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MOBILE TECHNOLOGY INTERVENTION FOR WEIGHT LOSS IN RURAL MEN: PROTOCOL FOR A PILOT PRAGMATIC RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Introduction: Overweight-obese men in the rural Midwest are an unrepresented, at-risk group exhibiting rising rates of cardiovascular disease, poor access to preventive care, and a rural culture that contributes to sedentary lifestyle and unhealthy diet. Self-monitoring of eating and activity has demonstrated efficacy for weight loss. Use of mobile technologies for self-monitoring eating and activity may address rural men's access disparities to preventive health resources and support weight loss.

Aim: To use a pragmatic randomized controlled trial with community-engaged approaches to support rural men with weight loss.

Methods and analysis Six-month feasibility pilot randomized controlled trial with contextual evaluation will determine the feasibility and acceptability of a smart phone self-monitoring app enhanced with discussion group (Lose-It Premium), short message service (SMS) text-based support, and Wi-Fi scale intervention (MT+) for achieving weight loss among rural, midlife men (age 40-65). We seek to determine preliminary efficacy of MT+ (n=40) to a comparison group receiving only a self-monitoring app (Lose-It Basic) (MT; n=40) 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 post-baseline. Statistical analysis will evaluate trial feasibility, preliminary efficacy of outcomes, and community capacity. Descriptive content analysis will evaluate intervention acceptability and contextual sensitivity.

Ethics and dissemination Protocol approved by the University of Nebraska Medical Center Institutional Review Board (IRB# 594-17-EP). Dissemination of findings will occur through ClinicalTrials.gov, local and scientific dissemination.

Registration details
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KEYWORDS rural population, mobile health technologies, men, weight loss, health disparities, self-monitoring, eating, activity

ARTICLE SUMMARY

Intervention Addresses Rural Access Disparity: Real time self-monitoring support through messaging, an app-based discussion board, and smart-scale seeks to address men's access barriers to information and social support while being sensitive to context. If successful, this intervention has potential to improve rural men's access to weight management resources.

Community-Engaged Intervention Development: Community-engagement through use of a community advisory board, local student nurse outreach, and participants' interview feedback supports cultural refinement of the intervention.

Data Collection Methods: Multiple methods (app analytics, focus groups, anthropometrics, and survey data) are used to address the research aims supporting the contextual sensitivity of the intervention.

Probabilistic Generalizability: The sample size is justified as a pilot feasibility trial. The results of this study will be used to update the power analysis for a future fully powered study and inform the logical feasibility of the intervention for rural men.

STRENGTHS AND LIMITATIONS

- This study expands previous research using mobile apps to include community tailoring of the recruitment and intervention approach specific for rural men.
- The combination of community-engaged approaches with a pRCT design delivers a weight loss intervention that facilitates local buy-in and is sensitive to context.
- Lack of masking in pRCT presents opportunity for sensitivity analyses that may quantify the impact of bias on study outcomes.
- Components of the real-world comparator are included in the expanded, more comprehensive intervention.

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INTRODUCTION

Background and rationale

Over 55 million American men are overweight or obese.[1] Rates among midlife and older men residing in midwestern states have tripled in the past 20 years, with 39% of men overweight or obese.[2-3] Rural men report overall poorer health than urban men.[4] Their obesity status predisposes high risk for metabolic syndrome and cardiovascular disease.[5-6] Historically, rural men were less likely to be overweight and obese due to the high levels of physical activity (PA) involved in agricultural occupations. Recently, the mechanization of agriculture has shifted men's work roles to more sedentary, technology-driven lifestyles, increasing the likelihood of developing overweight/obesity.

Mobile health applications such as messaging, apps and other interfaces available via mobile phone have demonstrated improvement in health behavior change for weight loss among adults[7-9],and in some hard-to-reach minority populations.[10]The benefit that mobile technologies may hold for engaging hard-to-reach rural men for weight loss is unknown, as few studies exist to date.

[11], attempt

weight loss, or participate in weight loss programs.Men, when compared to women, are less likely to use weight control practices[12-14] Poor access to weight loss resources is one reason.[15] Rural men also tend to exhibit dominant masculine norms,[16] which view help-seeking behaviors and health promotion strategies as feminine and weak.[6, 16] Health promotion activities oriented to rural men's work roles are preferred.[17] 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. The Rural Men's Health Study plans to address the current gaps in knowledge by delivering a contextually sensitive weight loss intervention that is feasible to the rural environment and acceptable to participants.

Aims

We aim to 1) determine the feasibility and acceptability of a mobile technology enhanced self-monitoring intervention (MT+) for achieving weight loss in routine care of overweight and obese men in the rural communities, 2) determine preliminary efficacy of the MT+ intervention in comparison to a basic self-monitoring app only (MT) in achieving weight loss (primary), and improved dietary and PA behaviors (secondary) at 3 and 6 months post-baseline, and 3) determine quantitative and qualitative indicators of community capacity (resource mobilization, partnership linkages) to support a relevant weight loss intervention for rural men.

METHODS AND ANALYSIS

Design overview

We propose a pilot, feasibility, pragmatic randomized controlled trial (pRCT) with an allocation ratio of 1:1. We will randomize 80 men into two groups: intervention and comparison. A pRCT is selected to maximize assessment of men's variations in treatment availability option (free comparator app) and in behavior and adherence while examining benefit and drawbacks that occur in the real-world rural setting. Hertzog[18] 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. As weight loss studies in rural men are a gap in the current literature it is important that we obtain

reliable estimates of effect size with which to perform a power analysis for subsequent research. So 30 participants per group will be needed, for a total of 60. Some participants will likely not complete the study, so we will enroll 80 men to allow for up to a 25% attrition rate. Participants will complete assessments at baseline, 3 and 6-months post-baseline.

Public and patient involvement

Community engagement was used to inform the development of this protocol involving health professions students and a community advisory board (CAB). The CAB members represent the rural sampling region (i.e., farmers, insurance and machinery dealers, extension staff, and community health workers) and meet quarterly to inform the study approach, material content and imaging, targeted venues for social marketing, dissemination of recruitment materials, and the direct referral of eligible participants. The funder requires student involvement in study activities. We are involving students in planning, implementation, and evaluation of community outreach and recruitment strategies. Participants were not involved in any of the recruitment of this study.

Participants, interventions, and outcomes

Participant eligibility

Inclusion criteria: 1) man age 40-69, 2) reside (majority of the time) in Northeast Nebraska, United States (RUCA code 4-10), 3) BMI of 28 (kg/m2) or higher and weight not greater than 396 pounds (BMI 50 or higher with clinician clearance), 4) smartphone owner with enabled messaging, 5) email account, 6) answer "no" to all questions on the PAR-Q17 health history assessment or are willing to get physician evaluation prior to enrolling, and 7) willing to share Lose-It! self-monitoring logs with the investigative team, and attend three assessment visits at the health department. Exclusion criteria: 1) recently lost 5% or more body weight, 2) currently taking medications that cause or are influenced by weight loss, 3) used weight loss app in the past to lose weight, 4) person from same household is enrolled in study, and 5) Type I diabetes or Type II diabetes with insulin dependence.

Intervention group

Self-Monitoring

MT+ will receive the Lose-It! Premium app, Withings© Body+ Composition smart scale, daily SMS messages, technology support, and a private group discussion board within the app. In addition to the self-monitoring, the premium version permits enhanced customization of goal setting, app-automated self-monitoring reminders, and customized email reports of self-monitoring trends important in supporting motivation and confidence during periods of behavioral inaction. The smart scale will provide automated recording of weight synced to the app., permitting immediate feedback, virtual rewards (i.e. badges for achievements) and visual maps of weight trends. The participant will be instructed in how to sync the scale with their smartphone at baseline. They will be instructed to weigh themselves daily at home on this scale which will automatically update to their app after each weighing.

Social Support

MT+ participants will be enrolled in a private, closed-group discussion board created and moderated by the research team. The discussion board will provide social support to MT+ participants while completing the trial to promote long-term success.[11, 12] The discussion board will also provide opportunity for social comparison of others' self-monitoring experiences providing a mechanism to influence judgment and behavior change towards one's own self-monitoring. The groups will be incentivized by a male moderator who will administer peer challenges weekly (see Appendix I) and will also respond to questions. Participants will also be encouraged to post weekly about their own successful strategies and progress reports related to their self-monitoring for weight loss.

Text messaging

A message library (see Appendix II) will be developed by the team based upon messaging content that has demonstrated usefulness for behavior change[20-23] and preferred by men.[22, 24, 25] Message content will include a variety of topics including reminders, eating and physical activity behaviors to be enacted and avoided, self-monitoring portion control, strategies for overcoming weight loss barriers, and health living challenges. Content will be adapted from healthy eating and physical activity promoting resources that include USDA Choose My Plate[26] and CDC and Prevention: Physical Activity[3]. PA includes targeted aerobic PA, monitoring of body weight, behaviors needed to sustain weight loss, promoting success and rewarding oneself, preventing failure, and avoiding temptations.[13] CAB members will inform and review the content of the messages for local relevance prior to dissemination to the participants. An online automatic service (Remind.com©) will be used to send the free messages to participants twice per day on Monday, Wednesday, and Friday at 8am and 11:00am, and once per day on Tuesday, Thursday, Saturday, and Sunday at 8am.

Troubleshooting support and re-engagement prompt

MT+ participants will have access to a 24-hour technology troubleshooting support from the investigative team via phone or text. The participant's food, activity, and weight log will be accessed once weekly by the investigative team to monitor adherence. If dietary intake, PA, or weight are not logged for greater than five days, he will receive a reminder text and phone call.

Comparison group

MT group of men will receive the Lose-It! Basic app. The basic app permits real-time self-monitoring of eating, PA, and weight – same as the Premium version. This app version is available for free and is widely accessible by any smartphone user.[27] MT participants will be asked at baseline to self-monitor their eating, PA, and weight daily. They will be instructed to weigh as often as they can and log the result into the app. They will not receive message prompts for self-monitoring, no self-monitoring trend reports, and no peer interaction via app customized social group. MT participants will only receive reminders for their assessment visit appointment times.

Technology orientation

Both groups will receive an assigned app username, password, and hands-on orientation to manual food logging and measuring basic step count at baseline. Both groups will receive a paper printed version of an App User Manual designed and adapted for the study.

Focus Groups

Two focus groups will be held 6 months post-baseline with a purposive sample of MT+ completers stratified according to their weight loss experience (successful or unsuccessful in achieving the 5% baseline body weight loss goal) to solicit their perceptions on the MT+ intervention efficacy, acceptability, and feasibility.[28] Two groups permits cross-case comparative analysis of the intervention.[29, 30] A semi-structured interview guide will facilitate 90-minute discussion led by two co-moderators. Moderator-debriefing and reflexive memos will also be

summarized after each interview and audio files will be transcribed verbatim. Collectively, these [31] items will create a decision trail which will serve as an audit demonstrating accountability.

Outcomes

Primary outcome

Primary outcome is loss of body weight (kg and % body weight) at 3 and 6 months compared to baseline. The Tanita Scale (TBF-215) will be used to measure height, weight, and BMI [32] at the baseline, 3, and 6 month assessment visits. Weekly, the graduate assistant (GA) will also log into each participant's Lose-It! account and export participant-logged weights.

Secondary outcomes

Secondary outcomes include improved diet and increased PA measured at 3 month and 6 months compared to baseline. Fruit and vegetable consumption will be measured using the Behavioral Risk Factor Surveillance System (BRFSS) Fruit and Vegetable Dietary Intake Module (6 items).[33] The BRFSS Physical Activity Questionnaire will also be used to measure self-reported PA of the participants [33]. To measure the sugar sweetened beverage intake, the Brief Questionnaire to Assess Beverage Intake (BEVQ-15) will be used to measure sugar sweetened beverage intake. Participant's "weekly summaries" will also be exported from the app which includes daily food log, PA, weights, and total daily step count.

Participant timeline (See Figure 1)

Recruitment and consent

Participant recruitment will occur through CAB and student outreach, Facebook blasting, website, press releases, business postings, community fairs, clinician office outreach, and direct referral. Recruitment of minority men will be sought through community health workers who

already have established local trust.

Enrollment screening calls will be conducted by GAs. The PAR-Q 17 health questionnaire will be used to determine if clinician clearance is required prior to the baseline visit. Thus, informed consent (see Appendix III) will be obtained prior to its completion during the screening call. Research electronic data capture (REDCap) will permit real-time participant consenting.

Study data will be collected and managed using REDCap electronic data capture tools hosted at UNMC. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies. REDCap at UNMC is supported by Research IT Office funded by Vice Chancellor for Research (VCR). This publication's contents are the sole responsibility of the authors and do not necessarily represent the official views of the VCR and NIH. When determined eligible, the participant will be invited to participate in the process of informed consent via a REDCap weblink to the secure consenting page sent via text message or email. After verifying their reading of the consent and answering relevant questions, the participant will provide a wet-signature, immediately verifiable online by the GA. The informed consent document specifies the posting of clinical trial information at ClinicalTrials.gov. A printed copy of the signed consent will be mailed to each participant immediately following conclusion of the enrollment interview.

Randomization and blinding

Random allocation of group assignment will occur using an allocation schedule created by the project statistician using a random number generator and "turn randomization" to ensure equal sample sizes. The outcome assessor will receive a REDCap code and designated app username and password, along with the participant's group assignment so to assist participants with successful download and orientation to the app version. Receipt of a smart scale and premium subscription prevents subject blinding. However, many published pRCT's do not blind treatment groups.[34] Our comparison group uses the basic app, which is routinely available for free in community care, thus is not a masked placebo. Our study aims seek to evaluate feasibility and preliminary efficacy of the mobile technology intervention, and mobilization of rural community resources within routine care. We considered the decision to unmask to be in the realm of these two aims reflective of this real-world, rural setting.

Measurements, data management, and analysis

Measures

Table 1 outlines the primary and secondary outcome measures. Measures at 3 month and 6 months will be compared to baseline. Additionally, health history, demographics, blood pressure, pulse rate, Comfort with Technology, health ITUES, and PROMIS -29 surveys will be collected for further analysis of participants profile and outcomes.

Table 1

Measure Description (Data Collection Time Points)		
Primary Outcomes: Body Mass Index and Weight		
Body mass index	Tanita Scale (TBF-215)	Baseline, 3 months, and 6 months
Weight	In-person measurement of weight by the Tanita Scale (TBF-215) Withings© Body+ Body Composition Smart Scale (MT+) Self-reported weight (MT)	Baseline, 3 months, and 6 months Daily measure (Recommended), Weekly average computed Daily (Recommended), Weekly average computed
Secondary Outcomes: Diet and Physical Activity		
Fruit and Vegetable Servings	BRFSS-Fruit and Vegetable Dietary Intake module[3]	Baseline, 3 months, and 6 months
Sugar-Sweetened/ Total Beverage Energy Intake	Brief Questionnaire to Assess Beverage Intake (BEVQ-15) [35]	Baseline, 3 months, and 6 months
Physical Activity	BRFSS- Physical activity module[33]	Baseline, 3 months, and 6 months
Report of daily log of dietary intake, physical activity, and weight	Weekly summary downloaded from app which includes participants self- report of dietary intake, physical activity, weight, and steps per day	Weekly reports exported during study

Height, weight, and BMI

The Tanita TBF-215 Body Composition Analyzer will be used to measure the participants height, weight, and BMI following their manual guidelines.[32] The participant will be

asked to remove shoes, socks, belt, and empty pockets. The participant will be asked to stand up straight so height can be accurately measured.

Food and beverage intake

To establish a baseline of food and beverage intake, the BRFSS Fruit and Dietary Intake Survey and the BEVQ-15 will be administered to participants at timepoints in table 1.[3, 35] Additional information will be exported from the app logs and analyzed. Each week, the GA will log into the participants web version of the app to retrieve the "weekly summary" of meals/day logged and average calories/day/week and export the data to participants ID labeled file.

Physical activity

The BRFSS physical activity questionnaire will be used to gather participants self-report [33] Additionally, like the food intake, each week the GA will retrieve from the app the of PA. "weekly summary" of PA and total daily step count.

Blood pressure and pulse rate

The ADC e-sphyg™ 2 9002 Automatic Sphygmomanometer will be used to measure blood pressure of the participants. The participant will be asked to wear loose clothing or a short sleeve short, to avoid caffeine, intensive exercise and smoking for at least 30 minutes before measurement. The participant will be instructed to not talk during the rest period or during measurement. The man's arm will be placed on a desk or table so that the middle of the arm is at the level of the heart. The outcome assessor will line up the cuff mark "artery" over the individual's brachial artery. For 5 minutes, the participant will quietly sit in a chair (feet on floor, back supported) and rest without talking. After obtaining a blood pressure, the participant will be asked to raise his arm for 10 seconds and wait another 30 seconds. Then the blood pressure procedure will be repeated with measurements spaced about one minute apart. The procedure will be repeated until two readings are within 5mmHg and average the two values together. Two resting pulse rates will also be obtained using the blood pressure cuff and these values will be averaged together and recorded.[36]

Health history and demographics

A brief health history survey will be administered at baseline. The PROMIS-29 will be administered at baseline, 3 month, and 6 months to measure general health and asked questions related to physical function, anxiety, sleep, fatigue, and pain.[37]

Technology experience

Comfort with Technology Survey[38] (baseline), and the Technology Feasibility and Acceptability survey which was adapted from the health-ITUES[39](3 and 6 months) to examine technology experience. The comfort with technology survey asks questions related to comfort, frequency, and purpose of technology use.[38] The modified health-ITUES evaluates technology usefulness.[39]

Data Management

The outcome assessor will receive a participant specific REDCap code to enter assessment information. To encourage participant retention, the GA will contact MT+ group participants if they fail to log their eating, activity, or weight in the Lose-it app for greater than five days. If the participant states he cannot log daily the GA will document reasons and encourage participant to post as often as he can.

Analysis

Aim 1- MT+ intervention feasibility and acceptability

Aim 1 will be evaluated through: 1) participation rates including number of men recruited and randomized over a 6-month period; 2) participant retention rates; 3) feasibility, usability, satisfaction ratings; 4) app logs of MT+; and 5) evaluative focus group feedback. 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 recruitment methods were the most effective. Qualitative content analysis[31] will guide interpretation of the focus group findings. The interview transcript and reflective memos taken during each focus group will comprise one unit of analysis for within/across case comparison. The topics outlined by the interview guide will be extracted and organized and transcripts read 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 [40] All data provided in a response to each question will be coded together. Incomplete, inference. competing, or alternative topics that present in the discussion but were not identified a priori will be aggregated and examined to determine their fit with the purpose.[41] A data matrix will be used to display the coded data to search for patterns across coding categories. The PI and GA 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 study's data set. Meaning, the findings are integrated to provide new understanding or explanation to the interpretation of the [41] Peer-debriefing and audit checking will occur weekly across the intervention outcome data. analysis by the PI and GA to assure accuracy of the findings.

Aim 2- Preliminary efficacy of MT+ to MT in achieving weight loss

The efficacy analyses 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 (i.e. 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 non-parametric methods.

Aim #3- Indicators of community capacity

Multiple indicators of community capacity will be used to evaluate support for the weight loss intervention applying best practice recommendations: 1) CAB- assessed community capacity change via survey report, participation level of CAB members (i.e. number of attended meetings, activities, resources allocated, partnership linkages), member attrition with reasons,

perceived benefits/skills gained, barriers and facilitators of retention, proposed strategies to increase retention, 2) student support in the outreach and recruitment will be tracked via number of hours of participation and partnership linkages.

Data Monitoring, Auditing, and Harm

Each participant will be given a unique study identifier, all protected health information will be masked, and REDCap data exports will be limited to the PI and the project statistician for generating reports and the conduct of statistical data analysis. Safety monitoring will be conducted monthly by the PI, study statistician, and independent data safety monitor. Per university policy, all serious adverse events (AE) and unintended effects of the intervention will be reported to the UNMC IRB and the independent data safety monitor (IDSM) within two days after the PI is notified of the AE. The technology safety report will include troubleshooting requests from participants, re-engagement attempts for participants who were not logging, and any technology related protocol violations. The enrollment safety report includes new enrollment counts, subject withdrawals, protocol violations, AE, and preliminary outcomes.

ETHICS AND DISSEMINATION

This protocol, including consent forms, has been approved by the University of Nebraska Medical Center Institutional Review Board (UNMC IRB# 594-17-EP). All protocol amendments

will be communicated immediately to the IRB, DSMP, ClinicalTrials.gov, CAB, participants, and funder. All participants will be informed of their right to confidentiality right to leave the trial at any point without loss of those benefits to which they were entitled. All data will be retained in HIPPA compliant REDCap database.

Access to data

The PI, study statistician, and the designated IDSM will have access to the final trial dataset. All proposed study specific case report forms for data collection will be coded by the participants unique study ID and maintained in REDCap. All data and other personal health information (PHI) will be removed from the study database upon completion of the study.

Ancillary and post-trial care

Post-trial care is not anticipated as this trial is classified as a low-risk intervention. Participants who express need for assistance will be informed of the UNMC support services and assisted in contacting them.

Dissemination policy

Trial is registered at ClinicalTrials.gov., Identifier: NCT03329079. Deidentified summary results will be posted to ClinicalTrials.gov for public access and disseminated in scientific forums and to the local rural communities.

AUTHORS' CONTRIBUTIONS

CE is PI directing all study components. KK is the statistician who co-leads data management.

FS, AY, and KS develop and manage the mobile technologies. PH provides protocol oversight, assessment fidelity planning and training, JM conducts enrollment screening, recruitment, CAB and focus group moderation. CP advises ethics board and protocol adherence. Manuscript drafted by CE, KS and all authors revised-approved the final version. All authors contributed substantially to study design and protocol conduct.

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Appendices Appendix I: Private Group Discussion Board- Moderator Weekly Posts

Week 1: Water

Thousands have lived without love, not one without water (Auden). A recent study found that drinking 16 oz of water before meals increases fat loss in overweight individuals on a diet. Drink one gallon of water per day. This can come from food or beverage. Fruits and vegetables contain more water than other foods. Carrying a refillable water bottle with you during the day can help you increase your water consumption.

For more information: https://www.mensjournal.com/food-drink/5-reasons-never-neglectwater/

Challenge: Increase your daily water consumption to 1 gallon per day.

Week 2: Increasing Physical Activity

Physical activity reduces the risks of heart disease and diabetes better than weight loss alone. The American Heart Association recommends 30 minutes of moderate activity 5 days per week.

Moderate activity includes walking, hiking, gardening, or golfing. Moderate activity makes you sweat but will not take your breath away.

A great way to start is by walking. Start by walking 10-15 minutes at a time to total 30 minutes a day.

For more information: https://healthyforgood.heart.org/move-more/articles/hate-exercise-5-

Challenge: exercise for an additional 30 minutes per week beyond what you are already doing.

steps-to-loving-exercise
Week 5: Avoiding Empty Calories Empty calories are calories that provide your body with no nutrition. They are found in packaged foods like cakes, cookies, candy, soda, alcohol, fast food etc. They are high calorie, low nutrition, and contain high amounts of sugar and solid fat. As a general rule, if it comes in a package it probably contains empty calories. Try eating more whole food calories in fresh fruits and vegetables, eggs, poultry, nuts, whole wheat bread, protein bars, or low-fat milk For more information: http://www.menshealth.co.uk/healthy/11-ways-to-cut-hundreds-ofempty-calories-a-day Challenge: Limit your empty calorie intake to 200 calories per day.
Week 4: Family/Friends Challenge Having family and friends involved in your diet and exercise program can contribute to your success. Let others know about your eating goals so healthy options can be available. Instead of watching TV with others, try going on an evening walk together. Encouraging others to get involved with you will not only be beneficial for you, but them as well! For more information: https://www.parents.com/fun/sports/exercise/10-ways-to-exercise-as-afamily/ Weekly challenge: Include your family in exercise 2 days this week.
Week 5: Portion Sizes

3

1
2

Serving size and portion size are not always the same. Serving size is the manufactures recommendation of the serving, portion size is how much is actually consumed. Your portion size should match the serving size.

Veggies: 1 cup of raw veggies or 2 cups of leafy greens. 1 cup is roughly size of a fist
Fruit: one medium apple or orange, ½ cup of sliced fruit. ½ cup is one cupped hand
Grains: 1 slice of bread. ½ cup of dry pasta or bread. ½ medium potato.
Protein: 3 oz of meat is the size of a deck of cards.
Fats: 1 oz of cheese is size of two dice. 1 tsp of butter is the size of one die.

It's important to accurately count your portion sizes to accurately log food for weight loss. If you are under counting your portion size, you will not account for calories you are consuming. For more information: https://healthyforgood.heart.org/eat-smart/articles/portion-size-versusserving-size

Challenge: Examine your portion sizes during at least one meal each day this week and try to improve your portion sizes. Use the information above as a guideline.

Sodium contributes to the development of high blood pressure, which is the one of the major

The American Heart Association recommends a sodium intake of 2300mg a day with an ideal

2300mg of sodium is equivalent to one teaspoon of salt.
Most sodium consumed by Americans does not come from table salt but is in processed foods.
The easiest way to avoid sodium is to avoid processed foods.
In the Lose-it! App, you can create a goal to limit your sodium intake to 2300mg daily. The app will automatically track sodium as you log food, so you can view your sodium

For more information: https://www.menshealth.com/health/a19548436/blood-pressure-guide/
Weekly challenge: Limit sodium intake to 2300mg daily.

Week 6: Avoiding Salt/Sodium

risk factors for heart disease. limit of 1500mg a day. consumption each day.
Week 7: Moving Every Hour A study was conducted in 2017 which found that patterns of sitting are associated with higher illness. Not only is exercise important, but so is moving every hour! It's easy to forget to move every hour, so try setting a timer on your phone or watch to get up and walk around. For more information: https://www.mensjournal.com/health-fitness/a-five-minute-walk-could-undo-an-hour-ofsitting-20141009/ Challenge: Move every hour from 9-5. The goal is to have 9/9 hours active!
Week 8: Improve Sleep Quality A good night's sleep is an important component to weight loss programs. The recommendation for sleep for adults is 7 hours per night. Insufficient sleep is linked to the development of chronic disease like obesity, diabetes, depression, and cardiovascular disease. Here are some tips for better sleep: 1. Make your bedroom a quiet and relaxing environment.

2. Turn off screens 30 minutes before bed 3. Be consistent. Get your body on a "sleep schedule" so you go to bed and wake up at the same time. 4. Avoid large meals before bed. 5. Exercise! Exercise is proven to improve sleep quality. For more information: https://www.mensjournal.com/style/sleep-better-live-better/ Challenge: Try to get 7 hours of sleep each night this week.
Week 9: Fit After 40 As we get older our bodies change and our metabolism slows. Staying fit after 40 is a little different than it was when you were in your 20s! Lean tissue mass will start to decline and fat mass will increase. Diet and exercise can help prevent this process. Here are some tips for weight loss after 40: 1. Start with moderate activity like walking. If you are already walking several times a week, try incorporating strength training into your routine. 2. Cut back on red meat. Increase intake of lean protein and veggies. 3. Avoid alcohol. Alcohol contains empty calories and provides no nutritional value. 4. Reduce stress. Stress causes increase in cortisol levels which is associated with increased body fat. Here is an article with additional tips for weight loss**:** **https://www.mensjournal.com/healthfitness/7-weight-diet-loss-tips-men-over-40/** Challenge: Try at least one of the four tips listed above this week.

Week 10: Strength Training
Strength training is an important piece to exercise.
The American Heart Association recommends strength training two days a week.
With a larger muscle mass, your metabolism increases and your body burns calories more efficiently.
Strength not only increases muscle mass but increases bone mas as well.
For more information: **https://www.mensjournal.com/health-fitness/beginners-guide-weight-training/**

Challenge: Incorporate strength training into your exercise program two days this week

Week 11: Reducing Stress
According to the American Heart Association, chronic stress can cause high blood pressure, is linked to heart disease, and can weaken your immune system.
During stressful times, it's important to continue to practice healthy lifestyle behaviors.
Some helpful tips to managing stress include:
1. Exercise
2. Get adequate sleep
3. Maintain a healthy diet
4. Spend time with family or friends.

For more information: https://www.mensjournal.com/health-fitness/20-science-backed-waysreduce-stress/
Challenge: Try at least one of the four tips listed above this week.

Week 12: Making a Diet Your Lifestyle
You made it!
Congrats, this is the final week of the study.

One thing you can do to stay on track is continue healthy eating and physical activity.
Continue to log your food to track your caloric intake.
Increase your physical activity to moderate or vigorous if tolerated.
There are various apps available to track food and activity which you can use after this study.
For more information: https://www.mensjournal.com/health-fitness/how-to-add-18-years-toyour-life-w436796/

Challenge: Make a plan and stick to it!

Appendix II: List of Text Messages

G=Goal Oriented/Self-Monitoring
1. Healthy isn't a goal. It's a way of living.
2. Work hard enough to raise your heart rate and break a sweat.
3. Today your goal is to exercise for 10 minutes, 3 times today.
4. Eat plenty of fruits of all colors today.
5. Did you eat the recommended amount of protein today? No beer is not protein.
6. Avoiding processed meats is best, try choosing fish or lean meat today.
7. Don't overeat. Your goal today is to control your portion sizes at meals.
8. How many servings of fruits or vegetables did you eat yesterday?
9. How many glasses of water did you drink yesterday?
10. Make sure half of the grains you eat are whole grains. Whole grains can help give you a feeling of fullness. Choose whole-wheat breads, pasta and oatmeal.
11. Take your time eating. Savor your food. Eat slowly. Enjoy the taste and textures of your food.
12. Make half your grains whole grains.
13. Try eating on a normal sized plate that is 8 inches round. It might look like the saucer to your coffee cup at first.
14. Short bouts of 10 minutes of moderate or vigorous activity count!
15. Avoid heavy gravies or sauces as they add fat and calories to otherwise healthy choices. (And they stain your shirt).

M = Motivational

16. No matter how slow you go, you're lapping everybody on the couch.
17. Good things come to those who sweat. Especially if you are moving when sweating.
18. 10,000 steps is roughly walking 5 miles. Then you can tell stories that you walked 5 miles for (fill in the blank).
19. Make it a lifestyle, not a duty.
20. Don't use the weekend as an excuse to give up on your goals.
21. Sweat is fat crying.
22. It's not easy, but it is worth it. Now repeat that every day.
23. Be stronger than your excuses.
24. Some activity is better than none.
25. You don't have to eat less you just have to eat right.
26. A one-hour workout is 4% of your day.
27. When you feel like quitting, ask yourself why you started.
28. Thank you for reading this text. You can lose ½ a pound by pushing the off button 20,000 times.
29. When tempted by junk food, turn your head to the left and then to the right. Repeat as necessary.
30. Attitude is everything! New day! New Strength! New Thoughts!
31. No matter how slow you go, you are still lapping everybody on the couch!

32. Will it be easy? NOPE! But it will be WORTH IT!!!
33. Nothing is impossible, the word itself says I’m Possible.

34. Strive for progress not perfection!
35. Being healthy is not a race, it's a journey!
36. You've Got This!!
37. You are stronger than you think!!
38. BLT's- Bites, licks, tastes count too.
39. You'll never change your life until you change something you do daily. The secret to success is found in your daily routine. This year—set a goal to change ONE thing about your day to be healthier. Keep the goal specific and measurable. Instead of saying you are going to exercise this year, tell yourself you are going to exercise for 30 min, 5 days this week. Repeat this each week until it becomes a habit.
40. Are you frustrated? Are you ready to quit? DON'T!! Remember why you started this in the first place!!
41. Every step you take toward your goal is a step closer to more time with your family!
42. Even if you lose ½ a pound a week you will still lose 26 pounds by this time next year. Keep going!
43. It takes 4 weeks for you to see your body changing, it takes 8 weeks for your friends and family, and it takes 12 weeks for the rest of the world to see the changes, but your heart sees it immediately.
44. Be stubborn about your goals and flexible about your methods.
45. Exercise in the morning, before your brain figures out what you're doing.
46. You don't have to be extreme, just be consistent.

47. It’s a slow process but quitting won’t get you there.
R = Reminder (for tracking, healthy eating, etc.)
48. Tracking your food intake is a key to success - remember to track today.
49. They key to healthy eating? Avoid any food that has a TV commercial.
50. Your safety is priority! It may be tempting to compete with others and set an unrealistic and unhealthy goal for increasing your steps.
51. Drink more water today"
52. What is moderate activity: I can talk while I do them, but I can't sing.
53. Remember to eat a variety of whole grains.
54. Make half your plate fruits and vegetables.
55. Remember to eat Breakfast.
56. Take a walk after lunch.
57. Make sure to get your steps in today.
58. 5 fruits and veggies a day!
59. Did you know….1 pound of fat is approximately the size of a large grapefruit?
60. Did you know 1 pound of fat is worth 3500 calories!!
61. Have you logged today?
62. Guzzle Guzzle the water – 64 oz!!
63. Don’t forget to log those workouts!
64. Daily health checklist: Drink water, eat a fruit or veggie every meal, workout, stretch, LAUGH and SMILE, try to sleep 8 hours.

65. Did you know weight loss is 30% workout and 70% diet??
66. Indulge by the rule of 1 – 1 scoop of ice cream, 1 small piece of pie, 1 piece of chocolate.
67. Exercise during commercials – get 10 lunges, 10 sit ups or 10 squats!
68. Park farther from the door and walk to get the mail, go to the store, or going to work.
69. Take stairs when you can.
70. Eat for energy, not for comfort!
71. Did you meet your fitness goals?
72. Have you logged your meals today?
73. Try redirecting your attention when those cravings hit, give it 15minutes before giving in! Drink some water!
74. It's Friday! Don't lose track this weekend- stay focused!
75. You don't have to eat less you just have to eat right.
76. Weekends count! Don't dip out on your diet.
77. Try to get 250 steps every hour. Get up and take a walk.
78. Ask for dressings, butter, and sour cream on the side.
79. Buffet time? Hit up the salad bar.
80. At the buffet? Make one trip. You don't have to eat it all.
81. A gas station hot dog has 400 calories. Pack a lunch today!
82. Remember to walk instead of drive when you can!
83. Switch your soda for water today. 1 can of soda has about 150 calories. 3 cans of soda is 450 calories!

84. Remember portion control— check the back of the bag for serving size!
85. Eat slowly and take small bites. It takes 20 minutes for your brain to register fullness.
86. Motivation is what gets you started habit is what keeps you going
87. Consistency is key!
88. At the gas station? Grab a protein bar instead! Protein keeps you full for longer.
89. Too cold to exercise? Try jumping jacks in your living room.
90. Buzz the Buffet. Take a walk around the buffet first before filling your plate. Choose your favorite foods and skip over your least favorite.
91. Don't skip meals! Skipping meals will make you hungrier and cause you to overeat at your next meal
92. Don't forget breakfast! Get your metabolism started today.
93. Food is fuel, not comfort.
94. Going cold turkey doesn't work. One healthy habit in, one bad habit out!
95. The best snacks are 200cal or less, filling yet satisfying. Snacking keeps up your metabolism throughout the day helping you burn calories and keep your energy levels up.
96. Remember, one serving of meat is the size of a deck of cards
97. Drink your first glass of water right when you wake up! Rehydrate and stimulate your digestive system.
98. Eating healthy is not a diet, it's a lifestyle.
99. Create healthy habits not restrictions.
100. Exercise gives you more energy and helps you stay focused.

101. Even if you lose ½ pound a week. You will still lose 26 pounds by this time next year. Just keep going.
102. Tip: put fruits and vegetables at eye level in the fridge so they are the first thing you see.
103. Tip: have fresh fruit like bananas or apples on the table so they are easy to grab on the go.
E = Educational (Tips, Physical Activity, Nutrition/Healthy Eating)
104. Regular physical activity helps build and maintain healthy bones and muscles, so you can beat your friend at arm-wrestling.
105. Regular physical activity helps reduce the risk of developing colon cancer.
106. Exercise controls weight.
107. Exercise improves mood.
108. Exercise boosts energy.
109. Exercise promotes better sleep.
110. You may want to work with your doctor to set up an activity program.
111. Estimating Portion Sizes: 1 egg is 2 ounces or 1/4 cup.
112. Adults should do strengthening activities at least 2 days a week.
113. If you haven't been active in a while, start slowly and buildup.
114. Estimating Portion Sizes: A golf ball is equal to 2 tablespoons or 1 ounce.
115. Estimating Portion Sizes: a deck of cards is 3 ounces.

116. Being active has benefits. It helps you feel better about yourself. It helps you sleep better. It helps you move around more easily.
117. Adults need about 150 minutes of moderate activity a week.
118. Vigorous-intensity aerobic activity means you're breathing hard and fast, and your heart rate has gone up quite a bit. If you're working at this level, you won't be able to say more than a few words without pausing for a breath.
119. Doing 1 minute of vigorous-intensity exercise is equal to about 2 minutes of moderate activity.
120. Satisfy your “sweet tooth”. Eat a natural dessert such as fruit.
121. Sodas or other beverages can add about 400 calories a day to men’s diet, water is a better choice.
122. Estimating Portion Sizes: Baseball is equal to 1 cup.
123. Medical authorities agree that 10,000 steps is a healthy number to strive for a day.
124. Calories are tiny creatures that make your clothes tight at night – did you know Coors Light has 102 calories, a Bud Light has 110 calories and a Michelob Ultra has 95 calories per bottle.
125. A six pack of Bud Light has 660 calories. You would have to walk 4.5 miles to burn off the calories.
126. Just 100 extra calories a day means 10 extra pounds a year.
127. If you don’t recognize the ingredient, your body won’t either.
128. Don’t be fooled by “low fat” or “sugar free.” This is code for “processed.” Stick to whole foods!
129. Avoid eating foods with ingredients you can’t pronounce.

130. Sugar craving? Swap the sweets for fresh or frozen fruit instead.
131. Craving fatty foods? Try a glass of milk, 1/2c of yogurt, or 1oz of cheese.
Holiday Messages
132. Turkey or ham? Turkey has 200 calories for a 4oz serving. Ham is close to 400 for the same size. Gravy adds more!
133. Watch out for appetizers! Fill a small plate, and don't come back for seconds.
134. Don't go nuts--- 1/2 cup of mixed nuts contains about 400 calories!
135. Don't drop the good habits. Keep up the good work over the holidays
136. It's okay to say "no" when you have had enough to eat.
137. Choose your indulgences carefully.
138. Don't make food the holiday focus: family, friendship, and laughter are better than food.
139. Go easy on the alcohol to save room for dessert.
140. Skip the dressings, butter, and gravy.
141. Eat 70% vegetables and 30% other foods.
142. Superbowl tip: Get up and walk during half time and commercials (or during the game if it's the commercials you like). If you want to watch it all, try and get a workout in before the big game!

Appendix III: Consent Form

University of Nebraska Medical Center

IRB PROTOCOL # 594-17-EP **Page 1 of 9**

ADULT CONSENT - CLINICAL BIOMEDICAL

Title of this Research Study
The Rural Men's Health Study

Invitation
You are invited to take part in this research study. The information in this form is meant to help you decide whether or not to take part. If you have any questions, please ask.

Why are you being asked to be in this research study?
You are being asked to be in this study because you are a 40 to 69 year old man, reside in the Northeast Nebraska region, your Body Mass Index (BMI) is 28 or higher (BMI 50 or greater with clinician clearance, less than 396 pounds), you are a smartphone owner with enabled text messaging, you speak and read English, have an email account, you have no health problems that would prevent you from becoming more physically active, and you are willing to share your self-monitoring logs from the Lose-It app with the investigative team.

What is the reason for doing this research study?
Rural men are less likely than the general population to receive diet and exercise counseling for weight loss. Men with BMI of 28 to 49 are classified as overweight or obese BMI of 50 or higher is classified as morbidly obese. This population is at increased risk of developing a number of chronic diseases such as insulin resistance, type 2 (adult-onset) diabetes, high blood pressure, heart disease and cancer. The preferred treatment for weight reduction is lifestyle modification that includes a diet that is high in fruits, vegetables and low fat dairy products, and regular moderate intensity physical activity supplemented by resistance exercise. This research is trying to see if a technology enhanced self-monitoring approach is effective in increasing healthy eating and physical activity and reducing body weight. A total of 80 participants are expected to enroll in this study.

What will be done during this research study?
The study will last for six months. You will be asked to come to meet with a research nurse for an independent meeting at the Northeast Nebraska Public Health Department in Wayne, NE, three times at regular intervals (baseline, 3, 6 months) to complete surveys and physical assessments, which will take approximately 60-90 minutes. The physical assessments will include weight, height, body mass index, blood pressure, and heart rate. The individual contents of your written survey will only be shared with the research team. The surveys will include questions about your

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health status, your eating and physical activity patterns, and your perceptions about technology.

Immediately after the baseline visit, you will be randomly assigned (as by the roll of a die) in a 1:1 ratio to one of two groups. All subjects will be assigned a temporary email address, that contains no personal identifiers, that will be used to create a Lose-It app account. At the end of the study, you will have the option to choose to obtain personal ownership of your Lose-It account. If you choose to obtain personal ownership of your account, our research staff will assist you in entering a new username and password. However, please be advised that our study will not pay for further access to the Lose-It app. Future access to Lose-It premium will require you pay the current market rate for the app. If you choose to forego a change of ownership, your Lose-It account will be deleted 30 days after completing the study. If you are in group 1, you will have access to Lose-It Premium app, receive daily text messaging, participate in an online social comparison group with other members of group 1, and receive a WiFi Smartscale for daily weighing over the next 6 months. If you are in Group 2, you will have access to the Lose-It Basic app to self-monitor your eating and activity for the next 6 months. Both groups will have access to the research nurse for questions and will receive assessments at 3 and 6 months.

An overview of the procedures you will participate in during the study office visits are outlined in the attached table: Schedule of Procedures.

In addition to the brief questionnaires collected at baseline, 3, and 6 months, you may be randomly invited to participate in a face to face focus group interview (approximately 90 minutes) at the end of the study (6 months) at the same community center where your assessments were collected. The questions for the interviews and focus groups will be: 1) What was the most helpful aspect of this study? 2) What other support would have helped you reach your goals? 3) Other comments. The interviews and focus groups will be recorded and analyzed to determine the major themes. Audio recordings of the focus groups will be destroyed after checked against the written transcripts for accuracy. At the end of the study, your temporary email account and attached Lose-It account will be deleted. You will have the option to set up a new Lose-It Basic account for free if you choose to continue using the app after the completion of the study.

What are the possible risks of being in this research study?

The possible risks of the procedures for assessing the biomarkers (resting blood pressure and resting heart rate) can be compared to procedures used in routine medical care and/or screens (i.e., blood pressure or heart rate measurement).

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Assessment of Behavioral Markers:The assessments include no sensitive questions and pose no risks to you beyond possible but unlikely fatigue during completion of the survey. If you become fatigued, you can take a break or complete the assessment on another day.

Assessment of Biomarkers:The likelihood of risks associated with the assessment of all biomarkers is small, and the seriousness of those risks in minimal. The exertion levels are the same as for those associated with routine clinician visit screenings.

Alternative Treatments and Procedures:You can obtain guidance from your primary care provider or follow self-directed programs of behavior change. The assessments provided might be available from health clubs or other facilities, but there would be a cost associated.

Use of smart phone to track physical activity:The risks associated with wearing your smart phone for tracking physical activity are minor discomfort and nuisance from wearing the device on the hip or pocket during waking hours.

Loss of confidentiality is a risk to participating in the study. You may find completing the written surveys and health assessments inconvenient or tiring. The research nurse will schedule all assessment sessions at times convenient for you, and you may call him/her at the number listed at the end of this form to reschedule if necessary. If you become tired before completing the surveys or health assessments, you may take a break. Lose-It Corporation, the owner of the Lose-It app, will not have access to any personal identifiable information about you or any other subjects in the study.

You may experience the following risks and discomforts as a result of each part of the physical assessment:

Resting Blood Pressure: arm discomfort during the procedure related to compression by the blood pressure cuff.

All of the tests will be administered by an experienced licensed or certified healthcare professional who will provide you with instruction and support during testing.

It is possible that other rare side effects could occur that are not described in this consent form. It is also possible that you could have a side effect that has not occurred before.

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What are the possible benefits to you?
You may learn about weight loss through self-monitoring of healthy eating and physical activity. If you adopt healthier eating and physical activity lifestyle behaviors, you may experience weight loss as well as promote health, prevent disability and/or premature death, and enhance quality of life as you age. You also may benefit from an improvement in cardiorespiratory (heart) fitness, increases in muscular strength, and percent body fat. You may not get any benefit from being in this research study.

What are the possible benefits to other people?
Cost-effective interventions that are acceptable to rural men and effective in achieving preventive health behavior change have the potential for decreasing health care costs by preventing chronic diseases and maintaining functional ability. This research protocol may provide a care delivery model that can be used by other providers of primary preventive services to rural clients. There may not be benefits to other people.

What are the alternatives to being in this research study?
You might obtain guidance from your primary health care provider about healthy eating and physical activity or follow a self-directed program of lifestyle behavior change for weight loss. The assessments provided might be available to you at health clubs or other facilities, but there would be a cost involved.

What will being in this research study cost you?
There is no cost to you to be in this research study. You will not be paid or reimbursed for transportation cost to and from the study site.

Will you be paid for being in this research study?
You will not be paid for transportation costs to and from the study site. Your compensation will be determined by the intervention arm to which you are randomly selected. Men in the MT+ intervention arm will receive the Lose-It Premium app (40.00) and a Nokia Body+ Wi-Fi scale (100.00), which they will be able to keep at the end of the study. Men randomized to the MT intervention arm will receive a stipend of $25 for each of the 3 assessment sessions. To receive payment you must provide your social security number, name, and address in order to comply with Internal Revenue service (IRS) reporting requirements. When payment is reported to the IRS, we will not say what the payment is for, only that you have been paid. If you do not wish to provide this information, you can still participate in the study; however, you will not be paid. Checks will be mailed at the end of 6 months of your participation after your final study visit.

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Who is paying for this research?
This research is being paid for by grant funds from the National Institute for Nursing Research. The University of Nebraska Medical Center College of Nursing receives money from the National Institute for Nursing Research to conduct this study.

What should you do if you are injured or have a medical problem during this research study?
If you are injured or have a medical problem as a result of being in this study, you should immediately contact one of the people listed at the end of this consent form.

How will information about you be protected?
You have rights regarding the privacy of your medical information collected before and during this research. This medical information, called "protected health information" (PHI), typically may include, depending upon the nature of this research, demographic information (like your address and birth date), the results of physical exams, as well as your medical history.

By signing this consent form, you are allowing the research team to have access to your PHI. The research team includes the investigators listed on this consent form and other personnel involved in this specific study at UNMC. Your PHI will be used only for the purpose(s) described in the section "What is the reason for doing this research study?"

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

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 of 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 information, then the researchers may not use the Certificate to withhold that information.

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The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or harm to self or others.

Who will have access to information about you?
Your PHI will be shared, as necessary, with the Institutional Review Board (IRB) and with any person or agency required by law. You are also allowing the research team to share your PHI with other people or groups listed below. All of these persons or groups listed below are obligated to protect your PHI.

By signing this consent form, you are allowing the research team to have access to your PHI. The research team includes the investigators listed on this consent form and other personnel involved in this specific study at the Institution.

Your PHI will be used only for the purpose(s) described in the section What is the reason for doing this research study?

You are also allowing the research team to share your PHI, as necessary, with other people or groups listed below:

- The UNMC Institutional Review Board (IRB)
- Institutional officials designated by the UNMC IRB
- Federal law requires that your information may be shared with these groups:
    - The HHS Office of Human Research Protections (OHRP)
    - National Institutes of Health (NIH)

You are authorizing us to use and disclose your PHI for as long as the research study is being conducted. You may cancel your authorization for further collection of PHI for use in this research at any time by contacting the principal investigator in writing. However, the PHI which is included in the research data obtained to date may still be used. If you cancel this authorization, you will no longer be able to participate in this research.

How will results of the research be made available to you during and after the study is finished?
The information from this study may be published in scientific journals or presented at scientific meetings but your identity will be kept strictly confidential.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website

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at any time.

What will happen if you decide not to be in this research study?
You can decide not to be in this research study. Deciding not to be in this research study will not affect your medical care or your relationship with the investigator, the University of Nebraska Medical Center or the Nebraska Medical Center. Your doctor will still take care of you and you will not lose any benefits to which you are entitled.

What will happen if you decide to stop participating once you start?
You can stop being in this research study (withdraw) at any time before, during, or after the treatment begins. Your doctor will still take care of you though you may not be able to get the research treatment. Deciding to withdraw will otherwise not affect your care or your relationship with the investigator, the University of Nebraska Medical Center, or the Nebraska Medical Center. You will not lose any benefits to which you are entitled.

Will you be given any important information during the study?
You will be informed promptly if the research team gets any new information during this research study that may affect whether you want to continue being in the study.

What should you do if you have any questions about the study?
You have been given a copy of "What do I need to know before being in a research study?" If you have any questions at any time about this study, you should contact the Principal Investigator or any of the study personnel listed on this consent form or any other documents that you have been given.

What are your rights as a research participant?
You have rights as a research subject. These rights have been explained in this consent form and in *The Rights of Research Subjects* that you have been given. If you have any questions concerning your rights or want to discuss problems, concerns, obtain information or offer input, or make a complaint about the research, you can contact any of the following:

- The investigator or other study personnel
- Institutional Review Board (IRB) by
- Telephone: (402) 559-6463
- Email: IRBORA@unmc.edu
- Mail: UNMC Institutional Review Board, 987830 Nebraska Medical Center, Omaha, NE 68198-7830.
- Research subject advocate
- Telephone 402-559-6941

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IRB PROTOCOL # 594-17-EP **Page 8 of 9**

- Email: unmcrsa@unmc.edu

Documentation of informed consent

You are freely making a decision whether to be in this research study. Signing this form means that:

- You have read and understood this consent form.
- You have had the consent form explained to you.
- You have been given a copy of The Rights of Research Subjects
- You have had your questions answered.
- You have decided to be in the research study.
- If you have any questions during the study, you have been directed to talk to one of the investigators listed below on this consent form.
- You will be given a signed and dated copy of this consent form to keep.

Signature of Subject _____

Date _____

My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the subject. In my judgment, the subject possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate.

Signature of Person obtaining consent _____

Date _____

Authorized Study Personnel

Principal

* Eisenhauer, Christine
phone: 402-844-7897
alt #: 402-844-7897
degree: PhD, APRN-CNS

Secondary

* Hageman, Patricia
phone: 402-559-1967
alt #: 402-559-1967
degree: PhD, PT

* Silva, Fabiana

* Pullen, Carol
phone: 402-559-6548
alt #: 402-559-6548
degree: Ed.D., RN

* Yoder, Aaron

IRBVersion 7

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Approved 08/21/2019
Valid until 08/21/2020

University of Nebraska Medical Center

- Email: unmcrsa@unmc.edu

Documentation of informed consent

You are freely making a decision whether to be in this research study. Signing this form means that:

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- You have had the consent form explained to you.
- You have been given a copy of The Rights of Research Subjects
- You have had your questions answered.
- You have decided to be in the research study.
- If you have any questions during the study, you have been directed to talk to one of the investigators listed below on this consent form.
- You will be given a signed and dated copy of this consent form to keep.

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phone: 402-559-6548
alt #: 402-559-6548
degree: Ed.D., RN

* Yoder, Aaron

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Approved 08/21/2019
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phone: 402-559-6627
alt #: 402-559-6627
degree: PhD

Participating Personnel

* Castaneda, Georgina
alt #: 402-375-2200
degree: CHW

* Salinas, Katherine (Katie)
phone: 402-559-6025
alt #: 402-255-0504
degree: RN, BSN

phone: 402-552-7240
alt #: 814-577-9127
degree: PhD

* Miller, Jessica
phone: 402-844-7923
alt #: 402-340-4699
degree: RN, BSN

* Zarate, Victor
alt #: 402-375-2200
degree: CHW

Institutional Review Board (IRB)

What Do I Need To Know Before Being In A Research Study?

You have been invited to be in a **research study**. Research studies are also called "clinical trials" or "protocols." **Research** is an organized plan designed to get new knowledge about a disease or the normal function of the body. The people who are in the research are called **research subjects**. The **investigator** is the person who is running the research study. You will get information from the investigator and the research team, and then you will be asked to give your **consent** to be in the research.

This sheet will help you think of questions to ask the investigator or his/her staff. You should know all these answers before you decide about being in the research.

What is the **purpose** of the research? Why is the investigator doing the research?

What are the **risks** of the research? What bad things could happen?

What are the possible **benefits** of the research? How might this help me?

How is this research different than the care or treatment I would get if I wasn t in the research? Are there other treatments I could get?

Does **everyone** in this research study get the same treatment?

Will being in the research **cost** me anything extra?

Do I have to be in this research study? Will the doctors still take care of me if I say **no**?

Can I **stop** being in the research once I ve started? How?

Who will look at my **records**?

How do I reach the investigator if I have more **questions**?

Who do I call if I have questions about being a **research subject**?

Make sure all your questions are answered before you decide whether or not to be in this research.

Academic Research & Services Building 3000 / 987830 Nebraska Medical Center / Omaha NE 68198-7830
402-559-6463 / FAX 402-559-3300 / Email: irbora@unmc.edu / http://www.unmc.edu/irb

Institutional Review Board (IRB)

THE RIGHTS OF RESEARCH SUBJECTS
AS A RESEARCH SUBJECT YOU HAVE THE RIGHT

to be told everything you need to know about the research before you are asked to decide whether or not to take part in the research study. The research will be explained to you in a way that assures you understand enough to decide whether or not to take part.

to freely decide whether or not to take part in the research.

to decide not to be in the research, or to stop participating in the research at any time. This will not affect your medical care or your relationship with the investigator or the Nebraska Medical Center. Your doctor will still take care of you.

to ask questions about the research at any time. The investigator will answer your questions honestly and completely.

to know that your safety and welfare will always come first. The investigator will display the highest possible degree of skill and care throughout this research. Any risks or discomforts will be minimized as much as possible.

to privacy and confidentiality. The investigator will treat information about you carefully, and will respect your privacy.

... to keep all the legal rights you have now. You are not giving up any of your legal rights by taking part in this research study.

to be treated with dignity and respect at all times.

The Institutional Review Board is responsible for assuring that your rights and welfare are protected. If you have any questions about your rights, contact the Institutional Review Board at (402) 559-6463.

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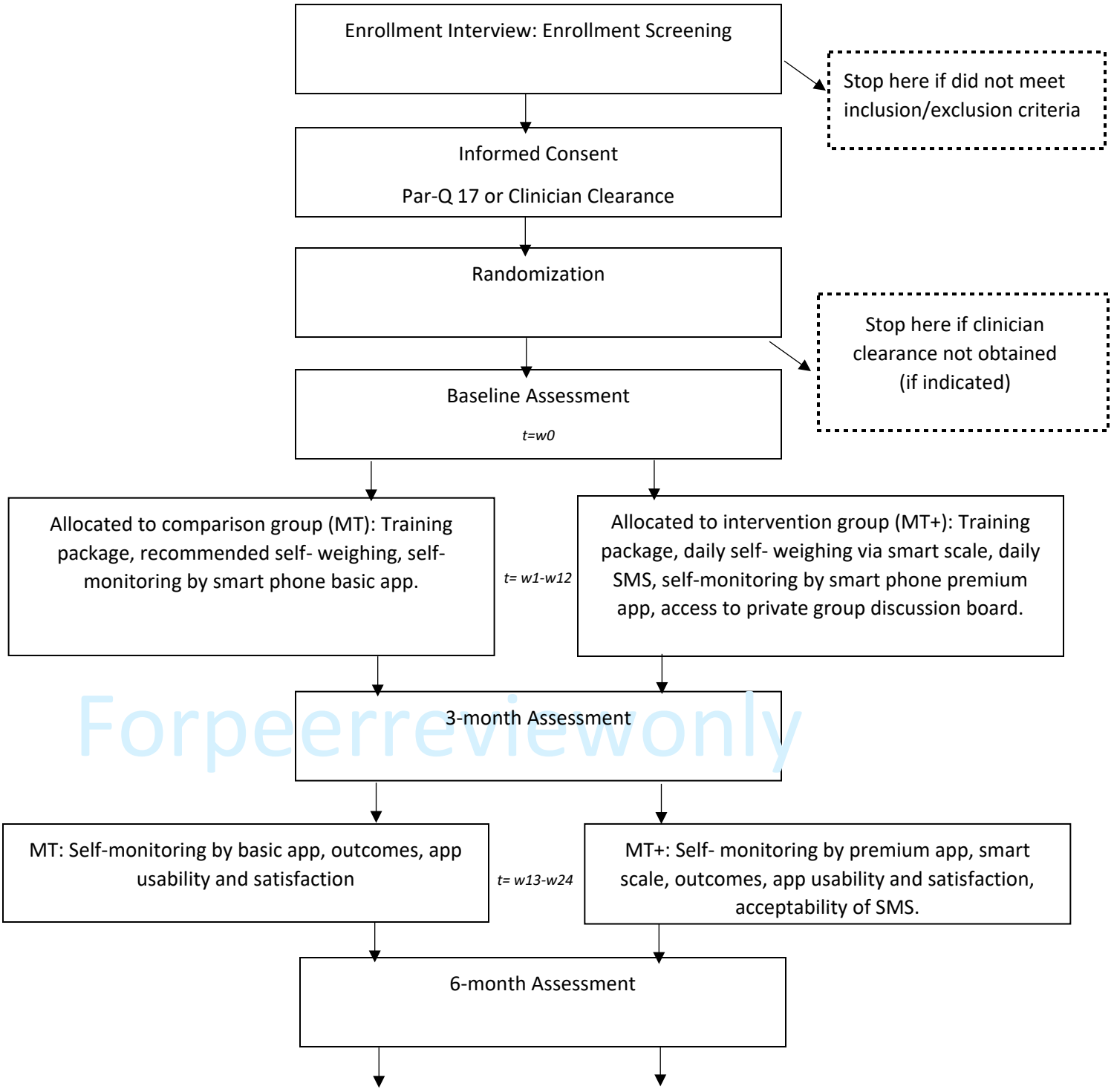
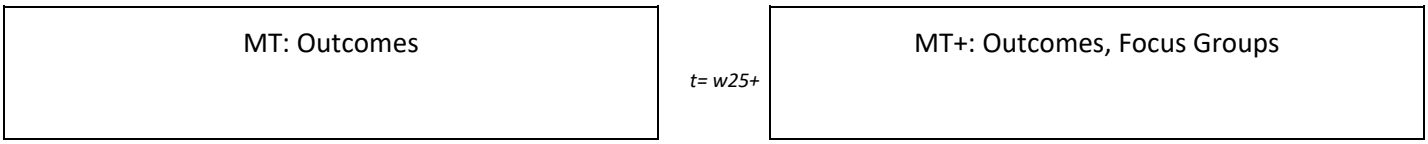
402-559-6463 / FAX 402-559-3300 / Email: irbora@unmc.edu / http://www.unmc.edu/irb

Figure 1: Participant Timeline




MT: Outcomes
t= w25+
MT+: Outcomes, Focus Groups

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials.

each of the items listed below.

provide a short explanation.

Ann Intern Med. 2013;158(3):200-207

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data	#2b	All items from the World Health Organization Trial	2

set		Registration Data Set	
Protocol version	#3	Date and version identifier	2
Funding2	#4	Sources and types of financial, material, and other support	
Roles and 2 responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	
Roles and 2 responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	
Roles and 11 responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have	

		ultimate authority over any of these activities	
Roles and responsibilities:	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committees committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	11

Introduction

Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	3
Objectives	#7	Specific objectives or hypotheses	3-4
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	4

Methods:

Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	4
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	4
Interventions:	#11a	Interventions for each group with sufficient detail to allow	5

description		replication, including how and when they will be administered	
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	5
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	5,6
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	5
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final	6

		value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	7
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	3-4

			14
#15	Strategies adequate participant	reach target sample size	Recruitment for achieving enrolment to
	4,7		
Methods: Assignment of interventions (for controlled trials)	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	
Allocation: sequence generation			3,7
	#16b	Mechanism of implementing the allocation sequence (eg,	
		Allocation 7	
concealment		central telephone; sequentially numbered, opaque, sealed	

mechanism		envelopes), describing any steps to conceal the sequence until interventions are assigned	
Allocation:	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	6-7 implementation

Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	7
Blinding (masking): emergency	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's	7

	unblinding	allocated	intervention during the trial
	Methods: Data collection, management, and analysis		
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Data collection plan: 9-10
retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention	

		protocols	
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values).	10-11
		Reference to where details of data management procedures can be found, if not in the protocol	
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the	10
		statistical analysis plan can be found, if not in the protocol	

Statistics: additional analyses	#20b	Methods for any additional adjusted analyses)	10
	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	
Statistics: analysis population and missing data			
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim	11

		results and make the final decision to terminate the trial	
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	11
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	11
Ethics and			

dissemination				
Research ethics approval	11	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	
Protocol amendments	11	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	
Consent or assent	7	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	
		#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	Consent or assent: n/a
Confidentiality		#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the	11

		trial	
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	12
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	11
Ancillary and post	#30	Provisions, if any, for ancillary and post-trial care, and for	11

	trial compensation to those harm from trial	participation	care who suffer
		#31a Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	
Dissemination policy: 11	trial results		
		#31b Authorship eligibility guidelines and any intended use of professional writers	
		#31c Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	
Dissemination policy: 11	authorship		
	reproducible research	Dissemination policy: 11	
	Appendices		
	Informed consent	#32 Model consent form and other related documentation given	22-28

	materials		to participants and authorised surrogates	
	Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

BMJ Open

MOBILE TECHNOLOGY INTERVENTION FOR WEIGHT LOSS IN RURAL MEN: PROTOCOL FOR A PILOT PRAGMATIC RANDOMIZED CONTROLLED TRIAL

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-035089.R1
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Date Submitted by the Author:	02-Jan-2020

Complete List of Authors:	Eisenhauer, Christine; University of Nebraska Medical Center College of Nursing, Northern Division Brito, Fabiana; University of Nebraska Medical Center, College of Public Health Yoder, Aaron; University of Nebraska Medical Center, College of Public Health Kupzyk, Kevin; University of Nebraska Medical Center College of Nursing Pullen, Carol; University of Nebraska Medical Center College of Nursing Salinas, Katherine; University of Nebraska Medical Center College of Nursing Miller, Jessica; University of Nebraska Medical Center College of Nursing, Northern division Hageman, Patricia; University of Nebraska Medical Center, Physical Therapy Education

Primary Subject Heading:	Nursing
Secondary Subject Heading:	Public health

Keywords:	PUBLIC HEALTH, PRIMARY CARE, PREVENTIVE MEDICINE

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MOBILE TECHNOLOGY INTERVENTION FOR WEIGHT LOSS IN RURAL MEN: PROTOCOL FOR A PILOT PRAGMATIC RANDOMIZED CONTROLLED TRIAL

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Word Count: 4342

ABSTRACT

Introduction: Overweight-obese men in the rural Midwestern United States are an unrepresented, at-risk group exhibiting rising rates of cardiovascular disease, poor access to preventive care, and poor lifestyle behaviors that contribute to sedentary lifestyle and unhealthy diet. Self-monitoring of eating and activity has demonstrated efficacy for weight loss. Use of mobile technologies for self-monitoring eating and activity may address rural men's access disparities to preventive health resources and support weight loss. Our pilot trial will assess the feasibility and acceptability of two mobile applications for weight loss in rural men to inform a future, full-scale trial.

Methods and analysis: A six-month randomized controlled trial with contextual evaluation will randomize 80 men using a 1:1 ratio to either a Mobile Technology Plus (MT+) intervention or a basic Mobile Technology (MT) intervention in rural, midlife men (ages 40-69 years). The MT+ intervention consists of a smart phone self-monitoring application enhanced with discussion group (Lose-It premium), short message service (SMS) text-based support, and Wi-Fi scale. The MT group will receive only a self-monitoring application (Lose-It basic). Feasibility and acceptability will be evaluated using number of men recruited and retained, and evaluative focus group feedback. We seek to determine point estimates and variability of outcome measures of weight loss (kg and % body weight) and improved dietary and physical activity behaviors (BRFSS physical activity and fruit and vegetable consumption surveys, data from Lose-It! application [kcal/day, steps/day]). Community capacity will be assessed using standard best

practice methods. Descriptive content analysis will evaluate intervention acceptability and contextual sensitivity.

Ethics and dissemination: This protocol was approved by the University of Nebraska Medical Center Institutional Review Board (IRB# 594-17-EP). Dissemination of findings will occur through ClinicalTrials.gov and publish pilot data to inform the design of a larger clinical trial.

Registration details:

ClinicalTrials.gov ID: NCT03329079; Pre-results

Protocol version 10, study completion date 8-31-2020

Roles and Responsibilities Funder: NIH/NINR Health Disparities Section 1R15NR017522-01

KEYWORDS rural population, mobile health technologies, men, weight loss, health disparities, self-monitoring, eating, activity

STRENGTHS AND LIMITATIONS

- The combination of community-engaged approaches with a pragmatic RCT design delivers a weight loss intervention that facilitates local buy-in and is sensitive to context.
- Components of the real-world comparator are included in the expanded, more comprehensive intervention.
- Trial available only to men with means and proficiency to own and operate a smartphone.
- This study expands previous research using mobile applications to include community tailoring of the recruitment and intervention approach specific for rural men to inform a large definitive trial.

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INTRODUCTION

Background and rationale

Over 55 million American men are overweight or obese.[1] Rates among midlife and older men residing in the midwestern United States (U.S.) have tripled in the past 20 years, with 75.3% [2] Rural men report of all adults in the United States age 40-59 years are overweight or obese. overall poorer health than urban men.[3] Their obesity status predisposes high risk for metabolic syndrome and cardiovascular disease.[4-5 3] Historically, rural men were less likely to be overweight and obese due to the high levels of physical activity involved in agricultural occupations.[6] However, the mechanization of agriculture has shifted men's work roles to more sedentary, technology-driven lifestyles, increasing the likelihood of developing [7 8]

overweight/obesity. Mobile health applications such as messaging and other interfaces available via mobile phone have demonstrated improvement in health behavior change for weight loss among adults[9-11], and in some hard-to-reach minority populations.[12] The benefit that mobile technologies may hold for engaging hard-to-reach rural men for weight loss is unknown. In addition, there has been limited study of men's health promotion through weight loss[13], particularly rural men.

Men, when compared to women, are less likely to use weight control practices[14], attempt weight loss, or participate in weight loss programs[15-17]. Poor access to weight loss resources is one reason. Rural men also tend to exhibit dominant masculine norms[18], which view help-seeking behaviors and health promotion strategies as feminine and weak.[5, 19] Health promotion activities oriented to rural men's work roles are preferred.[20] 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. The Rural Men's Health Study plans to address the current gaps in knowledge by delivering a contextually sensitive weight loss intervention that is feasible to the rural environment and acceptable to participants.

Aims

We aim to 1) determine the feasibility and acceptability of a mobile technology enhanced self-monitoring intervention (MT+) for achieving weight loss in routine care of overweight and obese men in rural communities, 2) determine the point estimates and variability of outcome measures at 3 and 6 months following MT+ and MT interventions for achieving weight loss and improved dietary and physical activity behaviors for sample size estimation for a larger trial, and 3) determine quantitative and qualitative indicators of community capacity (resource mobilization, partnership linkages) to support a relevant weight loss intervention for rural men.

METHODS AND ANALYSIS

Design overview

We propose a pilot, feasibility [21], pragmatic randomized controlled trial (pRCT) with an allocation ratio of 1:1. We will randomize 80 men into two groups: intervention and comparison. This pRCT will observe men in real-life rural conditions using varied versions of a mobile phone-based self-monitoring application: one that is free and available in the community setting [22] Recommendations of good practice for design and analysis and an enhanced, premium version.

of a pilot study note that 30 participants per group is a sufficient to estimate values for future trials sample size calculations. [23] [24] As weight loss studies in rural men are a gap in the current literature, it is important that we obtain reliable estimates of effect size with which to perform a power analysis for subsequent research. So 30 participants per group will be needed, for a total of 60. Some participants will likely not complete the study, so we will enroll 80 men to allow for

up to a 25% attrition rate. Participants will complete assessments at baseline, 3 and 6-months post-baseline.

Public and patient involvement

Community engagement was used to inform the development of this protocol involving health professions students from the disciplines of nursing, physical therapy, and public health. A community advisory board (CAB) was also developed. The CAB members represent the rural sampling region (i.e. farmers, insurance and machinery dealers, extension staff, and community health workers) and meet quarterly to inform the study approach, material content and imaging, targeted venues for social marketing, dissemination of recruitment materials, and the direct referral of eligible participants. The funding source for this pilot study requires student involvement in study activities. One goal of the supporting grant mechanism was to expose under-represented rural students to research. Therefore, we involved graduate and undergraduate student nurses from the study sampling region.[25] We are involving undergraduate level student nurses in planning, implementation, and evaluation of community outreach and recruitment strategies. Two graduate (Master's and PhD) level student nurses, who are part of the investigative team, will also be used to assist with implementation and evaluation of the intervention, as described below.

Participants and interventions

Participant eligibility

Inclusion criteria: 1) man age 40-69 years, 2) reside (majority of the time) in Northeast Nebraska, United States (RUCA code 4-10), 3) BMI of 28 (kg/m^2) or higher and weight not greater than 396 pounds (a man with a BMI of 50 or higher will require clinician clearance), 4) smartphone owner with enabled messaging, 5) email account, 6) answer "no" to all questions on the PAR-Q17 health history assessment or are willing to get physician evaluation prior to enrolling, and 7) willing to share Lose-It! self-monitoring logs with the investigative team, and

attend three assessment visits at the health department. An upper weight limit of 396 pounds reflects the upper measurement capacity for the Withings© Body+ Composition smart scale. Per the university Institutional Review Board (IRB) policy, a man with a BMI of 50 or higher will be required to have clinician clearance. We prioritized midlife men in our age selection (over younger men) based upon current national overweight/obesity trends and the breadth of current evidence supporting decreasing midlife risk factors (weight loss, physical activity) and increased healthy survival.[26 27 28] Exclusion criteria: 1) recently lost 5% or more body weight, 2) currently taking medications that cause or are influenced by weight loss, 3) used weight loss application in the past to lose weight, 4) person from same household is enrolled in study, and 5) Type I diabetes or Type II diabetes with insulin dependence.

Intervention group

Self-Monitoring

Lose-It! is a self-monitoring application designed for the general public and includes both a basic (free) and premium ($39.99/annually) version. MT+ will receive the Lose-It! premium application, Withings© Body+ Composition smart scale, daily SMS messages, technology support, and a private group discussion board within the application. In addition to the self-monitoring, the premium version permits enhanced customization of goal setting, application-automated self-monitoring reminders, and customized email reports of self-monitoring trends important in supporting motivation and confidence during periods of behavioral inaction. The smart scale will provide automated recording of weight synchronized to the application, permitting immediate feedback, virtual rewards (i.e. badges for achievements) and visual maps of weight trends. The participant will be instructed in how to synchronize the scale with their smartphone at baseline. They will be instructed to weigh themselves daily at home on this scale which will automatically update to their application after each weighing.

Social Support

MT+ participants will be enrolled in a private, closed-group discussion board created

and moderated by the research team. The discussion board will provide social support to MT+ participants while completing the trial to promote long-term success.[14, 15] The discussion board will also provide opportunity for participants to share their self-monitoring experiences, thus providing a mechanism to influence their peer participants to be aware about the value of their own self-monitoring. The groups will be incentivized by a male moderator who will administer peer challenges weekly (see Appendix I) and will also respond to questions. Participants will also be encouraged to post weekly about their own successful strategies and progress reports related to their self-monitoring for weight loss.

We tested discussion board topics with the CAB comprised of men and women from the region. In addition to this, acceptability feedback about discussion board topics was gathered from rural, male subjects in our preliminary study.[5] It is noted that the men desired both a combination of both gender-tailored and standardized private discussion board topics.

Text messaging

A message library (see Appendix II) will be developed by the team based upon messaging content that has demonstrated usefulness for behavior change[29-32] and preferred by men.[5, 31, 33, 34]

Message content will include a variety of topics including reminders, eating and physical activity behaviors to be enacted and avoided, self-monitoring portion control, strategies for overcoming weight loss barriers, and healthy living challenges. Content will be adapted from healthy eating and physical activity promoting resources that include USDA Choose My Plate and Centers for Disease Control: Physical Activity.[35, 36] Physical activity includes targeted aerobic physical activity, monitoring of body weight, behaviors needed to sustain weight loss, promoting success and rewarding oneself, preventing failure, and avoiding temptations.[16] CAB members will inform and review the content of the messages for local relevance prior to dissemination to the participants.

An online automatic service (Remind.com©) will be used to send the free messages to participants twice per day on Monday, Wednesday, and Friday at 8am and 11am, and once per day on Tuesday, Thursday, Saturday, and Sunday at 8am. The delivery time, frequency, and number of text messages was based on feedback from midlife, rural male participants in the

preliminary study.[5]

Troubleshooting support and re-engagement prompt

MT+ participants will have access to a 24-hour technology troubleshooting support from the investigative team via phone or text. The participant's food, activity, and weight log will be accessed once weekly by the investigative team to monitor frequency of logging. If dietary intake, physical activity, or weight are not logged for greater than five days, the participant will receive a reminder text and phone call from the assigned graduate level student nurse on the investigative team.

Comparison group

The MT group of men will receive the Lose-It! basic application. The basic application permits real-time self-monitoring of eating, physical activity, and weight – same as the premium version. The basic version is available for free and is widely accessible by any smartphone user.[22] MT participants will be asked at baseline to self-monitor their eating, physical activity, and weight daily. They will be instructed to weigh daily and log the result into the application.

They will not receive message prompts for self-monitoring, no self-monitoring trend reports, and no peer interaction via application-based customized social group. The MT participants will only receive reminders for their assessment visit appointment times.

Technology orientation

During the baseline visit, the community health worker will train men in both groups to use an assigned application username and password. Hands-on orientation training will be provided about how to use various features of the Lose-It! application (eg. log food intake, measure basic step count, etc). Both groups will receive a paper printed version of an Application User Manual designed and adapted for the study.

Focus Groups

Two focus groups will be held with participants comprising the MT+ group at 6 months

post-baseline. A purposive sample of MT+ completers stratified according to their weight loss experience (successful or unsuccessful in achieving the 5% baseline body weight loss goal) will be sought to solicit their perceptions on the MT+ intervention acceptability and feasibility.[37 38, 39] A semi-structured interview guide will be used during facilitation of a 90-minute discussion led by two co-moderators. Moderator-debriefing and reflexive memos will also be summarized after each interview and audio files will be transcribed verbatim. Collectively, these items will create a decision trail which will serve as an audit demonstrating accountability.[40] For a detailed participant timeline, see Figure 1.

Recruitment and consent

Participant recruitment will occur through CAB and student outreach, Facebook advertising, ClinicalTrials.gov, university webpage, press releases, business bulletin board postings in businesses, community fairs, clinician office outreach, and direct referral.

Recruitment of minority men, primarily with men who identify as non-white-Hispanic, will be sought through Spanish speaking community health workers who already have established local trust. The recruitment period will last for 18 months from June 2018-November 2019 for trial participants.

Enrollment screening calls will be conducted by a trained graduate student nurse. The physical activity readiness questionnaire (PAR-Q 17) will be used to determine if clinician clearance is required prior to the baseline visit. Thus, informed consent (see Appendix III) will be obtained prior to its completion during the screening call. Research electronic data capture (REDCap) will permit real-time participant consenting. Study data will be collected and managed using REDCap electronic data capture tools hosted at the university. REDCap is a secure, web-based application designed to support data capture for research studies. When determined eligible, the participant will be invited to participate in the process of informed consent via a REDCap weblink to the secure consenting page sent via text message or email.

After live verification of their reading of the consent and answering relevant questions, the participant will provide a wet-signature, immediately verifiable online by the graduate student nurse. The wet signature is a feature in REDCap which allows participants to sign consent forms online in real time, by signing their name with their finger or computer mouse on a document as if the participant is using a pen and paper.[41] This process does not require an additional confirmation procedure[42] and is customary in REDCap consenting and data collection.[41] The informed consent document specifies the posting of clinical trial information at

ClinicalTrials.gov. A printed copy of the signed consent will be mailed to each participant immediately following conclusion of the enrollment interview.

Randomization

Random allocation of group assignment will occur using an allocation schedule created by the project statistician using a random number generator and "turn randomization" to ensure equal sample sizes. The outcome assessor will receive a REDCap code and designated application username and password, along with the participant's group assignment so to assist participants with successful download and orientation to the application version.

Outcomes, measurements, data management, and analysis

Outcomes

Feasibility and acceptability

Feasibility and acceptability will be evaluated using number of men recruited and retained, CAB member feedback, application use, and evaluative focus group feedback from intervention participants.

Clinical outcomes

Preliminary efficacy of 3- and 6-month weight loss (kg and % body weight using a standard clinic scale) and improved dietary and physical activity behaviors (survey and data from

Lose-It! Application (kcal/day, steps/day) will be examined. The Tanita Scale (TBF-215) will be used to measure height, weight, and BMI[43] at the baseline, 3, and 6 month assessment visits.

Weekly, the graduate student nurse will also log into each participant's Lose-It! account and export participant-logged weights. Fruit and vegetable consumption will be measured using the Behavioral Risk Factor Surveillance System (BRFSS) Fruit and Vegetable Dietary Intake Module (6 items).[44] The BRFSS Physical Activity Questionnaire will also be used to measure self-reported physical activity of the participants.[44] To measure the sugar sweetened beverage intake, the Brief Questionnaire to Assess Beverage Intake (BEVQ-15)[45] will be used.

Participant's "weekly summaries" will also be exported from the app which includes daily food log, physical activity, weights, and total daily step count.

Community capacity

Community capacity will be assessed using a community capacity evaluation survey that [46] has been tested and applied with other rural U.S. communities for obesity prevention.

Descriptive content analysis will evaluate intervention acceptability and contextual sensitivity.

Measures

Figure 2 outlines the outcome measures. Measures at 3 month and 6 months will be compared to

baseline. Additionally, health history, demographics, blood pressure, pulse rate, Comfort with Technology survey, and health information technology usability evaluation scale (health ITUES) will be collected for further analysis of participants profile and outcomes (Figure 2).

Height, weight, and BMI

The Tanita TBF-215 Body Composition Analyzer will be used to measure the participant's height, weight, and BMI following their manual guidelines.[43] The participant will be asked to remove shoes, socks, belt, and empty pockets. The participant will be asked to stand up straight so height can be accurately measured. After height is measured, the participant will be asked to step off the scale, the scale will be zeroed, and the participant will step back on the scale to measure weight. Once the height and weight is confirmed, a paper copy of the participants values will print out with the calculated BMI.

Food and beverage intake

To establish a baseline of food and beverage intake, the Behavioral Risk Factor Surviellance Survey (BRFSS) Fruit and Dietary Intake Survey and the BEVQ-15 will be administered to participants at timepoints in Figure 2.[36, 45] The consumption of these are indicators of a healthy overall diet[6 36], and given the resource-constrained nature of feasibility studies we wanted to reduce participant's burden for data collection. Fruit and vegetable intake is an indicator used nationally to monitor and establish benchmarks of a healthy overall diet.[36] The Behavioral Risk Factor Surveillance System (BRFSS), in most states, the only source of uniform nutritional data for adults.[36] Sugar-sweetened beverage consumption are a major source of calories has received increasing attention in recent years as playing a role in the obesity epidemic.[45 47 48] Additionally, a lack of fruit and vegetable intake and is more common among men[49] and rural residents[50] which relates to our study population.

Additional information regarding fruits and vegetable and sugar- sweetened beverage intake will be exported from the application logs and analyzed. Each week, the graduate student nurse will log into the participants web version of the application to retrieve the "weekly summary" of meals/day logged and average calories/day/week and export the data to participants ID labeled file.

Physical activity

The BRFSS physical activity questionnaire will be used to gather participants self-report of physical activity.[44] Additionally, like the food intake, each week the graduate student nurse will retrieve from the application the "weekly summary" of physical activity and total daily step count.

Blood pressure and pulse rate

The ADC e-sphyg™ 2 9002 Automatic Sphygmomanometer will be used to measure blood pressure of the participants. This model was selected due to specifications +/- 3mmHg accuracy of cuff pressure consistent with acceptable standards, current acceptability of an oscillometric blood pressure unit in field and clinical areas [51], and prior successful prior use in a large clinical trial.[52] In addition, we did a test-retest before using this unit and the determined the auto feature was appropriate for field trials such as ours. Routine checks will be conducted for calibration will be conducted every 6 months as recommended by the manufacturer.

The participant will be asked to wear loose clothing or a short sleeve shirt, to avoid caffeine, intensive exercise and smoking for at least 30 minutes before measurement.[52] The participant will be instructed to not talk during the rest period or during measurement. The man's arm will be placed on a desk or table so that the middle of the arm is at the level of the heart. The outcome assessor will line up the cuff mark "artery" over the individual's brachial artery. For 5 minutes, the participant will quietly sit in a chair (feet on floor, back supported) and rest without talking. After obtaining a blood pressure, the participant will be asked to raise his arm for 10 seconds and wait another 30 seconds. Then the blood pressure procedure will be repeated with measurements spaced about one minute apart. The procedure will be repeated until two readings are within 5mmHg and average the two values together. Two resting pulse rates will also be obtained using the blood pressure cuff and these values will be averaged together and recorded.[53]

Health history and demographics

A brief health history survey will be administered at baseline. A generic demographics form was also administered to participants at baseline.

Technology experience

Technology experience will be evaluated with the Comfort with Technology Survey[54] (baseline), and the Technology Feasibility and Acceptability survey which was adapted from the health-ITUES[55](3 and 6 months). The comfort with technology survey asks questions related to [54] The modified health-ITUES evaluates comfort, frequency, and purpose of technology use. technology usefulness.[55]

Data management

The outcome assessor will receive a participant specific REDCap code to enter assessment information. To encourage participant retention, the graduate student nurse will contact MT+ group participants if they fail to log their eating, activity, or weight in the Lose-It! application for greater than five days. If the participant states he cannot log daily the graduate student nurse will document reasons and encourage participant to post as often as he can.

Analysis

Aim 1- MT+ intervention feasibility and acceptability

Aim 1 will be evaluated through: 1) participation rates including number of men recruited and randomized over a 6-month period; 2) participant retention rates; 3) feasibility, usability, satisfaction ratings; 4) application logs of MT+; and 5) evaluative focus group feedback.

Descriptive statistics will be calculated on all variables, including frequencies and percentages for recruitment/retention, demographic, and categorical variables. To determine feasibility of recruitment, a rate will be measured in the time it takes to enroll 80 participants. To determine feasibility of retention, we used a threshold retention of 70% which is similar to studies of weight loss in men.[56] Feasibility, usability, and satisfaction ratings will be measured from modified health-iTUES, which was originally validated by authors to measure technology usability, but has further been validated to be used as a customizable technology survey.[57] 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 recruitment methods were the most effective.

Qualitative content analysis[40] will guide interpretation of the focus group findings. The interview transcript and reflective memos taken during each focus group will comprise one unit of analysis for within/across case comparison. The topics outlined by the interview guide will be extracted and organized and transcripts read 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.[58] 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 and examined to determine their fit with the purpose.

[59] A data matrix will be used to display the coded data to search for patterns across coding categories. The principal investigator and graduate student nurse 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 study's data set. Meaning, the findings are integrated to provide new understanding or explanation to the interpretation of the intervention outcome data.[59] Peer debriefing and audit checking will occur weekly across the analysis to assure accuracy of the findings.

Aim 2- Variability of outcome measures and sample size estimation

Descriptive statistics of participant profiles for outcomes by time point and stratified by intervention group will be reported. The proportion of participants meeting the clinically meaningful threshold of 5% weight loss over the course of the study will also be reported. A maximum likelihood estimation method (i.e. mixed models) will be used in order to utilize all available data. Outcome variables that are not normally distributed will either be transformed or assessed with non-parametric methods. An independent group t-test will be used to assess overall weight loss at follow-up soley to estimate an effect size (Cohen's d for weight loss between groups) for sample size estimation for a future large trial.

Aim 3- Indicators of community capacity

Multiple indicators of community capacity will be used to evaluate support for the weight loss intervention applying best practice recommendations: 1) CAB- assessed community capacity change via survey report[46], participation level of CAB members (i.e. number of attended meetings, activities, resources allocated, partnership linkages), member attrition with reasons, perceived benefits/skills gained, barriers and facilitators of retention, proposed strategies to increase retention, 2) student support in the outreach and recruitment will be tracked via number of hours of participation and partnership linkages.

Data monitoring, auditing, and harm

Each participant will be given a unique study identifier, all protected health information will be masked, and REDCap data exports will be limited to the principal investigator and the project statistician for generating reports and the conduct of statistical data analysis. Safety monitoring will be conducted monthly by the principal investigator, study statistician, and independent data safety monitor. Per university policy, all serious adverse events (AE) and unintended effects of the intervention will be reported to the university IRB and the independent data safety monitor (IDSM) within two days after the principal investigator is notified of the AE.

The technology safety report will include troubleshooting requests from participants, re-engagement attempts for participants who were not logging, and any technology related protocol violations. The enrollment safety report includes new enrollment counts, subject withdrawals, protocol violations, AE, and preliminary outcomes.

ETHICS AND DISSEMINATION

This protocol, including consent forms, has been approved by the University of Nebraska Medical Center IRB (UNMC IRB# 594-17-EP). All protocol amendments will be communicated immediately to the IRB, DSMP, ClinicalTrials.gov, CAB, participants, and funder. All participants will be informed of their right to confidentiality right to leave the trial at any point without loss of those benefits to which they were entitled. All data will be retained in HIPPA compliant REDCap database. REDCap at UNMC is supported by Research IT Office funded by Vice Chancellor for Research (VCR).

Access to data

The principal investigator, study statistician, and the designated IDSM will have access to the final trial dataset. All proposed study specific case report forms for data collection will be coded by the participants unique study ID and maintained in REDCap. All data and other personal health information (PHI) will be removed from the study database upon completion of the study.

Ancillary and post-trial care

Post-trial care is not anticipated as this trial is classified as a low-risk intervention. Participants who express need for assistance will be informed of the UNMC support services and assisted in contacting them.

Dissemination policy

Trial is registered at ClinicalTrials.gov., Identifier: NCT03329079. Deidentified summary results will be posted to ClinicalTrials.gov for public access and disseminated in scientific forums and to the local rural communities.

AUTHORS' CONTRIBUTIONS

CE is PI directing all study components. KK is the statistician who co-leads data management. FB, AY, and KS develop and manage the mobile technologies. PH provides protocol oversight, assessment fidelity planning and training, JM conducts enrollment screening, recruitment, CAB and focus group moderation. CP advises ethics board and protocol adherence. Manuscript drafted by CE, KS and all authors revised-approved the final version. All authors contributed substantially to study design and protocol conduct.

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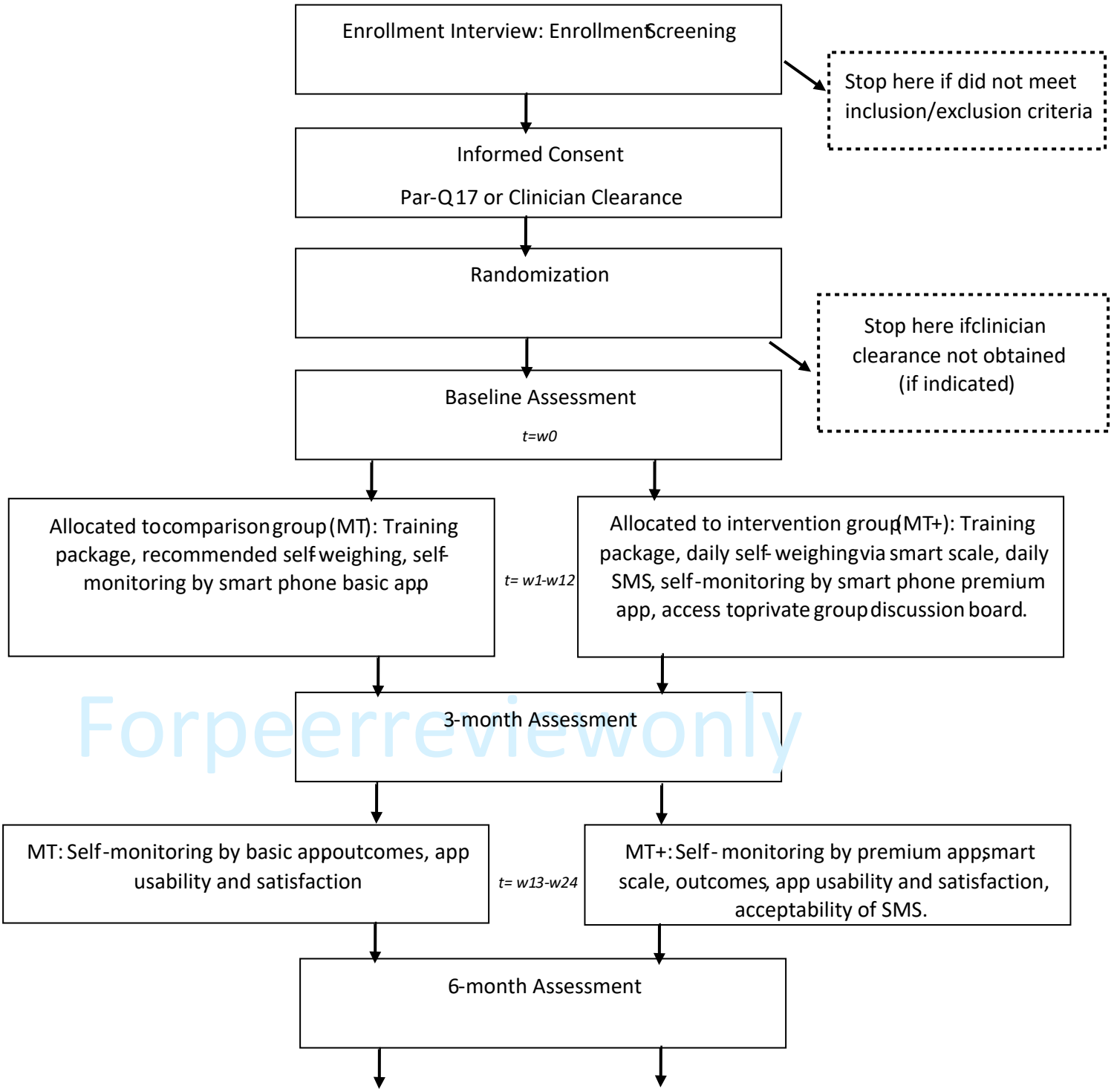
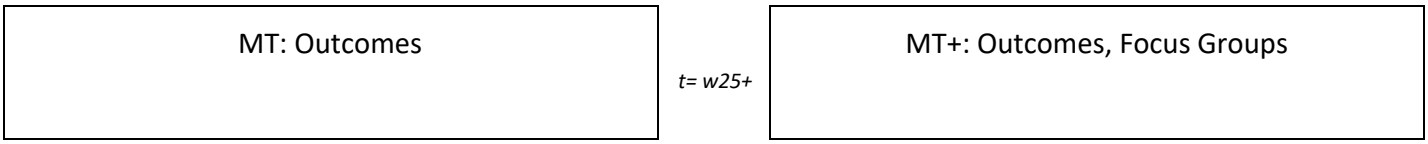
1 16

2 Figure 1: Participant Timeline
3 Figure 2: Measurements

4

[redacted]




MT: Outcomes
t= w25+
MT+: Outcomes, Focus Groups

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1 Figure 2: Measurements

Measure Description (Data Collection Time Points)		
Primary Outcomes: Body Mass Index and Weight		
Body mass index	Tanita Scale (TBF-215)	Baseline, 3 months, and 6 months
Weight	In-person measurement of weight by the Tanita Scale (TBF-215) Withings© Body+ Body Composition Smart Scale (MT+) Self-reported weight (MT)	Baseline, 3 months, and 6 months Daily measure (Recommended), Weekly average computed Daily (Recommended), Weekly average computed
Secondary Outcomes: Diet and Physical Activity		
Fruit and Vegetable Servings	BRFSS-Fruit and Vegetable Dietary Intake module[27]	Baseline, 3 months, and 6 months
Sugar-Sweetened/ Total Beverage Energy Intake	Brief Questionnaire to Assess Beverage Intake (BEVQ-15) [35]	Baseline, 3 months, and 6 months
Physical Activity	BRFSS- Physical activity module[34]	Baseline, 3 months, and 6 months
Report of daily log of dietary intake, physical activity, and weight	Weekly summary downloaded from app which includes participants self- report of dietary intake, physical activity, weight, and steps per day	Weekly reports exported during study

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Appendices Appendix I: Private Group Discussion Board- Moderator Weekly Posts

Week 1: Water

Thousands have lived without love, not one without water (Auden). A recent study found that drinking 16 oz of water before meals increases fat loss in overweight individuals on a diet. Drink one gallon of water per day. This can come from food or beverage. Fruits and vegetables contain more water than other foods. Carrying a refillable water bottle with you during the day can help you increase your water consumption.

For more information: https://www.mensjournal.com/food-drink/5-reasons-never-neglectwater/

Challenge: Increase your daily water consumption to 1 gallon per day.

Week 2: Increasing Physical Activity
Physical activity reduces the risks of heart disease and diabetes better than weight loss alone.
The American Heart Association recommends 30 minutes of moderate activity 5 days per

Moderate activity includes walking, hiking, gardening, or golfing. Moderate activity makes you sweat but will not take your breath away.
A great way to start is by walking. Start by walking 10-15 minutes at a time to total 30 minutes

For more information: https://healthyforgood.heart.org/move-more/articles/hate-exercise-5-

Challenge: exercise for an additional 30 minutes per week beyond what you are already doing.

week.

a day.

steps-to-loving-exercise

Week 3: Avoiding Empty Calories
Empty calories are calories that provide your body with no nutrition. They are found in packaged foods like cakes, cookies, candy, soda, alcohol, fast food etc.
They are high calorie, low nutrition, and contain high amounts of sugar and solid fat.
As a general rule, if it comes in a package it probably contains empty calories.
Try eating more whole food calories in fresh fruits and vegetables, eggs, poultry, nuts, whole wheat bread, protein bars, or low-fat milk.
For more information: http://www.menshealth.co.uk/healthy/11-ways-to-cut-hundreds-ofempty-calories-a-day
Challenge: Limit your empty calorie intake to 200 calories per day.

Week 4: Family/Friends Challenge

Having family and friends involved in your diet and exercise program can contribute to your success. Let others know about your eating goals so healthy options can be available.
Instead of watching TV with others, try going on an evening walk together. Encouraging others to get involved with you will not only be beneficial for you, but them as well!
For more information: https://www.parents.com/fun/sports/exercise/10-ways-to-exercise-as-afamily/

Weekly challenge: Include your family in exercise 2 days this week.

Week 5: Portion Sizes

Serving size and portion size are not always the same. Serving size is the manufactures recommendation of the serving, portion size is how much is actually consumed. Your portion size should match the serving size.

Veggies: 1 cup of raw veggies or 2 cups of leafy greens. 1 cup is roughly size of a fist.
Fruit: one medium apple or orange, ½ cup of sliced fruit. ½ cup is one cupped hand.
Grains: 1 slice of bread. ½ cup of dry pasta or bread. ½ medium potato.
Protein: 3 oz of meat is the size of a deck of cards.
Fats: 1 oz of cheese is size of two dice. 1 tsp of butter is the size of one die.

It's important to accurately count your portion sizes to accurately log food for weight loss. If you are under counting your portion size, you will not account for calories you are consuming.
For more information: https://healthyforgood.heart.org/eat-smart/articles/portion-size-versusserving-size

Challenge: Examine your portion sizes during at least one meal each day this week and try to improve your portion sizes. Use the information above as a guideline.

Sodium contributes to the development of high blood pressure, which is the one of the major

The American Heart Association recommends a sodium intake of 2300mg a day with an ideal

2300mg of sodium is equivalent to one teaspoon of salt.
Most sodium consumed by Americans does not come from table salt but is in processed foods.
The easiest way to avoid sodium is to avoid processed foods.
In the Lose-it! App, you can create a goal to limit your sodium intake to 2300mg daily. The app will automatically track sodium as you log food, so you can view your sodium

For more information: https://www.menshealth.com/health/a19548436/blood-pressure-guide/
Weekly challenge: Limit sodium intake to 2300mg daily.

Week 6: Avoiding Salt/Sodium

risk factors for heart disease. limit
of 1500mg a day. consumption
each day.

Week 7: Moving Every Hour

A study was conducted in 2017 which found that patterns of sitting are associated with higher illness.
Not only is exercise important, but so is moving every hour! It's easy to forget to move every hour, so try setting a timer on your phone or watch to get up and walk around. For more information:
https://www.mensjournal.com/health-fitness/a-five-minute-walk-could-undo-an-hour-ofsitting-20141009/
Challenge: Move every hour from 9-5. The goal is to have 9/9 hours active!

Week 8: Improve Sleep Quality

A good night's sleep is an important component to weight loss programs.
The recommendation for sleep for adults is 7 hours per night.
Insufficient sleep is linked to the development of chronic disease like obesity, diabetes, depression, and cardiovascular disease.
Here are some tips for better sleep:
1. Make your bedroom a quiet and relaxing environment.

2. Turn off screens 30 minutes before bed.
3. Be consistent. Get your body on a "sleep schedule" so you go to bed and wake up at the same time.
4. Avoid large meals before bed.
5. Exercise! Exercise is proven to improve sleep quality.

For more information: https://www.mensjournal.com/style/sleep-better-live-better/

Challenge: Try to get 7 hours of sleep each night this week.

Week 9: Fit After 40

As we get older our bodies change and our metabolism slows.

Staying fit after 40 is a little different than it was when you were in your 20s!

Lean tissue mass will start to decline and fat mass will increase.

Diet and exercise can help prevent this process.

Here are some tips for weight loss after 40:

1. Start with moderate activity like walking. If you are already walking several times a week, try incorporating strength training into your routine.
2. Cut back on red meat. Increase intake of lean protein and veggies.
3. Avoid alcohol. Alcohol contains empty calories and provides no nutritional value.
4. Reduce stress. Stress causes increase in cortisol levels which is associated with increased body fat.

Here is an article with additional tips for weight loss**:**

https://www.mensjournal.com/healthfitness/7-weight-diet-loss-tips-men-over-40/

Challenge: Try at least one of the four tips listed above this week.

Week 10: Strength Training
Strength training is an important piece to exercise.
The American Heart Association recommends strength training two days a week.
With a larger muscle mass, your metabolism increases and your body burns calories more efficiently.
Strength not only increases muscle mass but increases bone mas as well.
For more information: **https://www.mensjournal.com/health-fitness/beginners-guide-weight-training/**

Challenge: Incorporate strength training into your exercise program two days this week.

Week 11: Reducing Stress
According to the American Heart Association, chronic stress can cause high blood pressure, is linked to heart disease, and can weaken your immune system.
During stressful times, it's important to continue to practice healthy lifestyle behaviors.
Some helpful tips to managing stress include:
1. Exercise.
2. Get adequate sleep.
3. Maintain a healthy diet.
4. Spend time with family or friends.
For more information: https://www.mensjournal.com/health-fitness/20-science-backed-waysreduce-stress/
Challenge: Try at least one of the four tips listed above this week.

Week 12: Making a Diet Your Lifestyle You made it!
Congrats, this is the final week of the study.

One thing you can do to stay on track is continue healthy eating and physical activity.

Continue to log your food to track your caloric intake.
Increase your physical activity to moderate or vigorous if tolerated.
There are various apps available to track food and activity which you can use after this study.
For more information: https://www.mensjournal.com/health-fitness/how-to-add-18-years-to-your-life-w436796/
Challenge: Make a plan and stick to it! 11

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Appendix II: List of Text Messages

G=Goal Oriented/Self-Monitoring
1. Healthy isn't a goal. It's a way of living.
2. Work hard enough to raise your heart rate and break a sweat.
3. Today your goal is to exercise for 10 minutes, 3 times today.
4. Eat plenty of fruits of all colors today.
5. Did you eat the recommended amount of protein today? No beer is not protein.
6. Avoiding processed meats is best, try choosing fish or lean meat today.
7. Don't overeat. Your goal today is to control your portion sizes at meals.
8. How many servings of fruits or vegetables did you eat yesterday?
9. How many glasses of water did you drink yesterday?
10. Make sure half of the grains you eat are whole grains. Whole grains can help give you a feeling of fullness. Choose whole-wheat breads, pasta and oatmeal.
11. Take your time eating. Savor your food. Eat slowly. Enjoy the taste and textures of your food.
12. Make half your grains whole grains.
13. Try eating on a normal sized plate that is 8 inches round. It might look like the saucer to your coffee cup at first.
14. Short bouts of 10 minutes of moderate or vigorous activity count!
15. Avoid heavy gravies or sauces as they add fat and calories to otherwise healthy choices. (And they stain your shirt).

M = Motivational

16. No matter how slow you go, you're lapping everybody on the couch.
17. Good things come to those who sweat. Especially if you are moving when sweating.
18. 10,000 steps is roughly walking 5 miles. Then you can tell stories that you walked 5 miles for (fill in the blank).
19. Make it a lifestyle, not a duty.
20. Don't use the weekend as an excuse to give up on your goals.
21. Sweat is fat crying.
22. It's not easy, but it is worth it. Now repeat that every day.
23. Be stronger than your excuses.
24. Some activity is better than none.
25. You don't have to eat less you just have to eat right.
26. A one-hour workout is 4% of your day.
27. When you feel like quitting, ask yourself why you started.
28. Thank you for reading this text. You can lose ½ a pound by pushing the off button 20,000 times.
29. When tempted by junk food, turn your head to the left and then to the right. Repeat as necessary.
30. Attitude is everything! New day! New Strength! New Thoughts!
31. No matter how slow you go, you are still lapping everybody on the couch!
32. Will it be easy? NOPE! But it will be WORTH IT!!!

33. Nothing is impossible, the word itself says I'm possible.

3 6

34. Strive for progress not perfection!
35. Being healthy is not a race, it's a journey!
36. You've Got This!!
37. You are stronger than you think!!
38. BLT's- Bites, licks, tastes count too.
39. You'll never change your life until you change something you do daily. The secret to success is found in your daily routine. This year—set a goal to change ONE thing about your day to be healthier. Keep the goal specific and measurable. Instead of saying you are going to exercise this year, tell yourself you are going to exercise for 30 min, 5 days this week. Repeat this each week until it becomes a habit.
40. Are you frustrated? Are you ready to quit? DON'T!! Remember why you started this in the first place!!
41. Every step you take toward your goal is a step closer to more time with your family!
42. Even if you lose ½ a pound a week you will still lose 26 pounds by this time next year. Keep going!
43. It takes 4 weeks for you to see your body changing, it takes 8 weeks for your friends and family, and it takes 12 weeks for the rest of the world to see the changes, but your heart sees it immediately.
44. Be stubborn about your goals and flexible about your methods.
45. Exercise in the morning, before your brain figures out what you're doing.
46. You don't have to be extreme, just be consistent.

47. It’s a slow process but quitting won’t get you there.

R = Reminder (for tracking, healthy eating, etc.)
48. Tracking your food intake is a key to success - remember to track today.
49. They key to healthy eating? Avoid any food that has a TV commercial.
50. Your safety is priority! It may be tempting to compete with others and set an unrealistic and unhealthy goal for increasing your steps.
51. Drink more water today.
52. What is moderate activity: I can talk while I do them, but I can't sing.
53. Remember to eat a variety of whole grains.
54. Make half your plate fruits and vegetables.
55. Remember to eat breakfast.
56. Take a walk after lunch.
57. Make sure to get your steps in today.
58. 5 fruits and veggies a day!
59. Did you know….1 pound of fat is approximately the size of a large grapefruit?
60. Did you know 1 pound of fat is worth 3500 calories!
61. Have you logged today?
62. Guzzle Guzzle the water – 64 oz!
63. Don’t forget to log those workouts!

64. Daily health checklist: Drink water, eat a fruit or veggie every meal, workout, stretch, LAUGH and SMILE, try to sleep 8 hours.

4 7

65. Did you know weight loss is 30% workout and 70% diet?
66. Indulge by the rule of 1 – 1 scoop of ice cream, 1 small piece of pie, 1 piece of chocolate.
67. Exercise during commercials – get 10 lunges, 10 sit ups or 10 squats!
68. Park farther from the door and walk to get the mail, go to the store, or going to work.
69. Take stairs when you can.
70. Eat for energy, not for comfort!
71. Did you meet your fitness goals?
72. Have you logged your meals today?
73. Try redirecting your attention when those cravings hit, give it 15minutes before giving in! Drink some water!
74. It's Friday! Don't lose track this weekend- stay focused!
75. You don't have to eat less you just have to eat right.
76. Weekends count! Don't dip out on your diet.
77. Try to get 250 steps every hour. Get up and take a walk.
78. Ask for dressings, butter, and sour cream on the side.
79. Buffet time? Hit up the salad bar.
80. At the buffet? Make one trip. You don't have to eat it all.
81. A gas station hot dog has 400 calories. Pack a lunch today!
82. Remember to walk instead of drive when you can!
83. Switch your soda for water today. 1 can of soda has about 150 calories. 3 cans of soda is 450 calories!

84. Remember portion control— check the back of the bag for serving size!
85. Eat slowly and take small bites. It takes 20 minutes for your brain to register fullness.
86. Motivation is what gets you started habit is what keeps you going.
87. Consistency is key!
88. At the gas station? Grab a protein bar instead! Protein keeps you full for longer.
89. Too cold to exercise? Try jumping jacks in your living room.
90. Buzz the Buffet. Take a walk around the buffet first before filling your plate. Choose your favorite foods and skip over your least favorite.
91. Don't skip meals! Skipping meals will make you hungrier and cause you to overeat at your next meal.
92. Don't forget breakfast! Get your metabolism started today.
93. Food is fuel, not comfort.
94. Going cold turkey doesn't work. One healthy habit in, one bad habit out!
95. The best snacks are 200cal or less, filling yet satisfying. Snacking keeps up your metabolism throughout the day helping you burn calories and keep your energy levels up.
96. Remember, one serving of meat is the size of a deck of cards
97. Drink your first glass of water right when you wake up! Rehydrate and stimulate your digestive system.
98. Eating healthy is not a diet, it's a lifestyle.
99. Create healthy habits not restrictions.

100. Exercise gives you more energy and helps you stay focused.

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101. Even if you lose ½ pound a week. You will still lose 26 pounds by this time next year. Just keep going.
102. Tip: put fruits and vegetables at eye level in the fridge so they are the first thing you see.
103. Tip: have fresh fruit like bananas or apples on the table so they are easy to grab on the go.
E = Educational (Tips, Physical Activity, Nutrition/Healthy Eating)
104. Regular physical activity helps build and maintain healthy bones and muscles, so you can beat your friend at arm-wrestling.
105. Regular physical activity helps reduce the risk of developing colon cancer.
106. Exercise controls weight.
107. Exercise improves mood.
108. Exercise boosts energy.
109. Exercise promotes better sleep.
110. You may want to work with your doctor to set up an activity program.
111. Estimating Portion Sizes: 1 egg is 2 ounces or 1/4 cup.
112. Adults should do strengthening activities at least 2 days a week.
113. If you haven't been active in a while, start slowly and buildup.
114. Estimating Portion Sizes: A golf ball is equal to 2 tablespoons or 1 ounce.
115. Estimating Portion Sizes: a deck of cards is 3 ounces.

116. Being active has benefits. It helps you feel better about yourself. It helps you sleep better. It helps you move around more easily.
117. Adults need about 150 minutes of moderate activity a week.
118. Vigorous-intensity aerobic activity means you're breathing hard and fast, and your heart rate has gone up quite a bit. If you're working at this level, you won't be able to say more than a few words without pausing for a breath.
119. Doing 1 minute of vigorous-intensity exercise is equal to about 2 minutes of moderate activity.
120. Satisfy your “sweet tooth”. Eat a natural dessert such as fruit.
121. Sodas or other beverages can add about 400 calories a day to men’s diet, water is a better choice.
122. Estimating Portion Sizes: Baseball is equal to 1 cup.
123. Medical authorities agree that 10,000 steps is a healthy number to strive for a day.
124. Calories are tiny creatures that make your clothes tight at night – did you know Coors Light has 102 calories, a Bud Light has 110 calories and a Michelob Ultra has 95 calories per bottle.
125. A six pack of Bud Light has 660 calories. You would have to walk 4.5 miles to burn off the calories.
126. Just 100 extra calories a day means 10 extra pounds a year.
127. If you don’t recognize the ingredient, your body won’t either.
128. Don’t be fooled by “low fat” or “sugar free.” This is code for “processed.” Stick to whole foods!

129. Avoid eating foods with ingredients you can't pronounce.

Appendix III: Consent Form

University of Nebraska Medical Center

IRB PROTOCOL # 594-17-EP **Page 1 of 9**

ADULT CONSENT - CLINICAL BIOMEDICAL

Title of this Research Study
The Rural Men's Health Study

Invitation
You are invited to take part in this research study. The information in this form is meant to help you decide whether or not to take part. If you have any questions, please ask.

Why are you being asked to be in this research study?
You are being asked to be in this study because you are a 40 to 69 year old man, reside in the Northeast Nebraska region, your Body Mass Index (BMI) is 28 or higher (BMI 50 or greater with clinician clearance, less than 396 pounds), you are a smartphone owner with enabled text messaging, you speak and read English, have an email account, you have no health problems that would prevent you from becoming more physically active, and you are willing to share your self-monitoring logs from the Lose-It app with the investigative team.

What is the reason for doing this research study?
Rural men are less likely than the general population to receive diet and exercise counseling for weight loss. Men with BMI of 28 to 49 are classified as overweight or obese BMI of 50 or higher is classified as morbidly obese. This population is at increased risk of developing a number of chronic diseases such as insulin resistance, type 2 (adult-onset) diabetes, high blood pressure, heart disease and cancer. The preferred treatment for weight reduction is lifestyle modifications that include a diet that is high in fruits, vegetables and low fat dairy products, and regular moderate intensity physical activity supplemented by resistance exercise. This research is trying to see if a technology enhanced self-monitoring approach is effective in increasing healthy eating and physical activity and reducing body weight. A total of 80 participants are expected to enroll in this study.

What will be done during this research study?
The study will last for six months. You will be asked to come to meet with a research nurse for an independent meeting at the Northeast Nebraska Public Health Department in Wayne, NE, three times at regular intervals (baseline, 3, 6 months) to complete surveys and physical assessments, which will take approximately 60-90 minutes. The physical assessments will include weight, height, body mass index, blood pressure, and heart rate. The individual contents of your written survey will only be shared with the research team. The surveys will include questions about your

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health status, your eating and physical activity patterns, and your perceptions about technology.

Immediately after the baseline visit, you will be randomly assigned (as by the roll of a die) in a 1:1 ratio to one of two groups. All subjects will be assigned a temporary email address, that contains no personal identifiers, that will be used to create a Lose-It app account. At the end of the study, you will have the option to choose to obtain personal ownership of your Lose-It account. If you choose to obtain personal ownership of your account, our research staff will assist you in entering a new username and password. However, please be advised that our study will not pay for further access to the Lose-It app. Future access to Lose-It premium will require you pay the current market rate for the app. If you choose to forego a change of ownership, your Lose-It account will be deleted 30 days after completing the study. If you are in group 1, you will have access to Lose-It Premium app, receive daily text messaging, participate in an online social comparison group with other members of group 1, and receive a WiFi Smartscale for daily weighing over the next 6 months. If you are in Group 2, you will have access to the Lose-It Basic app to self-monitor your eating and activity for the next 6 months. Both groups will have access to the research nurse for questions and will receive assessments at 3 and 6 months.

An overview of the procedures you will participate in during the study office visits are outlined in the attached table: Schedule of Procedures.

In addition to the brief questionnaires collected at baseline, 3, and 6 months, you may be randomly invited to participate in a face to face focus group interview (approximately 90 minutes) at the end of the study (6 months) at the same community center where your assessments were collected. The questions for the interviews and focus groups will be: 1) What was the most helpful aspect of this study? 2) What other support would have helped you reach your goals? 3) Other comments. The interviews and focus groups will be recorded and analyzed to determine the major themes. Audio recordings of the focus groups will be destroyed after checked against the written transcripts for accuracy. At the end of the study, your temporary email account and attached Lose-It account will be deleted. You will have the option to set up a new Lose-It Basic account for free if you choose to continue using the app after the completion of the study.

What are the possible risks of being in this research study?

The possible risks of the procedures for assessing the biomarkers (resting blood pressure and resting heart rate) can be compared to procedures used in routine medical care and/or screens (i.e., blood pressure or heart rate measurement).

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Assessment of Behavioral Markers:The assessments include no sensitive questions and pose no risks to you beyond possible but unlikely fatigue during completion of the survey. If you become fatigued, you can take a break or complete the assessment on another day.

Assessment of Biomarkers:The likelihood of risks associated with the assessment of all biomarkers is small, and the seriousness of those risks in minimal. The exertion levels are the same as for those associated with routine clinician visit screenings.

Alternative Treatments and Procedures:You can obtain guidance from your primary care provider or follow self-directed programs of behavior change. The assessments provided might be available from health clubs or other facilities, but there would be a cost associated.

Use of smart phone to track physical activity:The risks associated with wearing your smart phone for tracking physical activity are minor discomfort and nuisance from wearing the device on the hip or pocket during waking hours.

Loss of confidentiality is a risk to participating in the study. You may find completing the written surveys and health assessments inconvenient or tiring. The research nurse will schedule all assessment sessions at times convenient for you, and you may call him/her at the number listed at the end of this form to reschedule if necessary. If you become tired before completing the surveys or health assessments, you may take a break. Lose-It Corporate owners of the Lose-It app will not have access to any personal identifiable information about you or any other subjects in the study.

You may experience the following risks and discomforts as a result of each part of the physical assessment:

Resting Blood Pressure: arm discomfort during the procedure related to compression by the blood pressure cuff.

All of the tests will be administered by an experienced licensed or certified healthcare professional who will provide you with instruction and support during testing.

It is possible that other rare side effects could occur that are not described in this consent form. It is also possible that you could have a side effect that has not occurred before.

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What are the possible benefits to you?
You may learn about weight loss through self-monitoring of healthy eating and physical activity. If you adopt healthier eating and physical activity lifestyle behaviors, you may experience weight loss as well as promote health, prevent disability and/or premature death, and enhance quality of life as you age. You also may benefit from an improvement in cardiorespiratory (heart) fitness, increases in muscular strength, and percent body fat. You may not get any benefit from being in this research study.

What are the possible benefits to other people?
Cost-effective interventions that are acceptable to rural men and effective in achieving preventive health behavior change have the potential for decreasing health care costs by preventing chronic diseases and maintaining functional ability. This research protocol may provide a care delivery model that can be used by other providers of primary preventive services to rural clients. There may not be benefits to other people.

What are the alternatives to being in this research study?
You might obtain guidance from your primary health care provider about healthy eating and physical activity or follow a self-directed program of lifestyle behavior change for weight loss. The assessments provided might be available to you at health clubs or other facilities, but there would be a cost involved.

What will being in this research study cost you?
There is no cost to you to be in this research study. You will not be paid or reimbursed for transportation cost to and from the study site.

Will you be paid for being in this research study?
You will not be paid for transportation costs to and from the study site. Your compensation will be determined by the intervention arm to which you are randomly selected. Men in the MT+ intervention arm will receive the Lose-It Premium app (40.00) and a Nokia Body+ Wi-Fi scale (100.00), which they will be able to keep at the end of the study. Men randomized to the MT intervention arm will receive a stipend of $25 for each of the 3 assessment sessions. To receive payment you must provide your social security number, name, and address in order to comply with Internal Revenue service (IRS) reporting requirements. When payment is reported to the IRS, we will not say what the payment is for, only that you have been paid. If you do not wish to provide this information, you can still participate in the study; however, you will not be paid. Checks will be mailed at the end of 6 months of your participation after your final study visit.

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Who is paying for this research?
This research is being paid for by grant funds from the National Institute for Nursing Research. The University of Nebraska Medical Center College of Nursing receives money from the National Institute for Nursing Research to conduct this study.

What should you do if you are injured or have a medical problem during this research study?
If you are injured or have a medical problem as a result of being in this study, you should immediately contact one of the people listed at the end of this consent form.

How will information about you be protected?
You have rights regarding the privacy of your medical information collected before and during this research. This medical information, called "protected health information" (PHI), typically may include, depending upon the nature of this research, demographic information (like your address and birth date), the results of physical exams, as well as your medical history.

By signing this consent form, you are allowing the research team to have access to your PHI. The research team includes the investigators listed on this consent form and other personnel involved in this specific study at UNMC. Your PHI will be used only for the purpose(s) described in the section "What is the reason for doing this research study?"

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

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 of 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 information, then the researchers may not use the Certificate to withhold that information.

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The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or harm to self or others.

Who will have access to information about you?
Your PHI will be shared, as necessary, with the Institutional Review Board (IRB) and with any person or agency required by law. You are also allowing the research team to share your PHI with other people or groups listed below. All of these persons or groups listed below are obligated to protect your PHI.

By signing this consent form, you are allowing the research team to have access to your PHI. The research team includes the investigators listed on this consent form and other personnel involved in this specific study at the Institution.

Your PHI will be used only for the purpose(s) described in the section What is the reason for doing this research study?

You are also allowing the research team to share your PHI, as necessary, with other people or groups listed below:

- The UNMC Institutional Review Board (IRB)
- Institutional officials designated by the UNMC IRB
- Federal law requires that your information may be shared with these groups:
    - The HHS Office of Human Research Protections (OHRP)
    - National Institutes of Health (NIH)

You are authorizing us to use and disclose your PHI for as long as the research study is being conducted. You may cancel your authorization for further collection of PHI for use in this research at any time by contacting the principal investigator in writing. However, the PHI which is included in the research data obtained to date may still be used. If you cancel this authorization, you will no longer be able to participate in this research.

How will results of the research be made available to you during and after the study is finished?
The information from this study may be published in scientific journals or presented at scientific meetings but your identity will be kept strictly confidential.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website

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at any time.

What will happen if you decide not to be in this research study?
You can decide not to be in this research study. Deciding not to be in this research study will not affect your medical care or your relationship with the investigator, the University of Nebraska Medical Center or the Nebraska Medical Center. Your doctor will still take care of you and you will not lose any benefits to which you are entitled.

What will happen if you decide to stop participating once you start?
You can stop being in this research study (withdraw) at any time before, during, or after the treatment begins. Your doctor will still take care of you though you may not be able to get the research treatment. Deciding to withdraw will otherwise not affect your care or your relationship with the investigator, the University of Nebraska Medical Center, or the Nebraska Medical Center. You will not lose any benefits to which you are entitled.

Will you be given any important information during the study?
You will be informed promptly if the research team gets any new information during this research study that may affect whether you want to continue being in the study.

What should you do if you have any questions about the study?
You have been given a copy of "What do I need to know before being in a research study?" If you have any questions at any time about this study, you should contact the Principal Investigator or any of the study personnel listed on this consent form or any other document that you have been given.

What are your rights as a research participant?
You have rights as a research subject. These rights have been explained in this consent form and in *The Rights of Research Subjects* that you have been given. If you have any questions concerning your rights or want to discuss problems, concerns, obtain information or offer input, or make a complaint about the research, you can contact any of the following:

- The investigator or other study personnel
- Institutional Review Board (IRB) by
- Telephone: (402) 559-6463
- Email: IRBORA@unmc.edu
- Mail: UNMC Institutional Review Board, 987830 Nebraska Medical Center, Omaha, NE 68198-7830.
- Research subject advocate
- Telephone 402-559-6941

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- Email: unmcrsa@unmc.edu

Documentation of informed consent

You are freely making a decision whether to be in this research study. Signing this form means that:

- You have read and understood this consent form.
- You have had the consent form explained to you.
- You have been given a copy of The Rights of Research Subjects
- You have had your questions answered.
- You have decided to be in the research study.
- If you have any questions during the study, you have been directed to talk to one of the investigators listed below on this consent form.
- You will be given a signed and dated copy of this consent form to keep.

Signature of Subject _____

Date _____

My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the subject. In my judgment, the subject possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate.

Signature of Person obtaining consent _____

Date _____

Authorized Study Personnel

Principal

* Eisenhauer, Christine
phone: 402-844-7897
alt #: 402-844-7897
degree: PhD, APRN-CNS

Secondary

* Hageman, Patricia
phone: 402-559-1967
alt #: 402-559-1967
degree: PhD, PT

* Silva, Fabiana

* Pullen, Carol
phone: 402-559-6548
alt #: 402-559-6548
degree: Ed.D., RN

* Yoder, Aaron

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University of Nebraska Medical Center

- Email: unmcrsa@unmc.edu

Documentation of informed consent
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- You have been given a copy of The Rights of Research Subjects
- You have had your questions answered.
- You have decided to be in the research study.
- If you have any questions during the study, you have been directed to talk to one of the investigators listed below on this consent form.
- You will be given a signed and dated copy of this consent form to keep.

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Signature of Person obtaining consent _____
Date _____

Authorized Study Personnel
Principal
* Eisenhauer, Christine
phone: 402-844-7897
alt #: 402-844-7897
degree: PhD, APRN-CNS

Secondary
* Hageman, Patricia
phone: 402-559-1967
alt #: 402-559-1967
degree: PhD, PT

* Pullen, Carol
phone: 402-559-6548
alt #: 402-559-6548
degree: Ed.D., RN

* Silva, Fabiana

* Yoder, Aaron

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phone: 402-559-6627
alt #: 402-559-6627
degree: PhD

Participating Personnel

* Castaneda, Georgina
alt #: 402-375-2200
degree: CHW

* Salinas, Katherine (Katie)
phone: 402-559-6025
alt #: 402-255-0504
degree: RN, BSN

phone: 402-552-7240
alt #: 814-577-9127
degree: PhD

* Miller, Jessica
phone: 402-844-7923
alt #: 402-340-4699
degree: RN, BSN

* Zarate, Victor
alt #: 402-375-2200
degree: CHW

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Institutional Review Board (IRB)

What Do I Need To Know Before Being In A Research Study?

You have been invited to be in a **research study**. Research studies are also called "clinical trials" or "protocols." **Research** is an organized plan designed to get new knowledge about a disease or the normal function of the body. The people who are in the research are called **research subjects**. The **investigator** is the person who is running the research study. You will get information from the investigator and the research team, and then you will be asked to give your **consent** to be in the research.

This sheet will help you think of questions to ask the investigator or his/her staff. You should know all these answers before you decide about being in the research.

What is the **purpose** of the research? Why is the investigator doing the research?

What are the **risks** of the research? What bad things could happen?

What are the possible **benefits** of the research? How might this help me?

How is this research different than the care or treatment I would get if I wasn t in the research? Are there other treatments I could get?

Does **everyone** in this research study get the same treatment?

Will being in the research **cost** me anything extra?

Do I have to be in this research study? Will the doctors still take care of me if I say **no**?

Can I **stop** being in the research once I ve started? How?

Who will look at my **records**?

How do I reach the investigator if I have more **questions**?

Who do I call if I have questions about being a **research subject**?

Make sure all your questions are answered before you decide whether or not to be in this research.

Academic Research & Services Building 3000 / 987830 Nebraska Medical Center / Omaha NE 68198-7830
402-559-6463 / FAX 402-559-3300 / Email: irbora@unmc.edu / http://www.unmc.edu/irb

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Institutional Review Board (IRB)

THE RIGHTS OF RESEARCH SUBJECTS
AS A RESEARCH SUBJECT YOU HAVE THE RIGHT

to be told everything you need to know about the research before you are asked to decide whether or not to take part in the research study. The research will be explained to you in a way that assures you understand enough to decide whether or not to take part.

to freely decide whether or not to take part in the research.

to decide not to be in the research, or to stop participating in the research at any time. This will not affect your medical care or your relationship with the investigator or the Nebraska Medical Center. Your doctor will still take care of you.

to ask questions about the research at any time. The investigator will answer your questions honestly and completely.

to know that your safety and welfare will always come first. The investigator will display the highest possible degree of skill and care throughout this research. Any risks or discomforts will be minimized as much as possible.

to privacy and confidentiality. The investigator will treat information about you carefully, and will respect your privacy.

... to keep all the legal rights you have now. You are not giving up any of your legal rights by taking part in this research study.

to be treated with dignity and respect at all times.

The Institutional Review Board is responsible for assuring that your rights and welfare are protected. If you have any questions about your rights, contact the Institutional Review Board at (402) 559-6463.

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Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials.

each of the items listed below.

provide a short explanation.

Ann Intern Med. 2013;158(3):200-207

	Reporting Item		Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1

Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	#3	Date and version identifier	2

Funding	2	#4	Sources and types of financial, material, and other support
Roles and responsibilities: contributorship	2	#5a	Names, affiliations, and roles of protocol contributors
		#5b	Name and contact information for the trial sponsor
Roles and responsibilities: sponsor contact information	2	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have
Roles and responsibilities: sponsor and funder	11		

		ultimate authority over any of these activities	
Roles and responsibilities:	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committees committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	11
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3

Background and rationale: choice of comparators	3	#6b	Explanation for choice of comparators
Objectives	3-4	#7	Specific objectives or hypotheses
Trial design	4	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)

Methods:

Participants, interventions, and outcomes

Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	4
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	4
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	5
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose	5

		change in response to harms, participant request, or improving / worsening disease)	
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	5,6
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	5
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median,	6

		proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	7
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	3-4

		reach target sample size	
	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	
	#16b	Mechanism of implementing the allocation sequence (eg,	
Recruitment	#15	Strategies for achieving adequate participant enrolment to	4,7

Methods: Assignment

of interventions (for controlled trials)

Allocation: sequence generation 3,7

Allocation concealment mechanism 7

central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned

Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	6-7
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	7
Blinding (masking): emergency	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's	7

unblinding allocated intervention during the trial		
Methods: Data collection, management, and analysis	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol
Data collection plan 8-9	#18b	Plans to promote participant retention and complete follow-

				Data collection plan: 9-10
	retention		up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	
	Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	10-11
	Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	10

Statistics: additional analyses		adjusted analyses)	
	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	
	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	
	#20b	Methods for any additional analyses (eg, subgroup and	10
Statistics: analysis	10		

population and missing data			
Methods: Monitoring			
			Data monitoring: 11
formal committee			
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	11

Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	11
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	11

Ethics and

dissemination			
Research ethics approval	11	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval
Protocol amendments	11	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)
Consent or assent	7	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
		#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
ancillary studies	43 44		Consent or assent: n/a

Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	11
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	12
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	11
Ancillary and post	#30	Provisions, if any, for ancillary and post-trial care, and for	11

	trial		care
compensation to those		participation	who
suffer harm from trial			
		#31a Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	
Dissemination policy: 11			
	trial results		
		#31b Authorship eligibility guidelines and any intended use of professional writers	
		#31c Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	
Dissemination policy: 11			
	authorship		
			Dissemination policy: 11
	reproducible research		

Appendices

Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	22-28
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a