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Feasibility, acceptability and effects of a group pelvic floor muscle telerehabilitation program to treat urinary incontinence in older women

Mélanie Le Berre[1,2], Johanne Filiatrault[1,2], Barbara Reichetzer[3,4,5] and Chantale Dumoulin[1,2]

Abstract

Introduction: Urinary incontinence (UI) is one of the most prevalent health concerns in women age 65 and over. The recommended first-line treatment for UI is individual pelvic floor muscle training (PFMT). However, healthcare systems worldwide are unable to meet the demand for this resource-intensive approach. Recently, the Group Rehabilitation Or IndividUal Physiotherapy (GROUP) trial showed that group-based PFMT was not inferior to individual PFMT to treat UI in older women, despite using fewer resources. This study aims to assess the feasibility, acceptability and effects on UI-related symptoms and associated quality of life (QoL) of an online adaptation of the GROUP program (teleGROUP) for UI in older women.

Methods and analysis: This pilot study will involve the recruitment of 32 older women with UI. Participants' attendance to online sessions, adherence to weekly home exercises, and side effects, in addition to the physiotherapist's fidelity to the program delivery will be collected to evaluate the program's feasibility. Participants' dropout rates, reasons for dropout, satisfaction and usability scores will be collected to evaluate the program's acceptability for participants. A survey will evaluate the program's acceptability for the physiotherapists. Additionally, at the end of the study, qualitative semi-structured interviews and focus groups will investigate further feasibility and acceptability. To measure the effects of teleGROUP, number of weekly leakages and percentage reduction will be the primary outcomes.

Keywords

Urinary incontinence, telerehabilitation, aged, women's health

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Introduction

Urinary incontinence (UI), defined as 'any involuntary leakage of urine',[1] is one of the most frequent health conditions in women age 65 and over.[2,3] Half of community-dwelling women in this age group suffer from UI, with 25% reporting severe symptoms, with over 10 episodes/week.[2–4] As the number of older people around the world is projected to double by 2050, the proportion of women age 65 and over will continue to grow accordingly.[5] A corresponding increase in UI incidence and severity is thus anticipated, which in turn will increase the number of women requiring UI treatment. UI is considered a serious medical condition that affects other medical conditions.[6,7] It engenders significant psychosocial

[1]School of Rehabilitation, Faculty of Medicine, Université de Montréal, Montreal, QC, Canada
[2]Centre de recherche de l'Institut universitaire de gériatrie de Montréal (CRIUGM), Montreal, QC, Canada
[3]Department of Obstetrics and Gynecology, Centre Hospitalier de l'Université de Montréal, Montreal (CHUM), Montreal, QC, Canada
[4]Department of Obstetrics and Gynecology, Faculty of Medicine, Université de Montréal, Montreal, QC, Canada
[5]Institut universitaire de gériatrie de Montréal (IUGM), Montreal, QC, Canada

Corresponding author:
Chantale Dumoulin, Centre de recherche de l'Institut universitaire de gériatrie de Montréal, 4545 Queen-Mary road, office M5816, Montreal, QC, Canada H3W 1W4.
Email: chantal.dumoulin@umontreal.ca

problems and can lead to a restriction in social and physical activities.[8,9] UI is also associated with poor self-rated health and impaired well-being.[10,11] It can also interfere with sexual relationships and quality of life (QoL), as well as increased nursing home admissions, and can thus seriously impede healthy aging.[7–14]

The recommended first-line treatment for UI in women is individual pelvic floor muscle training (PFMT) (Level of evidence 1; Grade of recommendation A), an approach supported by international clinical practice guidelines[15–17] and findings from recent randomized controlled trials (RCTs).[18–21] Yet, this treatment appears to be a resource-intensive approach that healthcare systems in many countries are currently unable to meet. Despite the negative impact of UI and the evidence supporting the efficacy of PFMT, less than a third of older women with UI receive treatment.[22,23] The major barriers to implementing this treatment include the lack of adequate human and material resources to address this problem through individual physiotherapy sessions.[24–26]

Recently, a non-inferiority RCT – the Group Rehabilitation Or IndividUal Physiotherapy (GROUP) trial (ClinicalTrials.gov, NCT02039830) – showed that group-based PFMT was not inferior to individual PFMT to treat UI in older women, despite using fewer resources and being more cost-effective.[27–29] However, with the worldwide COVID-19 pandemic, public health authorities prevented gatherings to stop the virus' spread. These safety measures therefore limited the possibilities of in-person group intervention approaches, particularly for older women. This context highlighted the importance of providing online options, which could also benefit women living in rural or remote areas, where pelvic floor rehabilitation services are scarce, particularly in the winter season when weather conditions are not optimal.

Telerehabilitation, defined as the remote delivery of rehabilitation services using information and communication technology, has already offered promising results for the treatment of various orthopaedic and neurological conditions.[30–39] Therefore, with the ultimate goal of increasing the accessibility of continence care for older Canadian women through an online adaptation of an effective and less resource-intensive group-based PFMT program, this pilot study aims to: (1) assess the feasibility and acceptability of the online adaptation of the GROUP program (the teleGROUP program) for UI in women age 65 years and over; and (2) assess the effects of teleGROUP on UI-related symptoms and associated QoL in this population.

Methods

Study design

This pilot study will use a convergent mixed-method pre-post design with a quantitative and a qualitative components.

Eligibility criteria

Women will be eligible to participate if they meet the following criteria:

- Aged 65 years or older. This age cut-off was used in other studies on UI.[21] Older women show a different genitourinary profile than younger women, notably due to menopause and age-related muscle loss;[40]
- Are able to walk safely and autonomously without any mobility device;
- Have stress or mixed UI, confirmed by the questionnaire for incontinence diagnosis[41];
- Have at least three urine leakages per week, persisting for three months or more[28,29];
- Report no cognitive deficit (mini mental state examination (MMSE) score of 24/30 or more)[42];
- Have internet access;
- Understand French;
- Accept to complete a gynaecological examination, a 7-day bladder diary and questionnaires; and
- Provide informed consent.

Women with the following characteristics will be excluded:

- Have risk factors known to interfere with PFMT or the evaluation of pelvic floor muscles (PFM), including chronic constipation[43,44] (as defined by the International Working Committee for Chronic Constipation),[45] important pelvic organ prolapse (Baden-Walker score > stage 2),[46] or any other comorbidities with a potential impact on treatment (i.e. diabetes, active cancer, respiratory conditions, etc)[28]
- Are currently taking medication for UI or that affects skeletal muscles[28];
- Are considered severely obese with a body mass index over 35[47];
- Had an active urinary or vaginal infection in the past three months[28];
- Underwent a change in hormonal therapy in the past six months[28];
- Received pelvic floor physiotherapy, underwent surgery or any other treatment for UI or pelvic organ prolapse in the past year.

Recruitment and sample size

Participants will be recruited through advertisements in community centres, newspapers, social media channels, a participant database, promotion through various relevant media, groups and associations, and referrals from collaborating gynaecology and urology clinics in three large hospitals in the Montreal metropolitan area. Pilot studies are not commonly required to include sample size estimations.[48]

However, as this study aims to assess the effects of an intervention, sample size calculations estimated that a total sample of 32 older women with UI would be required to ensure a power of $1-\beta = 95\%$ with an α error of 0.05 and an estimated effect size of 0.73[29] to detect a statistically significant difference in the number of urine leakages between PRE and POST, with a conservatively anticipated attrition rate of 15% based on previous studies.[29] These 32 older women will be divided into four cohorts of seven to nine participants.

Intervention

Physiotherapists with specialized training in pelvic floor rehabilitation will establish participants' eligibility during an initial individual in-person evaluation session. They will also teach participants how to correctly contract their PFM through vaginal digital palpation.[49]

Participants will then be invited to take part in an online adaptation of the GROUP program[28,29]: the teleGROUP program, which is a 12-week online group-based PFMT program composed of 12 weekly one-hour training sessions that participants will be able to attend from their home. An experienced pelvic floor physiotherapist will deliver all sessions via the Zoom videoconference platform to groups of six to eight women. If needed, participating women will receive an introduction to Zoom and support via phone before starting the teleGROUP program. All participants will be provided with an exercise booklet detailing the various exercises and their progression from initiation to maintenance, and support material for 12 educational capsules.

Each weekly virtual session will begin with a one to three-minute individual exchange between the physiotherapist and each participating woman in a private breakout room to discuss UI episodes and exercise adherence for the previous week. In the meantime, the rest of the group will socialize in the 'main room' of the Zoom session. All virtual sessions will then be divided into a 10–15-min educational component, including motivational capsules to foster adherence, and a 30–45-min PFM exercise component. The educational component will cover various topics, including the anatomy of the pelvic floor, pathophysiology of incontinence, PFM pre-contraction, bladder control, voiding parameters and others, supported by educational documents, video and testimonials (see Appendix 1). The exercise component will include a progression over three phases lasting four weeks each, allowing for increasing difficulty in the duration, number of repetitions and position (from lying, to sitting, to standing)[28] of four PFM exercises. These four exercises will target strength, speed of contraction, endurance and coordination. At the end of each virtual training session, a functional exercise will integrate PFM contractions through a dance activity. Time permitting, participating women will also perform pelvic and abdominal muscle exercises. Figure 1 provides an overview of the virtual sessions. In addition to their attendance to the weekly sessions, participating women will also be asked to perform the same exercises individually at home, for a total of five days per week of PFMT for the duration of the intervention. Upon completion of the 12-week program, participants will be asked to practice a maintenance exercise regimen.

Outcomes and data collection

Data will be collected at four time points: before the intervention, after confirmation of eligibility (PRE1) with the physiotherapist, before the first session of the 12-week intervention (PRE2), after the 12-week intervention (POST) and six months after the end of the 12-week intervention (FOLLOW-UP). Data will also be collected throughout the program by the treating physiotherapist. Table 1 provides an overview of the data collection process of the study.

Quantitative data

Eligibility. A member of the research team will enquire about the inclusion and exclusion criteria for the participants during a pre-screening telephone interview. Subsequently, participants will undergo an individual in-person evaluation with a specialized physiotherapist, located in their area, to confirm their eligibility to the study. During this evaluation, the physiotherapist will ensure that each potential participant do not have cognitive deficit, as attested with a MMSE score of 24/30 or more[42] and confirm the information collected during the telephone interview. The physiotherapist will also complete an intravaginal evaluation including:

- The PERFECT assessment scheme to assess PFM function through digital vaginal palpation.[50,51] The PERFECT is an acronym with P for power of the PFM contraction, measured with the modified Oxford 6-point muscle strength scale during a maximal voluntary contraction (0–5 scale, with higher scores indicating a stronger contraction), E for endurance of the PFM contraction (maximal duration that a maximal voluntary contraction can be sustained, measured from 0 to 10 s), R for repetitions (the number of repetitions of the specific maximal voluntary contraction that can be achieved, measured from 0 to 10 contractions), F for fast contractions (measured as the number of fast 'contract-relax' maximal contractions), E for elevation of the posterior vaginal wall during the PFM contraction (yes/no), C for co-contraction of the lower abdominal muscles during the PFM contraction (yes/no), and T for timing, with the presence of synchronous involuntary contraction of PFM on coughing (yes/no). This scheme has shown high validity and a high correlation with a

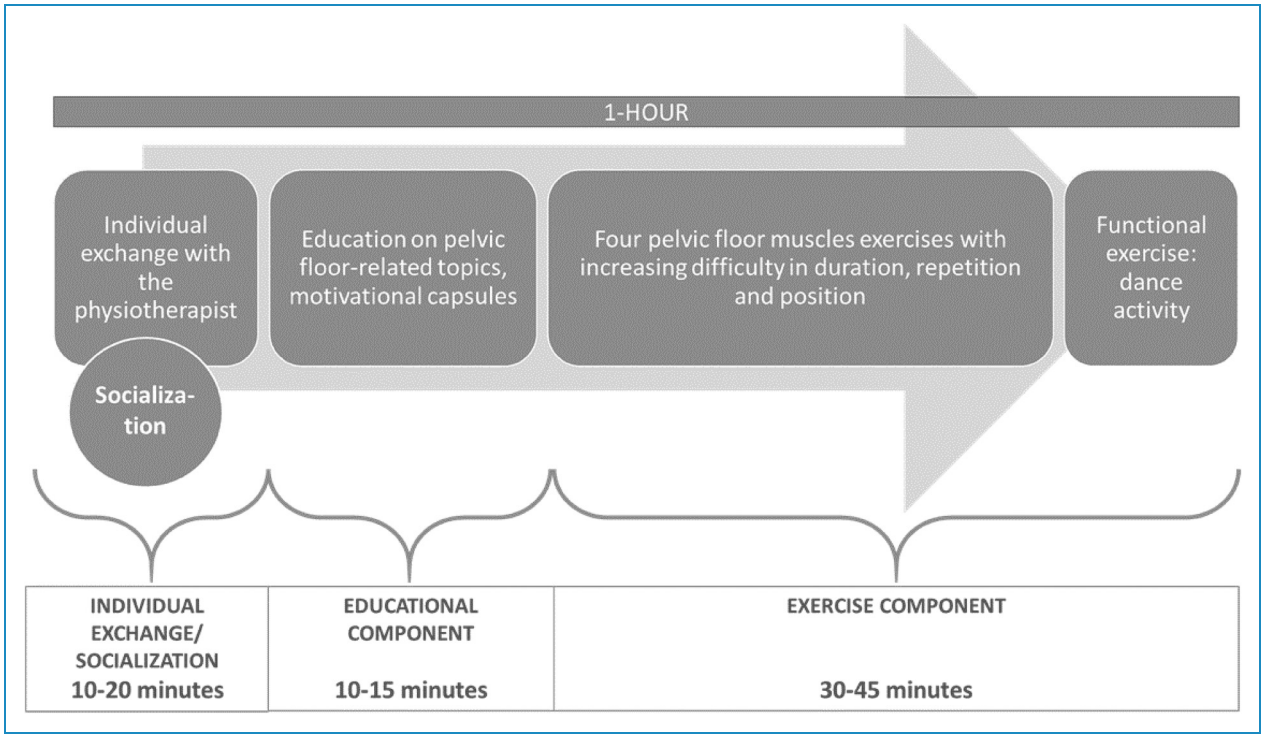

Figure 1. Overview of the weekly one-hour sessions with the treating physiotherapist.

manometric perineometer ($r = 0.79$) and high test-retest reliability (r between 0.93 and 0.99).[50]
- The Baden-Walker grading system[46] to investigate the presence and stage of any pelvic organ prolapse, scored from 0 to 4, with higher scores indicating a more advanced stage. This score is frequently used in research[52] and widely accepted in routine clinical contexts.[53]

If the participant is ineligible based on any of these tests during the evaluation, the physiotherapist will stop the assessment and provide individualized counselling for the remaining allocated time.

Baseline data. If the participant is eligible, the physiotherapist will also complete an additional intra-vaginal evaluation test:

- The vaginal atrophy index to assess vaginal atrophy with observations of the vulvovaginal area (overall score of 6–15, with lower scores indicating more severe symptoms of vaginal atrophy).[54] This measure is commonly used in clinical practice and research.[55]

The physiotherapist will then pursue the evaluation to collect baseline data. They will report the participant's MoCA score[56,57] and collect sociodemographic and health data, including age, height, weight, socioeconomic status, medical history and medication, parity and obstetric history, duration of UI symptoms and general health characteristics.

Feasibility. To measure the feasibility of the teleGROUP program, the physiotherapist leading the teleGROUP program will record various implementation outcomes in a logbook throughout the program:

- Attendance to weekly sessions by participating women (reach).[58]
- Integrity of the teleGROUP program elements delivered by the physiotherapist during each session (fidelity).[58]
- Adherence to weekly home exercises by participating women (dose),[58] as reported by the participant during the one-on-one exchange at the beginning of each session.
- Complications and side effects reported by participating women.

At the six-month follow-up (FOLLOW-UP), participants will also be asked about their adherence to the maintenance exercise program.

Acceptability. To measure the acceptability of the teleGROUP program, physiotherapists evaluating the participants will answer a survey based on the Theoretical Framework of Acceptability (TFA),[59] using similar

Table 1. Overview of the schedule of the study's enrolment, intervention components and assessments.

	Enrolment			Intervention and follow-up				
		0m		1m	2m	3m	9m	
TIMEPOINT	March 2021 to January 2022	Eligibility visit/PRE1	Before program initiation/PRE2				POST	FOLLOW-UP
ENROLMENT:								
Pre-screening telephone eligibility interview	X							
Informed consent		X						
In-person individual evaluation session with the evaluating physiotherapist		X						
ELIGIBILITY ASSESSMENTS:								
Mini mental state examination (MMSE)		X						
PERFECT assessment scheme		X						
Baden-Walker grading system		X						
BASELINE ASSESSMENTS:								
Vaginal atrophy index (VAI)		X						
Montreal cognitive assessment (MoCA)		X						
Sociodemographic and health data		X						
INTERVENTION COMPONENTS:								
Pelvic floor muscle contraction teaching (during the in-person individual evaluation)		X						
Zoom introduction and phone support			X					
12-week online group-based PFMT program + individual home exercise program				⟷	⟷	⟷		
Maintenance exercise program							⟷	⟷
Quantitative component								
FEASIBILITY ASSESSMENTS:								
Attendance to weekly sessions (reach)				⟷	⟷	⟷		
Integrity of the teleGROUP program elements (fidelity)				⟷	⟷	⟷		
Adherence to weekly home exercises (dose)				⟷	⟷	⟷		

(continued)

Table 1. Continued.

	Enrolment	Intervention and follow-up					
		0m		1m	2m	3m	9m
TIMEPOINT	March 2021 to January 2022	Eligibility visit/PRE1	Before program initiation/PRE2				POST FOLLOW-UP
Complications and side effects				←	—	→	
Adherence to the maintenance exercise program							X
ACCEPTABILITY ASSESSMENTS:							
Acceptability survey of the evaluating physiotherapists			X				
Dropout rates and reasons for dropouts				←	—	→	
Single-item satisfaction question							X X
System usability scale (SUS)							X X
EFFECTS ASSESSMENTS:							
7-day bladder diary		X	X				X X
7-day bladder diary (leakages only)				←	—	→	
International consultation on incontinence questionnaire module on UI symptoms (ICIQ-UI) short form		X	X				X X
International consultation on incontinence questionnaire module on quality of life (ICIQ-LUTS QOL)		X	X				X X
Australian pelvic floor questionnaire (APFQ)		X	X				X X
Atrophy symptom questionnaire (ASQ)		X					X X
Geriatric self-efficacy index (GSE)		X					X X
Broome pelvic muscle exercise self-efficacy scale (PMSES)		X					X X
Online technologies self-efficacy scale (OTSES)		X					X X
Adapted Dowell-Bryant incontinence cost index (DBICI)		X					X X
Estimation of costs associated with treatment							X
Patient global impression of improvement (PGI-I)							X X

(continued)

Table 1. Continued.

	Enrolment			Intervention and follow-up				
		0m		1m	2m	3m		9m
TIMEPOINT	March 2021 to January 2022	Eligibility visit/PRE1	Before program initiation/PRE2				POST	FOLLOW-UP
Single-item satisfaction tool							X	X
Qualitative component								
Treating physiotherapist's logbook				←	—	→		
Semi-structured interviews with the treating physiotherapist							X	
Focus group/semi-structured interviews with the participants							X	

questions to those used in literature, adapted to the context of the study (see Appendix 2).[60,61]

The dropout rates and reasons for dropout will also be collected throughout the intervention. Additionally, at the end of the 12-week PFMT intervention (POST) and at the six-month follow-up (FOLLOW-UP), participating women will rate their satisfaction with the program using a single-item tool ('completely satisfied', 'somewhat satisfied' or 'not at all satisfied')[62] and fill the system usability scale (SUS) to describe their experience with the online group-based PFMT program (10 items, 0–100 overall score, with higher scores indicating a higher usability). The SUS is currently the most widely used standardized questionnaire for the assessment of perceived usability[63] and has demonstrated high internal consistency with Cronbach's alpha, between 0.85 and 0.91.[64]

Clinical effects. To measure the clinical effects of the intervention on UI-related symptoms, participants will report on the following clinical data before the intervention (PRE1), before the first session of the online group-based PFMT program (PRE2), immediately after the 12-week PFMT intervention (POST), and six months after the end of the program (FOLLOW-UP):

- The 7-day bladder diary, recording urine leakage, reasons for urine leakage and mictions.[65,66] The number of leakages, measured by the 7-day bladder diary, is considered one of the most reliable measures of success for UI treatment and has been widely used in this type of research.[67–69] Furthermore, the 7-day bladder diary has shown a high compliance rate.[66,68,70] The primary outcome measures will be the number of weekly leakages and their percentage reduction, recorded through the 7-day bladder diary between PRE and POST measurements. Participants will also record their leakage in a bladder diary throughout the program and report them weekly to the physiotherapist, during the one-on-one exchange at the beginning of each session.
- The International consultation on incontinence questionnaire module on UI symptoms (ICIQ-UI) short form[71]: A four-item questionnaire evaluating UI symptoms (0–21 overall score, with greater values indicating increased severity). The ICIQ-UI is widely used and has shown a high convergent validity with urodynamic testing (kappa of 0.77 and correlation coefficient of 0.84)[72,73] and clinical diagnosis using both urodynamic testing and uroflowmetry.[74] It also showed high test-retest reliability (90% similarity and correlation coefficients ranging from 0.91 to 0.96).[72,74]
- The International consultation on incontinence questionnaire module on QoL (ICIQ-LUTS QOL)[67]: a 20-item questionnaire evaluating QoL in UI patients (0–14 overall score with greater values indicating increasing problems). The ICIQ-LUTS QOL provides a detailed and robust measure to assess the impact of UI on QoL with a focus on social impacts of UI.[75] It has shown excellent test-retest reliability (correlation coefficient between 0.80 and 0.96).[75]
- The Australian pelvic floor questionnaire (APFQ): a questionnaire assessing multiple pelvic floor symptoms including bladder (0–45 scores), bowel (0–34 scores), sexual function (0–21 scores) and prolapse symptoms (0–15 scores), with greater values indicating increased severity of symptoms. The APFQ has shown high face validity according to healthcare professionals and high convergent validity with urodynamic testing and physician diagnosis.[76,77] It also demonstrated high test-retest reliability

(80–100%), good internal consistency (Cronbach's alpha between 0.65 and 0.87) and excellent responsiveness.[76,78]

In addition to UI-related symptoms, participants will also report other symptoms and indicators before the intervention (PRE1), immediately after the 12-week PFMT intervention (POST), and six months after the end of the online group-based PFMT program (FOLLOW-UP):

- The atrophy symptom questionnaire (ASQ): a five question questionnaire investigating atrophy symptoms and their impact on daily life and sexual function (0–15 overall score, with greater values indicating increased severity).[79] It has shown excellent test-retest reliability (correlation coefficient of 0.85).[80]
- The geriatric self-efficacy index (GSE): a 12-item questionnaire to measure older adults' level of confidence in avoiding urine leakage (0–120 overall score, with higher scores indicating higher level of self-efficacy). It has shown high responsiveness to change and its sensitivity of 75.1% and specificity of 78.2% in detecting changes in UI status make it a clinically useful tool.[81]
- The Broome pelvic muscle exercise self-efficacy scale (PMSES): a questionnaire to measure the level of confidence in performing PFMT exercises (14 items with responses ranging from 0 to 100 for part A and nine items with responses ranging from 0 to 100 for part B, both with higher scores indicating higher level of confidence). An overall mean self-efficacy score will be calculated (also ranging from 0 to 100). This scale has shown high internal consistency (Cronbach's alpha of 0.97) and good test-retest reliability (correlation coefficients between 0.64 and 0.72).[82]
- The online technologies self-efficacy scale (OTSES)[83]: a 29-item questionnaire measuring technology self-efficacy (30–120 overall score, with higher scores indicating lower self-efficacy). It has shown high internal consistency with Cronbach's alpha, between 0.91 and 0.95.[83,84]
- The adapted Dowell-Bryant incontinence cost index (DBICI): a measure of costs and expenses incurred by participants for UI care (i.e. incontinence products, associated treatments) and technology-related costs (i.e. internet connexion, device used).[28,85,86] This tool has shown high test-retest reliability with minimal differences between assessments on Bland-Altman's plots.[85] Transportation-related costs (distance in km × gasoline price at the time of intervention) for the participant's initial evaluation will also be calculated.
- The physiotherapist's working hours and the fees associated with the technology used to lead the class will also be calculated to estimate the costs of the teleGROUP program.

Participants will fill two additional questionnaires after the 12-week online group-based PFMT program (POST) and six months after the program (FOLLOW-UP):

- The patient global impression of improvement (PGI-I): A single-item global index used to measure improvement of urinary continence following PFMT on a 7-point scale that ranges from 1 ('very much better') to 7 ('very much worse'). The PGI-I has shown acceptable convergent and discriminant validity for measuring outcomes in studies of behavioural treatment for UI.[87]
- Satisfaction with treatment: A single-item tool to capture satisfaction with treatment: 'satisfied' (does not need other treatments); 'unsatisfied' (would like another treatment for UI).[62]

Throughout data collection, women will be offered sufficient time, and breaks as needed, in order to fill all questionnaires. Participants will be also adequately compensated for their time.

Qualitative data. The treating physiotherapist leading the online group-based PFMT program will write in a logbook throughout the intervention and at the end of each 12-week online group-based PFMT program, to document the intervention and the reasons for any deviation from the teleGROUP program and to reflect on their experience. At the end of the study, the physiotherapist will be interviewed in a semi-structured approach, using an interview guide developed from the seven dimensions of the TFA,[59] three of the five Consolidated Framework for Implementation Research (CFIR) domains[88] and additional open-ended questions on satisfaction.

Additionally, participating women will be invited to take part in focus groups at the end of each 12-week online group-based PFMT program via Zoom, or individual interviews if they are not available at the time of the focus group. During these focus groups and interviews, participants will be asked to describe their experience and discuss potential challenges and satisfaction with the program, using relevant observations from the physiotherapist's logbook as prompts when appropriate. The focus group guide was also developed using the seven dimensions of the TFA,[59] three of the five CFIR domains[88] and additional open-ended questions on satisfaction (see Appendix 3). All focus groups and interviews will be recorded and transcribed verbatim.

Data analysis and statistical methods

Quantitative data. Eligibility, baseline, feasibility and acceptability data will be tabulated and interpreted using descriptive statistics at each relevant time point, using means, medians, standard deviations and interquartile ranges for continuous variables and frequency distributions for categorical and binary variables, as appropriate.

As the negative binomial mixed model is well suited for this type of data,[89] we will use it to analyze the effects of the online group-based PFMT program on the primary outcome (urine leakage episodes on the 7-day bladder diary) and

investigate the differences between the PRE1, PRE2 and POST values. To analyze the long-term effects of the PFMT program on the number of urine leakages, we will also investigate these differences by adding the FOLLOW-UP values to the model. Additionally, we will further explore the changes in the number of urine leakages over time through a repeated measures design by adding the weekly leakage values to the model.

If the data are normally distributed, one-way repeated analyses of variance (ANOVA) will investigate differences between the PRE1, PRE2, POST and FOLLOW-UP values for the secondary outcomes, which include ICIQ-UI, ICIQ-LUTS QOL, AFPQ, ASQ, GES, Broome's scale, OTSES scores and UI-associated cost data from the DBICI. If the ANOVA is significant, post-hoc paired-samples *t*-tests will identify which time points show differences. If the data are not normally distributed, a Friedman test will investigate any differences between the PRE1, PRE2, POST and FOLLOW-UP values. If the Friedman test is significant, post-hoc Wilcoxon signed-rank tests will identify which time points show differences.

Treatment costs, PGI-I scores and satisfaction findings will also be reported using descriptive statistics.

The statistical significance level of all statistical tests will be set at $p < 0.05$. All statistical analyses will be performed using R and SPSS, version 26.0.0.0.[90]

Qualitative data. All focus groups' and interviews' verbatim will be analyzed by two reviewers using a qualitative data analysis software.[91,92] The transcripts will undergo a thematic analysis, following a hybrid deductive and inductive approach of coding.[93] The initial codes will be extracted from seven dimensions of the TFA[59] and three of the five domains included in the CFIR framework[88] to build a preliminary codebook. Additional codes will be added inductively throughout the thematic analysis in an iterative process, either as separate codes from the preliminary codebook or as an expansion of the existing codes into more precise sub-codes.[93]

Data integration. The feasibility, acceptability and effects quantitative data will be integrated with the focus groups' and interviews' findings using joint displays, following a mixed-methods convergent design.[94,95] This approach allows combining data together through a table, with the feasibility, acceptability and effects findings as columns, and the participating women and their specific cohort as rows. Through this visual representation using greyscale colour codes, we will then attempt to identify patterns to explain any observed differences in the perceived feasibility and acceptability between the participating women or their cohort. Such mixed-methods designs are helpful to 'draw out new insights beyond the information gained from the separate quantitative and qualitative results'.[94]

Patient and public involvement

This research echoes the needs and priorities of older women, expressed in a Citizens Jury.[96] No patients were involved in the design of the study or recruitment to and conduct of the study.

Ethics and dissemination

The Ethics Committee Board of the Research Centre of the Institut universitaire de gériatrie de Montreal (CRIUGM) approved this study (CER VN 20-21-33) on 8 March 2021.

The research team will send the consent form to the participants by mail after their telephone eligibility evaluation. Each participant will provide informed consent during the individual in-person evaluation. Participants will have time to ask questions before giving consent.

To mitigate risks related to data confidentiality, participants will receive a study identification number. A separate password-protected encrypted file linking study identification numbers with contact information will be maintained for the duration of the study. Any interaction taking place within the class will remain confidential. Furthermore, the participating women will see the physiotherapist individually in a breakout room when discussing their private data. They will not have to disclose any personal information to the group.

Upon completion of the study, we will present the findings at academic and clinical conferences, and publish a peer-reviewed article. The results of this pilot study will inform the development of a larger RCT and support implementation efforts in clinical settings.

Strengths and limitations

This pilot study relies on a rigorous mixed-method design and uses validated standardized measurement tools. Consequently, it promises to offer rich and complete findings on the feasibility, acceptability and both short-term and long-term effects of an innovative PFM group telerehabilitation program for older women with UI.

However, it also has some limitations which must be mentioned. This study's specific inclusion and exclusion criteria and the intensive nature of the intervention could limit the generalizability of results to a wider population of older women with comorbidities and polypharmacy. However, by adopting the same criteria and outcome measures as those used in the GROUP trial,[28,29] it allows for the qualitative comparison of the effects of receiving the intervention online versus in-person in similar populations.

This pilot study also includes a limited sample size and no control group. This limits the strength of the conclusions on the potential effects of teleGROUP. However, by combining a feasibility and acceptability study with a pilot effect study, these findings will enable us to provide important supporting information required in the development of a larger RCT, notably power calculations needed to establish

sample size. This work thus constitutes an essential step in the development of pelvic floor telerehabilitation in the province of Quebec and elsewhere.

Conclusions

This trial will pave the way for the assessment of an online group-based PFMT through an RCT, with the ultimate goal of improving access to continence care for all older women during the COVID-19 pandemic and beyond. Providing an online option for group-based PFMT would allow older women to receive safe UI treatment even during pandemic periods, and also increase accessibility for women living in rural or remote areas where pelvic floor rehabilitation services are unavailable or scarce. Online group-based PFMT is also useful for women, who may not be able to attend rehabilitation outside their home due to weather conditions or either their own or their partner's health conditions.

Contributorship: MLB, JF, BR and CD all made substantial contributions to the development or design of the study and the interpretation of data. MLB wrote the first draft of the protocol and CD, JF and BR then revised the content of subsequent drafts and agreed on the final version prior to submission for peer review.

Ethical approval: The Ethics Committee Board of the Montreal Geriatric University Institute Research Center (CRIUGM) approved this study (CER VN 20-21-33).

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ORCID iD: Mélanie Le Berre https://orcid.org/0000-0002-8461-4274

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