

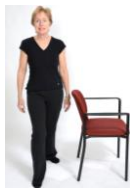
Group physiotherapy compared to individual physiotherapy to treat urinary incontinence in aging women: Design and methods of a non-inferiority randomised controlled trial.

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Hypothesis / aims of the study

- Clinical practice guidelines recommend **pelvic floor muscle training (PFMT) as a first-line treatment** for stress or mixed UI in women, although lack of human and financial resources limits delivery of this first-line treatment [1].
- Preliminary data suggests that group-based treatments (as opposed to individual) may provide the answer.



Individual treatment

VS



Group-based treatment

- To date, no adequately powered trials have evaluated the effectiveness or cost-effectiveness of group compared to individual PFMT for UI in older women.

The objective of the **GROUP (Group Rehabilitation Or Individual Physiotherapy for UI in Aging Women)** trial is to determine if group-based PFMT for women 60+ with stress or mixed UI is not meaningfully less effective, sustainable and affordable than recommended individualised PFMT.

Study design, materials and methods

- The study is designed as a **non-inferiority** randomized controlled trial, conducted in two Canadian facilities.
- Participants include 364 community-dwelling women.

Inclusion criteria

- Aged 60 years old and over
- Have stress or mixed UI symptoms (≥3 times/week, for 3 months or more)
- Able to have a gynecological examination

Exclusion criteria

- Have a BMI ≥ 35;
- Experiencing important organ prolapse (POPQ>2);
- Received physiotherapy treatment or surgery for UI in the past year;
- Currently taking any medication for UI or medications affecting skeletal muscles;
- Experiencing any leakage of stool or mucus;
- Have an active urinary or vaginal infection in last 3 months;
- Recent change in hormonal replacement;
- Any comorbidities or risk factors interfering with the study (e.g. constipation, reduced mobility, respiratory, cardiovascular or memory problems, cancer, diabetes)

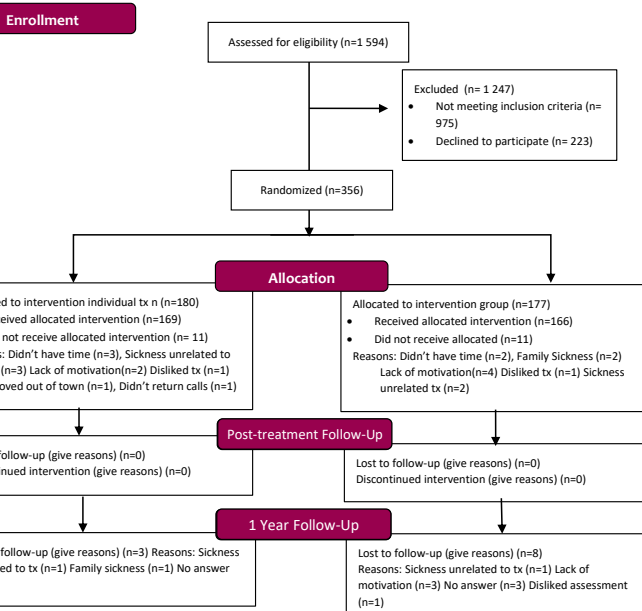
- Randomly-assigned participants will follow a 12-week PFMT, either in one-on-one sessions or as part of a group, supervised by a physiotherapist. Interventions included:
 - 15-min. educational period:** covers lifestyle interventions and PFM precontraction
 - 45-min. exercise component:** PFM strength, rapidity, endurance and coordination. Between PFM exercises, lower extremity strength and functional exercises (dance) are performed.

- Blinded assessments at baseline, immediately post-intervention and at one year, include the **7-day bladder diary, the 24h pad test, symptoms and quality of life questionnaires (ICIQ-UI SF, ICIQ-N, ICIQ-LUTSqol, ICIQ-VS), adherence and self-efficacy questionnaire (Geriatric Self-efficacy Index and Brooms Self efficacy questionnaire), PFM morphometry and function (US and dynamometry) and cost assessments (Dowell Bryant Incontinence Cost Index).**
- Sample size calculations followed CONSORT Guidelines for non-inferiority trials. Based on clinical relevance (minimum clinically relevant difference = 10%) [2] and our pilot data [3], we set the 'margin of equivalence' as a 10% difference (individual minus group) between mean % reduction in the number of UI episodes.

- Primary analysis will test our main hypothesis that group-based treatment is not inferior to individualized treatment one year after randomization with respect to the primary outcome: relative (%) reduction in the number of leakages on the 7-day bladder diary.
- Basic descriptive analysis will be followed by multivariable analyses. Specifically, two multivariable linear models, of increasing complexity, will be used to adjust the estimated difference between the % reduction at 1 year in the two groups for, respectively, (1) only the two stratification variables (center and type of UI), as well as the baseline number of UI episodes (to account for regression to the mean phenomenon).

Results and concluding message

- This trial was registered as NCT02039830.
- Recruitment was conducted : September 2012 to March 2017.



| Characteristics | Participants (n = 356) |
|--------------------------------|------------------------|
| Mean age ±SD (yr) | 67,83 ± 5,66 |
| Mean BMI ±SD (kg/m2) | 27.17 ± 4.62 |
| Parity ±SD (deliveries) | 1.78 ± 1.32 |
| UI episodes on 7 day diary ±SD | 14.60 ± 14.09 |
| ICIQ-UI SF score ±SD | 12.25 ± 3.27 |

Should this study find that a group-based approach is not less effective than individual PFMT, and more cost-effective, this trial will impact positively continence-care accessibility and warrant a change in clinical practice.

References:

- Abrams P, Cardozo L, Khoury S, Wein A.(2013) 5th International Consultation on Incontinence Paris, ICUD-EAU: 1101-1227.2.
- Piaggio, G. et al (2006). JAMA 295(10): 1152-1160.3.
- Elliott V, De Bruin E, Dumoulin C.(2015). Neurourol Urodyn 34(3): 236-243.

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