CLINICALTRIALS.GOV STUDY DOCUMENT

Title: Comparative Impact of Hydrotherapy and Land-Based Exercise on Pelvic Floor Muscle Endurance in Pregnant Women

NCT Number: Not yet assigned

Unique Protocol ID: 010/05/2024/ISRB/FGSR/SCPT

Document Date: 10 May 2024

STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

1. Study Design and Participants

This experimental randomized controlled study was conducted in a private physiotherapy center. The study screened 291 pregnant women in their second and early third trimesters to determine their eligibility. Out of these, 35 were excluded, of whom 28 did not meet the inclusion criteria, 4 refused to participate, and 3 were excluded due to other reasons. The remaining 256 eligible participants were randomly assigned using a sealed-envelope technique into two groups: hydrotherapy-based pelvic floor muscle training (HPFT, n = 128) and land-based pelvic floor muscle training (LPFT, n = 128). During follow-up, 3 participants from each group were lost to follow-up and 3 participants from each group discontinued the intervention due to reasons including schedule conflicts, absenteeism, or withdrawal of consent. Consequently, 125 participants in each group were included in the final analysis.

2. Eligibility Criteria

Women were eligible to participate if they were aged 20–35 years, had a singleton pregnancy confirmed by ultrasound, gestational age between 18 and 32 weeks, absence of obstetric complications such as placenta previa, gestational diabetes or preeclampsia, medical clearance from an obstetrician to participate in hydrotherapy and moderate physical activity, ability to understand and follow instructions, willingness to participate in regular exercise sessions, and willingness to attend follow-up assessments for 6 weeks.

3. Exclusion Criteria

Participants were excluded if they were below 20 years or above 35 years, had gestational age outside the 18–32-week range, multiple pregnancy, obstetric complications such as placenta previa, uncontrolled gestational diabetes or pregnancy-induced hypertension, open wounds or infections contraindicating hydrotherapy, musculoskeletal conditions limiting safe participation in aquatic exercise, history of cardiovascular or respiratory disorders, fear of water or discomfort in aquatic environments, inability to complete follow-up evaluations, or refusal to participate during the intervention period.

4. Randomization and Group Allocation

Eligible participants were randomly allocated into two groups using a sealed-envelope technique. Group A received hydrotherapy-based pelvic floor muscle training and Group B received land-based pelvic floor muscle training. The manuscript does not report additional allocation-concealment or blinding procedures.

5. Baseline Assessment

Baseline assessment was performed at week 0 before commencement of the intervention. Pelvic floor muscle strength was assessed using the Modified Oxford Grading Scale, pelvic floor muscle endurance using a perineometer, and urinary incontinence using the International Consultation on Incontinence Questionnaire.

6. Hydrotherapy-Based Pelvic Floor Muscle Training

Group A underwent a structured hydrotherapy-based pelvic floor muscle training programme in a heated indoor therapy pool. The programme was conducted three times per week for six weeks, with each session lasting 30 minutes and water temperature maintained between 32°C and 34°C. The programme consisted of warm-up and breathing control, pelvic floor activation in buoyant positions, dynamic aquatic strengthening, and cool-down and relaxation.

7. Land-Based Pelvic Floor Muscle Training

Group B underwent a structured land-based pelvic floor muscle training programme in a physiotherapy setting. The programme was conducted three times per week for six weeks, with each session lasting 30 minutes. It consisted of warm-up and body awareness, isolated pelvic floor muscle contractions, functional integration, and relaxation and stretching.

8. Outcome Measures and Assessment Schedule

Pelvic floor muscle strength was assessed using the Modified Oxford Grading Scale, graded from 0 to 5. Pelvic floor muscle endurance was assessed using a perineometer by measuring intravaginal pressure generated during sustained voluntary pelvic floor muscle contraction and recorded in cmH_2O. Urinary incontinence was assessed using the International Consultation on Incontinence Questionnaire. Assessments were performed at week 0, week 3 and week 6.

9. Materials Required

The materials required included a heated indoor therapy pool maintained at 32–34°C, flotation devices, aqua dumbbells, perineometer, assessment couch, and equipment required for the land-based pelvic floor muscle training programme.

10. Follow-up and Withdrawals

Three participants from each group were lost to follow-up and a further three participants from each group discontinued the intervention because of schedule conflicts, absenteeism, or withdrawal of consent. The final analysis included 250 participants, with 125 participants in each group.

11. Ethical Approval

The study was reviewed and approved by the Institutional Scientific Review Board (ISRB) with approval number 010/05/2024/ISRB/FGSR/SCPT. The ISRB approval date was 10 May 2024. Written informed consent was obtained from all participants before commencement of the study. The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki.

12. Statistical Analysis Plan

Statistical analyses and data visualization were conducted using R version 4.3.0. Descriptive statistics were summarized using means with standard deviations or frequencies with percentages, as appropriate. The longitudinal outcome data were analyzed using a mixed-effects random-intercept model with participant ID as the random effect. The model evaluated time effects, group effects and group × time interaction effects. Bonferroni post hoc testing was used for pairwise comparisons across assessment time points. Changes from baseline between groups were evaluated, and partial eta-squared (ηp^2) was reported as an effect-size measure. Correlation analysis was also performed for the variables reported in the manuscript. Statistical significance was set at $p < 0.05$.

APPENDIX 1 – INFORMED CONSENT FORM

I, _____, agree to take part in the study conducted by **Dr. Pavithra S, Lecturer and Research Scholar, Saveetha College of Physiotherapy, SIMATS.**

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I acknowledge that the study has been explained to me and I agree to participate in the study. I am willing to provide information regarding my health status to the investigator and allow the investigator to access my relevant medical records for the purpose of the study.

I agree to participate in the assessments and intervention programme and make myself available for the follow-up assessments required during the study period. I have been informed about the purpose, procedures, interventions, and measurements involved in the study, and my queries regarding the study have been clarified.

I have been informed that this study involves allocation into one of two exercise groups, and I agree to participate regularly throughout the 6-week study period.

I provide consent to the investigator to use photographs, if required, with my face masked, for educational purposes only.

No funds, fees, or remuneration will be taken from or provided to the participants during the course of the study.

I understand that my participation is voluntary and that I have the right to withdraw from the study at any stage without providing a reason.

Place: _____

Date: _____

Participant's Signature: _____

Investigator's Signature: _____