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## GROUP PHYSIOTHERAPY COMPARED TO INDIVIDUAL PHYSIOTHERAPY TO TREAT URINARY INCONTINENCE IN AGING WOMEN: DESIGN AND METHODS OF A NON-INFERIORITY RANDOMISED CONTROLLED TRIAL.

### Hypothesis / aims of study

Urinary incontinence (UI), one of the most prevalent health concerns confronting women above 60, affects up to 55% of older community-dwelling women, 20 to 25% with severe symptoms. 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. To date, no adequately powered trials have evaluated the effectiveness or cost-effectiveness of group compared to individual PFMT for UI in older women. Given demographic projections, high prevalence of UI in older women, costly barriers and group PFMT's promising results, there is a clear need to rigorously compare the short- and long-term effectiveness and cost-effectiveness of group versus individual PFMT.

The overall 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 and older with stress or mixed UI is not meaningfully less effective, sustainable and affordable than the currently recommended individualised (one on one) PFMT.

### Study design, materials and methods

The study is designed as a non-inferiority randomized controlled trial, conducted in two Canadian facilities. A non-inferiority design was chosen because 1) individual PFMT is the standard of care in Canada; 2) recent literature and our preliminary data on aging women suggest that group-based PFMT may be effective; 3) the anticipated lower cost, and 4) the potential to improve accessibility to care through a group approach (overcoming lack of human and financial resources). Therefore, the intent of this study is to demonstrate that an experimental treatment (group PFMT) is not substantially worse than a control treatment (individual PFMT).

Participants include 364 ambulatory, community-dwelling women, aged 60 and older, with stress or mixed UI. Women are recruited from community ads, newspapers ads, the Research Center's bank of participants and local gynaecology and urology clinics.

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#### 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

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#### 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)
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Randomly-assigned participants will follow a 12-week PFMT, either in one-on-one sessions or as part of a group, under the supervision of a physiotherapist. For both groups, the weekly 1hour sessions include a 15-min. educational period and a 45-minutes exercise component. The educational period covers lifestyle interventions and PFM precontraction. The exercise component includes 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). 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.

Sample size calculations follows CONSORT Guidelines for non-inferiority trials. Based on clinical relevance [2] (minimum clinically relevant difference = 10%) and our pilot data [3], we set the 'margin of equivalence' as corresponding to a 10% difference between mean % reduction in the number of UI episodes in the 'standard treatment' of the individual intervention minus the group-based intervention arm. We calculated N = 364 (155 subjects per group + 15% attrition rate by one year) for which the probability that

the upper boundary of the 2-tailed 95% CI for the difference in the mean relative reduction (Individual – Group) excludes the 'upper threshold of non-inferiority' (10% difference), and will reach at least 90%.

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); and (2) (if necessary) in addition to variables in model (1): any variable, for which a clinically important imbalance between the two arms is revealed by descriptive analyses.

#### Results:

This trial was registered. Recruitment began September 2012 and is expected to end in March 2017. To date, 1,594 women were assessed for eligibility and 356 participants have been allocated to either individual or group interventions. Participants were aged between 60 and 89 years old ( $67.83 \pm 5.66$  years), the mean BMI was  $27.17 \pm 4.62$  kg/m<sup>2</sup> and the parity ranged from 0 to 8 ( $1.78 \pm 1.32$  deliveries). Participants reported an average of  $14.60 \pm 14.09$  UI episodes on a 7-day bladder diary and had a score of  $12.25 \pm 3.27$  on the ICIQ-UI SF. Of the 356 randomized participants, 180 have been allocated to individual treatment and 177 to group intervention. To date, 335 participants have been evaluated post intervention and 324 have completed the one year follow up evaluation.

The most common reason of exclusion (37%) was not meeting the study inclusion criteria in terms of UI type and severity. Other reasons of exclusion were: a chronic condition or disease that prevented participation in the study (26% all conditions combined) or not being available to attend the 12-weeks program due to time constraints or geographical location (20%). As for the recruitment sources, most participants (56%) were recruited through local newspapers. In addition, 12% responded to community ads, 10% were part of the participants bank or were referred by a friend and 3% were referred by medical doctors (generalist or specialists).

#### Concluding message

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

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#### Disclosures

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**RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** Research Ethics Committee of Institut Universitaire de Gériatrie de Montréal (CER IUGM 12-13- 002), Centre Hospitalier de l'Université de Montréal (CE12.347), Centre Hospitalier de l'université de Sherbrooke (#12-170-M5). **Helsinki:** Yes **Informed Consent:** Yes