Official title: Lymphatic System Stimulation in Heart Failure

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# CONSENT TO TAKE PART IN A RESEARCH STUDY

**Title of Study:** Lymphatic system stimulation and fluid overload symptoms in patients with heart failure

**Principal Investigator:** Rida Gharzeddine, PhD, RN

**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 the research** is to evaluate a non-pharmacological, behavioral ***The-Optimal-Lymph-Flow* (TOLF)** program on fluid overload symptoms, such as pain, shortness of breath, swelling of legs or arms. fatigue and poor sleep in patients with heart failure.

This study is a randomized study. This means, like flipping a coin, you will be assigned to one of the two behavioral education groups (Group #1 and Group #2). There are no special requirements or criteria to be in either group. You will have 50% chance of being assigned to either Group #1 or Group #2.

If you take part in the research, you will be asked to participate in two in-person research visits and 3 telehealth sessions to learn self-management strategies to manage fluid overload symptoms. You will also be asked to weigh yourself daily in the morning and keep a log. Your time in the study will take 5 weeks and will also involve 2 in-person 40-60 minutes study visits at Cooper University Hospital to complete study questionnaires and measure your weight and height. During these research visits, you will also be asked to undergo bioimpedance measurement (flow of an electric current through body tissues which can then be used to calculate an estimate of total body water) on you while you are standing on the bioimpedance measurement scale to assess your body fluid change and your body composition. We will also measure your fluid in your upper body using an FDA approved devise that uses low-power electromagnetic signals.

**Possible harms or burdens:** No known harms of taking part in the study and the burden of taking part in the study is minimal. There are “no foreseeable risks” to practice the self-management strategies. No injuries and complaints have been reported from our previous research.

*Possible Benefits of taking part in the study*:
Whether you are assigned to Group#1 or Group #2, there are some direct benefits that you may expect from your participation in this study.

(a) May feel empowered by learning about self-management strategies to manage fluid overload symptoms.
(b) May relieve your pain, shortness of breath, swelling of extremities by carrying out the self-management strategies.
(c) May prevent your fluid build-up by being closely monitored for daily weight.

**An alternative to taking part in the research study**: Participation in this study is completely voluntary and you are not obligated 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 the questions and should expect to be given answers. 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. Rida Gharzeddine is the Principal Investigator of this research study., Dr. Mei Fu, Dr. Elizabeth Cerceo and Dr. Amine Al Soueidy are Co-Principal Investigators (Co-PIs) for 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. Rida Gharzeddine may be reached via email: rida.gharzeddine@rutgers.edu; or mobile phone 201-657-0912 or office at 856-225-6993

Dr. Mei Rosemary Fu may be reached via email: mei.r.fu@rutgers.edu or mobile phone 973-986-1758 or office at 856-225-6152.

Dr. Elizabeth Cerceo may be reached via email: cerceo-elizabeth@cooperhealth.edu; or mobile phone 856-577-8975 or office at 856-342-3150

Dr. Amine Al Soueidy may be reached via email: alsoueidy-amine@cooperhealth.edu; or mobile phone 267-694-4645 or office at 800-826-6737

The Principal investigator, Co-PIs, and or other members 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 supported by Rutgers Busch Biomedical Grant Program.

**Why is this study being done?**
This study is being done to evaluate acceptability and efficacy of “The-Optimal-Lymph-Flow (TOLF)”, a non-pharmacological behavioral program for patients with heart failure to reduce body fluid accumulation and fluid overload symptoms, including pain, shortness of breath, swelling of extremities, fatigue, and sleep symptoms.

**Who may take part in this study and who may not?**
Any English-speaking patient with heart failure who is greater than 18 years or older, has New York Heart Association (NYHA) functional class II to IV, and willing and able to complete the home-based TOLF self-management program upon discharge from the hospital to home.

**Why have I been asked to take part in this study?**
Because you have heart failure, have New York Heart Association (NYHA) functional class II, III, or IV, and have one of the following fluid overload symptoms of pain, shortness of breath, swelling of extremities, fatigue, and sleep symptoms.

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

This study will last 5 weeks and will involve 2 in-person research visits. In-person Visit #1 will be prior to learning the self-management strategies, and In-person Visit #2 will be right after you complete the program.

A total of 80 study subjects between the ages of 18 and 80 will be 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:

1. Participate in ONE in-person 40-minute behavioral program session to learn the self-management strategies to prevent fluid accumulation and manage fluid overload symptoms such as pain, shortness of breath and swelling of extremities.
2. Participate in THREE 15 to 20-minute telehealth sessions to enhance self-management strategies to prevent fluid accumulation and manage symptoms over the course of 4 weeks.
3. Participate in TWO in-person research visits of 40-60 minutes to:
    - Complete several questionnaires about your background (age, education, etc.), pain and symptoms, and quality of life.
      **You are free to skip any questions that you prefer not to answer.**
    - The researchers will measure your weight and height.
    - The researchers will assess your body fluid level using bioimpedance measurement (flow of an electric current through body tissues which can then be used to calculate an estimate of total body water) to assess your body fluid change and your body composition.

You will be assigned to Group #1 and Group #2 and receive the educational and behavioral program to learn self-management strategies to prevent fluid accumulation and manage symptoms. Self-management strategies in Group #1 and Group #2 are similar, that is, both programs are educational and behavioral programs focus on information about fluid accumulation, measurement of daily weight for fluid accumulation, lymphatic system, and self-management strategies. Patients assigned to Group #1 will receive self-management strategies to understand the importance of monitoring daily weight for fluid overload; and those assigned to Group #2 will receive self-management strategies to promote fluid flow and the importance of monitoring daily weight for fluid overload. There are no special requirements or criteria to be in either group. You will have 50% chance of being assigned to either Group #1 or Group #2. The teaching and follow up sessions will be audio-recorded. The audio recording will be used by the research team only. The purpose of the recording is to ensure the provided teaching and instructions were delivered as intended.

If you choose to take part in the study, we will ask you to sign this consent form before you have any procedures with the study staff that are part of the study.

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

No known harms of taking part in the study and the burden of taking part in the study is minimal. There are “no foreseeable risks” to practice the self-management strategies. No injuries and complaints have been reported from our previous research.

You may experience frustration that is often experienced when completing questionnaires. Some questions may be of a sensitive nature, and you may therefore become uncomfortable as a result. However, such risks are not viewed as being in excess of “minimal risk.” If, however, you become uncomfortable by questions, you may stop at any time or choose not to answer a question.

There are “no foreseeable risks” to practice the self-management strategies. No injuries and complaints have been reported from our previous research.

*Bioimpedance Measurement*: This is a noninvasive procedure. No immediate or long-range risks are foreseen from the use of the bioimpedance device for limb fluid change and body composition.

*The remote dielectric sensing (ReDS):* This is FDA approved device and uses low-power electromagnetic signals emitted between 2 sensors embedded in a wearable vest. No immediate or long-range risks are foreseen from the use of this device

**Are there any benefits to me if I choose to take part in this study?**
Whether you are assigned to Group#1 or Group #2, there are some direct benefits that you may expect from your participation in this study.

(a) May feel empowered by learning about self-management strategies to manage fluid overload symptoms and prevent lymph fluid build-up.
(b) May relieve your fluid overload symptoms and decrease fluid build-up by carrying out the self-management strategies.
(c) May prevent your fluid build-up by being closely monitored for daily weight.

**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 will receive compensations for taking part in this study according to the following schedule:

- $40.00 at your first visit (0-week visit)
- $40.00 at your second visit (5-week visit)
- A total of $80.00 ($20/per week) for 4 weekly submissions of your daily measurement of weight and record of your weight and blood pressure, and report of your symptoms on your second visit (5-week visit).
- You will also be given a digital scale for taking daily weight.
- You will also be given Omron Blood Pressure Monitor for daily blood pressure monitoring.

**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.

We will make every effort to protect your confidentiality. You will be assigned a unique study ID; study data

recording for the research will only use the subject study ID without your identifying information. Your study information will be stored in locked files accessible only to the research coordinator, research team members, or the PI and Co-PIs. Electronic data will be stored in a password protected computer accessible only to the PI and Co-PIs, the research team members, and the research coordinator. Data analysis will be carried out and reported in the aggregate data so that individual identities are not revealed. Your confidentiality will be protected for the online assessment since you will use your unique study ID to access the online assessment.

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, 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?**
After information that could identify you has been removed, de-identified information collected for this research may be used for other research we conduct without obtaining additional informed consent from you. This de-identified information may be shared with scientific journals where this research is published at the time of submission.

**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. Rida Gharzeddine at 201-657-0912 or 856-225-6993 Or via email: rg1041@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.

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## PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

**What Is The Purpose Of The Research And How Will My Information Be Used?**
You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help investigators answer the questions that are being asked in the research.

**What Information About Me Will Be Used?**

- All information in your medical record
- Medical history or treatment
- Medications
- EKG and/or EEG reports
- Pathology reports, specimen(s) or slide(s)
- Operative reports (about a surgery)
- Emergency Medicine reports

**Who May Use, Share or Receive My Information?**

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

- Rutgers University Investigators Involved in the Study
- 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

- Hospital Personnel as Necessary For Clinical Care:
    - Cooper University Health Care (Cooper)
- Non-Rutgers Investigators On the Study Team: Cooper University Health Care (Cooper)
- A data safety monitoring board

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

**Will I Be Able To Review My Research Record While The Research Is Ongoing?**
No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

**Do I Have To Give My Permission?**
No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

**If I Say Yes Now, Can I Change My Mind And Take Away My Permission Later?**
Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. Any data that has already been collected cannot be withdrawn because there may not be any identifiers to link the data with you.

If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell them of your decision: **Dr. Rida Gharzeddine at 201-657-0912-986-1758 or 856-225-6993 Or via email: rg1041@rutgers.edu**

**How Long Will My Permission Last?**
Your permission for the use and sharing of your health information will last until end of the research study.

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## 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: _____