Protocol
Version 2.1

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

IRB ID: 2026-0548

October 28, 2026

Administrative Information

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

2. **Protocol Version:** 2.1 (modified on 10/28/2026 using SPIRIT 2025)

3. **Roles/Responsibilities:** Principal Investigator/Sponsor - Cynthia Beers; Co-Investigator - Leslyn Keith; Research Coordinator/Data Manager - Siobhan Huggins; Statistical Analysis - Alexandre Amato, Joanna Dudek; Medical Consultants - Alexandre Amato, MD; Psychology Consultant - Joanna Dudek, PhD

Open Science

4. **Trial Registration:** This clinical trial will be registered with ClinicalTrials.gov.

5. **Protocol and statistical analysis plan:** The full protocol will be submitted for publication as a protocol paper and will be available at ClinicalTrials.gov once registered.

6. **Data Sharing:** De-identified participant data collected during the Mind-Body Chair Yoga Study will be stored on password-protected computers and in encrypted, password-protected cloud-based storage. Access will be limited to authorized members of the research team, including the Principal Investigator, Co-Investigator, and designated study personnel. Participants will be assigned a unique study identification number, and all direct identifiers will be removed from datasets used for analysis. The master list linking participant names to study ID numbers will be stored separately with additional password protection and accessed only when necessary for study administration. Quantitative results will be reported only in aggregate, and no individual participant will be identifiable in publications or presentations. Data will be retained in accordance with applicable IRB and institutional policies.

7. **Funding and conflicts of interest:** Funding for this study may be obtained through community-based crowdfunding (e.g., GoFundMe). Outreach will be directed to individuals as well as various physicians, surgeons, lipedema product/services vendors, and lipedema advocacy organizations. Donations will be accepted under a written policy providing that: (a) all contributions are unrestricted, and donors have no role in study design, conduct, data analysis, interpretation, or the decision to publish; (b) no donor will receive advance access to results; (c) donor recognition is in no way contingent on findings; and (d) donors contributing above $1000 will be listed in the publication, with the aggregate contribution from commercial sources (device, garment, surgical, or supplement vendors) disclosed as a category.

   A member of the statistical and medical consulting team (Alexandre Amato) is an author of the lipedema symptoms questionnaire and of the lipedema screening questionnaire referenced in this protocol. This constitutes a potential non-financial competing interest. It is mitigated by the placement of both instruments in supporting roles (neither is a primary outcome nor a basis for the sample size) and by pre-specification of all outcome roles in the registered protocol before recruitment begins.
   The study sponsor also serves as a principal investigator (PI) for this study. In this dual role, she provides administrative and logistical support and contributes to study design, protocol development, and study oversight. PI involvement in data collection is limited to administration of the 30-second chair stand assessment analysis of qualitative data to generate

themes. To reduce the potential for this dual role to influence study results, the de-identified study dataset will be maintained by the Research Coordinator/Data Manager. PI will not participate in data management, statistical analysis, or interpretation of study results (with the exception of de-identified qualitative data) and will not have access to unblinded group-level data. The PI will not have access to unblinded group-level data, and other designated members of the research team will conduct the statistical analyses. Study findings will be reported regardless of whether they support the study hypotheses.

The Principal Investigator/Sponsor will maintain full responsibility for the scientific integrity of the study. The Co-Principal Investigator (Co-PI) will provide support for oversight of research activities to ensure the study is conducted ethically and adheres to the IRB-approved protocol. Additionally, the PI/Sponsor designed the intervention under evaluation, delivers it, and participates in its evaluation. This is disclosed as a competing interest and is mitigated by independent generation and concealment of the allocation sequence, blinded scoring of the performance-based outcomes, blinded statistical analysis, and independent second coding of qualitative data.

8. **Dissemination policy:** Study results will be published in a peer-reviewed open-access journal, and the findings from the study will be shared at relevant professional meetings and conferences. A plain language study summary will be disseminated to study participants, healthcare professionals, and the public using relevant blogs and social media outlets.

Introduction

9a. Background and rationale: Lipedema is a chronic adipose, lymphatic, and metabolic disorder characterized by disproportionate fat accumulation, pain, tenderness, and a potentially progressive reduction in functional mobility. The condition primarily affects women and is frequently underdiagnosed or misdiagnosed, resulting in delayed treatment and worsening disability. As the disease progresses, impaired mobility often limits participation in activities of daily living, reduces physical function, and contributes to pain, psychological distress, and diminished quality of life (Dudek et al., 2016; Clarke et al., 2023; Kunzová et al., 2025).

Lymphedema is a chronic disorder of the lymphatic system characterized by impaired lymphatic transport and the accumulation of protein-rich interstitial fluid, resulting in persistent swelling, tissue fibrosis, and an increased risk of infection (Mortimer & Rockson, 2014; Executive Committee of the ISL, 2020). Lymphedema frequently coexists with lipedema, increasing symptom severity and further limiting mobility, physical function, and independence while compounding the psychological burden associated with both conditions (Ghods et al., 2020; Simarro Blasco et al., 2025; Keith et al., 2024).

Because pain and impaired mobility directly affect independence, participation in daily activities, and long-term health outcomes, preserving and improving functional mobility while reducing pain are primary goals of conservative management for individuals with lipedema and lymphedema. Current conservative treatment typically includes compression therapy, manual lymphatic drainage, and exercise-based interventions (Executive Committee of the ISL, 2020; Mortimer & Rockson, 2014). However, many individuals are unable to participate in traditional exercise programs because of pain, heaviness, fatigue, impaired balance, and fear of worsening their symptoms (Dudek et al., 2016; Herbst et al., 2021). As a result, there is a critical need for accessible, low-impact interventions that improve functional mobility while also reducing pain and supporting psychosocial well-being.

Mind–body interventions, including yoga, breathwork, and meditation, have demonstrated benefits for individuals with chronic pain, mobility limitations, and mental health conditions (Stephens, 2017; Kuhn, 2026). These practices promote autonomic nervous system regulation, improve body awareness, reduce stress, and encourage safe, gentle movement. Chair-based yoga is particularly well-suited for individuals with lipedema and lymphedema because it can be adapted to varying functional abilities, reduces barriers to participation, and may facilitate meaningful improvements in mobility while providing secondary benefits for pain and mental health.

Between January and March 2026, a community-based mind–body chair yoga program was conducted within the Lipedema Simplified, LLC community through a Citizen Science study. Participants observed improvements across multiple health spheres, with enhanced functional mobility emerging as one of the most potentially clinically meaningful outcomes. Improvements were also observed in pain, sleep quality, and mental health. Although these observations are promising, they were derived from a community-based project without the methodological rigor of a randomized clinical trial. A controlled clinical study is therefore needed to determine whether a structured chair yoga intervention can produce clinically significant improvements in functional mobility while also improving secondary outcomes, including pain, lipedema symptom severity, and mental health.

9b. Explanation for Choice of Comparator: The comparator group will serve as a wait-list control for the chair yoga intervention. During the study period, participants in this group will receive the same once-weekly support group sessions conducted via a password-protected Zoom platform but will not participate in the chair yoga program. All participants in the comparator group will have the opportunity to participate in an identical gentle chair yoga class after completion of the 12-week follow-up assessment.

The inclusion criteria for the comparator group will be identical to those of the intervention group. This design will allow us to determine whether participation in the support group alone produces similar benefits or whether the addition of the chair yoga intervention provides incremental improvements in outcomes.

10. Objectives related to benefits and harms: This study aims to determine whether a mind– body intervention using chair yoga, breathing exercises, and guided meditation is feasible and improves functional mobility in individuals with lipedema, with additional benefits for pain, lipedema symptom severity, and mental well-being.

a) **Benefits:** Participants may experience several potential benefits. One of the main anticipated benefits is improved functional mobility and physical function, enabling participants to perform activities of daily living with greater ease, confidence, and independence through gentle chair yoga, breathwork, and guided meditation. Several other potential benefits include reduced pain levels; decreased severity of lipedema symptoms; enhanced mental well-being, including improved mood, resilience, and overall quality of life; greater body awareness and self-management skills for living with lipedema and/or lymphedema; increased confidence in movement, helping to reduce fear of physical activity; access to a supportive community of individuals with shared experiences; and practical self-care strategies, including chair yoga, breathing exercises, meditation, and relaxation techniques that participants can continue using after the study concludes.

b) **Harms:** There are potential harms that a participant may experience as a result of

participating in this study. Loss of confidentiality is a potential risk, although efforts have been made to minimize it (password-protected websites, HIPAA-compliant Zoom and DocuSign, and participants can turn their cameras off and include only their first name).

Although this is a gentle form of physical activity, the potential for soreness and discomfort still exists, especially if joint hypermobility is a comorbidity. For this reason, participants will be screened for this condition using the validated Five-Part Hakim-Grahame Questionnaire (Hakim & Grahame, 2003) to define generalized joint hypermobility. As an additional safeguard, all participants will be provided with joint protection strategies and cautioned to avoid over-stretching.

Participation in this activity may trigger memories of psychological or emotional trauma. Alternative/optional movements and poses are always provided to mitigate the chance of injury or emotional/physical discomfort. Note: Participants can contact PI or psychological staff members Robyn Baron-Durst, MS and Jeffrey Migdow, MD, if psychological issues arise.

Methods: Participant and public involvement, trial design

11. Participant and public involvement: Participants and members of the public were not formally involved in the design, conduct, or planned reporting of this clinical trial. The study was informed by observations from a previous community-based chair yoga project conducted within the online lipedema community. At the conclusion of the trial, participants will be invited to provide feedback regarding their experiences with the study procedures and intervention. This feedback will be used to evaluate participant satisfaction and to inform the design and implementation of future research.

12. Trial design: A mixed-methods, two-arm parallel randomized controlled trial (RCT) will be conducted to evaluate the feasibility and effectiveness of a remote gentle chair yoga intervention, combined with a support group. The primary outcome will be feasibility of the program. Secondary/exploratory outcomes will include functional mobility, pain, lipedema symptom severity, and mental health. Participants will be randomly assigned in a 1:1 ratio using a masked design to either the chair yoga intervention plus support group or the support group alone.

Methods: Participants, interventions, and outcomes

13. Trial setting: online, using a HIPAA-compliant Zoom platform and a password-protected webpage.

14. Eligibility criteria: Eligibility criteria will include a designation as female at birth, at least 18 years old, and a formal diagnosis of lipedema. Participants will additionally be screened for eligibility using the framework for research case definitions of lipedema proposed by Keith et al., 2024. Participants must be able to read, speak, and understand English as well as have internet access. Individuals will not be enrolled in the study if they have any cardiovascular condition or recent surgery (within 6 weeks) for which exercise is contraindicated without physician clearance; active infection; untreated deep vein thrombosis; high-risk pregnancy; or cognitive/psychiatric disabilities that prevent informed consent. Additionally, individuals will be excluded if they are diagnosed with a serious mental health condition or have suffered a recent major life crisis.

15. Intervention and comparator: Intervention duration is a total of 7 weeks, including orientation, intervention, and exit interview. Additional follow-up by repeating all study assessments will occur 12 weeks post-intervention. PI will lead all chair yoga sessions. The Yoga Group support chat will be led by Jeffrey Migdow, MD, and the Comparator Group support chat will be led by Robyn Baron-Durst, MS.

Activities for the Yoga Group:

- Twice per week, for one hour each session, a gentle chair yoga practice will include:
  - The Yoga Practice – 40 minutes
  - Breathing Practice – 10 minutes
  - Guided Meditation – 10 minutes
- Weekly recorded 10–15-minute Breathing Meditation
- Once per week, a one-hour support chat will be led by Jeffry Migdow, MD

The live and recorded yoga sessions will be accessed on a password-protected webpage that is accessible only to the Yoga Group participants and research study staff. Participants who are not available for live sessions can watch recordings, but they must do this within one week of the live class. Attendance records will be kept for both live and delayed participation.

Support chats will be accessed on a password-protected webpage that is specific to the participants' assigned group (Yoga Group or Comparator Group) and research staff. Support chat sessions will allow all participants to control how much of their image or voice is shared with other participants. For instance, participants may choose to turn off video and/or audio and only have their first name listed (for those with the same first name, last initial may also be used). Participants who have their audio muted by choice can participate by writing comments/questions in the chat function or can call the PI.

Activities for Comparator Group:

- Once per week, one-hour support chats will be led by Robyn Baron-Durst, MS

A separate support chat will be used for the Comparator Group. Participants can control their own audio and video as described above.

16. Outcomes: The primary outcome will be feasibility of a remote mind-body chair yoga intervention for women with lipedema. This will include assessment of recruitment, retention, adherence, intervention completion, adverse events, and participant program acceptability.

Secondary outcomes will include change in functional mobility as measured by the Lower Extremity Functional Scale (LEFS), the Upper Extremity Functional Index (UEFI) (Stratford et al., 2001) , and the 30-Second Chair Stand (Dahlberg et al., 2025). Changes in lipedema symptom severity will be measured using the Lipedema Symptoms Assessment Questionnaire (QuASiL) (Amato et al. 2020). This instrument was published in German and English by Rapprich et al. (2011) but has not yet been validated in those languages. An additional secondary outcome will be pain severity. This will be assessed with the Brief Pain Inventory (BPI) (Cleeland & Ryan, 1994). This is routinely used in clinical trials involving patients with lipedema. Lastly, mental health will be measured using a newly developed lipedema-specific tool, the Lipedema Psychological Functioning Questionnaire, that will be validated during the course of this clinical trial.

17. Harms: Adverse events will be collected actively rather than passively, with equal ascertainment in both arms.

(a) Analyzed safety dataset. A weekly check-in, identical in both arms and with an identical recall period, will ask: “In the past seven days, have you experienced any new or worsened symptom (for example: pain, soreness, joint problems, a fall or near-fall, dizziness, shortness of breath, or emotional distress)?” with a free-text field and a question on the action taken. This common weekly item constitutes the safety dataset for between-arm comparison.

(b) Intervention-specific surveillance. For participant protection, an immediate post-class check will additionally be administered in the yoga arm. Because this creates more detection opportunities in that arm, it will be analyzed and reported separately as intervention-specific surveillance and will not be pooled with the common weekly data.

(c) Participants who withdraw will be invited, optionally, to give a reason.

Events will be tabulated by arm and by severity, with the investigator’s judgement of relatedness. Participants will be instructed to stop the activity and seek medical assessment where appropriate.

18. Participant timeline: Recruitment will begin on October 30, 2026, pending IRB approval and completion of registration with ClinicalTrials.gov, and will continue until the proposed sample size is reached or at the start of the Intervention. The Intervention time period will be January 29, 2027 - March 19, 2027 (7 weeks).

Intervention schedule for the Yoga Group will be:

- Orientation: January 29, 2027, 3-4 PM
- Chair Yoga Sessions: February 1, 2027 - March 10, 2027
  Mondays and Wednesdays, 3-4 PM EST
- Support Chats: February 5, 2027 - March 12, 2027
  Fridays, 3-4 PM EST
- Debrief/feedback/exit interview: Friday, March 19, 2027, 3-4 PM EST

Intervention Schedule for the Comparator Group will be:

- Orientation: January 29, 2027, 4-5 PM
- Support Chats: February 5, 2027 - March 12, 2027
  Fridays, 4-5 PM EST
- Debrief/feedback/exit interview: Friday, March 19, 2027, 4-5 PM EST

19. Sample size: This is a randomized pilot and feasibility trial. The sample size is not based on statistical power for efficacy, but on the precision with which the trial estimates the parameters needed to design a definitive trial. Seventy participants will be randomized 1:1. Assuming the 82.7% retention observed in the investigators' 2026 community project, approximately 58 participants (29 per group) will complete the post-intervention assessment.

	Screening (from 15 Oct 2026)	Baseline / Allocation (29 Jan 2027)	Intervention (1 Feb – 10 Mar)	Midpoint (week 4)	Post intervention / close out (19 Mar)	Follow-up (12 weeks)
Eligibility: documented diagnosis + application of case-definition framework	✓					
Screening questionnaire (structured adjunct)	✓					
Informed consent (incl. recording and safety monitoring clauses)	✓					
Hakim–Grahame hypermobility questionnaire	✓					
Demographics, lipedema stage/type, location, emergency contact	✓					
Randomization (only after baseline submitted)		✓				
Chair yoga, 2×/week (yoga arm only)			✓			

	Screening (from 15 Oct 2026)	Baseline / Allocation (29 Jan 2027)	Intervention (1 Feb – 10 Mar)	Midpoint (week 4)	Post intervention / close out (19 Mar)	Follow-up (12 weeks)
Recorded breathing meditation, 1×/week (yoga arm)			✓			
Support chat, 1×/week (both arms)			✓			
LEFS		✓		✓	✓	✓
UEFI		✓		✓	✓	✓
30-second Chair Stand		✓		✓	✓	
Lipedema Symptoms Questionnaire (QuASiL)		✓		✓	✓	✓
Brief Pain Inventory (BPI)		✓		✓	✓	✓
Global rating of change					✓	
Co-intervention checklist		✓			✓	

	Screening (from 15 Oct 2026)	Baseline / Allocation (29 Jan 2027)	Intervention (1 Feb – 10 Mar)	Midpoint (week 4)	Post interventi on / close out (19 Mar)	Follow-up (12 weeks)
Attendance/Adheren ce log			continuous			
Common weekly safety check-in (both arms)			weekly	✓	✓	
Post-class surveillance (yoga arm, reported separately)			each class			
Exit interview / qualitative debrief (both arms) Participant Program Acceptability Questionnaire					✓	

At this size, retention will be estimated with a 95% confidence interval of approximately ±9 percentage points; the standard deviation of the key secondary outcome, the Lower Extremity Functional Scale (LEFS), will be estimated to within approximately −16% to +23% of its true value, which is the principal input required to size a definitive trial. If no serious adverse events occur among the 35 participants allocated to chair yoga, the upper 95% confidence bound for the event rate will be 8.2%.

For transparency, with 29 completers per group, a two-sided α of 0.05, 80% power, and adjustment for baseline scores (assuming a baseline-to-post-intervention correlation of 0.5), the smallest between-group difference the trial could reliably detect is approximately 0.65 standard deviations. The between-group difference in LEFS will therefore be reported as an estimate with its 95% confidence interval, interpreted against the 9-point minimal clinically important difference (Binkley et al., 1999), and not as a test of efficacy.

Although the study is not powered to detect definitive between-group efficacy differences, the results will provide preliminary evidence regarding the potential effects of a gentle chair yoga intervention on mobility, pain, lipedema symptom severity, and mental health outcomes in individuals with lipedema and will inform the design and sample size calculations for a future larger randomized controlled trial.

20. Recruitment: Participants will be recruited through community-based outreach and online methods targeting individuals with lipedema. Recruitment methods will include: free 60-minute educational webinars related to lipedema and the study opportunity; announcements posted on social media platforms directed toward individuals with lipedema; a study webpage providing additional information about the study, eligibility criteria, study requirements, and contact information; flyers distributed through healthcare provider offices and other relevant community settings; and outreach to lipedema advocacy organizations for distribution through their communication channels. All recruitment materials, announcements, emails, flyers, and webpage content will be reviewed and approved by the Institutional Review Board (IRB) before dissemination.

Individuals interested in participating will be directed to the study webpage, where they will receive information about the study and may voluntarily contact the research team or complete an online interest form. Potential participants will undergo eligibility screening according to the IRB-approved procedures before enrollment. Participation is voluntary, and individuals may choose whether to contact the study team or participate without any impact on their healthcare, services, or relationship with any organization involved in recruitment.

Methods: Assignment of Interventions

Randomization

21. Sequence generation: The allocation sequence will be computer-generated using permuted blocks of randomly varying size (2 and 4) in a 1:1 ratio, stratified by prior yoga experience (yoga-naïve vs yoga-experienced). The sequence will be generated by Siobhan Huggins, who has no role in recruitment, intervention delivery, or outcome assessment, using MinimPy (https://minimpy.sourceforge.net/).

22. Allocation concealment mechanism: The allocation sequence will be held solely by the independent randomizer in a password-protected file inaccessible to the Principal Investigator (also the yoga facilitator) and recruitment staff. Allocation for each participant will be released only after eligibility has been confirmed, and the complete baseline assessment has been submitted.

23. Implementation: PI & Co-PI will screen and enroll participants. Research Coordinator/Data Manager will generate the allocation sequence and assign participants to arms. The PI will be informed of allocation only to grant access to the appropriate password-protected session page.

24. Blinding: This is an open-label trial. Blinding of participants and of the intervention provider is not feasible given the nature of the intervention. Outcomes other than the 30-second chair stand are participant-reported and therefore cannot be assessor-blinded; this is acknowledged as a limitation. The 30-second chair stand will be recorded by the PI/Sponsor and Co-PI via Zoom. Recordings will be given to the assessor (co-PI/Joanna Dudek), who is blind to the group allocation, to count and document repetitions. Group allocation will be coded as A and B in the analysis dataset, and the analysis of the key secondary clinical outcome, together with its written interpretation, will be completed and dated before the allocation code is revealed.

Methods: Data collection, management, and analysis

25. Data collection methods: All yoga sessions will be recorded using the HIPAA-compliant Business Plus version of Zoom, which provides encrypted transmission of data. Recorded sessions will be transferred to an encrypted, password-protected secure server or encrypted, password-protected cloud storage within 24 hours of each session.

Electronic research data, including questionnaires, attendance records, and study documents, will be stored on password-protected computers and in encrypted, password-protected, cloud-based storage. Access to research data will be limited to authorized members of the research team, including the Principal Investigator and designated study personnel responsible for study administration and data analysis.

Each participant will be assigned a unique study identification number. Research datasets used for analysis will be de-identified (linked), meaning that direct identifiers (e.g., name, email address, contact information) will be removed from the research dataset. The master file linking participant identities to study identification numbers will be stored separately in an encrypted, password-protected file accessible only to the Principal Investigator.

26. Data management: Audio and video recordings will be transcribed to ensure all important information is recorded for the Qualitative Analysis. These transcriptions will only be viewed and de-identified by the PI for data collection purposes only. Recordings will be retained solely for study administration, quality assurance, and verification purposes and will be permanently deleted two (2) weeks after the completion of the final yoga session. Recordings of the 30-second chair stand assessments will be stored separately from class recordings, retained until blinded scoring has been completed and documented, and deleted thereafter.

Only de-identified data will be used for statistical analyses and dissemination of study findings. Individual participants will not be identifiable in any publication, presentation, or report. Quantitative results will be presented only in aggregate form, and any quotes used in qualitative results discussion will not contain identifiable information.

De-identified research data and study records will be retained for three (3) years following completion of the study in accordance with standard human subjects research practices. At the conclusion of the retention period, all electronic files containing identifiable information will be permanently and securely deleted using secure deletion methods. Any paper records, if generated, will be cross-cut shredded.

27. Statistical methods: Analyses will follow the intention-to-treat principle: all randomized participants will be analyzed in the arm to which they were allocated, regardless of adherence.

Feasibility outcomes are the primary outcomes. Recruitment rate, retention, adherence, questionnaire completion, acceptability, and adverse events will be summarized descriptively with 95% confidence intervals against pre-specified progression criteria: retention ≥ 80%, and ≥ 70% of participants attending at least 8 of 12 yoga sessions live or by recording within seven days.

Key secondary clinical outcome. The key secondary outcome, functional mobility, will be assessed using the Lower Extremity Functional Scale. Data will be analyzed using a linear mixed model of post-baseline observations at week 4 and post-intervention. The model will

include the allocated arm, categorical time, the arm-by-time interaction, baseline scores, the baseline-by-time interaction, and the randomization stratification factor.

Participant-level repeated observations will be modelled using a pre-specified covariance structure. The estimate is the adjusted between-arm mean difference at the post-intervention assessment, reported with a 95% confidence interval and a standardized effect size. All available post-baseline observations will be included under a missing-at-random assumption.

A complete-case ANCOVA of the post-intervention score, adjusted for the baseline value and the stratification factor, will be reported as a sensitivity analysis. Baseline characteristics will be reported descriptively by arm without significance testing.

All other quantitative exploratory outcomes will be analyzed with the same model structure. No adjustment for multiplicity will be applied, and no claim of efficacy will be made; confidence intervals are the substantive result and p-values, where reported, are descriptive. A per-protocol analysis restricted to adherent participants, and an exploratory dose-response analysis using attendance as a continuous predictor, will be reported as secondary. Analyses will be conducted in SPSS v29. The statistical analysis plan will be finalized, dated, and registered before the database is locked.

Qualitative responses will be analyzed using an inductive thematic approach: The primary investigator will read and review transcripts from weekly support group meetings as well as responses to open-ended survey questions to search for patterns and potential themes. Themes will then be reviewed, refined, and interpreted with the agreement of the co-investigator.

Methods: Monitoring

28. Data monitoring committee: No independent data monitoring committee will be constituted. This is a minimal-risk behavioral intervention of seven weeks' duration and no interim efficacy analysis is planned. Pre-specified pause criteria are nevertheless defined: an individual participant will be withdrawn from active sessions pending clinical review following any serious adverse event, any fall causing injury, or any acute cardiorespiratory symptom during a session; a session will be halted if an event occurs that affects more than one participant; and the study will be paused for IRB consultation if any serious adverse event is judged related to the intervention, or if two or more participants withdraw citing intervention related harm. The Principal Investigator and Co-Investigator will jointly review all reported adverse events weekly. Serious or unanticipated events will be reported to the IRB within 5 calendar days of becoming aware of the event with the complete report submitted within 10 calendar days, per IRB policy.

29. Trial monitoring: The Research Coordinator/Data Manager will maintain attendance logs, questionnaire completion records, and an adverse-event log, reviewed weekly with the Principal Investigator and Co-Investigator. All protocol deviations will be logged and reported in the final publication.

Ethics

30. Research ethics approval: This study will be conducted in accordance with the ethical principles of the Declaration of Helsinki, applicable federal regulations, and institutional policies governing research involving human participants.

The study protocol, informed consent documents, recruitment materials, and any other participant-facing materials will be submitted to the Institutional Review Board (IRB) for review and approval before the initiation of any study-related activities. Participant recruitment and enrollment will not begin until written IRB approval has been obtained.

Any protocol amendments that may affect participant safety, study conduct, scientific integrity, or participant rights will be submitted to the IRB for review and approval before implementation, unless an immediate change is necessary to eliminate an apparent hazard to participants.

Continuing review, progress reports, and study closure will be conducted in accordance with IRB requirements. Any unanticipated problems involving risks to participants, serious adverse events that meet reporting criteria, or other reportable events will be reported to the IRB within the required timeframes and in accordance with institutional policies.

Written informed consent will be obtained from all participants before they participate in any study procedures.

31. Protocol amendments: Any proposed amendment to the study protocol will be reviewed and approved by the Principal Investigator (PI) and the Co-Investigator in consultation with the study investigators. Amendments will be evaluated to determine whether they constitute substantive changes that could affect participant safety, scientific validity, study procedures, eligibility criteria, outcome measures, informed consent, or regulatory compliance.

No substantive protocol amendment will be implemented until approval has been obtained from the Institutional Review Board (IRB), except when immediate changes are necessary to eliminate an apparent hazard to study participants, in accordance with applicable regulations and institutional policies.

Following IRB approval, substantive protocol amendments will be communicated, as applicable, to all relevant parties, including: the Institutional Review Board (IRB) or Research Ethics Committee (REC); the clinical trial registry in which the study is registered (e.g., ClinicalTrials.gov), with updates made in accordance with registry requirements; any applicable regulatory authorities, if required by law or regulation; study personnel, who will receive training on revised procedures before implementation; current study participants, when the amendment affects their participation, safety, rights, or informed consent. Revised informed consent documents will be used when required, and participants will be re-consented as appropriate.

Minor administrative amendments that do not affect participant safety, study conduct, scientific integrity, or the risk-benefit profile will be managed in accordance with IRB policies and documented in the study records. All protocol amendments, including the rationale, approval dates, and implementation dates, will be maintained in the trial master file and other applicable regulatory documentation.

32. Consent or assent: Individuals expressing interest in the study will be directed to the study webpage, which describes the study objectives, procedures, eligibility criteria, potential risks and benefits, time commitment, and investigator contact information. The webpage will clearly state that this is a research study and that participation is entirely voluntary.

Potential participants who appear to meet the eligibility criteria will be provided with the IRB-approved informed consent document electronically through DocuSign. Participants will be encouraged to carefully review the consent form and will have the opportunity to contact a member of the research team by telephone to ask questions or obtain clarification before deciding whether to participate. The research team will ensure that prospective participants understand the study procedures, risks, benefits, and their rights as research participants before informed consent is obtained.

Written informed consent will be obtained electronically using DocuSign before the initiation of any study-related procedures, including eligibility screening, baseline assessments, and data collection. Participants will receive a copy of the fully executed informed consent document for their records.

Because support chats will be conducted in a group format and recorded for research purposes, participants will be informed that other individuals enrolled in the study may be visible or audible during the sessions. Participants will be instructed not to share personal health information or other private information during the recorded sessions. The research team will take reasonable steps to protect participant confidentiality; however, participants will be informed that complete confidentiality cannot be guaranteed when participating in a group session in which other participants may be present.

Because participants may be randomized to the Yoga Group, each participant's healthcare provider will be asked to complete and electronically sign a medical clearance form confirming that the participant is medically appropriate to participate in a gentle chair yoga program should they be assigned to the intervention group. Medical clearance must be received before enrollment is finalized.

Participation in the study is strictly voluntary. Participants may decline to participate or withdraw from the study at any time without penalty or loss of benefits to which they are otherwise entitled. Withdrawal from the study will not affect their current or future medical care or relationship with their healthcare providers.

Electronic informed consent documents and medical clearance forms will be securely stored in accordance with institutional policies and applicable privacy regulations. Access to identifiable participant information will be restricted to authorized members of the research team.

33. Confidentiality: Participant confidentiality will be maintained throughout all phases of the study. Each participant will be assigned a unique study identification number, and identifiable information will be stored separately from research data in a secure, encrypted, password-protected file accessible only to the Principal Investigator and authorized study personnel.

Access to identifiable participant information and research records will be limited to members of the research team who require access for study administration, monitoring, data management, or analysis. All research personnel will follow institutional policies and applicable regulations regarding the protection of human research participant information.

Research datasets used for statistical analysis and reporting will contain only de-identified data. Study findings will be presented in aggregate form, and no individual participant will be identifiable in any publication, presentation, report, or dissemination activity resulting from this research. Any qualitative data or participant quotations used in reporting will be reviewed to

ensure that they do not contain information that could reasonably identify an individual.

Procedures for secure storage, management, retention, and destruction of research records, including video recordings, transcripts, and electronic study files, are described in the Data Management section of this protocol.

Participants will be informed during the consent process that group support chats will be recorded for research purposes and that other study participants enrolled in the session may be visible or audible in the recording. Participants will be instructed not to disclose personal health information or private information during recorded sessions.

34. Ancillary and post-trial care: This study involves a low-risk behavioral intervention consisting of a gentle chair yoga program. Participants will be instructed to participate within their individual abilities and to modify or discontinue any activity that causes discomfort, pain, dizziness, or other concerning symptoms. Any adverse events or concerns related to participation in the study intervention will be documented, evaluated, and managed according to the study safety monitoring procedures and institutional requirements.

The study team will not provide ongoing medical care or treatment for lipedema or other health conditions as part of this research study. Participants will be encouraged to continue receiving routine medical care from their healthcare providers throughout the study period.

After completion of the 12-week follow-up assessment, participants in the comparator group will be provided an opportunity to participate in an online gentle chair yoga program with this study's instructor as well as access to the yoga program materials, including instructional resources, if applicable. Participants in both groups will be provided with a summary of the study findings upon completion of the study, if they indicate interest in receiving this information. No additional post-trial medical care or long-term follow-up will be provided as part of this study.

References

Amato, A. C. M., Amato, F. C. M., Benitti, D. A., & Santos, R. V. D. (2020). Translation, cultural adaptation, and validation of a lipedema symptoms questionnaire. Jornal Vascular Brasileiro, 19, e20200049.

Binkley, J.M., Stratford, P.W., Lott, S.A., Riddle, D.L. (1999). The Lower Extremity Functional Scale (LEFS): scale development, measurement properties, and clinical application. *Phys Ther, 79*(4), 371–383.

Clarke, C., Kirby, J. N., Smidt, T., & Best, T. (2023). Stages of lipoedema: experiences of physical and mental health and health care. *Quality of Life Research, 32*(1), 127-137.

Dahlberg, L. E., Karlsson, O., Sirard, P., Lohmander, L. S., & Kiadaliri, A. (2025). Reliability of digitally instructed self-reported 30-second chair stand test for lower extremity function. Osteoarthritis and Cartilage Open, 7(2), 100613.

Dudek, J. E., Białaszek, W., Ostaszewski, P. (2016). Quality of life in women with lipoedema: a contextual behavioral approach. *Quality of Life Research, 25*(2), 401–408. doi:10.1007/s11136-015-1080-x.

Executive Committee of the International Society of Lymphology. (2020). The diagnosis and treatment of peripheral lymphedema: 2020 consensus document of the International Society of Lymphology. *Lymphology*, 53, 3-19.

Stratford, P. W., Binkley, J. M., & Stratford, D. M. (2001). Development and initial validation of the Upper Extremity Functional Index. Physiotherapy Canada, 53(4), 259-267.

Ghods, M., Georgiou, I., Schmidt, J., & Kruppa, P. (2020). Disease progression and comorbidities in lipedema patients: A 10-year retrospective analysis. *Dermatologic therapy, 33*(6), e14534.

Hakim, A.J., Grahame, R.. (2003). A simple questionnaire to detect hypermobility: an adjunct to the assessment of patients with diffuse musculoskeletal pain. *Int J Clin Pract*, 57, 163–6. 7.

Herbst, K. L., Kahn, L. A., Iker, E., Ehrlich, C., Wright, T., McHutchison, L., ... & Larson, E. (2021). Standard of care for lipedema in the United States. *Phlebology, 36*(10), 779-796. 8.

Keith, L., Seo, C., Wahi, M. M., Huggins, S., Carmody, M., Faerber, G., ... & Rockson, S. G. (2024). Proposed framework for research case definitions of lipedema. *Lymphatic research and biology, 22*(2).

Kuhn, A. L. (2026). Accessible Mind-Body Movement Therapies for Low Back Pain Management. *The Journal for Nurse Practitioners, 22*(6), 93-105, https://doi.org/10.1016/j.nurpra.2026.105788.

Kunzová, M., Lagová, E., and Keith, L. (2025). Mental and physical health burden and quality of life in Czech women with lipedema. *Front. Glob. Women's Health 6*:1629077.

Cleeland, C. S., & Ryan, K. M. (1994). Pain assessment: global use of the Brief Pain Inventory. Annals of the Academy of Medicine, Singapore, 23(2), 129-138.

Mortimer, P. S., & Rockson, S. G. (2014). New developments in clinical aspects of lymphatic disease. *The Journal of Clinical Investigation, 124*(3), 915-921.

Simarro Blasco, J. L., Michelini, S., Andrés-Gasco, M., Lebrero García, A., Ortega Abad, D., Margalejo Lombardo, J., ... & Martín Martínez, M. A. (2025). Clinical Signs at Diagnosis and Comorbidities in a Large Cohort of Patients with Lipedema in Spain. *Biomedicines, 13*(12), 3049.

Stephens, I. (2017). Medical yoga therapy. *Children, 4*(2), 12.