DSMB Protocol:
CHOICES Study
Revised

Melissa Laska, PhD
Principal Investigator

As of 9/5/14

1U01 HL096767

Table of Contents

1. ABSTRACT

The goal of this research is to develop and test innovative strategies to help prevent unhealthy weight gain in college students attending 2-year community or technical colleges. The intervention we propose for Phase 2, and will refine through our formative experiences in Phase 1, will be based on social ecological and social networks models with students randomized to conditions. Students (n=440) with BMIs between 20.0 and 34.9 will be recruited to participate in an intervention trial that lasts 24 months. After the initial screening and consent procedures, students will complete baseline measures that include: assessment of body composition; blood pressure and a blood draw; a behavioral and psychosocial survey; medical and weight history and two 24-hour online dietary recalls. After the completion of baseline assessments, students will be randomized into treatment or control conditions. Students randomized into the intervention condition will participate in a 1-credit course offered through their 2-year college that focuses on eating, activity, sleep and stress management as ways to help maintain or achieve a healthy weight; three course sections will be offered to accommodate students' scheduling needs and learning preferences. A web-based social network and support component will be introduced as part of this course and will continue as the intervention channel for 20 months following the 1-credit course. This supported intervention phase will use a study-designed website to reinforce, inform and encourage exchange and support between all intervention participants. Students will be asked to track their weight and weight-control behaviors on the website and intervention staff will interact with participants electronically or through phone calls offering encouragement and helping with problem solving. Control students will receive their health assessments and usual care including existing public health information on maintaining a healthy weight and information regarding health services offered on their school's campus. The effectiveness and sustainability of the intervention approaches will be evaluated.

2. SPECIFIC AIMS

Primary Aims

The primary aim is to examine the effectiveness of a 24-month weight gain prevention intervention to positively affect BMI in 2-year college students. Our hypothesis is that students randomized to an intervention condition will experience a smaller increase in mean BMI post treatment, as compared to students randomized to the control condition.

Secondary aims

Examine the effectiveness of a weight gain prevention intervention to positively affect weight in 2-year college students.

Compare the effects of the intervention and control groups with regard to change in BMI and weight from baseline to four months and from baseline to 12 months.

We will also conduct exploratory analyses examining how diet, activity and screen time differ between control and intervention groups.

3. BACKGROUND AND SIGNIFICANCE

Obesity Risk in 4-Year and 2-Year College Students

Nationally representative data from National Health and Examination Survey (NHANES) shows that 28.5% of 20-39 year olds are obese and 57.1% are overweight or obese[1]. While overweight and obesity are more prevalent among middle aged and older adults, major weight gain (>10kg) is the highest during ages 25-34[2]. One common life transition for many young adults is the move away from home and into college. Nelson et al (2007)[3] conducted one of the first studies to examine the prevalence, trends and disparities in overweight and obese 4-year college students. Using a nationally representative sample, they found that between 1993 and 1999, the combined prevalence of overweight and obesity rose from 26.7% to 35.2% of the college population and that increases were statistically significant different for African Americans, students in lower socioeconomic positions, and males. Other research examining prevalence rates in specific college student populations found overweight/obesity prevalence estimates ranging from 27% of the student population to about 8% of the population[4-6]. While much of the literature in this field is limited by the use of self-reported height and weight, attrition, and limited external validity, for the most part, these data underscore the growing obesity problem in college age young adults.

We know much less about the prevalence of obesity in students attending 2-year and technical colleges. While overall college enrollment has increased in the past 4 decades, 2-year community or technical college enrollment has increased for those in the lowest SES groups and enrollment in 4-year colleges have increased most among students from higher SES families[7]. Nelson et al examined data from a survey of students from 14 Minnesota colleges and universities which showed that, compared to 4-year students, 2-year students were twice as likely to be obese as compared to students attending 4-year colleges[8]. Two-year college students are also more likely to be older, female, have at least one child, work more than 20 hours per week and come from lower socioeconomic households[9, 10]. Data from the National Center for Educational Statistics (http://nces.gov/dasolv2/tables/) suggest that 38.6% of people of color will attend a two-year college.

Activity, Diet, Stress, Sleep in College Students

Examining the etiology of weight related issues in the college-age population (18-23 year olds) is hampered by a paucity of data, especially data with good external validity. An exception are data from the National Longitudinal Study of Adolescent Health where investigators examined longitudinal patterns of physical activity and sedentary behavior in a nationally representative cohort of youth transitioning from adolescence into young adulthood[11]. At baseline, about 35% of the sample was participating in at least five or more weekly sessions of moderate to vigorous physical activity each week. As the cohort transitioned into young adulthood, only 4.4% of the sample continued to meet these activity levels. Of the 65% of the sample that was not active during adolescence, only 3.6% transitioned to greater levels of activity as they reached young adulthood. As for screen time, at baseline 54% of the sample was spending 14 or fewer hours in front of the television or playing video or computer games and 17.3% of these adolescents increased their screen time to greater than 14 hours a week as they entered adulthood. Unfortunately, this research did not examine differences in the trends in activity patterns by those attending college and those not attending college.

Driskell et al (2005)[12] found that only about half of university students sampled met the American College of Sports Medicines recommendations of 20-30 minutes of moderate to vigorous physical activity most days of the week. Nearly half of the sample of freshmen and sophomore students reported that their physical activity habits were influenced by their desire to lose weight -- representing a significant difference in response as compared to the upper-level students[12]. Data collected as part of the Harvard School of Public Health College Alcohol Study (CAS) showed that approximately two-thirds of college students nationally (73% of males and 68% of females) reported engaging in three or more days of vigorous physical activity (VPA) for 20 minutes or more during the week while they were in high school[13]. However, only half (52% of males and 44% of females) of these same students reported the same activity levels in college.

Some research examines change in dietary patterns and food choices as students transition into college. The National College Health Risk Behavior Survey[14] found that 74% of college students did not eat at least 5 servings of fruits and vegetables and nearly 25% reported consuming at least two servings of high fat foods during the day preceding the survey. Butler et al (2004)[6] examined self-reported changes in freshmen women between starting college and 5 months later. Between the first and fifth month of college, females reported a decrease in their vegetable and milk intakes. Other research[15-17] compares student intake to national dietary guidelines and finds that students fall short of most recommendations, especially eating a variety of foods, eating fruits, vegetables, whole grains, and dairy products and choosing a diet that is moderate in sugar and sodium. Levitsky[18] identified that the consumption of junk foods, meal frequency and the number of snacks accounted for 47% of the variance in weight gain during the first 12 weeks of college in a sample of students at Cornell University.

In addition to changes in diet and physical activity, many college students experience high levels of stress[19, 20]. College students face stress from new life events as well as from a new set of daily hassles they likely face as they enter a new environment. New college students experience levels of autonomy and freedom they have never experienced in addition to increased responsibilities for managing their time and dealing with new interpersonal relationships[21]. This stress can result in various maladies including headache and depression[22], suicidal ideation[23], and decreased immune function[24]. Stress has been associated with over-eating, obesity and poorer mental health, and these studies have included both animal and human subjects[25-28]. Stress is also related to depression among college students that may in turn be associated with obesity[22]. With increased levels of stress, and its potential to impact mental health, a focus on coping with stress as part of weight management seems warranted.

The association between sleep and unhealthy weight has been well established in adults. Modest reductions in sleep duration are associated with significant increases in obesity risk in adults[29-31]. A 13-year prospective study of 496 young adults showed an association between short sleep duration and obesity at age 27; those reporting less sleep had a 7.4 greater chance of being overweight as compared with young adults getting more sleep; the associations persisted after controlling for a number of confounders, including level of activity and demographic characteristics[31]. Low levels of sleep are well documented in college students[32] and may be playing some role in the increased risk for obesity. There is very little research on the effectiveness of stress reduction programs for

college age students. Past interventions have evaluated the effectiveness of teaching the relaxation response, using cognitive behavioral therapy, and mindfulness therapies[33-36] with mixed results.

Previous intervention studies with college students. There is very little research on interventions to prevent weight gain in college age students. Stice et al (2006)[37] conducted an intervention study using a semester-long college course on eating disorders and obesity that employed psychoeducational approach. A comparison group was used rather than a randomized control group but they found that intervention participants gained significantly less weight than control participants who gained an average of 4.5 kg at six-month follow-up. Hivert et al (2007)[38] evaluated the effectiveness of an educational/behavioral intervention delivered through small group seminars using a randomized trial with a sample of 115 non-obese Freshman. At the end of the 2-year intervention, there was a statistically significant difference in weight gain and BMI between the two groups. At 24 months, students randomized to the control group gained an average of 0.7 kg (s.e.m.=0.6) while students randomized to the intervention group lost an average of 0.6 kg (s.e.m.= 0.5). Change in BMI was also statistically significant with average BMI change increasing in the control group by 0.2 units (s.e.m.- 0.2) and average BMI change decreasing in the intervention group by 0.3 units (s.e.m.- 0.2). A recently published study by Gow et al (2010)[39] examined the prevention of weight gain in first-year college students using an online intervention. The study included 170 students randomly assigned to one of 4 conditions: control; 6-week online intervention; 6-week weight and caloric feedback via email; and a 6-week combined feedback and online intervention. The control group increased their BMI by 0.18 BMI units (SD=4.68) while the combined intervention group decreased their BMI by 0.25 BMI units (SD=5.14). Importantly, the only intervention group that showed a statistically significant difference in BMI compared to the control group was the intervention group that combined participant monitoring, feedback and education. The table in Appendix 1 shows a brief summary of these 3 intervention studies in college students. These studies used small samples and lacked generalizability; however, they were all able to detect significant differences in weight or BMI through behavioral/educational approaches that are feasible and appropriate for college students. None of these intervention studies involved students in 2-year colleges.

Use of online courses at colleges. Online course offerings have increased tremendously over the past several years. More than two-thirds of post-secondary institutions in the United States offer online opportunities for learning, and most of them believe that online learning is an important component of their long-term plan. Reasons cited for offering online courses included increasing student access, attracting students from outside traditional service areas, improving student retention, and increasing strategic partnerships with other institutions, among others. In the fall term of 2006, nearly 20% of all college students, or 3.48 million students, were enrolled in at least one online course. A majority of that online course enrollment occurred among undergraduate students attending public institutions and/or two-year institutions[40]. Cousineau et al, (2006)[41] reported on the feasibility of delivering a web-based nutrition education course for college students. They describe the formative work done to create the content, the prototype web program development and the feasibility testing done with student and college health professionals. While the web-course was not evaluated, process data suggested that this approach was feasible, compelling and relevant to college students.

Understanding social networks of young adults through electronic approaches. Young adults increasingly use electronic media, including phone, iPods and computers, as a way to communicate with their peers. In the past decade, virtual social networks such as MySpace, Facebook and Twitter have exploded as a way the young adults connect with each other. The use of these virtual social networks as a tool for health promotion is just beginning to be explored[42, 43]. There is a large body of research on network analysis, the theory and techniques used to describe relationships among individuals, organizations, or political entities and the research is closely tied with understanding the diffusion of innovations in groups[44, 45]. We are increasingly aware of the effect of social networks on health. Valente (2004)[46] and Christakis (2007, 2008)[47, 48] have reported social networks and their relationship to substance use[46], smoking[48] and obesity[47]. Relevant to this study, Christakis (2007) shows compelling evidence, using social network analysis that obesity appears to spread through social ties.

Recent work has examined the structure of social networks that develop through a web-based health promotion program. Cobb et al (2010) examined the social network structure of QuitNet, an online social network that focuses on smoking cessation. The social network features of QuitNet began in 1997 and uses multiple forms of social support including asynchronous channels such as email and synchronous channels such as chat rooms[49]. In addition users can join virtual "clubs", buddy lists to view others' progress, post testimonials and publicly share quit dates in order to receive and give support to other members. Cobb et al used network analysis to identify active QuitNet members and subgroups based on connectedness and if they were key players, newcomers or integrators. Their research helps establish a foundation for evaluating and understanding how online social networks with a goal toward health promotion may harness the power of social support and social influence. Still, there is much to learn about how social networks form and are maintained in online communities and if, and how, this source of social influence can be used to positively impact the health behaviors of an online community.

4. OVERVIEW OF DESIGN

This research uses individuals as the unit of assignment and analysis, and will occur in two phases. Phase 1 was the formative stage (with lessons learned described below) and Phase 2 is informed by what was learned in Phase 1 and will include a randomized intervention with an intensive intervention phase (4 months) and a web-based supported intervention phase (twenty months).

The intervention will be tested in 2-year college students recruited from three community and technical colleges in the Minneapolis/St. Paul area. After baseline data collection, respondents will be randomized to two conditions: Control or Intervention. If randomized to Intervention, for the 4-month intensive intervention period, we will offer a 1-credit course at the community colleges. There will be 3 sections available in this course: online-only; online-enhanced or hybrid; and a face-to-face, in person class. We will ask respondents randomized to intervention to make a first and second choice for their section preference and will attempt to have students spread evenly across the 3 sections. It is common practice for colleges to offer both an on-line and a face-to- face version of a course; increasingly, they are offering a hybrid course that includes both online and face-to-face instruction. During our formative phase we heard from students that they would like to be able to choose their class section in order have an option that fits best with their schedule as well as

preferred learning styles. During this intensive intervention phase, students in all three sections will be introduced to, and will engage in, a study website that will not be accessible to control students but will provide networking opportunities, social support, opportunities for monitoring behavior and setting goals, feedback on progress and general information to intervention students. All sections of the course will be exposed to the same web-based supported intervention for 24 months.

5. STUDY POPULATION AND ELIGIBILITY

Three community colleges have agreed to participate in this research including Anoka-Ramsey Community College, Saint Paul College and Inver Hills Community College. Letters of support and information on each college have been obtained. The table below shows the characteristics of the student body. These colleges attract an ethnically and racially diverse and low-income group of young adults.

Student Characteristics from Recruited Community Colleges

	Anoka Ramsey Community College	**St. Paul College**	**Inver Hills Community College**
Student enrollment 2009	9,725	6,479	7,152
% Minority students	12%	50%	21%
% Black non-Hispanic	6%	35%	10%
% Hispanic	2%	3%	4%
% American Indian/Alaska Native	1%	1%	1%
% Asian/Pacific Islander	3%	11%	6%
% Non-Resident Alien	Less than 1%	Less than 1%	Less than 1%
% Unknown	2%	4%	10%
Retention Rate (% Full/Part Time)	45/55	40/60	41/59

In order to participate in the CHOICES study, participants must be between the ages of 18 and 35 and intend to be available for a 24-month intervention. There are a number of exclusion criteria, which have been adopted for all of the EARLY trials. The only additional CHOICES-specific exclusion criterion is that participants will be ineligible to participate if they are trying to gain weight.

6. RECRUITMENT

Recruitment Sources

The colleges we have recruited enroll about 25,000 students per academic year and report a 40-60% retention rate between first matriculation and finishing their 2-year program. Therefore, we have an ample population group from which to recruit but we will need to use the best approaches for recruiting students who are most likely to complete two-years of community college and find ways to retain them in the study, including providing incentives for participation in intervention and evaluation activities. Each of our participating 2-year colleges has agreed to help us recruit participants into the Phase 2 trial. During our formative phase, we heard that emails from student

services, information on the study provided during registration and having a presence on campus (such as a booth or table in a common area) are good ways to recruit students.

Recruitment Process
To ensure that we get a diverse sample, we will work with each college human resources center to query names of students who have a free or waived ACT or SAT fees, received free or reduced lunch in high school, full or partial Pell grant eligibility in college, participation in Admission Possible as a high school student, recipient of a Wallin, Page, or Gates scholarships.

For students responding with interest to the study, we will conduct a brief screening phone call to assess eligibility criteria which include: 1) ability to speak and understand English, 2) conditions that may preclude their participation in the study such as current treatment for an eating disorder or current participation in a commercial weight loss program, 3) intent to stay in the area for the next 2 years; and 4) self-reported height and weight that place their BMI between 20.0 and 29.9. We will provide a verbal overview of the study, answer the student's questions regarding the study, and schedule an appointment to confirm BMI and eligibility to enroll in the study. To increase recruitment rates in the study, we instituted an IRB-approved referral process whereby enrolled participants receive a $25 Target gift card for every person they refer who is eligible and enrolls in the CHOICES study.

Recruitment Tracking
Participants will be tracked from the time of first contact through the screening process and documentation will include screening status, eligibility (or reasons for ineligibility), and participation (or reasons for non-participation). The recruitment "tracker" we will use will provide specific feedback to all the EARLY sites on what methods worked in recruiting the most participants.

Recruitment of Women and Minorities
We expect that at least 50% of our sample will be female and that minorities will make up approximately 30% of the sample. We will attempt to recruit a sample that includes at least 30% males according to agreed upon recruitment goals for the EARLY trials.

7. DATA COLLECTION AND MEASUREMENTS

Data Collection Contacts
As part of their willingness to participate in the CHOICES study, the community colleges have agreed to assign a staff member to assist Stacey Moe, who serves as the CHOICES Project Coordinator and Evaluation Coordinator, and her data collection team with needs as they arise while on campus for data collection activities. Specifically, these staff members will be asked to assign locations for data collection activities and to assist with any last minute items as needed by the data collection staff, such as student schedules.

Measurements
Appendix 2 details data collection measures and instruments. The measures/protocols identified with a star (*) are common to all EARLY Trials.

Individual-level measures
Students will be assessed during a clinic visit where body composition measures, blood pressure and a fasting blood draw will be directly measured and where the students will complete a behavioral/psychosocial questionnaire.

Anthropometry*
Height will be measured (and recorded to the nearest 0.1 cm) in duplicate using a portable stadiometer graduated in centimeters with a horizontal measuring block. Body weight will be measured in duplicate on a scale with a built-in body fat analyzer and will be recorded to the nearest 0.1 kg. Waist girth/circumference will be measured by following the NHANES III protocol. Using a Gullick tape measure, all measures will be taken in duplicate and recorded to the nearest 0.5 cm.

Blood pressure*
Following a 5-minute resting period, blood pressure will be measured on the participant's right arm using a Dinamap blood pressure machine while the participant is seated. Two measurements will be taken at 1-minute intervals. Duplicate measurements with systolic blood pressure differing by $\leq$10 mmHg and diastolic blood pressure differing by $\leq$6 mmHg should be obtained. If these criteria are not met, a third measurement will be taken.

Blood Assays
Fasting blood samples will be obtained from each student during an early morning clinic visit. Fasting blood samples will be obtained by venipuncture for serum insulin, glucose and lipids (total cholesterol, triglycerides, LDL-cholesterol, and HDL-cholesterol). Whole blood samples will be collected on ice and centrifuged within 20 minutes. Insulin and serum lipids will be measured in the University of Minnesota reference laboratory. A metabolic syndrome cluster score (MCS*)* [(50)] will be calculated for each individual using: weight circumference, Homeostasis Model Assessment (HOMA) index[(51)], fasting triglycerides, HDL-cholesterol and systolic blood pressure. The ability to use a continuous distribution of MCS will enhance statistical power and the use of a composite score is responsive to important metabolic changes that cannot be detected by dichotomous outcomes based solely on clinical cutpoints.

Dietary behavior*
Using the ASA-24 assessment method, two 24-hour recalls will be obtained for each participant within a 2-week timeframe and will include a weekday and a weekend day. In addition, eating behaviors will be measured through questions about participant sugar-sweetened beverage consumption, eating away-from-home practices, weight management practices, and daily meal patterns.

Physical activity and sedentary behavior*
In order to assess physical activity, we will be using the Paffenbarger Physical Activity Questionnaire and the Global Physical Activity Questionnaire (GPAQ). The rationale for using the Paffenbarger questionnaire is that it has commonly been used in studies of weight control and physical activity. The questionnaire can provide total energy expenditure in leisure-time physical activity, total time spent in leisure-time physical activity, and mode of leisure-time physical activity.

The rationale for using the GPAQ is that it includes information on household, occupational, and transportation physical activity. It has been recommended to be superior to the IPAQ. In order to assess sedentary behavior, we are using the CARDIA Sedentary Behavior Questionnaire. This questionnaire is based on the original PACE Questionnaire, but has been modified to include additional clarity on specific forms of sedentary behavior.

Student Survey

Psychosocial constructs

The behavioral/psychosocial survey will include items that tap psychosocial constructs that have been shown in the empirical literature to be correlates or predictors of obesity, eating patterns and activity patterns including: knowledge, beliefs and attitudes around diet and physical activity, perceived opportunities and barriers to healthful diet and activity, perceived role models of healthful diet and activity behaviors, self-efficacy, and social support and social cohesion. In accordance with the common elements being collected in the EARLY trials, we will also collect data on depressive symptomotology*[52], sleep, smoking and alcohol, unhealthy weight loss practices and perceived neighborhood environments

We will be able to collect more specific measures of the social network via the website created as part of the web-based supported intervention phase. We will use a web-application that provides a transactional history of all events occurring on the site including postings, response to postings, submitting behavioral logs and requests for information. Through these online data we will be able to examine characteristics of the social network that develops. We are also planning to conduct interviews with our intervention group at 12 and 24 months to obtain in-depth qualitative information on how social networks formed and how they worked to enhance healthy weight maintenance.

Demographics, socioeconomic status and family structure and family history

We will include questions on age, race/ethnicity, number of people living in the household, marital status, occupation, educational levels, and income levels in the family survey using items that have been agreed upon by all of the EARLY investigators. We will also ask participants to complete weight history and family medical history questions on the survey.

Stress management behaviors

During the pilot phase we will develop and test questions to assess the use of stress management approaches that we will advocate in our intervention such as meditation, yoga, breathing exercises, and walking for stress reduction.

We will evaluate the reliability of the newly created or adapted items on the survey by having a sample of 2-year college students take the survey twice within a period of two weeks. We will evaluate the internal consistency of items written as scales and we will examine construct validity. Based on this formative work, we will finalize our survey in the winter so that it is ready for baseline data collection in early spring.

8. QUALITY ASSURANCE AND QUALITY CONTROL

The first level of quality control involves monitoring adherence to data collection protocols. The evaluation coordinator (Ms. Moe) will be responsible for training the staff and monitoring the operation of the study. The second level of quality control involves monitoring the completeness of the data collected. For survey data, we will use optical-scan forms and the survey staff will be trained to quickly scan the forms before leaving the field to make sure that all are fully completed. Once forms are returned to research offices, they will be reviewed to identify any empty fields; if incomplete forms are discovered, an attempt will be made to collect the missing data. We generally have very little missing data as our staff is trained to briefly peruse the surveys and data collection instruments for missed sections at the clinic visit. The third level of quality control involves monitoring the quality of the scanning and data entry operation. The scannable forms will be scanned by Data Recognition Corporation, a local firm with whom we have worked for nearly 20 years. Entered data will be assessed for reliability by having our programmer (Mr. Baker) select a 1% simple random sample of all forms for manual verification against the originally entered forms. The fourth level of quality control involves editing all files. For each data collection form, the programmer will generate item frequencies and review them with Drs. Lytle, Hannan and Ms. Moe. Out-of-range and other questionable values will be identified; corrections will be made using a standard protocol developed during the baseline data collection period. The fifth level of quality control is the creation and maintenance of analysis files. The programmer will be responsible for certifying all files as ready for analysis and will safeguard the integrity of the files. We will prepare all analysis files, selecting cases and variables as needed.

9. RANDOMIZATION AND MASKING

Following baseline measures, we will block students on college, weight status and gender and then randomly assign students within block into the intervention or control condition. We will not be able to mask assignments as students will know if they are participating in an intervention that involves a 1-credit college course and a web-supported intervention or if they are receiving more standard information on healthy weight management. Likewise, the intervention staff will not be blinded. However, measurement staff, including those collecting heights, weights and body composition data, will be blinded to treatment status of all participants.

10. INTERVENTION

Overview of the Intervention

After baseline data collection, respondents are randomized to two conditions: Control or Intervention. If randomized to Intervention, for the 4-month intensive intervention period, we will offer a 1-credit course at the community colleges. There will be 3 sections available in this course: online only; online-enhanced or hybrid; and a face-to-face course option. We will ask respondents randomized to intervention to make a first and second choice for their section preference and will attempt to have students spread evenly across the 3 sections. During this intensive intervention phase, all students randomized to the intervention condition will also be introduced to and invited to participate in a web-based supportive component. This web-based supportive component will be in place for 24 months, continuing for 20 months after the end of the one-credit course.

Theoretical Rationale/Model Underlying the Intervention

Our ecological conceptual model is included in Appendix 3 and is informed by ecological theories of health behavior [44, 53], social cognitive theory[54], and social network theory[46]. It posits that weight related factors and biomarkers are associated with each other and that they are most proximally influenced by mutable behaviors including energy intake, energy expenditure, and other health-related behaviors. Those behaviors occur within the context of personal factors and the physical and social environments. In students attending community or technical colleges, we believe these individual factors are particularly important. Formative research suggests these students may have limited skills related to menu planning, shopping for healthful foods and simple meal preparation. In addition, their busy schedules make eating out and on the run a common occurrence. Stress is likely and may impact what and how much food is eaten. Other intra-individual attitudes and beliefs related to weight, support for healthful options and their own lifestyle preferences are likely strong determinants of their behavioral choices. Since most of them are living on their own or with roommates, the foods available in their home are likely different than foods available in the homes in which they grew up due to the cost of foods, their ability to shop frequently enough to keep fresh food in their home, their ability and time to prepare meals and their own food preferences. The physical environment to which the students are exposed as they move through their day (from home to school to work to picking up children at day care or visiting friends) affects their options, cues and barriers and reinforcers for activity, as well as the food choices and the portion sizes of food they consume. Finally, the social environment provides normative messages, support or lack of support, role modeling and a larger, and complicated, network of influences that appear to affect the health of individuals in that network both directly and indirectly[46-48]. Our intervention focuses on four key areas: eating and nutrition, activity and sedentary behaviors, sleep, and managing stress. The model recognizes that the associations posited in the model and the effects of the intervention, will likely be influenced by moderators, including gender, race/ethnicity, age, depression, and weight status. In addition, the model directs the evaluation model by providing a picture of potential mediation effects, and expected directions of associations.

Description of Intervention

The intervention focuses on four primary areas: nutrition, activity and sedentary behaviors, managing stress and getting enough sleep and links those behaviors to the importance of energy balance.

The intervention begins with a 1-credit course. The 1-credit course is based on an online course that was developed at the University of Minnesota and delivered to college undergraduates for the first time in the fall of 2009. This course was in development when the grant application was being developed. Dr. Lytle invited the course developers to be investigators on this application (Ms. Kjolhaug, Mr. DeNeui and Dr. Gardner) with the intent to evaluate the impact of the online course in 2-year colleges. In addition, 2 other versions of the course will be offered including the online class with 5 face-to-face sessions (online-enhanced/hybrid) and a face-to-face course where all classes are held on the 2-year college campuses. In addition to didactic elements, the course includes self-monitoring of eating, activity, sleep and stress and goal setting related to changes in those behaviors. All versions of the course provide very practical information and hands-on skills development for preparing healthful, low cost meals, finding ways to be active during the day,

Planned Elements of the CHOICES Intervention Social Network Website

Intervention website Components	Details	Social Networking capacity
1. Self-monitoring/self assessment	There will be several self-monitoring sections on the website that include: 1) daily body weight, and 2) behaviors related to maintaining a healthy weight including: eating breakfast, consumption of sugar-sweetened beverages, fast food, fruits and vegetables, hours of screen time, minutes of physical activity; amount of quality sleep and engagement in stress-reduction activities. We may also create some self-assessment tools for our behaviors of interest (similar to E-Chug; E- Toke) to help raise awareness of personal behaviors.	
2. Goal setting and feedback	Tied into the self-monitoring we will have participants set goals on the website. This section is a place for students to share their goals as well as share stories, pictures, and accomplishments. This is an open forum where students will comment on each other's small victories and challenges. Study staff will respond if no one else has. This component provides opportunity for affirmation and encouragement.	**Yes**
3. Tips & Resources	This section provides information, such as tips and resources, on all behavior topics. Study interventionists provide the information for this section.	
4. Chat room/forum	This section is a place for students to ask questions. It is open to everyone and students will be encouraged to provide answers and ideas. "Expert opinion" / study staff will be involved in the discussion and make sure everyone's questions are being answered. Comments will be associated with a user name.	**Yes**
5. Hot Topics	This section pulls in information that is "hot" in the media through a variety of formats, including myths/facts, monthly quizzes, debates, etc. Study interventionists provide the information for this section but students can respond/comment.	**Yes**
6. Events/Calendar	This section includes information on local events and opportunities related to healthy eating and activity options. The calendar will include color-coded designations for students from different schools. It will also include child-friendly events.	**Yes**
7. Personal Hotline	This section will be private and personalized. The student will be able to send a confidential question about a personal challenge or health issue to a study interventionist. The interventionist will provide referral, information or problem-solving advice over the phone. This is not a space for medical emergencies or mental health counseling.	
8. What's for Dinner?	This section provides a dinner menu idea with an associated shopping list and recipe. It would include substitutions for dietary needs (vegetarian, gluten-free, etc.) The menu will change weekly. It will emphasize meals that are cheap, fast and healthy. Study interventionists provide the information for this section but students can respond/comment.	**Yes**
9. Monthly Give-Away	This section provides monthly prizes for participation such as a) # of times accessing the site, b) completing quizzes, and c) achieving weight or behavioral goals. Examples of give away items include: ITunes gift card, water bottle, canoe at Calhoun, resistance bands, REI gift card, gym/yoga memberships, useful kitchen supplies such as a thermos, crock pot, blender, or salad spinner, veggie brush, etc.	
10. Personal page/profile	Participants post information about themselves they are willing to share	**Yes**

Standardizing Delivery of the Intervention

The course (including its three sections) will be offered at all three of our participating colleges. Based on our formative work we decided that our intervention staff will take the primary responsibility for delivering the course with an instructor from each college included as the

instructor of record. Using our own intervention staff will provide the optimal delivery both in completeness and fidelity of content and delivery. We are finalizing a course manual with standardized lessons, assignments, and readings to maximize consistent delivery across our interventionists. During the 20-month web-based supported intervention the study interventionists will be responsible for the content and the follow-up that will occur. During this phase intervention participants from all three colleges will be engaging with each other on a common CHOICES intervention website; therefore all intervention participants will get the same delivery in this phase.

Facilitating Participants' Retention in the Intervention

For this trial to be successful, we need to be able to successfully recruit and retain individuals to participate in four sets of measurement activities and to complete activities related to the intervention. We conducted interviews and focus groups as part of Phase 1 to learn the most appropriate ways to recruit individuals into a study, barriers to recruitment and retention, ways to minimize drop out and the best ways to track participants. Between October 2009 and April 2010, a total of 30 staff were interviewed across three colleges (Inver Hills Community College, Saint Paul College and Century College), including 13 Student Service (student life directors, retention coordinators, health services and enrollment services), 12 faculty, three administrators and two food service staff members. Research staff also conducted 13 one-on-one interviews with college students and held 10 focus groups with a total of 44 student participants. In all, we gathered information from a total of 87 individuals.

From this formative phase we heard that the topics we are interested in (weight management through healthy eating, activity, sleep and stress management) are seen as interesting and important to students and staff. In addition we heard that colleges do not offer weight management classes that cover nutrition, activity, sleep and stress management. Therefore, we will be providing a new and unique opportunity for students and will not overlap and compete with other college classes. Students told us that they are not likely to attend intervention sessions that are not credit-based. Therefore, we changed our original intervention plan (which was to offer a 1-credit-online course and a not-for-credit weight management program) to a plan that provides 3 sections of the same 1-credit class. In addition, students told us they preferred to choose the type of class they would take rather than be randomized into a section; therefore, we are allowing students that have been randomized into the intervention condition to self-select into a section. Our plan is to ask students to choose a first and second choice for course delivery and then we will fill the sections so there is approximately the same number of students in each section.

We acknowledge that retaining students into the 20-month web-based supported phase will be more difficult. We will work toward creating incentives and rewards for participation in web-based activities (such as creating contests). In addition, we plan on having opportunities for face-to-face events to help keep participants connected.

Intervention Contact Schedule

During the first 4 months of the intervention, students who choose the online version of the course will have no face-to-face contact but will have regular weekly online contact with the course instructor (a study interventionist) associated with the course material. Students who choose the online-enhanced version of the class will receive the online course in addition to 5 face-to-face

sessions led by study interventionists; each face-to-face session is 55 minutes in length. Students choosing the face-to-face course will meet with course instructors (study interventionists) weekly for the 16-week course; each class is 55 minutes in length.

During the 20-month web-based supported intervention phase, participants are expected to log onto the website at least once every two weeks; we will design activities and incentives that will encourage active participation. Our formative assessment also suggested that some face-to-face activities would be welcome, therefore we are considering planning a monthly get- together for participants that might involve a social activity such as a fun run, cooking class, yoga workshop or potluck.

11. SAFETY MONITORING

Potential Risks

The risks to participants are minimal. The only invasive procedure is a blood draw and participants may choose to refuse to participate in the blood draw but participate in all other aspects of the study. Other measures that we will collect include; height, weight, waist circumference, blood pressure, self- reported eating, activity, sleep, and stress management techniques. They will be asked to complete a behavioral/psychosocial survey. Some of the questions on the survey may be sensitive in nature; there are a few questions about cigarette smoking, alcohol consumption, and depression, but the majority of questions are about eating and physical activity. Students will have the option of refusing to answer any question.

Surveillance and Reporting Procedures

In accordance with the EARLY DSMB 1 and 2, we will follow all procedures as outlined by the EARLY Safety Subcommittee. These include documenting any adverse events (and potentially serious adverse events) at the measurement clinic visits and during intervention contacts. The common EARLY protocol clearly outlines what is considered an adverse event and how adverse are to be handled. We will follow the EARLY protocol. We will also track medication use and will adopt common safety alerts as detailed in the EARLY protocol and outlined in Appendix 4.

Safety Monitoring Plan

The specific forms that are included in our safety-monitoring plan include the Medical Events Form, the Serious Adverse Events (SAE) Form, and the Participant Termination Form. The purpose of the Medical Events Form, which is completed by trained study staff members in order to collect information on adverse events and to identify serious adverse events, is administered at data collection visits. The purpose of the Serious Adverse Events Form, which is completed by the study clinician, is to collect information on Serious Adverse Events for reporting to the DSMB, the IRB and NIH. It also identifies the need for expedited reporting to NIH. It is completed whenever an SAE is identified (based on the Medical Events Form during regular data collection visits or based on interim reporting, such as during an intervention contact). The purpose of the Participant Termination Form is to collect information on how many participants terminate from the study (which is defined as stopping both intervention and data collection aspects of the study). It is completed by trained research staff members whenever a termination occurs.

12. POWER AND SAMPLE SIZE

For the power analysis we will initially ignore the impact of the Individually Randomized Group Trial (IRGT) design[55], and will examine in a second step the impact on power of the IRGT and of drop-outs. The primary hypothesis postulates a difference in the baseline-adjusted log-BMI at the final assessment period (following the 24 month intervention period) between students in the control and intervention groups. Based on population trends in this age group, we expect to see a mean increase in BMI in the control group between baseline and the final assessment period. We expect that exposure to the intervention will result in a mean BMI for the intervention group that is either unchanged, reduced, or has increased to a lesser extent than the BMI in the control group between baseline and the final assessment periods. We refer to the difference in BMI between the two groups as the differential change between the groups. We examine the numbers needed to detect a 3%, 4% and 5% differential change between the intervention and the control experiences. On the log-scale these are shifts of magnitude Δ=-0.0305, -0.0408, or -0.0513, respectively. The 2-sided Type I error will be set at 0.05, giving a critical Z-value=1.96. Power at 80% will be examined, with critical Z-values=0.84. Correlation of BMI over 24 months to a year will likely be in the range (0.7 – 0.9) and we take the more conservative value, r=0.8. The delta method[56] shows i) that the correlation of the log-transformed BMI is the same (to first order), and ii) that the variance of the log-transformed variable is approximated by the squared coefficient of variation of the untransformed BMI (CV^2). We take CV=0.11 based on data from 2278 young adults age 23-28 years old from the Project EAT study. Let N denote the total number of students. In a baseline adjusted_ANCOVA[57] the variance of the experimental effect adjusted for baseline is

$$CV^2(1/(N/2)+1/(N/2))(1-r^2)$$

and the power requirement is

$$\Delta^2/\{CV^2(4/N)(1-r^2)\} \geq (Z_{1-a/2} + Z_{power})^2$$
$$N \geq (Z_{1-a/2} + Z_{power})^2\, 4\, CV^2\, (1-r^2)/\Delta^2$$

Students clustered within classes and synergy promoted by the web-based supported intervention will probably work in subgroups smaller than the full intervention sample; however, the ICC in the smaller subgroups will be higher than in the whole group. No prior estimates of the ICC are available. Based on experience in dyads, in schools, in medical clinics, in 4-year universities, and in large communities we will assume the ICC developing in the whole intervention group to be in the range 0.002 to 0.005. Instead of the simple factor (2/N + 2/N) in the formula for the variance of the intervention detectable effect (Δ) we will have a design effect[58], $DEFF=1+(N/2-1)_x ICC$, applicable to only the second of the 2/N, that is, in the intervention group only. The DEFF is effectively $1+(N/2)_x ICC$ because N is large. Thus allowing for the IRGT, the dependence of the variance of Δ on N and the ICC becomes
$\{2/N + (2/N)_x(1+N/2_x ICC)\} = 4/N_x(1+(N/4)_x ICC$, corresponding to an inflation of the variance by a factor $(1+N/4_x ICC)$. The table incorporates a range of potential values of the ICC coming from the IRGT design.

Power 80%

	Δ=	*3%*	*4%*	*5%*
ICC(IRGT)=	0.005	245	128	78
	0.004	237	126	77
	0.003	231	125	77
	0.002	222	122	76

The table shows the sample size needed to detect the stated percent differential change of 3%-5% in BMI between the intervention and the control groups using a 2-sided test at 5% Type I error rate with power set at 80% for different levels of the ICC generated by the synergy in the IRGT. A dropout rate of 20% has been included in the calculations. A sample size of approximately 240 provides reasonable power to detect the small 3% difference in BMI between intervention and control values at follow-up adjusted for baseline. We had budgeted for a sample of 440 based on previous sample size calculations. We will still plan on enrolling a sample of approximately 440; this assures adequate sample if our dropout rate is higher than expected and also allows us to conduct secondary analyses examining moderating effects such as gender or baseline levels of depression.

We have adequate power for our secondary aims that will evaluate change in weight in kg and differences in BMI and weight change in the treatment conditions at 4 months and 12 months. Power for differential change in weight will be similar to power for differential percent change in BMI as height will be almost constant at the ages under study. The detectable Effect Size for log(BMI) is 0.27; the same design parameters yield the same ES for weight gain. In Project EAT the observed increase translates to 4 lb in two years, and an ES=0.27 translates to the intervention group increasing by only 0.5 lb. Such a result is detectable at 80% power. For comparing the intervention effect at 4 months against the effect at 2 years, the variance of the test-statistic would be approximately doubled. Our 80% larger sample size (e.g. 440/245) nearly compensates for the larger variance. Power for the comparison at 4 months and 12 months would be approximately 76%, adequate for a secondary hypothesis.

The sample size calculations are very conservative: 1) we include ICC in our calculations to account for clustering that may occur in an IRGT; 2) we set a drop out rate of 20% even though our research generally results in dropout rates in the 10-15% range; 3) we used a conservative estimate 0.80 as the correlation over 2 years in BMI; and 4) we plan for a sample size that is 80% above the estimated sample size to detect a 3% difference between control and intervention conditions with 80% power and 2-sided Type I error will be set at 0.05. We are likely overpowered for our primary analysis but believe that it is important to have adequate power to conduct exploratory analyses with confidence. Some of the other exploratory analyses that we will conduct including an examination in nutrient intake (specifically kilocalories, total fat, saturated fat and fiber intake) and activity and screen time between control and intervention students. In addition, as exploratory analysis we will examine the moderating effects of gender, socioeconomic status, race and depression on outcomes.

13. ANALYSIS PLAN

*Phase 2 – Evaluation of the experimental program***.** Primary data will consist of baseline, post-class (4-month), annual (12-month) and final (24-month) measurements of BMI. Participants will be balanced by gender and over-weight status ($\geq$25 kg/m^2) by block randomization. Importantly, the randomization will be crossed with colleges, making the student-level the appropriate unit of randomization. However the web-based supported aspect of the intervention (0-24 months) will build synergy between all participants, and hence this trial becomes an "individually randomized group trial"[55] which affects power estimation and analysis methods (see above). Randomization will occur after baseline data are collected on all consenting participants, immediately prior to the registration period for fall classes.

The primary hypothesis is that, compared to the controls, those in the intervention will have a smaller increase in mean BMI post treatment. The primary hypothesis will be tested using covariance pattern modeling estimated using mixed model regression. Covariance pattern modeling accounts for correlation in longitudinal data (due to measuring the same individuals over time) by allowing the residuals to correlate. Condition (Intervention, Control), Time (Baseline, 4-month, 12-month, and 24-month), and their interaction will be modeled as fixed effects. The overall test of any difference in BMI by intervention condition is the Time x Condition interaction, a 3 degree of freedom test. Planned contrasts will be used to isolate intervention effects at 4, 12, and 24 months using single degree of freedom tests. Although not required for a valid test of the randomized experiment, baseline values of possible confounders (e.g., gender, race/ethnicity, SES) will be included as covariates to account for residual confounding not fully balanced in the randomization. Similarly, a number of recruitment strategies were employed. Baseline differences in BMI by recruitment strategy will be examined, as will differences in attrition and BMI over time. If indicated, recruitment strategy will be controlled for by incorporating into all models. Finally, moderation of the intervention effect will be examined by including potential moderators as main effects and interactions with condition and time. Potential moderators are gender, socioeconomic status, race and depression.

The repeated measures general linear mixed model includes time as a fixed effect and examines the effect of the intervention on the outcome using the interaction between time and condition. This model does not, however, explicitly model individual-level change over time. To examine individual-level change over time and how this change relates to condition, we will augment these analyses using a series of conditional, multilevel models of change (also referred to as growth curve models or random coefficient models). These models examine inter-individual differences in intra-individual change by fitting a trajectory, characterized by an intercept and slope, to each store. The intercept and slope can be regressed on predictors and covariates of interest. These models allow for flexible handling of time, and can parsimoniously model nonlinear change in BMI over time.

Exploratory analyses will examine the effect of experimental condition on a number of secondary outcomes including nutrition, moderate to vigorous physical activity (MVPA), leisure screen-time, hours and quality of sleep, substance use, stress-management, depressive symptoms, and the use of relaxation techniques. These secondary outcomes will be modeled similarly to the main outcomes via both covariance pattern models as well as growth curve models. Distributions of continuous

outcomes will be examined to ensure the assumptions of Gaussian residuals are reasonably supported; for example, skewness in the distributions of MVPA and of screen-time may require the square-root transformation. Discrete outcomes (e.g., substance use as a Y/N outcome) can be accommodated using a link function and estimating the models using generalized linear mixed modeling.

Per protocol analyses will be conducted to supplement the primary, intention-to-treat analyses. These models will allow for inclusion of a measure of intervention 'exposure'. Because not all participants received equal amounts of the intervention (e.g., not all participants received the class), these analyses will provide additional information to determine whether variability in intervention exposure was associated with differential response.

Missing data will occur in the study, with the majority likely due to study dropout over time and a small minority due to incomplete responding or censoring. The goal is to develop an analysis plan that can accommodate this missing data in such a way as to minimize any bias this may introduce into the estimates.

We will first evaluate the missingness mechanism by comparing those who provide complete data with those who do not on the outcome of interest (i.e., BMI) at baseline. No differences between groups is consistent with a missing completely at random mechanism. The weaker assumption of missing at random is supported if the two groups do not differ on the outcome at baseline after controlling for differences on a set of baseline demographic characteristics. We expect to identify a small number of baseline characteristics that will allow us to assume the data are missing at random, and these covariates will be included in all analyses.

Once the missing data mechanism is evaluated (and the assumption of missing at random appears tenable), outcome analyses adjusting for the presence of missing data will be conducted. Our primary approach will be through the use of full information maximum likelihood. This approach is efficient, consistent, requires few decisions, is easily incorporated into the primary statistical model (i.e., covariance pattern model estimated via mixed model regression), and is currently available in software (e.g., SAS, MPlus). All identified relevant baseline covariates will be included in all models.

Finally, we will conduct sensitivity analyses using multiple imputation. This technique shares many statistical properties with maximum likelihood (e.g., efficient and consistent), and has the major advantage of easily incorporating missing data on covariates. The primary drawbacks are requiring more decisions and steps. We expect the two approaches to result in similar estimates and standard errors.

14. DATA MANAGEMENT

Data Confidentiality

Confidentiality of data will be provided in the following manner: Unique identification numbers will be assigned to each student when they consent and then used to collect and link data from each visit and measurement period throughout the study. The IDs will also link relevant process data for the students randomized into the intervention conditions to the anthropometric, behavioral and psychosocial data. Students' interface with the internet-based components of the intervention will include password protection. Mr. Baker, our programmer, will maintain the electronic databases. The data file that links names with identification numbers will be password protected. All paper files will be stored in locked files in the Division of Epidemiology and Community Health.

Data Analysis

A single author or writing group will prepare a manuscript proposal using a proposal form, and will submit the manuscript proposal to Dr. Leslie Lytle who will review the proposal to ensure the correct data sources are being used and the data analysis does not conflict with data being used in other approved papers. Note: if two or more authors submit a similar manuscript proposal independently of each other, Dr. Lytle will encourage the authors to collaborate on the paper and to negotiate first authorship. Once approved, the proposed lead author will disseminate the proposal to all members of the study team, soliciting interest in co-authorship with the understanding that authorship requires input on the manuscript. Upon approval, and if needed, a data analysis team will be assigned to each paper and will coordinate with the lead author in completing all data analysis. Lead authors are responsible for soliciting input from the co-authors and for providing reasonable timelines for co-authors. All authors should participate actively, provide input as appropriate, and meet reasonable deadlines. Efforts should be made to accommodate the expression of differing interpretations and alternate analyses prior to the completion of the manuscript, so that all points of view are considered. However, the final decisions on matters of content, wording, and interpretation are the responsibility of the first author.

Data Release

The data management/analysis team will prepare and distribute a limited access dataset to the NHLBI project office for limited access use. The data release documentation provides detailed, organized documentation of study variables and clear instruction on how to install and access the data.

15. TRIAL ORGANIZATION

Please see Appendix 5 for the organizational chart of the CHOICES study.

16. TIMELINE AND IRB STATUS

The main trial for the CHOICES study will begin in the Spring of 2011 and end in the Spring of 2014. Please see Appendix 6 for the detailed timeline of the main trial.

Appendix 7 includes the CHOICES consent form. We currently have IRB approval for the study but will provide updates in the form of protocol change requests to the IRB as needed. We have also applied for and received our Certificate of Confidentiality from NIH.

17. REFERENCES

1. Ogden CL, Caroll MD, Curtin LR, McDowell MA, Tabak CJ, Flegal KM. Prevalence of overweight and obesity in the United States. *JAMA.* 2006;295:1549-1555.

2. Williamson DF, Kahn HS, Remington PL, Anda RF. The 10-year incidence of overweight and major weight gain in US adults. *Arch Intern Med.* 1990;150:665-672.

3. Nelson TF, Gortmaker SL, et al. Disparities in overweight and obesity among US college students. *Am J Health Behav.* 2007;31(4):363-373.

4. Huang TT, Harris KJ, Lee RE, Nazir N, Born W, Kaur H. Assessing overweight, obesity, diet, and physical activity in college students. *J Am Coll Health.* Sep-Oct 2003;52(2):83-86.

5. Haberman S, Luffey D. Weighing in college students' diet and exercise behaviors. *J Am Coll Health.* Jan 1998;46(4):189-191.

6. Butler SM, Black DR, Blue CL, Gretebeck RJ. Change in diet, physical activity, and body weight in female college freshman. *Am J Health Behav.* 2004;28(1):24-32.

7. Adelman C. *Moving into town -- and moving on: The community college in the lives of traditional-age students.* Washington, D.C.: U.S. Department of Education;2005.

8. Laska M, Pasch KE, Lust K, Story M, Ehlinger E. The differential prevalence of obesity and related behaviors in two- versus four-year colleges. *Obesity.* 2011; 19:453-456.

9. Nelson MC, Pasch KE, Lust K, Story M, Ehlinger E. Post-secondary settings for young adult obesity prevention: Thinking beyond the 4-year college. In preparation.

10. McLaren L. Socioeconomic status and obesity. *Epidemiol Rev.* 2007;29:29-48.

11. Gordon-Larsen P, Adair LS, Nelson MC, Popkin BM. Five-year obesity incidence in the transition period between adolescence and adulthood: the National Longitudinal Study of Adolescent Health. *Am J Clin Nutr.* Sep 2004;80(3):569-575.

12. Driskell JA, Kim YN, Goebel KJ. Few differences found in the typical eating and physical activity habits of lower-level and upper-level university students. *J Am Diet Assoc.* May 2005;105(5):798-801.

13. Nelson TF, Gortmaker SL, Subramanian SV, Wechsler H. Vigorous Physical Activity Among College Students in the United States. *Journal of Physical Activity and Health.* 2007;4:496-509.

14. Centers for Disease Control and Prevention. Guidelines for school and community programs to promote lifelong physical activity among young people. *MMWR Morbitity and Mortality Weekly.* 1997;46:1-36.

15. Schuette LK, Song WO, Hoerr SL. Quantitative use of the Food Guide Pyramid to evaluate dietary intake of college students. *J Am Diet Assoc.* May 1996;96(5):453-457.

16. Anding JD, Suminski RR, Boss L. Dietary intake, body mass index, exercise, and alochol: Are college women following the Dietary Guidelines for Aemricans? *College Health.* 2001;49:167-171.

17. DiGiacchino R, DeBate MT, Sargent RG. Racial and gencer differences in weight status and dietary practices among college students. *Adolescence.* 2001;26(144):819-833.

18. Levitsky DA, Halbmaier CA, Mrdjenovic G. The freshman weight gain: a model for the study of the epidemic of obesity. *Int J Obes Relat Metab Disord.* Nov 2004;28(11):1435-1442.

19. Humphrey R, McCarthy P, Popham F, et al. Stress and the comtemporary student. *Higher Education Quarterly.* 1998;52(2):221-242.

20. VonAh D, Ebert S, Ngamvitroj A, Park N, Kang D. Predictors of health behaiors in college students. *J Adv Nurs.* 2004;48(5):463-474.

21. Ross SE, Niebling BC. Sources of stress among college tudents. *College Student Journal.* 1999;Retrieved from Looksmart database on 8/10/04.

22. Voelker R. Stress, sleep loss, and substance abuse create potent recipe for college depression. *JAMA.* May 12 2004;291(18):2177-2179.

23. Hirsch JK, Ellis JB. Differences in life stress and reasons for living among college suicide ideators and non-ideators. *College Student Journal.* 1996;30(3):377-387.
24. Kang DH, Fox C. Th1 and Th2 cytokine responses to academic stress. *Res Nurs Health.* Aug 2001;24(4):245-257.
25. Bovier PA, Chamot E, Perneger TV. Perceived stress, internal resources, and social support as determinants of mental health among young adults. *Qual Life Res.* 2004;13:161-170.
26. Greeno CG, Wing RR. Stress-induced eating. *Psychol Bull.* May 1994;115(3):444-464.
27. Dallman MF, Pecoraro N, SAkana SF, et al. Chronic stress and obesity: A new view of "comfort food". *PNAS (Proceedings from the National Academy of Science).* 2003;100(20):11696-11701.
28. Stunkard AJ, Allison KC. Two forms of disordered eating in obesity: binge eating and night eating. *Int J Obes Relat Metab Disord.* Jan 2003;27(1):1-12.
29. Lumeng JC, Somashekar D, Appugliese D, Kaciroti N, Corwyn RF, Bradley RH. Shorter Sleep Duration Is Associated with Increased Risk for Being Overweight at Ages 9 to 12 years. *Pediatrics.* 2007;120:1020-1029.
30. Gangwisch JE, Malaspina D, Boden-Albala B, Heymsfield SB. Inadequate sleep as a risk factor for obesity: analyses of the NHANES I. *Sleep.* Oct 1 2005;28(10):1289-1296.
31. Hasler G, Buysse DJ, Klaghofer R, et al. The association between short sleep duration and obesity in young adults: a 13-year prospective study. *Sleep.* Jun 15 2004;27(4):661-666.
32. Pilcher JJ, Ginter DR, Sadowsky B. Sleep quality versus sleep quantity: Relationships between sleep and measures of health, well being and sleepingess in college students. *J Psychosom Res.* 1997;42(6):583-596.
33. Heaman D. The quieting response (QR): a modality for reduction of psychophysiologic stress in nursing students. *J Nurs Educ.* Jan 1995;34(1):5-10.
34. Johansson N. Effectiveness of a stress management program in reducing anxiety and depression in nursing students. *J Am Coll Health.* Nov 1991;40(3):125-129.
35. Nicholson T, Belcastro PA, Duncan DF. An evaluation of a university stress management program. *College Student Journal.* 1989;23(1):76-81.
36. Astin JA. Stress reduction through mindfulness meditation. Effects on psychological symptomatology, sense of control, and spiritual experiences. *Psychother Psychosom.* 1997;66(2):97-106.
37. Stice E, Orjada K, Tristan J. Trial of psychoeducational eating disturbance intervention for college women: A replication and extension.". *Int J Eat Disord.* 2006;39:233-239.
38. Hivert MF, Langlois MF, Berard P, Cuerrier JP, Carpentier AC. Prevention of weight gain in young adults through a seminar-based intervention program. *Int J Obes.* 2007;31(8):1262-1269.
39. Gow R, Trace S, Mazzeo S. Preventing weight gain in first year college students: An online intervention to prevent the 'freshman fifteen'". *Eating Behaviors.* 2010;11:33-39.
40. Allen IE, Seaman J. *Online Nation: Five Years of Growth in Online Learning*. Needham, MA: Sloan Consortium; 2007.
41. Cousineau TM, Franko DL, Ciccazzo M, Goldstein M, Rosenthal E. Web-based nutrition education for college students: Is it feasible? *Eval Program Plann.* 2006;29:23-33.
42. Abbasi K. MMR and the value of word of mouth in social networks. *J R Soc Med.* 2008;101:215-216.
43. Romano AM. A Changing Landscape: Implications of Pregnant Women's Internet Use for Childbirth Educators. *The Journal of Perinatal Education.* 2007;16(4):18-24.
44. Valente T. Communication Network Analysis. In: Hayes AF, Slater MD, Snyder LB, eds. *The SAGE Sourcebook of Advanced Data Analysis Methods for Communication Research*. Thousand Oaks, CA: Sage Publications; 2008:247-273.
45. Valente T, Davis RL. Accelerating the Diffusion of Innovations using Opinion Leaders. *Ann Am Acad Pol Soc Sci.* 1999;566:55-67.

46. Valente T, Gallaher P, Mouttapa M. Using Social Networks to Understand and Prevent Substance Use: A Transdisciplinary Perspective. *Substance Use and Misuse.* 2004;39(10-12):1685-1712.
47. Christakis NA, Fowler JH. The Spread of Obesity in a Large Social Network over 32 Years. *N Engl J Med.* 2007;357:370-379.
48. Christakis NA, Fowler JH. The Collective Dynamics of Smoking in a Large Social Network. *N Engl J Med.* 2008;358:2249-2258.
49. Cobb N, Graham A, Abrams D. Social Network Structure of a Large Online Community for Smoking Cessation. *Am J Public Health.* 2010;100:1282-1289.
50. Kelly AS, Kaufman CL, Steniberger J, Dengel DR. Body Mass Index and Fasting Insulin Explain the Association between the Metabolic Syndrome and Measures of Cardiovascular Risk in Overweight Children. *Diabetes.* 2008;57(Supplement 1):A490.
51. Matthews D, Hosker J, Rudenski A, Naylor B, Treacher D, Turner R. Homeostasis model assessment: insulin resistance and b-cell function from fasting plasma glucose and insulin concentrations in man. . *Diabetologia.* 1985;28:412-419.
52. Radloff LS. The CES-D scale: A self-report depression scale for research in the general population. *Applied Psychology Measures.* 1977;1:385-401.
53. Sallis JF, Owen N, Fisher EB. Ecological Models of Health Behavior. In: Glanz K, Rimer BK, Viswanath K, eds. *Health Behavior and Health Education: Theory, Research, and Practice*. 4th ed. San Francisco: Jossey-Bass; 2008:465-485.
54. Bandura A. *Social foundations of thought and action*. Englewood Cliffs, NJ: Prentice-Hall; 1986.
55. Pals S, Murray DM, Alfano C, Shadish W, Hannan P, Baker W. Individually Randomized Group Treatment Trials: A Critical Appraisal of Frequently Used Design and Analytic Approaches. *Am J Public Health.* 2008;98(8):1418-1424.
56. Billingsley P. *Probability and Measure*. 2nd ed. New York: John Wiley & Sons, Inc.; 1986.
57. Murray DM. *The Design and Analysis of Group-randomized Trials*. New York: Oxford University Press; 1998.
58. Kish L. *Survey Sampling*. New York, NY: John Wiley & Sons; 1965.
59. Little R, Rubin DB. *Statistical Analysis with Missing Data*. 2nd ed. Hobenken, NJ: John Wiley and Sons, Inc; 2002.

Appendices

1. **Description of Intervention Studies**
2. **Data Collection Tools and Instruments**
3. **Conceptual Model**
4. **Safety Alert Levels and Procedures**
5. **Organizational Chart**
6. **Study Timeline: Phase 2**
7. **CHOICES Consent Form**

Appendix 1
Description of Intervention Studies

Study: Primary Outcome/Hypothesis	Sample	Study Design	Intervention	Outcomes
Stice E, Orjada and Tristan. *Int J Eat Disord.* 2006;39:233-239 Study purpose: To describe the results of a psychoeducational class to reduce the risk of eating disorders and enhance weight gain prevention.	• n = 95 • Women attending University of Texas, Austin • Mean age = 21.3 • 69% Caucasian • Average BMI = 21.9	• 25 students in an eating disorder seminar (Intervention) were matched with 70 students in other courses • Pre/post survey • 6 month follow-up • Self-reported height and weight	• Seminar with 42 hours of instructional time • Topics covered: - Pathology of eating disorders - Epidemiology of eating disorders - Obesity and energy balance - Risk factors for obesity - Prevention and intervention programs for eating disorders/obesity	• BMI post treatment: - Intervention: 21.1 (3.0) - Matched comparison: 22.2 (3.3)* • BMI 6 month follow up: - Intervention: 21.2 (2.93) - Matched comparison: 22.4 (3.4)* * $p < 0.001$
Hivert et al. *Int J Obes.* 2007;31:1262-1269 Hypothesis: a small group, seminar-based educational and behavioral program aimed at improving lifestyle would prevent the usual weight gain observed in young university students.	• n = 115 • Freshmen in Faculty of Medicine at University of Sherbrooke • Mean age – Control = 19.5 • Mean age – Intervention = 19.9 • 82% Female • Primarily Caucasian • Average BMI = 22.4	• Randomized groups • Assessed change in weight and BMI over 2-year follow up (12 month, 24 month) • Measured height and weight	• Small group interactive seminars • 23 seminars over 2 years • 17 hours of instructional time • Topics covered: - Knowledge regarding weight gain - Health recommendations - Behavioral modifications - Problem solving - Goal-setting - Monitoring	• <u>Change in weight (kg) at 12 month:</u>* - Control: +1.2±0.5 - Intervention: -0.2±0.4 • <u>Change in weight (kg) at 24 month:</u>* - Control: +0.7±0.6 - Intervention: -0.6±0.5 • <u>Change in BMI at 12 month:</u>* - Control: +0.4±0.2 - Intervention: -0.1±0.1 • <u>Change in BMI at 24 month:</u>* - Control: +0.2±0.2 - Intervention: -0.3±0.2 * $p < 0.05$
Gow R, Trace, Mazzeo. *Eat Behav.* 2010;11:33-39 Hypothesis: Relative to participants in the no treatment control condition, participants in the feedback, Internet intervention and combined feedback and Internet intervention groups would have lower BMIs at post-testing.	• n = 159 • Freshmen at a southeastern public university • Mean age = 18 • 74% Female • 53.8% Caucasian • Average BMI = 24.4	• Randomized groups into 4 arms: 1. Control (n=40) 2. Internet Intervention (n=40) 3. Feedback Intervention (n=39) 4. Combined Intervention (n=40) • Pre/post after 6 week Intervention • Measured height and weight	• 6 week Intervention • <u>Feedback Intervention:</u> - Weighed themselves and reported it to the study on the Blackboard - Received e-mail feedback • <u>Internet Intervention:</u> - 6 session internet class - Topics covered: -- Significance of obesity -- "Toxic" college environment -- Healthy behaviors -- Media literacy -- Motivation • <u>Combined Intervention:</u> - Received weight feedback - Received Internet Intervention	• Change in BMI pre-post:* - Control: 24.6 (0.9) - Combined Intervention: 24.1 (0.9) * $p < 0.05$

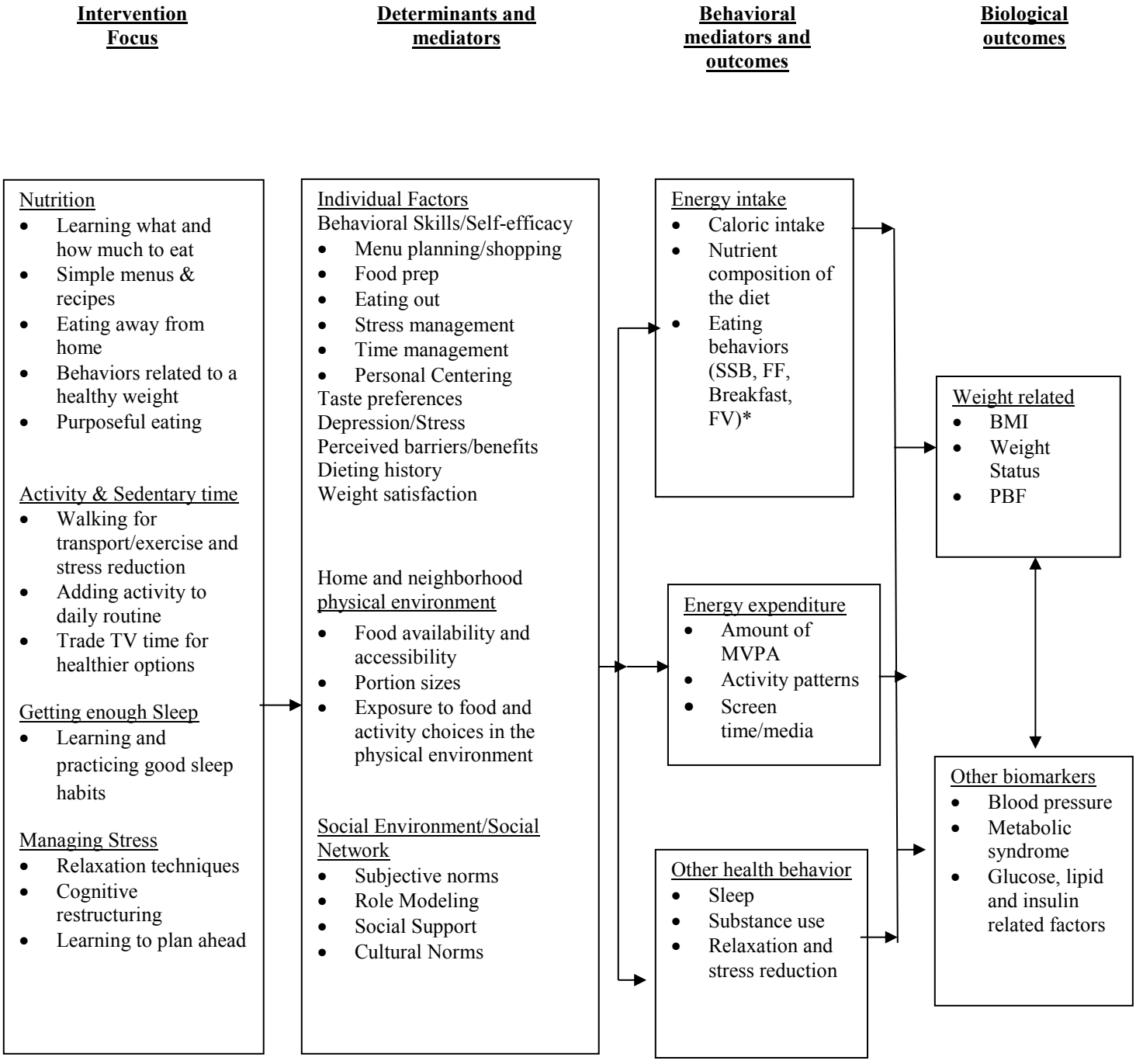
Appendix 2
Data Collection Tools and Instruments
Measures corresponding to the conceptual model

*These measures/protocols are common to all EARLY Trials

	Measure	How Assessed	Measurement Period
Biological Outcomes	*Weight-related outcomes*: BMI/Prevalence overweight/obese* Percent body fat* *Other biomarkers*: Metabolic Syndrome Blood Pressure*	Height/weight Direct measure Waist circumference Direct measure	B, 4m, 12m, PT B, PT
	Glucose, lipids, insulin*	Blood Draw Direct measure	B
Behavioral Mediators and Outcomes	*Energy intake*: calories, nutrients, eating behaviors*	ASA24 online dietary recall* Behavioral/psychosocial survey	Recall: B, PT Survey: B, 4m, 12m, PT
	Energy expenditure: MVPA*, activity patterns*, screen time*	Behavioral/psychosocial survey	B, 4m, 12m, PT
	Other health behavior: Sleep*, substance use*, relaxation and stress	Behavioral/psychosocial surveys	B, 4m, 12m, PT
Determinants and Mediators	*Individual Factors* Behavioral Skills, Self - efficacy Preferences Stress/depression* Perceived benefits/barriers Dieting History* Weight satisfaction	Behavioral/Psychosocial Surveys	B, 4m, 12m, PT
	Home and Neighborhood Physical Environment Food availability and accessibility*	Behavioral/Psychosocial Surveys	B, 4m, 12m, PT
	Portion sizes*	ASA24 online dietary recall	B, PT
	Exposure to choices in physical environment	Behavioral/psychosocial survey	B, 4m, 12m, PT
	Social Environment Subjective norm, perceived role modeling, perceived social support, cultural norms	Behavioral/psychosocial survey	B, 4m, 12m, PT
Moderators	Gender*	Self-report	B, 4m, 12m, PT
	SES*	Self-reported income, education	
	Baseline wt*	Direct measure	
	Depression*	CES-D (behavioral/psychosocial survey)	
	Intervention dose	Process data (intervention only)	

CES-D= Center for Epidemiology Study of Depression, B=Baseline, PT=Post treatment (24-month)

Appendix 3
Conceptual Model



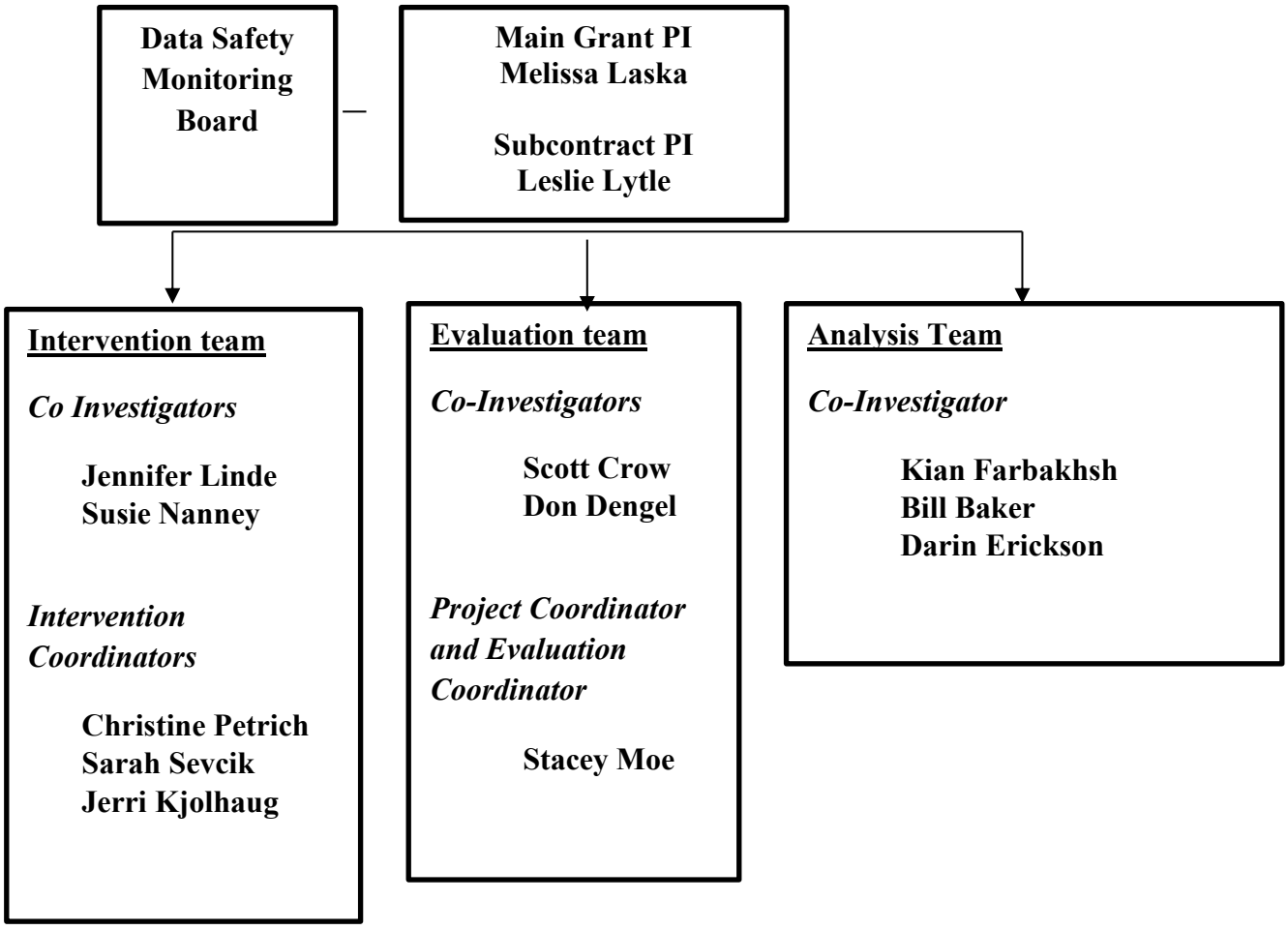
*SSB = Sugar sweetened beverage
FF = Fast food
FV = fruits and vegetables

Appendix 4
Safety Alert Levels and Procedures

This document sets guidelines for safety alerts that require a response from study personnel. Each alert level will trigger some action (referral or otherwise) that preserves the participant's safety. All of these events will be included in DSMB safety reports. Other safety variables that are not on this table (i.e., that do not require a response from study personnel) will also be reported to DSMB. These safety alert values and actions should be on the appropriate data collection form and included in training of data collection personnel.

Alert	***Advice to participant or action by study staff***	***Deadline for giving advice or taking action***
Blood pressure (average BP at any data collection visit)		
SBP >= 180 OR DBP >=110 mmHg	Participant should be advised to see a health care provider within 1 week.	24 hours
SBP 160-179 OR DBP 100-109 mmHg	Participant should be advised to see a health care provider within 1 month.	1 week
SBP 140-159 OR DBP 90-99 mmHg	Participant should be advised to see a health care provider within 3 month.	1 month
SBP < 90 mmHg	Staff should ask participant, "Are you feeling dizzy or lightheaded? If yes, participant should be counseled to see a health care provider within 1 month.	At study visit
Laboratory tests (if results are available within 6 months of blood draw)		
LDL-cholesterol > 160 mg/dl	Consult your primary care provider within 3 months	1 month from when lab result is available
Triglycerides >= 500 mg/dl	Consult your primary care provider within 1 month	1 month from when lab result is available
Blood sugar < 60 mg/dl 126-199 mg/dl ≥200 mg/dl	Consult your primary care provider within 1 month Consult your primary care provider within 3 months Consult your primary care provider in 1 month	2 weeks from when lab result is available 1 month from when lab result is available 2 weeks month from when lab result is available
BMI < 18.5 kg/m2	Consult your primary care provider within 1 month	1 month
Rapid weight loss (defined as > 15lb/month)	Consult your primary care provider within 1 month	1 month
Site-specific alert (to be defined by site)	Site specific (to be determined by site)	Site specific (to be determined by site)

Appendix 5
Organizational Chart



Appendix 6
Study Timeline: Phase 2

March 2011 to August 2011:	Recruit, Screen, Consent Participants (Cohort 1) Conduct Baseline Assessments; Randomize (Cohort 1)
September 2011 to December 2011:	Recruit, Screen, Consent Participants (Cohort 2) Conduct Baseline Assessments; Randomize (Cohort 2)
August 2011 to December 2011:	Intensive Intervention Phase: 1-credit Course (Cohort 1)
January 2012 to May 2012:	Intensive Intervention Phase: 1-credit Course (Cohort 2)
January 2012 to August 2013:	Web-based Supported Intervention Phase (Cohort 1)
January 2012 to March 2012:	Conduct First Interim (4-mo) Assessments (Cohort 1)
May 2012 to January 2014:	Web-based Supported Intervention Phase (Cohort 2)
May 2012 to June 2012:	Conduct First Interim (4-mo) Assessments (Cohort 2)
September 2012 to October 2012:	Conduct Second Interim (12-mo) Assessments (Cohort 1)
January 2013 to March 2013:	Conduct Second Interim (12-mo) Assessments (Cohort 2)
September 2013 to October 2013:	Conduct Follow-up (24-mo) Assessments (Cohort 1)
January 2014 to March 2014:	Conduct Follow-up (24-mo) Assessments (Cohort 2)
May 2014:	Trial Ends

Appendix 7
CHOICES Study: Choosing Healthy Options in College Environments and Settings
CONSENT FORM

Purpose of the Study
You are invited to participate in a research study that is looking at the prevention of unhealthy weight gain in 2-year community college students in the Twin Cities metro area. Dr. Leslie Lytle at the University of Minnesota, School of Public Health, is leading this study. You are being asked to take part in this study because you showed interest when responding to one of our study advertisements at your college.

What is Involved
The entire study will last two-and-a-half years and examines two ways to help college students achieve or maintain a healthy weight. If you agree to be in the study, you agree to be placed (by random assignment) into one of two different kinds of programs. One program involves receiving health education information about eating healthfully, being active, getting adequate sleep and managing stress. The other program involves enrolling in a one-credit college course on eating healthfully, being active, getting adequate sleep and managing stress and having access to a study website that will support those behaviors. If you are randomized to the one-credit course, the cost of the course will be paid for by the research program; in other words, you will not have to pay for this course. All students participating in the study will also be asked to participate in four measurement activities during the two years. The first measurement session will occur during the spring/summer of 2011. The second will take place in the winter of 2012. The third will take place in the summer/fall of 2012, and the final measures will take place during the summer/fall of 2013. If you agree to participate in the study, this is what will be involved:

First (Spring/Summer 2011) and Fourth/Final (Summer/Fall 2013) Measurement Sessions:

- Body composition measures, including height, weight and body fat percentage using the Tanita body fat analyzer scale), waist circumference, and blood pressure measurements
- A survey asking questions about your physical activity, eating habits and health attitudes
- Completion of two on-line dietary recalls, in which you will document all the foods and beverages you consumed the previous day. This will be completed for 1weekday and 1 weekend day.
- A fasting blood draw (which is optional)

Second (Winter 2012) and Third (Summer/Fall 2012) Measurement Sessions:

- Body composition measures will include height, weight and body composition (using the Tanita body fat analyzer scale).
- A survey that asks questions about physical activity, eating habits and health attitudes

Most of these measures will occur during a face-to-face visit at a local clinic in Minneapolis or at your community college. The completion of the two dietary on-line recalls will happen wherever you have Internet access. At the measurement visits, we will take your height using a standard height board and we will assess your weight and body composition using a body analyzer scale. The body analyzer scale is just like stepping on a bathroom scale but it tells us more information about how lean or muscular you are. If you agree to have your blood drawn, that blood draw will happen at a second clinic visit. We will ask you to have blood drawn (about 5 tablespoons) during the first and final measurement sessions (or 2 times total). If you consent to have your blood drawn for this study at the University of Minnesota, your visit will be documented in the Fairview medical records.

Individual Health Information

With regard to the blood draw, your individual health information that may be used by research personnel to conduct this research includes: demographics (your name and address) and results of laboratory blood draw tests. Your Protected Health Information (PHI) created or received for the purposes of this study is protected under the federal regulation known as HIPAA. Refer to the attached HIPAA authorization for details concerning the use of this information. We will send you the results of your blood draw and let you know if follow-up by a physician is recommended.

Ownership of the Blood Samples
The University of Minnesota will own the blood samples. Once your blood is drawn and sent to the laboratory, it will be processed and stored using a unique code number. The samples will not be identified with your name.

Risks of Being in the Study
There are minimal risks associated with being in the study. Some of the questions on the surveys may be sensitive in nature. There are a few questions about cigarette smoking, alcohol consumption, and depression, but the majority of questions are about eating and physical activity. Other potential risks of the study include some risks as a result of drawing blood. You may feel a pin-prick from the needle and bruising may happen on the area where blood was drawn, but most people say they don't bruise at all. Also, weight loss can increase the chances that you might become pregnant. If you do become pregnant during this study, please inform study personnel immediately. Lastly, there is a risk that rapid weight loss may lead to gallstones.

Benefits of Being in the Study
You will not receive any direct benefit for being in the project.

Research-Related Injury
In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that your have suffered a research-related injury, let the researchers know right away.

Compensation
You will receive a $100 Target gift card each time you participate in one of the four measurement sessions (for a total of $400). If you complete the 2 optional blood draws, you will receive an extra $50 Target gift card for each blood draw completed (for a total of $100). This means that you can receive a total of $500 in Target gift cards for participating in all measurements at all measurement data collection sessions.

Confidentiality
All data that may identify you will be kept private and will be stored safely in locked files or in password protected data files. A number will be assigned to each participant at the start of the project and this number will be used for record keeping and data analysis. Your data may be shared with other researchers; however, we will not share any data that may identify you. We will never share any data or information that could be linked to you and you will never see your name in any reports or published papers. To help protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Researchers will use the Certificate to resist any demands for information that would identify you, except as explained here. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation for Federally funded projects or for information that must be disclosed in order to meet the requirements of the Federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a

member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. Exceptions: A Certificate of Confidentiality does not prevent researchers from voluntarily disclosing information about you, without your consent in incidents such as child abuse, and intent to harm yourself or others.

Voluntary Nature of the Study
You may choose whether or not you want to be involved in this project. Whether or not you take part in this study will not affect your current or future relationship with the University of Minnesota or your college. If you decide to be involved you are free to withdraw at any time without affecting these relationships.

Contacts and Questions
The researcher leading this project is Dr. Leslie Lytle. If you have any questions, you may call Dr. Lytle at (612) 624-3518. You may also call Stacey Moe, Project Coordinator, at (612) 626-8607. If you have any questions or concerns regarding this study and would like to talk to someone other than the researcher(s), you are **encouraged** to contact the Research Subjects Advocate Line, University of Minnesota Medical Center, Fairview Riverside Campus, 2200 Riverside Avenue, Minneapolis, Minnesota 55454; (612) 625-1650.

Consent Statement:

____ 1. Yes, I agree to take part in this project and I say it is OK for you to do the blood test on me.

____ 2. Yes, I agree to take part in this project but I say it is NOT OK for you to do the blood test on me.

____ 3. No, I do NOT agree to participate in any part of this project.

_____ _____
Your Name (Please print) Your Signature

_____
Date