

Title: Person-Centered Approach to Promoting Healthy Weight and Reducing Pain in Older Adults in Camden-New Jersey

Identifiers: NCT07095673

Document Date: 2/17/2025

CONSENT TO TAKE PART IN A RESEARCH STUDY

Title of Study: HealthyWE: Person-Centered Approach to Promoting Healthy Weight and Reducing Pain in Adults in Camden New Jersey

Principal Investigator: Thomas A. Dahan, PhD

STUDY SUMMARY: This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not.

The purpose of this proposed project is to pilot test a weight loss program called HealthyWE will help adults lose weight and decrease pain among adults in Camden City New Jersey. The proposed study is a one group pretest and posttest design.

If you take part in the research study, you will be asked to complete weekly in-person 60-minute sessions over the course of 13 weeks. We will provide a FitBit-style tracking device to help you monitor your physical activity but will not collect any information from tracking device.

We will ask you to complete questionnaires about your health and quality of life. We will also measure your height and weight. You will have three in-person visits to complete the questionnaires and to have your height and weight measured which will take approximately 60 minutes each. The first visit will occur before you start the weight loss program. The second visit will occur in the 5th week of the program. The third visit will occur two months later after completing the weight loss program.

Your time in the study will take 13 weeks.

Possible harms or burdens: Possible risks or discomforts to you for participating in this study are very low. There are no known risks for participating in the muscle-tightening deep breathing muscle-tightening pumping, and shoulder exercises and no injuries and complaints have been reported from our previous research. However, you may feel like your privacy is being invaded by completing the research study questionnaires

Possible Benefits of taking part in the study:

There are some direct benefits that you may expect from your participation in this study. You:

- (a) May feel empowered by learning about self-management strategies to manage hydration, a healthy diet and weight by following a nutrition-balanced diet.
- (b) May relieve your pain by carrying out the self-management strategies of home-based exercises.
- (c) May improve quality of life and mental health symptoms by managing stress and carrying out sleeping hygiene practices.

An alternative to taking part in the research study. You are free to participate in other research studies on weight loss and decreasing pain. Your alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this study?

Dr. Thomas Dahan is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

Dr. Thomas Dahan may be reached via email: Tom.dahan@rutgers.edu or office at 856-225-2344.

The Principal Investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Sponsor of the Study:

This study is funded by the New Jersey Department of Health

Why is this study being done?

This study is being done to reduce and manage obesity and increase self-efficacy for keeping a healthy weight and improve pain, quality of life, and mental health symptoms using the **HealthyWE** Program among adults in Camden City New Jersey.

Who may take part in this study and who may not?

Any English-speaking individual with age greater than 19 years who are active with no impairment or physical and mental disabilities with Body Mass Index (BMI) of greater than 25. Non-English speaking individuals may receive translation services.

Why have I been asked to take part in this study?

You have been asked to take part in this study because you have concerns about your weight and experiencing pain.

How long will the study take and how many subjects will take part?

This study will last 13-weeks. A total of 80 study subjects 19 years of age and older will take part in this study.

What will I be asked to do if I take part in this study?

In this study you will be asked to:

- Participate in trainings where you will practice the home-based exercises for 13 weeks.
- Record when you practice the exercises with the FitBit tracker that we will provide to you.
- Participate in sessions of in-person 60-minute session over the course of 13 weeks.
- Participate in three in-person research visits of 60 minutes each to:
 - Complete questionnaires about your health and quality of life.
 - Measure your height and weight

What are the risks of harm or discomforts I might experience if I take part in this study?

There are no known risks of harm or discomforts of taking part in the study and the burden of taking part in the study is minimal. There are no foreseeable risks when individuals perform the home-based exercises of muscle-tightening deep breathing, muscle-tightening pumping, and shoulder exercises. No injuries and complaints have been reported from our previous research.

You may feel like your privacy is being invaded by completing the questionnaires.

It is possible that you may become tired during the study interviews

Are there any benefits to me if I choose to take part in this study?

The benefits of taking part in this study may be that you relieve your pain by performing the home-based exercises. You may also experience an improvement in your quality of life and feel empowered by learning about strategies to manage your weight.

However, it is possible that you may not receive any direct benefit from taking part in this study.

What are my alternatives if I do not want to take part in this study?

There are no alternative treatments available. Your alternative is not to take part in this study.

How will I know if new information is learned that may affect whether I am willing to stay in the study?

During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will I receive the results of the research?

In general, we will not give you any individual results from the study. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Will there be any cost to me to take Part in this study?

There will be no cost for you to participate in this study.

Will I be paid to take part in this study?

You have the option to enroll as an AmeriCorps member, which provides \$1,100 in compensation for participating in 100 hours of community service. The activities we teach you will contribute to your accumulated hours. In addition, all participants will receive a FitBit-style tracker as incentive to participate, and this is yours to keep.

How will information about me be kept private or confidential?

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

The research team will keep your name on a list of people who have been in the study. In order to protect the information we have about you, the list of names of people in the study will be kept in a password-protected computer file accessible only to members of the research team. You will be assigned a unique study ID code and the information produced by this study will be identified by a code number only. The code key connecting your name to specific information about you will be kept in a separate locked file cabinet and password-protected computer file.

The research team may use or share your information collected or created for this study with the following people and institutions:

- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- A description of this clinical trial will be available on [ClinicalTrials.gov](https://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 at any time.

What will happen to my information—data, recordings and/or images—and biospecimens collected for this research after the study is over?

Any information that could identify you will be removed to make it de-identified. The de-identified information collected for this research study may be used for other research we conduct without obtaining additional informed consent from you. This de-identified information may also be shared with scientific journals and at scientific conferences.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?

It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time. If you do not want to enter the study or decide to stop taking part,

your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

Who can I contact if I have questions?

If you have questions, concerns or complaints about the research, wish more information, you can contact the Principal Investigator: **Dr. Thomas Dahan at 856-225-2344 or via email: tom.dahan@rutgers.edu**

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research subject, you can contact the Rutgers IRB or the Rutgers Human Subjects Protection Program via phone at (973) 972-3608 or (732) 235-2866 or (732) 235-9806 OR via email irboffice@research.rutgers.edu, or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

AGREEMENT TO TAKE PART IN RESEARCH

Subject Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name (Print): _____

Subject Signature: _____ Date: _____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print): _____

Signature: _____ Date: _____