

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-neglect-water/>

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-steps-to-loving-exercise>

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

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-of-empty-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-a-family/>

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 manufacturer's 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-versus-serving-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.

Week 6: Avoiding Salt/Sodium

Sodium contributes to the development of high blood pressure, which is one of the major risk factors for heart disease.

The American Heart Association recommends a sodium intake of 2300mg a day with an ideal limit of 1500mg a day.

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 consumption each day.

For more information: <https://www.menshealth.com/health/a19548436/blood-pressure-guide/>

Weekly challenge: Limit sodium intake to 2300mg daily.

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-of-sitting-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.

<p>2. Turn off screens 30 minutes before bed.</p> <p>3. Be consistent. Get your body on a “sleep schedule” so you go to bed and wake up at the same time.</p> <p>4. Avoid large meals before bed.</p> <p>5. Exercise! Exercise is proven to improve sleep quality.</p> <p>For more information: https://www.mensjournal.com/style/sleep-better-live-better/</p> <p>Challenge: Try to get 7 hours of sleep each night this week.</p>
<p>Week 9: Fit After 40</p> <p>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:</p> <ol style="list-style-type: none">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. <p>Here is an article with additional tips for weight loss: https://www.mensjournal.com/health-fitness/7-weight-diet-loss-tips-men-over-40/</p> <p>Challenge: Try at least one of the four tips listed above this week.</p>
<p>Week 10: Strength Training</p> <p>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 mass as well. For more information: https://www.mensjournal.com/health-fitness/beginners-guide-weight-training/</p> <p>Challenge: Incorporate strength training into your exercise program two days this week.</p>
<p>Week 11: Reducing Stress</p> <p>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:</p> <ol style="list-style-type: none">1. Exercise.2. Get adequate sleep.3. Maintain a healthy diet.4. Spend time with family or friends. <p>For more information: https://www.mensjournal.com/health-fitness/20-science-backed-ways-reduce-stress/</p> <p>Challenge: Try at least one of the four tips listed above this week.</p>
<p>Week 12: Making a Diet Your Lifestyle</p> <p>You made it! Congrats, this is the final week of the study.</p>

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!

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. The 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



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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 is 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 costs 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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- 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

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

* Silva, Fabiana

* Yoder, Aaron

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- You have decided to be in the research study.
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phone: 402-559-6627
alt #: 402-559-6627
degree: PhD

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

Participating Personnel

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

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

* Salinas, Katherine (Katie)
phone: 402-559-6025
alt #: 402-255-0504
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 doctor 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.

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.

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>