The Feasibility and Effectiveness of a Remote Mind-Body Chair Yoga Intervention on Functional Mobility in Individuals with Lipedema: A Randomized Controlled Trial

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INFORMED CONSENT &

HIPAA AUTHORIZATION FORM

The Feasibility and Effectiveness of a Remote Mind-Body Chair Yoga Intervention on Functional Mobility in Individuals with Lipedema

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IRB Protocol Number	
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1. Invitation to Participate

You are invited to take part in a clinical research study for women with lipedema. Before you decide whether to participate, you must understand why the study is being done, what participation involves, the possible risks and benefits, and your rights as a research participant. Please read this form carefully and ask any questions you have before deciding.

2. Purpose of the Study

The purpose of this study is to examine the feasibility and effectiveness of a remote, gentle mind-body chair yoga intervention for individuals with lipedema. The study will examine whether participation in chair yoga combined with a support group is associated with changes in functional mobility and other quality-of-life outcomes.

The study will examine outcomes including functional mobility, pain, mental well-being, and lipedema symptom severity. Information collected from participants may help researchers better understand whether a remote mind-body approach is practical and potentially useful for people living with lipedema.

3. Why Am I Being Asked to Participate?

You are being asked to participate because you might meet the study's eligibility requirements for adults with lipedema. The research team will review your eligibility before enrollment.

4. How Many People Will Participate?

Approximately 70 participants are expected to take part in this study.

5. What Will Happen If I Participate?

If you agree to participate, you will complete an online consent process and baseline questionnaires. You will also complete questionnaires during and/or after the intervention period. The questionnaires will ask about your functional mobility, pain, mental well-being, lipedema symptoms, and general health. Some questionnaires may take approximately 30–40 minutes, depending on the assessment.

Participants will be randomly assigned to one of two study groups. Random assignment means that the group you enter is determined by chance rather than by you or the research team.

One group will participate in a gentle remote chair-yoga program together with a support group. The yoga program will include gentle movement, breathing practices, guided meditation, and related mind-body practices. The other group will participate in an online support group without the yoga intervention during the study period.

Participants in the support-group-only group will be offered the opportunity to receive the yoga intervention after completion of the study, subject to the study's operational schedule and resources.

The research team may provide online educational materials and study communications. You will be given instructions about the timing of questionnaires, sessions, and follow-up activities before you begin.

As part of the enrollment process, participants will be required to obtain medical clearance from their healthcare provider before beginning the study intervention. This clearance is intended to confirm that participation in the study activities, including gentle chair-based yoga, is appropriate based on the participant's current health status.

Participants should be aware of this requirement before signing the Informed Consent and HIPAA Authorization Form. Obtaining medical clearance may require contacting a healthcare provider and completing a study-specific medical clearance form. Participants will not be enrolled in the study or begin study activities until the required medical clearance has been received.

We recognize that obtaining medical clearance may require additional time or effort. This requirement is included as a safety measure to help ensure that participation is appropriate for each individual.

6. Study Duration and Time Commitment

Your participation is expected to last approximately 7 weeks, including baseline assessments, the intervention/support period, and follow-up assessments. The specific schedule will be provided by the research team.

Participants will be asked to complete a brief follow-up assessment online approximately three months after completing the study intervention. The assessment is intended to evaluate whether any changes experienced during the study are maintained over time.

7. Risks and Discomforts

The risks of participation are expected to be minimal; however, no research study is completely without risk. Possible physical discomforts from gentle movement may include muscle soreness, fatigue, temporary discomfort, or changes in swelling. As with physical activity, there is a possibility of injury. Breathing, meditation, or discussion of health experiences may also produce temporary emotional discomfort or emotional release.

Participants are encouraged to work within their own abilities, use modifications or props, rest when needed, and stop any activity that causes pain, dizziness, shortness of breath, or other concerning

symptoms. You should promptly report study-related concerns to the study team. If you believe you are experiencing a medical emergency, seek emergency medical care rather than waiting for a response from the research team.

You should discuss participation with your healthcare provider when appropriate, particularly if you have significant medical conditions, recent surgery, cardiovascular concerns, joint limitations, a history of cellulitis, or other conditions that could affect safe participation.

8. Possible Benefits

You may or may not receive a direct personal benefit from participating. Possible benefits may include increased awareness of movement, breathing, relaxation, self-compassion, or mind-body strategies. Participants may also experience changes in perceived mobility, pain, severity of your lipedema symptoms, or well-being; however, these benefits cannot be guaranteed.

The primary potential benefit of this research is the knowledge gained about the feasibility and potential effects of remote mind-body chair yoga for people with lipedema.

9. Alternatives to Participation

Your alternative is not to participate in the study. You may continue to receive routine care and pursue other activities or services that are available to you outside of the study. The research team can discuss questions about whether participation is appropriate for you.

10. Voluntary Participation and Withdrawal

Participation is completely voluntary. You may choose not to participate or may stop participating at any time, for any reason, without penalty or loss of benefits to which you are otherwise entitled.

If you decide to withdraw, the research team may ask whether information already collected may continue to be used. To the extent permitted by applicable law and the IRB-approved study procedures, information already collected may not be able to be removed from research records. The research team may also stop your participation if it is determined to be necessary for your safety, if you no longer meet study requirements, or if the study is stopped.

11. Confidentiality and Protection of Your Information

The research team will make reasonable efforts to protect the confidentiality of information collected during the study. Your research data will be assigned a study identification code, and identifying information will be kept separately from research data when feasible.

Research records may include your questionnaire responses, study participation information, and information necessary to conduct the study. Results may be presented at scientific meetings or published in academic or professional publications. Reports will use aggregate or de-identified information whenever possible so that individual participants are not identified.

Because this study is conducted remotely, electronic systems used for study communication, questionnaires, sessions, and/or data storage may involve the transmission of information over the

internet. The research team will use the study-approved systems and reasonable safeguards to protect study information.

Sessions are recorded for study administration or quality purposes; participants will be informed of the recording procedures and retention period before recording occurs.

12. Use of Your Research Information

Information collected for this study may be used for the research purposes described in this Informed Consent & HIPAA Authorization form and may be included in future scholarly reports related to this research, subject to the permissions and requirements of the approving IRB and applicable law.

12A. HIPAA Authorization for Use and Disclosure of Health Information

As part of this research study, you are required to obtain medical clearance from your healthcare provider before participating. By signing this consent form, you authorize your healthcare provider to disclose to the research team the health information requested on the study's Healthcare Provider Medical Clearance Form.

What information may be disclosed?

The information disclosed by your healthcare provider will be limited to the information requested on the Healthcare Provider Medical Clearance Form. This may include:

- your healthcare provider's determination regarding whether you may safely participate in this research study, including the gentle chair yoga intervention if you are assigned to that group;
- any precautions, limitations, or modifications your healthcare provider recommends for your participation; and
- any additional health information your healthcare provider chooses to include on the medical clearance form that is relevant to your safe participation.

This authorization does not authorize the research team to obtain your complete medical record or other health information from your healthcare provider that is not included on the Healthcare Provider Medical Clearance Form.

Who may disclose this information?

You authorize your healthcare provider, including the healthcare provider who completes the study's Healthcare Provider Medical Clearance Form and the provider's practice or organization, to disclose the information described above.

Who may receive and use this information?

The information may be received and used by the Principal Investigator, Co-Investigator, and authorized members of the research team. The information may also be reviewed by the Institutional Review Board (IRB) and governmental or regulatory authorities responsible for research oversight, as permitted or required by law.

Why will this information be used?

The information will be used to determine whether you meet the medical clearance requirements for participation in this study, to help protect your safety during participation, and to identify any precautions, limitations, or modifications recommended by your healthcare provider.

How long will this authorization remain in effect?

This authorization will remain in effect until the end of the research study, including completion of follow-up activities, unless you revoke it earlier in writing.

Can I revoke this authorization?

You may revoke this authorization at any time by notifying the Principal Investigator in writing at: cindy@cindybeers.com

Revoking your authorization will not affect health information that has already been disclosed or actions already taken in reliance on your authorization. Information already obtained may continue to be used as necessary to maintain the integrity of the research and as permitted by applicable law.

If you revoke your authorization before completing the study, you may no longer be able to participate because medical clearance and the use of related information are necessary for study participation.

Do I have to sign this authorization?

No. Signing this authorization is voluntary. However, the research team cannot enroll you in this study without the required medical clearance. Therefore, if you do not authorize disclosure of the information requested on the Healthcare Provider Medical Clearance Form, you cannot participate in this research study.

Your decision not to sign this authorization or participate in the study will not affect your regular medical care, payment for healthcare, health insurance enrollment, or eligibility for benefits.

Could my information be disclosed again?

The federal HIPAA Privacy Rule may no longer protect health information disclosed to the research team and could potentially be redisclosed. The research team will protect the confidentiality of your information as described in this consent form and as required by applicable law.

By signing this Informed Consent and HIPAA Authorization form, you authorize the use and disclosure of your protected health information as described in this section. You will receive a copy of the signed consent form, including this authorization.

13. Costs and Compensation

There is no fee to participate in this study, nor will you be paid for your participation.

14. Medical Care for Research-Related Injury

If you believe you have been injured as a result of participating in this study, contact the study team using the information provided above. During the chair yoga practice, you will be provided with modifications and options for each movement so that you can participate at a level that is appropriate for your individual abilities and comfort. You will be encouraged to move within a comfortable, pain-free range of motion and to respect your body's limitations. You are not expected to achieve a particular position, range of motion, or level of flexibility. You may choose the option that feels most appropriate for you, modify or reduce a movement, pause or rest as needed, or choose not to participate in a particular movement. The instructor will provide verbal guidance and alternatives throughout the practice to support safe and comfortable participation.

If you believe you have been injured, contact your medical provider.

The study does not provide payment for medical treatment or financial compensation for injuries or other medical problems resulting from participation. You or your health insurance may be responsible for the costs of any medical care you receive.

15. Questions About the Study

If you have questions about the study, study procedures, or a research-related concern, contact:

Cynthia (Cindy) Beers, MS, E-RYT500
Email: cindy@cindybeers.com
Phone: 717-571-4610

If you have questions regarding your rights as a research participant, contact Pearl IRB.
Monday through Friday, 9-5 EST/EDT
support@pearlirb.com
317-899-9341 (main)
https://www.pearlirb.com/
10300 Kincaid Dr., Suite 200, Fishers, IN 46037

16. Questions About Your Rights as a Research Participant

If you have questions about your rights as a research participant, or if you wish to discuss a concern independently of the study team, contact the Institutional Review Board using the information provided at the beginning of this form.

17. Statement of Consent

By signing below, you confirm that:

- You have read this Informed Consent and HIPAA Authorization Form and had the opportunity to ask questions.
- Your questions have been answered to your satisfaction, or you know whom to contact with additional questions.
- You understand the purpose of the study and what participation involves.

- You understand the possible risks and potential benefits of participation.
- You understand that participation is voluntary and that you may stop participating at any time without penalty or loss of benefits to which you are otherwise entitled.
- You understand the HIPAA Authorization described in Section 12A and authorize the use and disclosure of your protected health information as described in that section.
- You understand that you may revoke your HIPAA Authorization as described in Section 12A.
- You voluntarily agree to participate in this research study and authorize the use and disclosure of your protected health information as described in this form.

You will receive a copy of this signed Informed Consent and HIPAA Authorization Form for your records.

Participant Name (print): _____

Participant Signature: _____

Date: _____