

## **Study Protocol and Statistical Analysis Plan**

**Official title:** Physical Therapy Intervention for Pelvic Organ Prolapses

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### **Study protocol**

High-Intensity Focused Electromagnetic Field (HIFEM) therapy is a noninvasive treatment that uses low-frequency electromagnetic waves (3–30 Hz) to stimulate muscle contractions. These waves generate electrical currents in targeted tissues, allowing pelvic floor muscles to contract without discomfort. This technology has been approved for treating urinary incontinence and is being explored as a potential option for improving pelvic floor strength and symptoms of pelvic organ prolapse (POP).

Although early studies suggest that HIFEM may improve pelvic floor muscle function, urinary symptoms, and quality of life, there is limited research comparing it with standard treatments such as pelvic floor muscle training (PFMT)±biofeedback. In particular, more evidence is needed to understand its effectiveness specifically for women with POP and to evaluate how acceptable this treatment is to patients.

This study aims to:

1. Evaluate the effects of HIFEM therapy on POP symptoms and pelvic floor muscle function.
2. Compare outcomes between HIFEM therapy, PFMT (with biofeedback and/or electrostimulation), and usual care.
3. Explore participant experiences and acceptability of these treatment approaches.

### **Methods**

This is a prospective, single-center randomized controlled trial with a nested qualitative interview study. It will include women aged over 20 years who are diagnosed with stage I–III pelvic organ prolapse (POP). Participants will be randomly assigned to one of three groups:

- HIFEM group: Participants will receive two 28-minute sessions per week for eight weeks using a noninvasive electromagnetic chair.
- Biofeedback group: Participants will undergo supervised pelvic floor muscle training, which may include biofeedback and/or electrostimulation.
- Usual care group: Participants will receive standard lifestyle advice and

education.

Outcomes will be assessed before and after the intervention period. Measurements will include validated questionnaires on POP symptoms and pelvic floor distress, clinical assessment of pelvic floor muscle function (e.g., digital palpation), and imaging using transperineal ultrasound.

### **Statistical Analysis**

Participant characteristics will be described using summary statistics. Categorical data will be reported as counts and percentages, while continuous data will be summarized using means and standard deviations. All analyses will follow the intention-to-treat principle and will be conducted using SPSS software.

Data will be tested for normality to determine whether parametric or non-parametric statistical methods are appropriate. Changes over time and differences between groups will be analyzed using repeated-measures methods, with adjustments made for any baseline differences if necessary. A significance level of  $p < 0.05$  will be used.

### **Qualitative Analysis**

To better understand participant experiences, qualitative data will be collected and analyzed using thematic analysis. The research team will identify key themes and discuss findings until agreement is reached, ensuring that participant perspectives are accurately represented.