DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
A Novel Telehealth Intervention using Nutrition and Exercise to Extend Intervention Benefits: Enhancing Physical Function in the Long-term for Older Adults Aim 2

CONCISE SUMMARY

The purpose of this research study is to learn about motivators, facilitators, and barriers of maintaining physical function and weight loss in older adults who have previously participated in a weight loss intervention and to develop and test a virtual nutrition and low-intensity chair exercise intervention using video-conference technology to maintain and extend the functional benefits following a weight loss intervention. Individuals who have completed a weight loss intervention within the last 9 months and lost ≥ 3% of body weight and improved their physical function will be eligible to participate. Study eligible participants will participate in a 12-week trial in which they will attend bi-weekly virtual nutrition and exercise sessions and bi-weekly telephone check-ins on the weeks not attending the virtual nutrition and exercise sessions. Participants will also wear a physical activity tracker as they work to increase their step counts and weekly physical activity. We will loan you a tablet to use for video-conferencing and train you to use it and you will be provided an activity tracker that you can keep once the study is complete. You will complete 3 assessments – one before starting the tele-nutrition and tele-exercise intervention, one at 6 weeks, and one following the 12 week intervention. Participants will come to Duke to complete the baseline screening visit and 12-week assessments. The 6-week assessment will be completed virtually. These assessments will take an hour to complete. Total study participation is about 15 weeks.

The greatest risk of being in the study is possible fatigue and muscle soreness associated with physical activity, possible loss of confidentiality, and that some topics covered in the interviews may make you feel some increased distressed.

If you are interested in learning more about this study, please continue reading below.

You are being asked to take part in this research study because you have previously participated in a weight loss intervention. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

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A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of Dr. Kathryn Starr and her research team's salaries will be paid by this grant.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, you will continue to receive care through your current providers. You should be in contact with your regular health care provider throughout the time that you are in the study and afterwards as needed.

WHY IS THIS STUDY BEING DONE?
The purpose of this research study is to test a tele-nutrition and tele-exercise intervention to maintain and extend the functional benefits following a weight loss intervention.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 15 people will take part in this study at Duke.

WHAT IS INVOLVED IN THE STUDY?
If you agree to be in this study, you will be asked to electronically sign and date this consent form. This study will ask your involvement in the following:

Pilot Trial (up to 15 participants; 2 in-person visits; 12 weeks)

Virtual Consent (Visit 1)
You will attend a virtual consent presentation during visit 1 conducted via Zoom or Webex. The consent presentation will include information about the study such as staff members, background, design, eligibility criteria, risks, and study timeline. Following the presentation, you will receive a link to review the electronic consent form. If you have questions, you may set up a time to ask questions, one-on-one, with the Clinical Research Coordinator or an Interventionist. If you are still undecided, you are welcome to take more time and think about it further. Following the consent presentation and signing of the consent form electronically, you will be scheduled for an on-site screening visit, Visit 2, to confirm your eligibility to participate in the study.

In-person Baseline Screening testing (Visit 2)– You will be asked to come to the Stedman Nutrition Center at Duke Center for Living to complete this visit. During this visit, you will complete a health history and we will measure your height and weight to assess your eligibility for the study. You will also undergo assessments of physical function, including the Short Physical Performance Battery, 30-second chair stand, 2-minute step test and a hand grip-strength measurement to test your upper body strength. Next, you will be loaned a tablet to use for the duration of the study. You will work with a member from the research team to practice logging in to the Zoom application that we will be using for the

intervention and assessment portions of this study. Next, you will be given a Physical Activity Monitor (Garmin), which you will wear for the remainder of the study. A member from the research team will help you download the commercially-available Garmin Connect mobile application to your provided tablet or your personal smartphone (you will be asked to agree to the terms and conditions listed in the Garmin Connect user agreement). You will receive an instruction sheet on how to use the Garmin and contact information in case you have any technical difficulties or questions during the study. You will complete Additionally, a member from the research team will provided detailed instructions and walk you through the virtual functional assessments that will be done using the Zoom platform at your home. Finally, you will be given a scale to record weekly weights. This visit will last approximately 90 minutes. This and the last visit at 12-weeks will be in-person, all other interactions will be done virtually.

Virtual Baseline testing (Visit 3) – Following the in-person baseline test, you will be asked to complete questionnaires regarding your quality of life, mental health, dietary intake and medical history using an electronic device and a link sent to your email. If you would prefer to complete these on paper rather than electronically, we will provide them at the in-person session along with self-addressed envelopes for you to mail back to us. Next, a trained member from the research team will conduct a video conference using Duke Zoom were they will administer the virtual physical function assessment. Completion of these questions and virtual assessment should take approximately 60 minutes to complete and will be done at baseline, 6-weeks, and 12-weeks.

Virtual Intervention (12 weeks)
Virtual one-on-one: There will be a one-on-one session to identify goals and determine calorie and exercise requirements.

Bi-weekly Virtual Intervention and check-ins: Following the one-on-one, you will participate in bi-weekly virtual nutrition and exercise intervention classes and check ins using video conferencing (Zoom) on the tablet. You will be participating in a group with other individuals like you. Each group session and check in will be lead by a Registered Dietitian or Interventionists. The group sessions will last 1 hour and 30 minutes where the focus will be on teaching skills to overcome personal and environmental barriers to enhance your ability and confidence to engage in physical activity and healthy eating habits. Additionally, a 15 minute guided exercise for older adults will be done at the end of each session to introduce you to different exercise types. These will include exercise videos developed by the National Institute on Aging specifically for older adults. Between every class an interventionist will conduct a 15–30 minute check in call with you to help you set goals and overcome any challenges you may be facing in regard to your ability to continue your weight maintenance. You will be asked to weigh yourself weekly with the scale provided and record your daily step counts.

Daily Walking: You will also be asked to spend time walking, on your own, to meet your individualized

daily step count goal. At Baseline, you will wear an activity monitoring device for 7 days and an average baseline step count will be determined and rounded up to the nearest 250 steps. You will then be asked to not go below your baseline step count throughout the duration of the study.

Weekly Exercise: We will also encourage everyone to exercise on their own for at least 30 minutes 3 times a week for the duration of the study.

Virtual Midpoint Testing (Visit 4) - At 6 weeks, you will be reassessed. You will be sent a link to complete questionnaires (or paper versions and mail them in) and a trained member of the research team will complete the virtual physical functional assessments as done at baseline.

Virtual Endpoint Testing(Visit 5) – After 12 weeks of participating in the intervention, you will be reassessed. You will be sent a link to complete questionnaires (or paper versions and mail them in) and a trained member of the research team will complete the virtual physical functional assessments. This should take approximately 60 minutes to complete both the questionnaires and virtual functional assessment.

In-person Endpoint Testing (Visit 6) – You will be asked to come to the Stedman Nutrition Center at Duke Center for Living to complete this visit. During this visit you will return your tablet and we will measure your weight and conduct functional assessments. Finally, we will ask you to complete a survey and provide feedback about your experience in the study.

HOW LONG WILL I BE IN THIS STUDY?

As a participant in the intervention, you will be in the study for about 15 weeks. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled.

WHAT ARE THE RISKS OF THE STUDY?

There are certain risks associated with participating in the study. You may discuss these risks with your health care provider if you choose.

The known risks are:

- Exercise: Mild to moderate physical activity is not without risk. The most common adverse consequences associated with participation in physical activity are fatigue and muscle soreness. There is also an increased risk of falling during exercise.
- Loss of Confidentiality – Loss of confidentiality is always a potential risk and every effort will be made to keep your information confidential; however, this cannot be guaranteed. You may refuse to answer any of the questions asked.

  - You should not use the tablet for personal use (for example, internet searching, texting, emailing, storing personal contacts, and downloading mobile apps) during the study. If you do so, this could add your personal information onto the tablet and potentially result in it being disclosed or sent to unauthorized persons. When you return the tablet at the end of the study, it will be cleaned to remove any of your personal information. If the tablet is lost or stolen during the course of the study, please contact the study team immediately.
  - There is some risk of loss of confidentiality due to the use of video conferencing to conduct the study intervention sessions. You will use Duke Zoom video conferencing program to participate in your sessions.
- Discomfort from questions – Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions, and you may take a break at any time during the interview process.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there may not be direct medical benefit to you. However, you find that your participation in the study intervention improves your ability to achieve lifestyle modifications that could be sustained as a part of your personal health regimen in the setting of your community environment. We also hope the information learned from this study will benefit others through a greater understanding of how to best maintain physical function following an intensive weight loss intervention.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of the study, results of your study-related tests may be reported to **NIH** and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives and affiliates of NIH, the Duke University Health System Institutional Review Board, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

As part of this study, Dr. Starr and her study team will ask you to complete questionnaires and assessments. Results of the assessments will not be included in your medical record as these are solely for this research study and not part of your regular care. The study results will be retained in your

research record for at least six years after the study is completed. At that time the research information not already in your medical record will be destroyed, or the information identifying you will be removed from the study results at DUHS. Any research information in your medical record will be kept indefinitely.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2) you have consented to the disclosure, including for your medical treatment; or

3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations.

If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

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Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO YOU?
There will be no costs to you as a result of being in this study

WHAT ABOUT COMPENSATION?
You will be reimbursed up to $100 for your expenses related to your participation (parking, gas, and time). You will be compensated $25 for completing the baseline assessment, $25 for completing the 6-week assessment and $50 for completing the 12-week assessment. Additionally, you will be able to keep your Garmin activity tracker for participating in this research study.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Kathryn Starr, PhD, RD at (919) 660-7571 during regular business hours and at (770) 363-8312 after hours and on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Starr in writing and let her know that you are withdrawing from the study. Her mailing address is Dr. Kathryn Starr, PhD, 201 Trent Drive, DUMC, Box 3003 Durham, NC 27710.

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We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Kathryn Starr at (919) 660-7571 during regular business hours and at (770) 363-8312 after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

Do you consent to participate in this research study?

- ○ Yes
- ○ No