47) & supported (r = .45)
Decisional Regret Scale[45]	Assess level of distress or remorse after making decisions	5	(Summed score/5) x 25; Range: 0–100	.81–.92	Correlates with Decisional Conflict Scale (r = 0.31–0.52 with r = –0.25 to –0.27 with Quality of Life
Preparation for Decision Making[46]	Evaluate the utility of a decision aid (SAK) in making decisions	10	(Summed score/10) x 25; Range: 0–100	.92–.96	Discriminates between different types of decision aids (ES = 1.8)
Preference for Safer Sexual Behaviors[47]	Evaluate values regarding safer sexual behaviors	1	Select 1 of 6 ordinal preference categories	Retest = .79 to 0.91	Discriminates between those making different decisions ($p < .05$)
Stage of Decision Making[48]	Evaluate a person's stage in decision-making process	1	Select 1 of 6 ordinal decision-making stage categories	No report	Negatively associated with Decisional Conflict Scale

E.9. Analysis Plan

E.9.a. Quantitative Data Analysis Plan

The key statistical test of interest is the *within-group difference* in scores between the baseline pre-intervention, and the three post-intervention time points. Because of expected collinearity among the instruments, statistical analyses will be performed separately for each of the instruments and for the SAK-P and SAK-E treatment groups. For each scale measured at an interval level, we will use a generalized linear mixed effects model, essentially a logistic regression that accounts for the pairing of subjects' scores across time.[49] For the two ordinal-level instruments, we will use a generalized linear mixed effects model based on a proportional odds model.[49] Of secondary interest is the difference in mean value between the post-intervention time point and each of the two follow-up time points, which will be used to assess *sustainability* of any effects. Thirdly, comparison of *between-group differences* (SAK-P vs SAK-E) will be measured from the same set of analyses.

E.9.b. Qualitative Data Analysis (QDA) and Numerical Coding of Text Data

Open-ended text responses will be analyzed using McLaughlin and Marascuilo's three-phase content analysisand technique.[50] In the first phase of the content analysis, two independent raters will identify individual *units* of analysis, i.e., a thought or a theme that appears in the response. Unit selections will be compared between the two, and interrater reliability (IRR) will be calculated. The investigators determined that an adequate IRR is 90% agreement. If this percent agreement is not reached, the investigators will discuss the units until consensus is reached. The second phase of content analysis requires an investigator to inductively sort the units into mutually exclusive and exhaustive *categories*, and then develop definitions for each category. A second investigator will independently sort the units into these categories based on the definitions (deductive), and an IRR will be calculated, with a goal of 90% agreement. This process will be conducted electronically with *QDA Miner 3.2*,[51] an easy-to-use, state of the art computer software for deductive and inductive analysis of text data. As the text for each participant is reviewed, the investigator that represent *units* as described above. The program calculates IRR when other investigators code the same text. Then, investigators will independently label the units with existing codes that represent the *categories*, and an IRR is calculated. A Command Log reports all activities that are conducted on the data. *QDA Miner* produces frequencies, percentages, tables, graphs, and charts of the variables and codes. Coding sequences and frequencies of data associated with each code can be produced, reviewed, and edited as needed to develop parsimonious, mutually exclusive categories that best represent the data.

E.9.c. Integration of Quantitative and Qualitative Data. xxx

QDA Miner software also has the capability of clustering variables (codes) from text data and other imported nominal, ordinal, and interval data associated with each case. Similarity or co-occurrence indices can be calculated. Results are displayed in the form of dendrograms,

concept maps and proximity plots. Thus, QDA Miner will assist with visualizing the integration and interpretation of all of our results.

F. PROCEDURE SAK-E DEVELOPMENT AND TESTING

The workflow illustrated in Figure 1 will be translated to an electronic high-fidelity interactive prototype, hyperlinked and easy to navigate, locate, and connect. The information will be delivered in multiple digital formats (images, text, video and animated scenarios) to serve visual, verbal and kinetic learning styles. The users will think with authentic tools and resources, confront choices designed to elicit a response, and gain detailed feedback so that they can understand the strengths and weaknesses of their choices and problem-solving processes. Throughout the SAK-E development process, we will evaluate the users' experience with accessing this information. When the SAK-E is presented to military women in this study, they **can access the web-based materials in the environment of their choice. By participating in the Virtual Date game, a bad outcome can be a private experience in which women have the opportunity to reflect and think about other options not chosen. This interactive interface delivery method empowers women to simulate obviously more risky choices without actually experiencing them.**

Sample

This phase of the study requires feedback from focus groups with women who correspond to the targeted user group (military women). We will recruit a total of 24 military women from flyers distributed at Reserve and National Guard Units in the Columbus, Ohio area (Appendix V). The flyer will describe the SAK-E, the purpose of the focus groups, and include a request for women who are willing to attend one 1-hour group meeting at the easily accessible Advanced Computing Center for the Arts and Design (ACCAD) near the OSU campus. The women will receive $20 gift certificates as an incentive to volunteer their time. In addition, an expert panel of 5 faculty with expertise in research related to safer sex practices from The Ohio State University College of Nursing and College of Public Health will be invited to critique the SAK-E.

Procedure

1. **Usability testing of the paper prototype.** Usability testing is an efficient means of finding out whether the system meets its intended purpose. Paper prototyping is an established design research tool established in the 1990s by the engineering field. A focus group of 8 women will be presented with a paper version of the interface that is manipulated by a person "playing the role of the computer," who does not explain how the interface is intended to work.[52] The initial prototype is a mocked-up rough representation of the idea (Figure 2). The rougher the design, the more willing people are to challenge its most basic assumptions. This prototype will help to represent screen layout, interface widgets, content, and unexpected user actions. Neilson estimated that productivity is increased 100-fold when changes

are identified before coding begins.[53] Outcomes from these sessions will be documented and distilled for inclusion in the implementation and refinement of the logic diagram, which will become the map for the interactive web prototype.

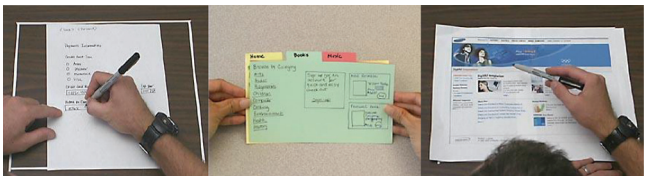

Figure 2. Website, tabbed layout, and home page prototypes.

2. **Production of a web prototype with interactive modules (programming, interface and interaction design).** Existing software supports the context of the overall tasks and workflow in the web-based prototype. The Design Model is based on user activity and employs the user's language and context. The model fits the user's mental model, as established in the paper prototyping phase. The content will be delivered via a typical web browser. Developed in concert with the interface architecture is the Interaction Design, which is distinct from technical design. The scope of the design is "everything but code" and includes: look and feel, language, screen objects and layout, navigation, and user assistance. The initial interface will include the *Sexual Health Calculator*, *SAK Guide,* the *Virtual Date Game,* and the *Quick Find Information Guide.*
3. **Focus group testing and evaluation of the SAK-E online interactive modules.** The SAK-E prototype will be used in two separate focus groups consisting of 8 military women. Participants will be asked to provide feedback on the system's interface, usability and the flow and content of the software in general and the sexual encounter scenarios, specifically. Usability testing is the principle means of finding out whether the system meets its intended purpose. The focus group will be tested for retention, engagement, and understanding in the following steps:

   Step 1 – Unobtrusive observation to measure the intuitiveness of the interface (20–30 minutes): Initially the focus group will be briefly introduced to the program and then surveyed to determine their expectations for programs that would cover safe sex subject matter. Next, the women will be asked to start the interaction and move through the levels to the best of their ability. We will not provide intervention or instruction and will observe and record the participants' progress.

   Step 2 – Interactive Observation (20–30 minutes): The design team will begin to interrupt individual participants during the interaction by posing questions regarding observed cues that implied success or delay in program use. Participants are encouraged to verbalize their criticisms of the Virtual Date interactive game. Since discussion is based on evolving patterns of interaction pre-prescribed questions are not possible.

   Step 3 – Survey (10–15 minutes): Participants are asked to reflect on their experience with the game, its interface and contents and indicate, in writing, their opinions on the strengths

and weakness of these areas (Appendix VI). This is a cerebral process that encourages the construction of experience ratings and summaries, and also benefits participants who best express themselves non-verbally. In addition, the panel of experts will evaluate the SAK-E. These evaluations will be used to establish criteria for refining the content and interaction for future development. **Data Analysis of Focus Group Questions.** Open-ended responses from the two focus groups will be analyzed using McLaughlin and Marascuilo's[50] three-phase content analysis technique conducted with QDA Miner 3.2 software, similar to the process of evaluating the final versions of the SAK-P and SAK-E (Aim #1) described in detail in Section E.9.c.

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BUDGET JUSTIFICATION

Personnel

Nancy Ryan-Wenger, PhD, RN; Director of Nursing Research; Principal Investigator (10% effort for 12 months for all 3 years of the study) will be responsible for the overall administration and direction of the project. She will conduct semimonthly research meetings with the co-investigators and project staff. She will be responsible for supervision of personnel of the grant. She will have overall responsibility for data analysis with the input of the co-investigators and research staff.

Victoria von Sadovszky, PhD, RN; Associate Professor of Nursing; Principal Investigator (15% effort for 9 months for all three years; 10% for 3 each year of the project) will assist Dr. Ryan-Wenger with the overall administration and direction of the project. She will have overall responsibility for recruitment and data collection with the input of the co-investigators and research staff. She will be responsible for training and supervising the research staff throughout the tenure of the study. Dr. von Sadovszky will oversee the advisory panel on sexual health and the feasibility study. Dr. von Sadovszky will also be responsible for preparation of abstracts, presentations, and manuscripts.

Elizabeth Barker, PhD, RN; Associate Professor of Clinical Nursing; Co-Investigator (10% effort for 12 months for all years of the project) will have overall responsibility for the collection and analysis of the qualitative data on the project. She will oversee the analysis team for those data. Dr. Barker will also be responsible for preparation of abstracts, presentations, and manuscripts related to the qualitative methodology or results.

Maria Palazzi, MA; Director of the Advanced Computing Center for the Arts and Design (ACCAD) and Associate Professor, Co-Investigator (10% for 24 months and 5% for 12 months) will serve as the director for all computer-generated animation segments in the PDA components, supervising graduate students working as animators and designers and serving as the point of contact between the content experts (Ryan-Wenger, von Sadovszky and Barker) and the production staff at ACCAD.

Rajiv Ramnath, PhD; Co-Director of Center for Enterprise Translation and Innovation (CETI) and Associate Professor, Co-Investigator (10% for 24 months and 5% for 12 months) will serve as the director for all the software supporting the information delivery of the project (GuideVue). He will supervise graduate students working on programming and designers of the information delivery system and serve as the point of content between the content experts (Ryan-Wenger, von Sadovszky and Barker) and Ms. Palazzi.

Trego, Lori, LTC, AN, USA PhD, CNM; Consultant will advise the PIs and Co-Is on how to recruit military women and assist in navigating the active duty military system.

Almonte, Angelica, CAPT, NC, USN, PhD; Consultant will advise the PIs and Co-Is on how to recruit military women and assist in navigating the active duty military system.

Kelly, Patricia, CAPT, NC, USN, PhD, RN, FNP, FAANP; Consultant will advise the PIs and Co-Is on how to recruit military women and assist in navigating the active duty military system.

Wilson, Candy, MAJ, USAF, NC, PhD, WHNP-BC; Consultant will advise the investigators about methods to recruit military women and navigate the active duty military system.

Christopher Holloman, PhD; Director of Statistical Consulting Services at The Ohio State University and Assistant Professor, (for 40 hrs.) has performed the power analysis for the project to determine the appropriate sample size. Dr. Holloman will oversee the statistical analysis for all quantitative data and write up those results.

William Matcham, BSN; AAS Tech Studies, Project Director (50% for 3 years) will direct the day-today management of the project. Mr. Matcham, a former Army veteran, will be responsible for on-line communication and data collection with study participants. Mr. Matcham is an information technology expert and has had experience in the role he is assigned here on another of Dr. von Sadovszky's research projects.

Chitra Sriram, MA, MFA; Consultant, ($3000 includes time and travel) will train the CETI and ACCAD personnel on use of the GuideVue software used to deliver the information in the SAK-E and be available for trouble-shooting on the project.

TBD; Graduate Research Assistant #1 (50% effort for 15 months) The Support Personnel for the Project includes a Graduate Research Assistant (GRA) from the College of the Arts for 18 months. The GRA will assist Ms. Palazzi with character development, storyboarding and the creation of animation for the game and other animation. Support for the GRA includes tuition, a monthly stipend, tech fees, and fringe benefits.

TBD; Graduate Research Assistant #2 (50% effort for 18 months) The Support Personnel for the Project includes a Graduate Research Assistant (GRA) from the College of Computer Science and Engineering. The GRA will assist Dr. Ramnath with programming and development of the electronic information delivery system for the SAK-E. Support for the GRA includes tuition, a monthly stipend, tech fees, and fringe benefits.

Supplies and Other Direct Costs

Publication Costs: $7910 for the production of 100 SAK-P booklets and risk calculators.

Digital printing of SAK-P	$1410
Guides 9″ × 4.5″	3800
Design Charges	1900
Adobe Creative Suite Upgrade	800

Postage: $500.00 ($3.33 x 150 mailings) of the SAK-P to study participants.

Analytical Services and Instrument Use: $7929 for GRA computer lab fees.

Honorarium: $480 ($20 gift certificates x 24 women) for completion of the focus groups for development of the SAK-E.

H. PROTECTION OF HUMAN SUBJECTS

H.1. Human Subject Involvement and Characteristics

Inclusion Criteria. 1) Female; 2) aged 18 to 55 years; 3) access to the internet; and 4) a willingness to participate in the study.

Exclusion Criteria. 1) Women who choose not to respond to invitations to participate; and, 2) to ensure independent observations across groups, women who participated in the SAK-P phase of the study will not be eligible to participate in the SAK-E phase. It is anticipated that the race, gender and ethnicity of the proposed subject population will reflect the demographics as shown in the table below for Army, Navy and Air Force personnel. No exclusions will be based on race, ethnicity or HIV status.

H.2. Research materials

Collected from the participants will include questionnaire data for the outcomes of interest, and demographic information including gender, age, ethnicity, and sexual history data. All materials will be collected specifically for research purposes.

H.3. Recruitment and Informed Consent

Participants will receive information about the study from e-mails sent to them from a DOD Survey Office. Investigators will not have access to these addresses. Women who are interested in learning more about the study have the option to access the link to the SAK Study Website, then, they will have the option to participate by placing an electronic signature on the informed consent document (Appendix I). If women choose to participate, they will provide an alternative/preferred email address for use during the study, and women in the SAK-P group will provide a mailing address as well. For more detail, see the Participant Recruitment methods in Section E. 4. above. This method avoids the potential problem that women will perceive that they are coerced to participate in the study.

H.4. Potential Risks and Protection against Risks

H.4.a. Potential Risks

The investigators believe that the potential risks of participation in this study are minimal, based on the FDA definition from 32 CFR 219.102(i): "the probability and magnitude of harm or

discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical and psychological examinations or tests." Some women may view the questions in the survey as personal and sensitive, but not threatening.

H. 4. b. Risk Protections

1. Procedures to avoid perception of coercion during subject recruitment are described above. Women have the choice to respond or not respond to any e-mails that are sent to them.
2. Procedures to protect the privacy of women are:

- All study personnel will complete Collaborative Institutional Training Initiative (CITI) for protection of human subjects.
- Data will be available only to study personnel.
- All on-line data will be stored on a secure, encrypted network at the OSU College of Nursing.
- Consent forms will be an on-line checked form.
- The Project Director (PD) will be the primary point of contact for research participants throughout data collection. The PD will be instructed to maintain strict confidentiality regarding all aspects of the project.
- Any printouts from databases will contain only ID numbers, and will be stored by the OSU Project Director in locked file cabinets in separate folders for each ID number. Periodic summary data printouts will not have ID numbers.
- SPSS data files will be kept on the password-protected College intranet file, with access limited to the PI, Co-Is, and Project Director.
- Electronic and paper data files will be kept for 15 years after the end of the study, then destroyed by proper electronic methods and by shredding.

H.4.c. Benefits of Research Participation

There is no guarantee or promise that the women will receive any benefit from this study, but we believe that the benefits of participation include:

- A unique way to learn about sexual health information, specifically safer sexual practices.
- Deeper understanding of their own behavior and how it may put them at risk for contracting a STD.

H.4.d. Inclusion of Women

The program is targeted toward women, so women will be actively recruited he proposed study within the limitations of the inclusion and exclusion criteria. Since motives behind engaging in sexual risk behaviors are different for women than men and the intervention targets these motivations, men will be excluded in this study.

H.4.e. Inclusion of Minorities

The military is has greater racial and ethnic diversity than the civilian population. We expect that the participants will be somewhat representative of the military population. The subject

recruitment method keeps investigators from deliberately selecting or avoiding selection of specific minorities.

Targeted/Planned Enrollment

Demographics	Army n (%)	Navy n (%)	Air Force n (%)
Women	76,193 (13.5)	52,546 (16.0)	64,275 (19.2)
Race/Ethnicity*			
Non-Hispanic White	74.6%	86.3%	73.0%
African-American	13.0%	6.9%	14.0%
Asian	2.1%	4.6%	1.1%
Hispanic	7.9%	1.8%	13.0%
Other	2.4%	0.4%	8.6%
Projected Enrollment	33% (n = 89)	33% (n = 89)	33% (n = 89)

I. INCLUSION OF CHILDREN

Military women are at least 18 years old and emancipated, therefore, children are excluded from participating in this study.

J. DATA MONITORING AND SAFETY PLAN

The PD will serve as the primary data manager, who will be supervised by Co-I von Sadovszky. Data will be protected as described below. Adverse events are not likely in this survey study.

K. SAFETY PLAN FOR ELECTRONIC DATA

Because the game and data collection will be available on the internet, certain security issues need to be addressed. The security needs of this project are: 1. protecting the data from inappropriate access; 2. protecting the data from accidental or intentional corruption; 3. protecting the data from accidental or intentional loss. The Ohio State University College of Nursing Information Technology staff will provide oversight for security and data storage; this will ensure that the hardware and software used for input cannot be tampered with. The server meets all federal regulations for security for both research and other types of sensitive data. The system is continuously audited and monitored. The network connecting the input terminal to the web server is fully owned by The College of Nursing and does not require SSL or similar technology to encrypt the transmitted data. Informed consent documents and demographic data received from the research subjects, as well as metadata regarding patterns of access to components of the SAK, will be stored by the application on the destination server. Once stored on the destination server, the data will be protected from intentional or accidental corruption or loss via a tape backup system. The backup media will be handled by and accessible by The College of Nursing Information Technology staff only.

L. VERTEBRATE ANIMALS

No animals will be used in this study.

M. TIMELINE

Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun
YEAR 1	2011					2012					
Start-up; refine and print SAK-P intervention materials			Recruit for SAK-P; collect baseline data			Begin SAK-P intervention		Collect SAK-P quantitative data X 2			
Create the web-based electronic version of the SAK-E						→	→	→ →	→	→ →	→
YEAR 2	2012					2013					
Analyze SAK-P data & plan qualitative evaluation	Collect SAK-P qualitative data				Analyze & integrate SAK-P quantitative and qualitative data						
Start-up SAK-E Intervention			Recruit for SAK-E; collect baseline data			Begin SAK-E intervention		Collect SAK-E quantitative data X 2			
YEAR 3	2013					2014					
Analyze SAK-E data & plan qualitative evaluation		Collect SAK-E qualitative data			Analyze & integrate quantitative & qualitative data				Write reports, abstracts, manuscript		