Study Protocol and Statistical Analysis Plan

The Rural Mens Health Study

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Protocol and Statistical Analysis Plan

Summary

Obesity is a major public health problem that disproportionately affects rural men[1]and promotes the development of chronic conditions such as diabetes, cardiovascular disease, arthritis, and cancer[2]. This study proposes to evaluate a 6-month mobile self-monitoring application (app) with Wi-Fi scale and text messaging intervention (MT+: mobile technology plus) for achieving weight loss in overweight and obese rural men. Weight loss interventions for rural men constitute a gap both in the literature and current NIH-NINR research portfolios. Using a pragmatic randomized controlled trial and community engaged research (CEnR) approaches, this study aims to: 1) determine the feasibility and acceptability of a smart phone self-monitoring app (*Lose-It Premium*) plus SMS text-based and daily weighing via Wi-Fi scale intervention (MT+) for achieving weight loss, 2) determine preliminary efficacy of MT+ to a comparison group receiving only a self- monitoring app (*Lose-It Basic*) (MT) in achieving the outcomes of weight loss (kg and % body weight-primary) and improved dietary and physical activity (PA) behaviors (secondary) at 3 and 6 months postbaseline, and 3) determine quantitative and qualitative indicators of community capacity to support a contextually relevant weight loss intervention. Eighty men (ages 40-69) with BMI of 28 $kg/m_{2 \text{ or higher}}$will be randomly assigned (1:1 ratio) to intervention group (MT+) or comparison group (MT). Men will complete baseline assessments (weight (kg), % body fat, BMI, height, blood pressure (BP), health history, dietary intake, PA intensity) and receive orientation to the mobile technologies (*Lose-It* app features, SMS, Wi-Fi scale). Men will track their dietary intake, PA, and weight on the *Lose-It* app for 26 weeks. After the 6-month intervention, post-measure assessments (weight-kg, % body fat, BMI, dietary intake, PA frequency/intensity, and technology usability surveys) will be collected at 3 and 6 months post-baseline. At 6 months post-baseline, two groups (n=8 each) of MT+ completers will be purposively selected to share their perceptions of the intervention efficacy in evaluative focus groups. A community advisory board (CAB) comprising local leaders within the men's social network, together with investigators and UNMC student nurses will guide community outreach efforts for study recruitment, implementation, and evaluation. Study findings will be evaluated with the CAB to inform local dissemination, future intervention revision, and determination of community capacity for support of a larger clinical trial.

Purpose

The specific aims of this study are:

Aim #1: Determine the feasibility and acceptability of a MT+ intervention for achieving weight loss in rural overweight and obese men. The aim will specifically address groups by 1) participation rates including number of men recruited and randomized over a 6 month period; 2) retention rates; 3) feasibility, usability, satisfaction ratings; 4) adherence record of logging by men in the intervention group; and 5) evaluative focus group feedback.

Aim #2: Determine preliminary efficacy of a MT+ intervention to a comparison group receiving only a basic self-monitoring app (MT) in achieving 1) weight loss (primary), and 2) improved dietary and PA behaviors (secondary) at 3 months post-baseline and follow-up at 6 months post-baseline in rural men.

Aim #3: Determine quantitative and qualitative indicators of community capacity (resource mobilization, learning opportunities-skills development, partnership linkages, participatory decision-making, and leadership) to support a relevant weight loss intervention for rural men.

Feasibility Substudy Aim: To determine the feasibility of men currently enrolled in our clinical trial to wear an activity sensor (Actigraph GT9X) for seven continuous days to objectively measure their continuous physical activity among the total volume of activity bouts across three gait dimensions: intensity, symmetry, and variability.

Background and Rationale

Obesity is disproportionately prevalent among rural men. Overweight/obesity rates among midlife and older men in Nebraska have tripled in the past 20 years, with 30% of men obese (n=133,470)[3, 4]. Associated with overweight and obesity, rural midlife men are at higher risk for metabolic syndrome and cardiovascular disease (CVD)[5]. Our preliminary study findings showed a high number of (CVD) risk factors (hypertension, etc.) among rural men[6]. The implication of high prevalence of overweight and obesity in rural men is a reduced life expectancy compared to rural women[7], and overall poorer health than urban men,[1] which contributes to increased economic and psychological burden to rural women and families.[8,9] Historically, rural men were less likely to be overweight and obese due to the high levels of physical activity involved in agriculture (Ag)-based occupations. Recently, the mechanization of Ag-service industries has shifted men's work roles to more sedentary, technology-driven lifestyles, increasing the likelihood of developing overweight/obesity. Despite the burden of obesity, no self-monitoring mobile technology interventions for weight loss in rural, U.S. males were found. Men, compared to women, are less likely to use weight control practices,[10] attempt weight loss, or participate in weight loss programs.[11-13] Access to weight loss resources is one reason.[14] Rural men tend to exhibit dominant masculine norms,[15] which view help-seeking behaviors and health promotion strategies as feminine and weak.[6, 15] Health promotion activities oriented to rural men's work roles are preferred.[16] Therefore, a weight loss intervention whose content is adapted to the local norms, is accessible through the privacy of a smartphone, and communicated in an acceptable tone is critical to engaging rural men.

Community engagement is imperative when designing a weight loss intervention for rural men. Community engagement is a collaborative process in which people affiliated by geographic proximity, special interest, or similar situations address locally relevant issues.[17] National Institutes of Health (NIH)[18] advocates for community engagement in clinical trials to improve recruitment/retention, research quality, relevance, and enhanced research impact in addressing health disparities.[19] Community-engaged

research (CEnR) with underserved, rural Ag populations has demonstrated positive outcomes for 1) improving service access,[20, 21]; 2) establishing service learning opportunities for college students[22]; 3) healthcare training models, and 4) garnering local health priorities for action.[23] Our preliminary study was the first to provide information about the feasibility of engaging rural men into clinical research with mobile technologies using community leaders from the men's social networks. CEnR strategies applied in our study supported 100% recruitment and retention of our sample.[6] We will use similar, but expanded community engagement efforts for this study in the form of community outreach guided by student nurses and a community advisory board (CAB). Community outreach via nurses has demonstrated improved study engagement and completion rates in previous pragmatic RCTs in rural Ag settings.[24] Using a CAB will create structure for obtaining local feedback and promote the social validity of our study, providing input across all study time points.[25-28] CABs improve the clarity of recruitment materials, social marketing strategies, and, when inclusive of lay representatives, enhance community engagement with hard-to-reach populations.[28-31] Using a collaborative group structure with bidirectional sharing of information across all members is important in establishing trust, power balance, and resource sharing.[32] The NIH R-15 Area Award that funds this proposal requires the involvement of undergraduate students in the research plan. Undergraduate student nurses are a community outreach and engagement resource for rural communities because of their previous experience as a student nurse on the rural, UNMC Northern Division campus in Norfolk, NE. Not only does the student's formal training in community outreach / community engagement as a component of their NRSG 413- Population-Centered Care course provide them with the skills to conduct community outreach and engagement planning, but they are more likely to plan meaningful and locally effective outreach strategies that can enhance partnership building for CAB and subject recruitment.

Self-monitoring eating and activity with smartphone-based applications helps overcome disparities related to access to weight loss resources in rural men. Self-monitoring (SM) of eating, activity, and weight is one of the most effective behavior-change techniques for weight loss.[33-35] Yet, SM is labor-intensive and compliance is often difficult, [34]as reported by rural men in our preliminary study.[6] At the individual level, men have reported that SM interventions frequently adopted by women do not apply to their gender-specific preferences.[36] Though, once men join a weight loss program, they are more likely to complete the program.[37] The rural environment, by nature of its unique make-up of culture, socioeconomic stressors, and geographic determinants, impedes access to resources for SM.[6, 38] Whereas smartphone technologies have now bridged this gap with the development of SM apps and Wi-Fi scales that permit real-time support for tracking eating, activity, and weight, a SM quality desired by men.[39-41] Rural men in our preliminary study tested mobile SM technology and found it most acceptable when it was easy to use, conveniently accessible, and feasible to wear across their varied work settings and roles.[6]

New smartphone-based apps, such as the *Lose-It* app, permit real-time engagement with users for tracking of eating and activity and don't require the wearing/managing of additional devices or paper-pencil self-monitoring, which may enhance adherence with

dietary logging, satisfaction, and usability among adults.[42] Recent analyses of SM interventions using mobile apps, including *Lose-It*, have recorded greater weight loss outcomes associated with the increased frequency of SM of eating and activity.[43]*Lose-It's* incorporation of evidence-based behavioral strategies for weight loss and persuasive technology lends to its superiority among other mobile weight loss apps,[44-45] including its access on a variety of platforms including android, iPhone, web, and tablet.[46] We propose to compare 1) a publicly available free version of a smart phone app (*Lose-It* basic) (MT) that permits a convenient, ready to use application that could potentially be recommended by any given health care provider with 2) a more comprehensive self-monitoring smart phone-base app (*Lose-It* Premiumwhich includes a social comparison group), combined with behavior change SMS messaging and daily self-weighing with a Wi-Fi scale (MT+). Our goal is to assess efficacy in overcoming disparities related to weight loss resources for rural men. The intent is to compare the *Lose-It* Basic app (free version) (MT) for tracking of daily weight, dietary intake, and physical activity with its companion, *Lose-It* Premium (paid version), that tracks a wider range of SM metrics for up-loading of weight with a Wi-Fi scale, physical activity, dietary, goal setting, and a private social comparison group, which enhances the value in the realtime tracking of these measures with comparison of past performance to one's goals, previous accomplishments, and the performance norms of similar groups.[47-50]Both the premium version of Lose-It app and the Nokia Body+ Smart Scale are publicly available for purchase.The premium version of the app costs 40.00 per year and offers enhanced goal setting functions and personalized weekly report for tracking progress. The Nokia Body+ Smart Scale costs 100.00 to purchase and syncs with the Lose-It app (either version) to provide real-time progress towards tracking weight loss goals.

Text messaging is an effective channel for promoting SM behaviors to achieve weight loss among rural men. Text messaging provides motivation, knowledge, and social support for behavior change.[40, 51-54] When supported by other program components, text messaging has been effective for improving SM behaviors (reducing weight, improving eating, increasing physical activity),[52, 55-57] resulting in greater than 5% baseline body weight loss after 3 months.[51] Behavior change augmented by text messaging has the advantage of reaching men instantly, yet allowing access to the message at the convenience of the recipient. Daily receipt of text messages at 8:00am, with content presented in a novel and non-repetitive fashion, has been documented as the preferred frequency and time for men,[56] including rural men.[6] In addition, texting is cost effective [58]and allows multiple messaging, with each text containing a different theme.[59] Message content addresses at least one behavior change concept,[60] such as motivation, education, and reminders.[59] Text messages can be directed toward the specific motivations for and barriers to physical activity [61]and healthy eating identified by men, [39]can encourage behavioral support outreach to family and friends, and should use concise language [40]and humor.[6] An example of a text message targeting interpersonal support for behavior change: Today, tell one friend or family member what your favorite healthy snacks are. When targeting weight loss, men's preference for the content of text messaging has ranged from behaviors to be enacted and avoided, strategies for overcoming challenges and creating healthy food environments, and healthy living challenges.[56, 62-63] This study seeks to build on the available evidence from our

preliminary study and other available evidence that text messaging may enhance selfmonitoring and behavior change for weight loss.

Social Ecological Perspective (SEP) frames multiple influences on rural men's health behaviors. Rural men are less likely to implement their own physical activity and weight loss interventions due to access constraints and environmental influences.[6, 64] Thus, combining individual health behavior change approaches with environmental-based support is necessary. [65]SEP asserts that the degree of fit between a persons biological, behavioral, and sociocultural needs and the environmental resources available to them serves as a key determinant of health.[66] This MT+ intervention applies SEP to impact multiple, nested layers of active and passive influence on men's health behaviors for weight loss.[66] Use of the *Lose-It* app and Wi-Fi scale enable intrapersonal behavior change through the daily SM behavior of logging eating, activity, and weight. Real- time feedback via the app promotes individual evaluation of eating and activity behaviors. The real-time social comparison and group support provided via the *Lose-It* app and text messaging promote interpersonal support to influence behavioral change. The use of CEnR strategies, through the CAB involvement and student nurse outreach, permit social networking and improved community-level support for rural men's weight loss. Social networking will garner resources to inform locally relevant social marketing strategies and enhance study recruitment. The CAB will provide input across all stages of the study, supporting the relevance of the intervention and optimizing the engagement of local resources. (See Figure 1). Serrano and colleagues [43]report of a largescale weight loss study using the*Lose-It* app (n=12,427,196) found that 15% of app users lost 5% of more of their baseline body weight. Subsample analyses from this study indicated that higher intensity app use (SM frequency) and the use of custom app features characterized higher levels of weight loss success (73% achieved clinically significant weight loss)- suggesting that customizing SM information via *Lose-It* app to particular subgroups could enhance weight loss success. Key behavioral factors found to be related to varying proportions of weight loss success can be enhanced by the frequency of self-monitoring, real-time feedback from self-monitoring which permits self-evaluation, and the receipt of prompts supporting eating and activity behavior change. These behavioral elements are associated with improved weight loss and decreased occurrence of weight regain.[34] Social support and customizable goal setting are additional evidence-based behavioral strategies associated with optimum weight loss.[34] Therefore, we plan to compare the efficacy outcomes between the widely available *Lose-It* Basic app (free) with a custom version of the *Lose-It* app (*Lose-It* Premium- paid $40) supplemented with intrapersonal, interpersonal, and community-level supports to maximize self-monitoring behaviors for weight loss success.

In summary, this study addresses a significant health disparity among overweight and obese rural men: access to and engagement with mobile technologies to achieve weight loss. Meeting the study aims will provide intervention protocol testing for application in a larger, fully powered R01 clinical study. This R01 will generate new scientific knowledge as there are few weight loss inquiries targeted to men in the U.S., and no such analyses were found with rural men. Scientific knowledge gained through community-engaged partnerships addresses a significant barrier to progress in the field of rural mens weight

loss research by garnering recruitment, retention, and local preferences for this hard-to-reach, underserved population. This study will have a substantial effect on strengthening the research environment at the UNMC-College of Nursings (CON) Northern Division (ND), located in Norfolk, NE (population 22,400, RUCA code 4-micropolitan area core) by providing CEnR opportunities for rural undergraduate and graduate students. This study also has the potential to impact nursing science through the training of future nurse researchers in rural research.

This study is innovative in that 1) it applies an intervention shown to be effective for weight loss in other populations, SM, to an unstudied and underserved population of overweight and obese rural, U.S. men, 2) while SM was found to be feasible and acceptable in our preliminary study, the delivery of a more comprehensive MT+ intervention (SM app with social comparison group, Wi-Fi scale, and SMS via smartphone intervention) has not been studied, and 3) the integration of CEnR with a pragmatic RCT is a novel way to design and deliver a weight loss intervention that facilitates local buy-in and is sensitive to context. The use of student nurses to support community outreach, the CAB to inform all stages of the study, and the use of both qualitative and quantitative data methods/analyses will support maximum community engagement for comprehensive understanding of SM eating and activity for weight loss. By involving rural undergraduate and graduate students in CEnR, we hope to ignite new opportunities for inquiry in this area based upon the ongoing, nurtured research relationships that community-engaged approaches have established and through learning from the experiences of others.[67]

A preliminary study demonstrated CEnR strategies and mobile technologies support feasible means to test weight loss interventions with rural men. Dr. Eisenhauer (PI) led an interdisciplinary team, which included two doctoral students and one MSN student, to examine the feasibility and acceptability of an mHealth SM intervention that included health related text messages and the use of the FitBit One® (fitness monitor) with a comparison app to log daily food intake and monitor activity. Using CEnR strategies, eight community leaders from six rural towns participated by contacting prospective participants directly, sharing materials about the study, and verifying their interest in participating prior to contact with the PI. Twelve rural men were recruited and participated in an initial assessment and orientation session. For three weeks, they received text messages and used the FitBit One® to self-monitor eating and activity, after which they attended a 90-minute focus group session. FitBit One® and text messaging were acceptable and useful; however, the food log options needed adaptation to reflect dietary norms of rural men.[6]This preliminary study informs the proposed study by determining that rural men were interested in SM of eating and activity behaviors and will send and receive text messages.[6] This study will continue using CEnR strategies, but will recruit a larger sample, utilize text messaging, and use a smartphone app designed for weight loss (*Lose-It*) with enhanced features for monitoring eating and activity. Obesity prevention and access to resources to promote healthy eating and activity is a local priority by both the district public health department [68]and among lay community members in our study region.[23]

Undergraduate students are a CEnR resource for rural communities. This study will expose 42 undergraduate and 2 graduate assistant student nurses (GAs) from the College of Nursing (CON) Northern Division (ND) to rural research. The two graduate assistants will not be asked to participate in the study for purposes of data collection. Rather these students will work in role of research assistant, for which they do not need consents but rather listed as a team members on the IRB protocol. The CON ND campus has 96 enrolled students, and 70% of the student body are from Northeast Nebraska. Senior-level undergraduate student nurses (n=42) during their populations health course are currently trained in community engagement and partnership building for health promotion. Study months 1-4, students will participate in groups of 6-8 (on a clinical rotation schedule to maintain feasibility) in designing and evaluating community outreach strategies (recruitment, social marketing for businesses, developing/adapting community engagement strategies for community leaders, best practice approaches for facilitating CAB) which will permit students critical analysis of and experience with community outreach and engagement. Under the direct supervision of their course faculty and in collaboration with the PI and Norfolk GA, students will develop, implement, and evaluate community outreach strategies for community engagement. Activities may include 1) developing multiple media recruitment materials, 2) strategically determining recruitment material dissemination, 3) establish community resource maps, and 4) identifying community leaders and lay persons to foster study engagement. Not only will the students formal course training provide them with the skills necessary to conduct these roles in this research study, but their understanding of the rural region makes them a valuable resource, as they are more likely to plan meaningful and locally effective outreach strategies. Two graduate-level students will be hired as graduate assistants on the project. The involvement of rural students from the ND in a community-based pragmatic trial has high impact. Through nurturing future rural nurse researchers and clinical nurses by training for community engagement/outreach principles that work best with rural populations, this creates the potential to stimulate research on this campus and in this rural region. The PI has supervised graduate assistants in the past and has adequate experience to hire and train students for the present study. The PI has previously mentored undergraduate students in rural community outreach [69]and doctoral students in qualitative data collection/analysis and dissemination.[6]

Sub-study

Physical activity behaviors (mode, intensity, and duration) are linked to promoting healthy weight, maintaining overall health, optimizing functional abilities such as gait and mobility patterns, and reducing risk of disability[3]. Knowledge about physical activity behaviors among hard-to-reach rural men is limited. In our current feasibility trial (R15) for promoting weight loss in rural men, we are using smart phones to measure mens step count as a general indicator of total physical activity. This method does not allow for complex analysis of activity quantity or quality, nor does it produce reliable gait data because of step count underestimation due to phone non-carrying time[4]. Wearable sensor-based multidimensional gait analysis is a quantitative method for predicting critical biomechanical measures of physical activity in specific populations and in real-world settings[5]. To our knowledge, there has been no established objective baseline for

complex analysis of physical activity behaviors, such as activity pattern analyses using a multidimensional gait metric in rural men.

Accrual

A total of 8-10 community advisory board members (CAB), 42 student nurses from the UNMC Northern Division NRSG 413 Population Centered Care course, and 80 rural male subjects (40 per group) are needed to achieve the proposed objectives. The sample will consist of 80 men (40/group) who meet the inclusion criteria. Hertzog [74]suggested that 30 participants per group in a pilot study is a sufficient sample size for aims involving between group differences and if the results are to be used to estimate the needed sample size for a future, fully- powered study. It is important for this study that we obtain reliable estimates of effect size with which to perform a power analysis for subsequent research, so 40 participants per group will be sought, for a total of 80. Some participants will likely not complete the study, so we will enroll 80 men to allow for up to a 30% attrition rate. Power for the repeated measures analysis of variance (RM-ANOVA) was determined using G*Power 3.1.9. A within-between interaction will be the primary test of significance (time*group interaction). Assuming a small effect size (f=.10),[75] a significance level of .05, 3 time points, and an estimate of .5 for the correlation between time points, 164 participants (82 per group) would be needed to have 80% power. Because this is a pilot study, a smaller sample size is justified, and the results of the pilot study will be used to update the power analysis prior to a future study.

Purposeful justification for the total number of community advisory board members and student nurses is based upon their information rich knowledge of the rural context as either community leaders or students in a rural college of nursing. Justification of the total sample size desired for the community advisory board is based upon optimal group function / interaction (8-10 persons) documented in previous advisory board work in agricultural based locales (Kingman, Yoder, Hodge, Ortega, & Field, 2004). Justification for inclusion of 42 student nurses was based upon the aim of the R-15 AREA NIH mechanism to expose undergraduate students to research. Community outreach is a concept taught in NRSG 413- Population Centered Care. It was deemed feasible to involve all students enrolled in this NRSG 413 course to the community outreach activity of this study- without excluding any student.

Kingman, D., Yoder, A., Hodge, N., Ortega, R., & Field, W. (2004). Utilizing expert panels in agricultural safety and health research. Journal of Agricultural Safety and Health, 11(1), 61-74.

Feasibility Substudy: We would like to recruit 15 men, newly joining and currently enrolled in our weight loss trial, via convenience sampling (asked in the calendar order they present for their baseline, 3-month, or 6-month assessment visit in the current clinical trial) to participate in this sub-study. Both arms in our clinical trial receive the same education/instruction about physical activity (i.e. goal of 10,000 steps per day). The men will be invited to participate in this sub-study during their regularly scheduled baseline, 3 month, or 6-month assessment visit with the research nurse at the Northeast

Nebraska Public Health Department in Wayne, NE. Intervention subjects: 40-69 years of age Community advisory board members: 19 or older UNMC Northern Division Student Nurses enrolled in NRSG 413: 19 or older.

Inclusion Criteria

Intervention Subject Inclusion criteria include 1) man age 40-69, 2) reside in the Northeast Nebraska region, 3) BMI between 28 (kg/m2) or higher and weight not greater than 396 pounds (BMI 50 or higher with clinician clearance), 4) smartphone owner with enabled text messaging, 5) speak and read English, 6) have an email account, 7) answer "no" to all questions on the PAR-Q17 health history assessment or are willing to get physician clearance prior to enrolling, 8) willing to share SM logs with investigative team, and 9) attend three assessment visits in Wayne, NE.
Community advisory board member inclusion criteria includes 1) adult (age 19 or older) who is identified by self or others as a community leader in Cedar, Dixon, Wayne, or Thurston counties, 2) willing to participate in monthly community advisory board meetings for duration of the study, 3) smartphone owner with enabled text messaging. Student nurse inclusion criteria includes 1) adult (age 19 or older) who is enrolled in the UNMC Northern Division's NRSG 413- Population-Centered Care course, 2) willing to participate in a small group discussion about rural community engagement/ community outreach strategies with other students enrolled in NRSG 413 and the principal investigator, Dr. Christine Eisenhauer, during their assigned course time, willing to complete a survey before and after this experience self-assessing their understanding of the public health nurses' role in conducting rural community engagement and outreach.

Substudy: Inclusion criteria would include 1) currently enrolled in the Rural Men's Health Study, and 2) willing to wear on the Actigraph GT9X on your waist for 7 continuous days (except for bathing) and mail back device in the stamped, pre-addressed envelope.

Exclusion Criteria

1) have recently lost 5% or more of body weight
2) are currently taking medications that cause or are influenced by weight loss (oral steroids, tricyclic antidepressants, lipase inhibitors)
3) have used weight loss app in the past to lose weight
4) family member from same household is enrolled in this study
5) Type I diabetes or Type II diabetes with insulin dependence.

UNMC Northern Division Student Nurses Enrolled in NRSG 413 Exclusion Criteria: none

Substudy exclusion criteria would include a man not currently enrolled in the Rural Men's Health study clinical trial.

Methods

This team will use multiple strategies to recruit rural
men based upon approaches that have been used successfully in this region and
demonstrated positive outcomes for recruitment and retention.[6, 23, 76, 77]One CEnR
strategy will be to develop a community advisory board. In study months 1-4, formal and
informal community leaders within rural men's social network/region (i.e., farmers,
insurance sales/machinery-implement dealers, extension board staff, and community
health workers) will be sought via community outreach strategies identified by UNMC
Northern Division (ND) student nurses and the PI. The PI and GA will invite community
leaders to serve on a CAB to inform the local priority issue of overweight/obesity among
rural men. The CAB composition will include 8-10 community members from the
sampling region[78] whose knowledge and experience provides insight into the
preferences and needs of the local men and hold potential to be stakeholders for
successful implementation of the study. [79]CAB members will meet face-to-face quarterly
across the three year study for a total of 12 meetings. Members will receive a stipend in
consideration of their time and travel costs.[80] CAB meetings will occur in person at the
Northeast Nebraska Public Health Department, led by two investigators trained in
CEnR, to promote group cohesion. Meetings will also include snacks, consistent with
CAB best practice in Ag-centered communities [79, 80]. Meetings will also be available via
Zoom video chat technology to CAB members, which is freely accessible on the internet
and feasible to use in low-band width internet locales via smartphone, PC, tablet, or
laptops, to limit access barriers (weather, time) which might inhibit attendance.
Community leaders will be encouraged to co-lead the CAB meetings supporting mutual
partnership and leadership development. CAB members will assist recruitment by 1)
informing the approach, material content and imaging, and targeted venues for social
marketing, and 2) the dissemination of recruitment materials and direct referral of
eligible participants. CAB members will be given the option to refuse to have their
opinions collected as research data, consistent with CEnR principles.

UNMC Northern Division Student Nurses Enrolled in NRSG 413- Population Centered
Care course receive training in community outreach / community engagement as an
expected course outcome. Students in this course will spend 2 hours of their assigned
course clinical time in group discussion with the principal investigator, Christine
Eisenhauer, who is an advanced practice public health nurse. The discussion will
involve planning community outreach and community engagement strategies for our
study region that may enhance recruitment and retention of CAB members and
subjects. Students will be asked to identify strategies for enhancing the planned
community outreach and community engagement specific to rural populations for this
study. Activities will include determining strategic recruitment material dissemination,
creating community resource maps, and identifying community leaders and lay persons
pivotal to enhancing community parternship. Prior to beginning the discussion, students
will be asked to complete a short survey about their understanding of the public health
nurse role in community outreach / community engagement. The students will be asked
to complete the same survey post discussion to determine if the discussion experience
enhanced their understanding of this role.

Intervention: The proposed feasibility study is a pragmatic RCT. Rural men (ages 40-69) will be recruited over a 12 month period to obtain a target enrollment of 80 subjects. Subjects will either be allocated to the intervention (Lose-It Premium with social comparison group, Wi-Fi scale for self-monitoring, plus SMS support messages for weight loss- MT+) (n=40) or the comparison group (Lose-It Basic- MT) (n=40). These group sizes reflect oversampling by 30% in each group to allow for attrition, based upon attrition rate averages.

Following informed consent and completion of baseline visit, eligible participants will be randomized 1:1 to either intervention or comparison group. Participants randomized to the MT+ group will receive *Lose-It* Premium version (value $40) and Wi-Fi Nokia Body+ scale ($100). Participants randomized to the MT group will receive *Lose-It* Basic version (free) plus a $25 stipend for their participation in each assessment point (3). The men will be randomly assigned to the intervention and comparison groups as they are enrolled using an allocation schedule created by the project statistician. The research nurses will not be blinded to the group assignment as they must conduct the app download on the subject's phone and conduct orientation training of the app with the subject that is specific to their assignment (basic app vs. premium app). Randomization will be predetermined using a random number generator and urn randomization to ensure equal sample sizes.

A comparison group (MT) (n=40) of men will receive the *Lose-It* Basic app. The basic app permits daily self-monitoring of eating and physical activity and manual logging of daily weight. MT participants will be asked at baseline to self-monitor their eating, activity, and weight daily. They will receive no text message prompts for self-monitoring, self-monitoring trend reports, or peer interaction via group. MT participants will complete assessments at baseline, 3 and 6 months postbaseline. MT participants will only receive text message reminders for their assessment visit appointment times.

Description of the Intervention Group (MT+). *Lose-It* Premium permits enhanced customization of goal setting, app automated self-monitoring reminders, customized email reports that outline self-monitoring trends important in supporting motivation and confidence during periods of behavioral action. The Nokia Wi-Fi scale will provide automated coaching, rewards and recording of weight synced to the *Lose-It* app permitting immediate feedback and visual maps of weight trends.

Research Staff Support-Reminder Prompts: MT+ participants will have research staff support available via phone. They will also receive reminder prompts for self-monitoring via text and phone when non-adherence with self-monitoring of dietary intake, physical activity or weight is incomplete for 5 days of greater.

Social Comparison Group: MT+ participants will be enrolled in a private social comparison group on *Lose-It Premium* comprised of other intervention group subjects from this study (same group composition as their texting subgroup). The purpose of the social group is to provide social comparison of others self-monitoring experiences

providing a mechanism to influence judgment and behavior change towards ones own self-monitoring. The social group will also provide social support to MT+ participants while completing the trial to promote long-term success.[81, 82] The social comparison groups will be moderated by a male investigator who will suggest topics for guiding discussion and peer challenges (ie. 10,000 steps per day for physical activity or 8-10 glasses of water per day). Men will also be encouraged to post useful strategies and progress reports related to self-monitoring and weight loss. Participants will be encouraged to post a minimum of weekly.

Text Messages: A text message library will be developed by the team based upon messaging content that has demonstrated usefulness for behavior change[51, 59, 83, 84]and preferred by men.[56, 62, 63]Text message content will include a variety of topics including reminders, nutrition and physical activity behaviors to be enacted and avoided, SM portion control, strategies for overcoming barriers, and health living challenges. Content for text messages will be adapted from healthy eating and physical activity promoting resources that include *USDA Choose My Plate*[85]and *CDC and Prevention: Physical Activity*[86]including targeted aerobic physical activity, monitoring of body weight, behaviors needed to sustain weight loss, promoting success and rewarding oneself, preventing failure and avoiding temptations.[51] Messages will also target interpersonal support surrounding weight loss behaviors (i.e. Tell your partner/friend about a way you have found to get in more physical activity steps a day). See exemplar of text messages in attached documents. Additional text messages developed will be submitted to IRB for approval. CAB members will inform the content of the text messages for local relevance prior to dissemination with the MT+ participants.

Research nurses will conduct face-to-face assessments and surveys with participants at baseline, 3 and 6 months post-baseline. Feasibility and acceptability measures of the intervention will be collected across the study. We will also conduct two evaluative focus groups with a purposively selected subsection of the intervention group (n=8 per group) to obtain perspectives on perceived outcomes and utilization of behavioral strategies from the intervention and the feasibility and acceptability of the technologies. (See Figure 2).

Procedures / Data Collection and Management. CAB. The community advisory board (CAB) will trial *Lose-It* Premium, including the social comparison group page, during study months 1-6 to identify potential areas in which male subjects may need additional instruction, facilitation, and ongoing support. The investigative team will discuss the CABs feedback and the PI will keep reflective research notes tracking decision-making processes. The CAB will also review the text message library to ensure message content is locally relevant and meaningful prior to intervention dissemination.

Rural Male Subjects. Two trained research nurses will conduct the assessments and will be flexible in working hours that match participants availability. The baseline visit will take approximately 90 minutes to complete. Men will complete questionnaires and have their blood pressure, weight, and resting heart rate assessed. Those men exhibiting risk that may contraindicate increasing physical activity or weight loss will be referred to their

primary care provider for written clearance to participate.[99] All questionnaires and biomarkers will be entered into a secure site through the Internet. All data will be entered in the REDCap server. The UNMC Research IT Office instructs investigators in its use and hosts the REDCap database of project data.

Baseline Instructions Provided to Both Groups. Each man will receive his *Lose-It* user ID and password, as well as written instructions to access the research nurse, and information about technical support. Temporary emails will be set up for each subject that contain no personal identifiers (ie. MensHealth1@gmail.com). These email accounts will be used only for the purpose of setting up a Lose-It account and receiving automated Lose-It account reports. No personal communication with subjects will happen through these email accounts. At baseline, both groups will receive an informational packet with verbal instruction focused on a lifestyle change plan for healthy eating and activity to accomplish weight loss. Our goal is that the participants will demonstrate a weight loss of 5% or more of their baseline body weight, which is the minimum weight loss documented to produce a decrease in health risks (diabetes, cardiovascular disease, hypertension).[100-101].

Smartphone Use: Each subject will be asked to wear their smart phone during waking hours on their hip or in a pocket.

Nutritional Plan: Recommended approaches for achieving negative energy balance through reduced caloric intake and increasing physical activity to recommended levels will be provided with the primary goal of losing 1-2 pounds a week during the 3 month intervention. Participants caloric eating plan goals will be calculated by the *Lose-It* app based on their age, gender, height, and activity level tracked in the app.

Physical Activity Plan: Current recommendations from public health agencies and scientific organizations including the NHLBI,(102) DHHS/CDC,[103, 104] and the ACSM [104, 105]outline physical activity as an important part of weight management. Participants will be advised to gradually meet minimal targets 10,000 steps per day (goal PA outcome on *Lose- It* apps) and 150 minutes a week of moderate-intensity or greater activity.

Daily Self-Weighing: Participants will be provided instructions for measuring and recording their weight daily. All participants will be 1) oriented to the text messaging process, 2) respond to a test text message to ensure receipt. Participants will receive an orientation, with written instructions and physical demonstration, to *Lose-It* Basic app. Instructional content will include how to post nutritional intake, recording physical activity and weight. Participants will be asked to wear their smart phone during waking hours over the next 26 weeks to input their dietary intake and track physical activity, and record their self-measured weight daily. Assessment visits at 3 and 6 months post-baseline will evaluate the participants change in biomarkers, self-report scales, and ongoing engagement with the *Lose-It* app and other health technologies. Each man will make an appointment for his next reassessment at the end of each visit. The nurse will text a visit reminder 2 weeks prior to the next appointment.

Additional Instructions for MT+. At the conclusion of the baseline visit, those participants randomized to the MT+ group will be given instructional training with demonstration for use of the 1) Nokia Body+ Wi-Fi scale, 2) instructional picture booklets demonstrating correct setup and use of the Wi-Fi scale [106] and the *Lose-It* Premium version app features, and 3) a technology support phone number. The GA will call the men within two days of their baseline visit to verify their success in using these feature and answer any questions. Investigators will monitor app usage statistics for MT+ participants daily and a GA will provide reminder prompts via text message, followed by phone call, when non-adherence is observed for greater than 5 days. Participants can also contact research staff for technical support via phone. Remind.com will be used to send the text messages. Remind.com provides free text messaging to any smartphone device through SMS and doesnt require app download. MT+ participants will receive a text message at 8:00am throughout the 3-month intervention period. MT participants will only receive a text reminder related to their next assessment point appointment by the research nurse.

Lose-It Account Retention Option for Subjects at end of Study: As subjects have matriculated through our study, many have requested their desire to retain their Lose-It account food log and physical activity data. Because we set up the accounts using dummy username and passwords- the men are not able to retain their log information in Lose-It (basic or premium accounts) unless we conduct a username and password change of ownership. We consulted with our community advisory board members on 1-14-19- whom
were in full support of offering subjects an option to change ownership of their Lose-It account upon study completion. We have written and tested a procedure for changing username and password (See Protocol for Lose-It accounts at the end of the study document) that will permit the subjects to select/input a password that is not known to us which will ensure the privacy of their Lose-It account after the time of password change. We will inform the subjects of this option for change of ownership at their 6-month visit, at which time a revised written consent will be obtained. For those subjects who have already completed the six month visit, we will contact them by text and email informing them of the option. Those completers who desire this option will be provided a telephone call during which an electronic version of the revised written consent will be obtained (as consistent with our procedures for obtaining informed consent at point of enrollment).

Focus Groups. Two evaluative focus groups will be held at 6 months post-baseline with a purposive sample of intervention group completers stratified according to their weight loss outcome (successful/unsuccessful in achieving 5% baseline body weight loss) to solicit their perceptions on the MT+ intervention efficacy, including acceptability/feasibility.[107] Use of two focus groups permits cross-case comparative analysis of the intervention.[70, 108] Focus group participants will receive $25 for their attendance and will be asked to maintain confidentiality of the contents of the focus group discussion. The 90-minute focus groups will be held at the same community center as the assessments and audio recorded. The PI, an experienced focus group moderator, will lead the discussion with a semi-structured interview guide informed by the tenets of the social ecological perspective and study aims. The focus group

questions will be pretested by the honors research students, who will also serve as scribes during the focus groups, noting non-verbal expressions/gestures, interactions, and other impressions that occur during the group discussion. Questions will be aimed at eliciting the men's experience and perceptions: How did you find the experience of tracking your eating, activity, and weight with the *Lose-It* app?, How did you find the experience of participating in a group comparison page with other study participants? Immediately after the interviews, the moderator and scribes will write reflective notes as to the groups interaction, which created/sustained the descriptive detail shared and provide peer-debriefing. The audio files will be transcribed verbatim. Collectively, the interview transcript, peer-debriefing, and reflexive memos will create a decision trail which will serve as an audit trail to demonstrate accountability.[109]Audio recordings will be deleted after being used to assure the accuracy of written transcripts during analysis.

Variable * Measure Description (Data Collection Time Points)
Baseline & Screening

PAR-Q17 (S****) **PAR-Q17, Physical**
Activity Readiness
Questionnaire- ACSM
Recommended[88-90]
(Baseline)
Demographic (S****) **Demographic**- (e.g.,
race, gender, age,
education, marital
status, occupation)-
from
CENTRIC**(Baseline)**
Aim 1 Feasibility and Acceptability
Fidelity (F***) **Component Specific Fidelity Check-list**-
Design, Training, Delivery, Receipt, Enactment.
Checklist from previous study[92] **(Baseline, 3, 6**
mo.)
Recruitment / Retention (O*) Weekly monitoring of recruitment and retention
counts (frequencies and percentages, PI
research notes specifying recruitment and
retention strategies/outcomes **(weekly)**
SM Adherence (CO**) Calculated as the % of actual number of days
data entered over 1 week- from Tsai et. al
study[91] **(weekly)**
Health ITUES Survey(O*) **Health Information Technology Usability**
Evaluation Scale (Health ITUES) Impact
subscale (3 item) Perceived Usefulness
subscale (12 item)- adapted from Schnall
study**(3, 6 mo.)**
Acceptability and Feasibility of SMS (O*) **SMS Survey**- from Eisenhauer et al study[6] **(3**
mo.)
Two Evaluative Focus Groups (MT+) (O*) Semi-Structured Interview questions (guided by
aims 1,2, and social ecological perspective) with

probes Participants perceptions of the intervention experience (i.e. perceived efficacy, behavioral strategies, challenges with adherence, satisfaction with technology) **(6 mo.)**

Aim 2- Preliminary Efficacy

Fruit and Vegetables Servings (O*) **BRFSS -Fruit and vegetable dietary intake module (6 items)-** CDC- moderate validity and reliability[93] **(Baseline, 3, 6 mo.)**

Sugar-Sweetened/ Total Beverage Energy Intake (O*)

Brief Questionnaire to Assess Beverage Intake (BEVQ-15)- Cronbach's a ranged .97 to .99, significantly correlated with three 24-hour dietary recalls[94] **(Baseline, 3, 6 mo.)**

Report of Daily Log of Dietary Intake, PA, and Weight (O*)

Lose-It app programmed to send automatic daily reports to researchers- Protocol from previous study using *Lose-It* app[43] **(weekly)**

Physical Activity (O*) **BRFSS- Physical activity module (7 items)**- CDC- moderate validity and reliability[95] **(Baseline, 3, 6 mo.)**

Weight (O*) **Tanita Scale (TBF-300)**- Tanita model manufacturer instructions [TBF-300, Tanita Corporation of America] **(Baseline, 3, 6 mo.)**

Nokia Body+ Wi-Fi Scale- Nokia model manufacturer instructions (**MT+ group-daily**)

Blood Pressure (O*) Protocol outlined by Perloff et al.[96] **(Baseline, 3, 6 mo.)**

Resting Heart Rate (O*) Protocol outlined by Perloff et al.[96] **(Baseline, 3, 6 mo.)**

Aim 3 Indicators of Community Capacity

Community Partners Profile (S****) Demographic Form (community location, leadership role, characteristics- Demographic Form from Eisenhauer et al.[6] **(Baseline)**

Community Capacity (O*) **Community Capacity Evaluation Survey (Baseline, 12, 24, 36 mo.)**- from previous study[97] for measures on dimensions of communication, trust, participation and influence, leadership, community power, collective efficacy, accomplishments and impact, group roles, participatory decision-making procedures, resource mobilization, sustainability, partnership linkages, and overall satisfaction.

PIs research notes / audit activities reports/logs / CAB minutes / Student questionnaire: CAB- Tracking of participation level of members in recruitment/retention strategies (i.e. # meetings, activities, resources allocated, partnership/network linkages, leadership roles assumed, participatory-decision-making), member attrition with reasons, perceived benefits/skills gained, barriers and facilitators of retention, proposed strategies to increase

retention. STUDENTS- log of community outreach activities, implementation time, and outcome, Questionnaire evaluating perceived community outreach skill (identify, engage, evaluate, leadership) administered pre-post clinical rotation, GA/Honors students activity log, dissemination events.

After providing informed consent, the men will be oriented to the ActiGraph GT9X by the research nurse. The men will be instructed to wear the ActiGraph GT9X on their right hip continuously for seven days[5,6,7], only removing the device for bathing. Subjects will also be provided with written instructions for device use in addition to the hands-on demonstration, a troubleshooting number, an activity questionnaire to capture recreational and vocational activity, and postage-paid return envelope. After wearing the device for seven days, the men will mail the device back to the UNO investigators, Drs. Knarr and Youn. Those men who return the device as indicated will be issued/mailed a $25.00 incentive for their participation. Phone and text reminders will be sent to subjects on the eighth day (the day after completing the 7-day testing) reminding them to return their ActiGraph by our GA. Those men not returning the Actigraph after the phone and text reminder will be sent a mailed letter encouraging them to return the device with a reminder that failure to return the device will result in no incentive received for their participation.

Analysis: Accelerometers that contain a minimum of five 10-hour days, including both weekday and weekend days, of tracking will be eligible for analysis[7, 8]. Our collaborating investigators-UNO biomechanical engineer, Dr. Knarr, and Information Science and Technology Specialist, Dr. Youn, will supervise the advanced analyses of our ActiGraph data with their UNO graduate students across four forms: 1) Traditional ActiGraph analysis (raw accelerations and step counts per 15 second bouts, 2) Custom bout and sedentary analysis, 3) Nonlinear activity pattern analysis, and 4) Applying deep-learning and advanced analytics[5,9.] Subjects who participate in this sub-study will be mailed a single-page, individualized, easy to read, plain language, graph report containing their peak activity and sedentary times, as well as a report of minutes of minimum, moderate, and vigorous physical activity from their 7-day measurement period. Subjects will be given the same troubleshooting number to call if they have any questions regarding interpreting this individualized physical activity report.

Statistical Analysis

Descriptive statistics will be calculated on all variables, including frequencies and percentages for recruitment/retention, demographic, and categorical variables. Means and standard deviations will be calculated for all continuous variables and measures at each time point. Feasibility and acceptability analyses for aim 1 are largely descriptive, as we will be assessing participation rates and percentages of eligible men and which were the more effective recruitment methods. Qualitative content analysis, as described by Hsieh and Shannon (110) will guide interpretation of the focus group findings from the intervention participant groups. The interview transcript, reflective memos and observation notes taken during each focus group will

comprise one unit of analysis for within/across case comparison. The topics outlined by semi-structured interview guide will be extracted and organized. The researcher will read the transcripts for substantive coding. Data facts will be organized under a priori coding categories. The categories are named a priori because they are built into the interview guide questions. A data fact will be defined as those data elements that recurred in the interview without lack of consensus or were least participant to errors in inference (111). All data provided in a response to each question will be coded together. Incomplete, competing, or alternative topics that present in the discussion but were not identified a priori will be aggregated by the researcher and examined to determine their fit with the purpose. These topics will be compared with the synthesized findings to challenge alternative explanations and unnoticed flaws in the researchers argument.(112). A data matrix will be used to display the coded data to search for patterns across coding categories. The PI and honors students will return to the data to explore patterns further, supporting iterative analysis. Data categories will be re-contextualized into an account that makes sense for the entire studys data set. Meaning, the findings are integrated to provide new understanding or explanation to the interpretation of the intervention outcome data (112). Peer-debriefing and audit checking will occur weekly across the analysis by the PI and GA to assure accuracy of the findings.

Aim #2: Determine preliminary efficacy of a MT+ intervention to a comparison group receiving only a basic self-monitoring app (MT) in achieving 1) weight loss (primary), and 2) improved diet and increased PA (secondary) at 3 months post-baseline and follow-up at 6 months post-baseline in rural men. The efficacy analyses for aim 2 will be tested via RM-ANOVA models, as they provide a direct measure of differences between the intervention and comparison groups in weight loss and dietary and PA behaviors across the study, as well as effect size estimates. Huynh-Feldt corrected F-tests will be used in order to account for any possible violation of sphericity. If there is a higher than expected attrition rate, a maximum likelihood estimation method (e.g. mixed models) will be used instead of RM-ANOVA in order to utilize all available data and not delete cases in a listwise manner. Overall weight lost at follow-up will be assessed via an independent groups t-test. Outcome variables that are not normally distributed will either be transformed or assessed with nonparametric methods.

Aim #3: Determine quantitative and qualitative indicators of community capacity (resource mobilization, learning opportunities-skills development, partnership linkages, participatory decision- making, leadership) to support a relevant weight loss intervention for rural men. For aim 3, multiple indicators of community capacity will be used to evaluate support for the weight loss intervention applying best practice recommendations (113), 1) CAB- assessed community capacity change survey report by CAB, participation level of members (i.e. # meetings, activities, resources allocated, partnership/network linkages, leadership roles assumed), member attrition with reasons, Qualitative indicators of community capacity in CAB include perceived benefits/skills gained, barriers and facilitators of retention, proposed strategies to increase retention, CAB evaluation of student outreach activities, 2) STUDENTS- clinical log of community outreach activities (type, number, hours) developed, implemented, and outcome,

leadership activities (dissemination via honors projects, clinical conference and class presentations). Qualitative indicators of community capacity among students will include perceived skill development, and leadership confidence. Graduate level students help in training sessions, data collection and implementation of intervention.

3) PARTICIPATORY DECISION- MAKING as an indicator of community capacity will be evaluated via CAB survey and tracked ongoing through study. PI research-field notes will record student-engaged activities and time points.

SubStudy Aim: To determine the feasibility among a convenience sample of rural men currently enrolled in our Rural Men's health study to wear the Actigraph GT9X (single wearable sensor) for seven continuous days to measure their physical activity among the total volume of activity bouts across three gait dimensions: intensity, symmetry, and variability.