Rural Engagement in TelemedTeam for Options in Obesity Treatment Solutions
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RESEARCH CONSENT FORM

Rural Engagement in TelemedTeam for Options in Obesity Treatment Solutions (RETOOL)

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- We are asking you to be in a research study.
- Research is done to answer a scientific question. Research studies may or may not help the people who participate.
- Joining this study is completely voluntary. If you say yes, you can quit the study at any time.
- You can still get medical care and other services from the University of Kansas Medical Center or the provider clinic even if you are not in the study.
- The research team will explain what happens if you decide to join the study. This conversation is called "informed consent."
- Informed consent includes a chance to get your questions answered before you make your decision. Please ask as many questions as you need.
- This consent form explains the study. Take as much time as you need to decide.
- If you decide to be in the study, you will be asked to sign this form.

Dr. Christie Befort is doing the study at the University of Kansas Medical Center (KUMC). About 560 people will be in the study.

Why is this study being done?

Obesity increases risk for 13 types of cancer and now affects over 40% of the U.S. adult population. Rural Americans have higher cancer rates than those who live in urban areas and often lack access to weight control programs and resources that promote healthy lifestyles. We are doing this study to learn about better ways to help treat obesity in rural areas.

How long will I be in this study?

Your participation in this study is expected to last about 18 months. The study includes a weight loss phase (Months 1-6) and a weight maintenance phase (Months 7-18).

What will I be asked to do?

This study will compare two methods for managing obesity in rural patients to see which will better help patients reach their weight loss goal and maintain that weight loss at 18 months.

Sixteen (16) primary care clinics will participate in the study. The clinics will be randomly assigned (like flipping a coin) to one of the following treatment arms. The clinics will each have a 50/50 chance of being in either group.

1. Local Care +: Quarterly visits with the patient and primary care provider.

2. Team Care: Group counseling via Zoom teleconference visits, led by a lifestyle coach working at KUMC; quarterly individual visits with the patient and lifestyle coach via Zoom; and quarterly team-visits with the patient, lifestyle coach and the primary care provider, in-person or via Zoom.

Patients from participating clinics are being recruited for the trial. If you decide to participate, you will receive the treatment assigned to your primary care clinic. Clinics will receive their arm assignments AFTER all 35 patients have been enrolled at the clinic.

If you are interested in being in the study, the researchers will ask you to complete an informed consent visit via Zoom with KUMC staff. KUMC staff will explain the study to you. If you are interested in participating, you will be asked to read this consent form. If you decide to participate you will be asked to sign the form. You will be given a copy of the form.

The primary objective of the study is to decrease your calorie intake, improve your diet quality, and increase your physical activity with a goal to achieve 10% weight loss over the first 6 months of the program, followed by maintenance of diet and physical activity behaviors for the next 12 months.

If you are assigned to the Local Care + arm

You will be given the following:

- Fitbit aria air home smart scale
- Fitbit activity tracker, including access to the Fitbit app.

You will be asked to do the following:

- Meet with your primary care provider for weight loss coaching on a quarterly basis, for a total of 6 visits.
- You will start meeting with your provider approximately 2 - 4 weeks after your consent visit.

During these coaching visits your primary care provider will help you develop an individualized weight loss plan that focuses on decreasing calorie intake, improving your

diet quality and increasing regular physical activity. To help you lose weight your primary care provider may discuss various other weight loss topics with you such as self-monitoring, goal setting, smart grocery shopping, meal planning, and managing triggers. Your provider may give you hand-outs on nutrition and physical activity to help with your weight management.

If you are assigned to the Team Care arm:
You will be given the following:

- Fitbit aria air home smart scale
- Weight loss and weight maintenance manuals
- Fitbit activity tracker, including access to the Fitbit app
- 18-month premium subscription to the fitness app, MyNetDiary

You will be asked to do the following:

- *Attend group weight loss coaching sessions*. You will start your coaching sessions approximately 4 – 6 weeks after your informed consent visit. You will receive 30 telemedicine-based group coaching sessions with a remote lifestyle coach. About 12 people from your provider's office will be in your group. Coaching sessions will each last 60-minutes and will be held via secure Zoom web-conferencing and recorded for quality assurance and training purposes. Sessions will be scheduled at a standing time (e.g., early morning, over the lunch hour, evening) and occur weekly for 12 weeks, bi-weekly for 12 weeks, and monthly for 12 months. You will need to use your own computer or mobile device and data plan to join the sessions. Prior to the first session, you will be provided technical assistance with an individual practice connection.

  During the sessions, you will use your weight loss and weight maintenance manuals, learn about the diet you will be asked to follow, and receive education on nutrition and physical activity. You will be instructed to eat 5 or more servings of fruits and vegetables per day and you will be encouraged to eat pre-portioned meals and nutritional shakes available at the grocery store to meet your calorie goals, and you will be given lists of recommended foods. You will be asked to work up to 225-250 minutes per week of moderate intensity exercise, such as brisk walking, in bouts of at least 10 minutes. You will work up to this goal slowly, beginning with 15 minutes per day, 3 days per week.

  You will be taught self-monitoring skills, learn ways to change your habits related to diet and exercise, be given the opportunity to share your experiences with other people in the group, and ask questions and problem-solve about how to lose weight and overcome barriers. You will also learn about how diet and physical activity impact disease risk.

  In some instances, a family member of a participant my also join the group if needed to support and assist with their participation.

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- *Track your diet, physical activity and weight*. As part of self-monitoring, you will be asked to keep track of the food you eat and monitor your physical activity and weight. You will be asked to log the food you eat in the MyNetDiary app. You will

be asked to wear the Fitbit activity tracker to capture your steps and minutes of physical activity per day. You will be asked to weigh yourself at least once per week using your smart scale. The smart scale will transmit your weight via Bluetooth to your Fitbit tracker. The premium MyNetDiary subscription includes a feature that will allow your Fitbit activity data to be synced to your MyNetDiary account. This will allow your diet, physical activity, and weight data to be stored in one place. While you have the study provided premium MyNetDiary account, your KUMC lifestyle coach will be able to view your tracking data.

To use your Fitbit tracker you will need to download the Fitbit app to your smart phone or computer, create a password protected Fitbit account with your personal email, then pair your tracker with your smart phone or computer. You will be asked to read and accept Fitbit's privacy policy, and asked to enter your birthdate, height, weight and sex.

To pair your aria air smart scale with your Fitbit tracker you will login to your Fitbit account and set up a new device using the menu options and on-screen instructions. Your aria air will then pair to your Fitbit tracker via Bluetooth.

To begin using the premium MyNetDiary account, you will need to download the app to your smart phone or go to www.mynetdiary.com on your computer and create a new password protected account using your personal email. You will be asked to enter your birthdate, height, weight and sex. Using the menu options in MyNetDiary you will link your MyNetDiary account with your Fitbit account and authorize MyNetDiary to access your Fitbit data.

If you prefer, you may use paper forms to track your diet and physical activity and mail or fax the forms to your lifestyle coach on a weekly basis.

- *Attend Individual Sessions with your KUMC Lifestyle Coach.* Each quarter, prior to a team visit, you will meet individually with your lifestyle coach to review your current progress toward your goals; discuss your health, diet and physical activity; and review your medications. Your coach will prepare a brief report summarizing your progress and any challenges you may be facing and share the report with your provider. The first individual session will occur a couple weeks before or after the group starts. You will have 6 individual sessions with your lifestyle coach over the course of the study.

- *Attend Team Visits*. Following your individual sessions with your lifestyle coach, you will meet with your provider to discuss your health and weight loss efforts. Your provider will review the progress report provided by the lifestyle coach and use it to guide the discussion. Your lifestyle coach will join via telemedicine to facilitate. You will have 6 team visits with your provider and lifestyle coach over the course of the study.

Patients in both arms will be asked to complete the following:

- Data Collection Visits. You will meet via Zoom with KUMC staff four times for data collection over the course of the 18-month period--at the consent/baseline visit and at 6 months, 12 months and 18 months. At each of these visits, KUMC staff will observe you measuring your weight on your study provided smart scale. They will also review and document your current medications at these visits.

- Questionnaires. At the 6, 12 and 18-month timepoints you will be asked to complete a series of questionnaires either online or via paper. The surveys will ask questions about your current health status, diet quality, physical activity, quality of life, and how you feel about your communications with your provider (and the KUMC lifestyle coach if you are in the Team Care arm.)

- Patient Experience Interview. A subset of participants (1 or 2 from each clinic) will be randomly selected for an interview to help researchers better understand barriers to weight loss and maintenance, experiences with provider and team-based visits, and barriers related to living in a rural community. These interviews will be recorded. You do not have to agree to do the interview to be in the study.

What are the risks of being in the study?

Time and Effort Risks. In both arms, study participation will involve meeting periodically with your primary care provider and completing various data collection activities over the 18-month study period. In the Team Care arm, participation will also involve attendance at weekly to monthly coaching sessions and periodic visits with your lifestyle coach.

Exercise Risks. You may feel some tiredness during your exercise, and your heart rate and blood pressure will increase. Under extreme conditions, this can lead to a serious cardiac event such as a heart attack, but this risk is very rare. There is also a risk for physical activity related injury, such as a sprained ankle or falling. To protect against these risks, during the screening process your clinic provider reviewed your medical history, assessed your suitability for participation in the study, and gave his/her approval for you to participate in the intervention. To further guard against risk, the intervention recommends a gradual increase in physical activity and use of moderate rather than high intensity activities.

Rapid Weight Loss Risks. Losing weight very quickly (more than 3 pounds per week for several weeks) is typically associated with very low-calorie diets and may lead to inadequate nutrition or gallstones. This study recommends a higher calorie diet (>1000 kcal/day) to guard against these risks. Some patients with diabetes may be susceptible to low blood sugar. Weight loss also has the potential to increase risk of low blood pressure for patients who are using medications that lower blood pressure.

Questionnaire, Data Collection, and Weight-Management Coach Risks. There is a risk that you may feel uncomfortable answering some of the questions in the questionnaires.

Another risk is that you may feel uncomfortable when measuring your weight during the data collection visits or talking about weight or health issues with your provider. If you are in the Team Care arm, you may feel uncomfortable in the group coaching sessions or when meeting individually with your lifestyle coach. If you feel uncomfortable at any time you may stop sharing or participating all together.

Social, Cultural or Legal Risks: There are minimal to no social, cultural or legal risks to your participation in the study.

Financial Risks: You may have a co-pay or be billed for your quarterly team visits with your provider if your insurance does not cover the cost of each visit or if you do not have insurance. It is anticipated however that at least some of the visits will be covered by insurance under your normal standard care.

The study team may communicate with you via text to send appointment and survey reminders, etc. Standard text messaging rates may apply based on the plan you have with your mobile phone carrier. As text message delivery is subject to mobile carrier network availability, message delivery is not guaranteed. You may opt out of these texts by replying “STOP” to any study messages you receive.

Participants in both arms may incur data use charges when you join any of the Zoom data collection visits. In the Team Care arm you may incur data use charges when you join the group Zoom sessions.

In the Team Care Arm you will be responsible for paying the cost of the data used by the myNetDiary or Fitbit apps based on the rates of your mobile phone plan. In the Local Care + arm, if you use the Fitbit tracker provided by the study, you will be responsible for paying the costs of any data used by the Fitbit app based on the rates of your mobile phone plan.

Privacy and Confidentiality Risks. Risks to privacy and/or confidentiality may result from sharing private identifiable or personal information with the study team. In both arms, staff at your primary care clinic will know you are participating in the study for visit scheduling and other study purposes.

Text messages shared with the study team may not be secure and could be read by others (e.g., if your phone is unlocked and someone sees your messages). You should make sure to protect your phone with a password to protect your privacy. You may opt out of these texts by replying “STOP” to any study messages you receive.

Patients in both arms will use the Zoom application to attend data collection visits with KUMC staff. These visits will not be recorded. Patients in the Team Care arm will also use the Zoom app for the coaching sessions and for the 1:1 and Team Visits. Participants in the Team Care arm will also use the MyNetDiary and Fitbit mobile applications that are provided by vendors not associated with KUMC. Participants in the

Local Care + arm may use the Fitbit mobile application. Although every reasonable effort has been taken, confidentiality during internet communication procedures cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study. Before signing up for and downloading these mobile apps, please carefully review their terms of agreement and/or privacy policy to learn more about how your personal information could be used for the vendor's business purposes. We cannot protect or safeguard the confidentiality or integrity of your personal data if you use an insecure network to transmit your data over the internet. The research team is available to answer additional questions.

The Fitbit Aria Air home smart scale, Fitbit activity tracker, and Zoom conferences used by participants in both arms, may use Bluetooth to send and receive data. Private information sent by Bluetooth could be intercepted by others. There are weaknesses in Bluetooth that people can take advantage of to view information. These weaknesses can also make it possible to control devices that use Bluetooth. Bluetooth connections can be made with devices that are 160 feet away or less.

If you are in the Team Care arm, you can install the MyNetDiary app on your phone if you want to. Using the app may have some risks. Private information could be intercepted by others while you use the app. The app is designed to send and receive information with encryption, which makes it very difficult for others to view the data. However, many free Wi-Fi hotspots in public places are not secure and this makes interception possible. It is not always easy to tell if a Wi-Fi connection is protected or not. If you lose your phone or lend it to others, they may be able to see information about you. You should make sure to protect your phone with a password if you decide to install the app for this study. There are ways to disable your phone remotely if it is lost or stolen. This is something that you should set up on your phone. For example, on an iPhone, the Find My iPhone app can locate your phone and erase its data. Another risk of using the mobile app is that others around you may be able to see your screen. They may be able to see private information that you do not want to share.

If you are in the Team Care arm additional risks to privacy and/or confidentiality may result from sharing information with other patients participating in the group coaching sessions. In some instances, a family member of a participant my also join the group if needed to support and assist with their participation. Ground rules will be established at the beginning of the study to include recommendations to join sessions from a private room or location and for all participants in the group sessions to respect the privacy of the other participants. There is however, a risk that confidentiality could be breached by another participant. Because first names and likenesses will be recorded during the group Zoom sessions, there is a risk your confidentiality may be breached if recordings are not securely maintained.

In both arms, your information will be protected as described in the confidentiality and privacy section below.

Are there benefits to being in this study?
You will receive an 18-month behavioral weight loss intervention, a smart scale and an activity tracker. You may benefit by losing weight and maintaining that weight loss.

If you are in the Team Care arm you will also receive weight loss and maintenance manuals, and 18-months use of myNetDiary, a premium fitness app.

The information gained in this study will help determine if alternative ways of managing obesity in rural areas can help people lose weight and maintain that weight loss long-term.

Will I have any costs or payments for being in the study?
You received a ClinCard (which works like a debit card) with a $25 balance for completing the baseline survey. You will receive an additional $25 in your ClinCard account for completing your consent and baseline data collection visit. You will receive $50 in your account for completing the follow-up data collection visits and surveys at 6, 12 and 18 months. If you are selected for, and complete the participant interview, you will receive $20. In total, if you complete all regularly scheduled visits and surveys and complete the participant interview you will receive $220. If you leave the study early, you will be paid only for the visits and surveys you complete. Within a week of each data collection visit, payment will be added onto your card by computer. The money will be available within 1 business day. You can use the ClinCard at an ATM or at a store. No one at KUMC will know where you spend the money. If your card is lost or stolen, please call (866) 952-3795.

In addition, if you complete both the survey and Zoom weigh-in visit at the final 18-month milestone, your name will be entered into a drawing for a $200 gift card or a comparably priced item, eg. i-Pad. One drawing will be held at your clinic after data collection activities at the practice are complete. You will be notified of the outcome after the drawing if your name is entered.

The KUMC Research Institute will be given your name, address, social security number, and the title of this study to allow them to set you up in the ClinCard system. Study payments are taxable income. A Form 1099 will be sent to you and the Internal Revenue Service if your payments are $600 or more in a calendar year. If you do not provide a valid social security number or tax identification number, 30% of your payments will be set aside by KUMC and sent to the IRS for withholding on your behalf.

Will the researchers get paid for doing the study?
The institution (KUMC Research Institute, Inc.) will receive payments from the sponsor, NIH, for conducting this study. Payments will be used for research purposes only.

What other choices do I have if I don’t want to be in the study?
You can choose not to be in the study. You can decide to leave the study at any time. Leaving will not affect the treatment or services you get at KUMC.

How will my confidentiality and privacy be protected?

The researchers will keep your identity confidential, as required by law. Absolute confidentiality cannot be guaranteed because persons outside the study team may need to look at your study records. In the Team Care arm, in some instances, a family member of a participant my also join the group if needed to support and assist with their participation.

The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

If you sign this form, the research team will collect, use and share your private health information as described below. If you decide not to sign this form, you cannot be in the research study.

Study data includes information from your study activities and from your medical record. Your health care providers may release your private health information to Dr. Befort and the research team. The team may use any and all of your information needed for the study. Your medical records may contain your name, address, phone, date of birth, social security number, or other identifiers. Others at KUMC might need to look at your research records. They include KUMC Research Institute, the Institutional Review Board or other committees and offices that review and monitor research studies.

You may not be able to see your records relating to the study until after the study is over and the results are known. Any research information that is put in your medical record will be kept indefinitely.

The research team will share your study data with people outside KUMC. These groups or agencies may make copies of study data for audit purposes. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may not protect it. These groups may include:

- Federal agencies that oversee human research (if a study audit is performed)
- Experts who inspect the study information to see if the study is being done correctly and if it is still safe to continue
- Other groups that help manage or provide services to support the study
- Ethics committees that review the study for other locations

Your permission to use and share your health information will not expire unless you cancel it. To cancel your permission, please write to Dr. Befort. The mailing address is Dr. Christie Befort, University of Kansas Medical Center, 3901 Rainbow Boulevard, MS 1008, Kansas City, KS 66160. If you cancel your permission, you will be withdrawn from the study. The researchers will stop collecting any additional information about you unless they need information about a side effect of the study intervention. They are permitted to use and share information that was gathered before they received your

cancellation.

The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

Certificate of Confidentiality
This research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). This protects the researchers from being forced to give out personal information about you for legal proceedings. This does not stop you from voluntarily releasing information about yourself or your participation in this research.
One exception to the Certificate is if you agree that we can give out research information that identifies you. Your information will be shared for the purposes listed in this consent form. Other exceptions are information we must report if we learn about child abuse or neglect or if we think you might harm yourself or others.

Information about your research participation may be included in your medical record. The Certificate of Confidentiality does not prevent releases of information in your medical record for routine purposes such as treatment or billing purposes. Any research information in your medical record might be included when copies are sent for routine purposes.

What if I decide to leave the study?
You can choose to cancel your permission for researchers to use your health information. If you want to cancel your permission, please write to Dr. Befort using the contact information provided above. If you cancel permission to use your health information, you will be withdrawn from the study. The researchers will stop collecting any additional information about you about you unless they need information about a side effect of the study intervention. They are permitted to use and share information that was gathered before they received your cancellation.

Will I be told about research results?
You will be told about any study results that directly affect your personal medical care. At the end of the study, we will send you a letter with a summary of the results.

How will my research information and specimens be used in the future?
In the future, researchers at KUMC and at other locations might re-use the information from this study for other research. If that happens, information that could identify you will be removed first. You will not be asked if you agree to the future research that has identifiers removed.

Who can I talk to about the study?
Dr. Befort or other members of the study team should answer all your questions before you sign this form. They will also tell you if they learn anything new that might affect your decision to stay in the study. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints. If you have questions about your

rights as a research subject, or if you want to talk with someone who is not involved in the study, you may contact the KUMC Institutional Review Board at (913) 588-1240 or humansubjects@kumc.edu.

CONSENT

Dr. Befort or the research team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

By signing this form, you say that you freely and voluntarily consent to participate in this research study. You have read the information and had your questions answered. ***You will be given a signed copy of the consent form to keep for your records.***

_____
Print Participant's Name

_____ _____ _____
Signature of Participant Time Date

_____
Print Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

In the future, the researchers may conduct additional studies about obesity. If you agree, the researchers may contact you to see if you want to join future studies. You would receive a separate consent form describing the future studies.

☐ Yes, I would like to be contacted if I qualify for future studies. _____
Signature

☐ No. Please do not contact me about future studies. _____
_ Signature

Schedule of Activities

Timeline	Quarter		Q1			Q2			Q3			Q4			Q5			Q6	
	Month	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**
Local Care +	Quarterly Visits with Primary Care Provider (6 sessions)	1			1			1			1			1			1		
Team Care	Group Coaching Frequency	Weekly (for 12 Wks)			Bi-Weekly (for 12 Wks)			Monthly (for 12 Months)											
	Group Coach Sessions (30 total)	4	4	4	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1
	Individual Sessions (6 total)	1			1			1			1			1			1		
	Team Visits (6 total)	1			1			1			1			1			1		
Data Collection	Milestones	BL					6M						12M						18M
	Surveys	X					X						X						X
	Physician Clearance to Participate	X																	
	Consent	X																	
	Weight	X					X						X						X
	Medication Televideo Interview	X					X						X						X