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Research

Group-based pelvic floor muscle training is a more cost-effective approach to treat urinary incontinence in older women: economic analysis of a randomised trial

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KEY WORDS

Conservative treatment
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Exercise therapy
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Economics

ABSTRACT

Question(s): How cost-effective is group-based pelvic floor muscle training (PFMT) for treating urinary incontinence in older women? **Design**: Economic evaluation conducted alongside an assessor-blinded, multicentre randomised non-inferiority trial with 1-year follow-up. **Participants**: A total of 362 women aged ≥ 60 years with stress or mixed urinary incontinence. **Intervention**: Twelve weekly 1-hour PFMT sessions delivered individually (one physiotherapist per woman) or in groups (one physiotherapist per eight women). **Outcome measures**: Urinary incontinence-related costs per woman were estimated from a participant and provider perspective over 1 year in Canadian dollars, 2019. Effectiveness was based on reduction in leakage episodes and quality-adjusted life years. Incremental cost-effectiveness ratios and net monetary benefit were calculated for each of the effectiveness outcomes and perspectives. **Results**: Both group-based and individual PFMT were effective in reducing leakage and promoting gains in quality-adjusted life years. Furthermore, group-based PFMT was ≥ 60% less costly than individual treatment, regardless of the perspective studied: –$914 (95% CI –970 to –863) from the participant's perspective and –$509 (95% CI –523 to –496) from the provider's perspective. Differences in effects between study arms were minor and negligible. Adherence to treatment was high, with low loss to follow-up and no between-group differences. **Conclusion**: Compared with standard individual PFMT, group-based PFMT was less costly and as clinically effective and widely accepted. These results indicate that patients and healthcare decision-makers should consider group-based PFMT to be a cost-effective first-line treatment option for urinary incontinence. **Trial registration**: ClinicalTrials.gov NCT02039830. **[Cacciari LP, Kouakou CRC, Poder TG, Vale L, Morin M, Mayrand M-H, Tousignant M, Dumoulin C (2022) Group-based pelvic floor muscle training is a more cost-effective approach to treat urinary incontinence in older women: economic analysis of a randomised trial. *Journal of Physiotherapy* 68:191–196]**

Introduction

Urinary incontinence (UI) is an important and under-recognised problem affecting the lives of many adults.[1,2] More frequent in women and increasing with age, UI is one of the most prevalent health concerns in older women.[2,3] Up to 55% of older women suffer from UI and 20 to 25% of them regularly experience severe symptoms (more than 10 episodes/week).[2] UI is not only a frequent and undeniable social problem that engenders embarrassment, negative self-perception and social isolation,[4–7] it also leads to considerable personal and societal expenditures.[3,8]

Combined direct and indirect annual UI-related costs for both individuals and society were estimated to exceed CA$5 billion in Canada (2014),[3] US$19.5 billion in the USA (2000)[9] or £818 million in the UK (2004),[10] which in most cases are covered out of pocket and not reimbursed by third-party payers. Although coverage for treatment varies across countries, the combined high prevalence and hidden nature of incontinence leads to a large direct economic burden on individuals, most often older women.[11]

Clinical practice guidelines recommend supervised pelvic floor muscle training (PFMT) as the first-line treatment for women with the most common UI subtypes, stress or mixed UI (Level A evidence).[12,13] Most often provided in individual physiotherapy sessions, PFMT reduces the number of leakage episodes and quantity of leakage, while improving UI-related quality of life.[14] Despite this recommendation, PFMT is currently not consistently offered. Services

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are scattered and inconsistent; they are frequently not covered by public healthcare systems, which leads to under-treatment worldwide.[15,16]

Group-based PFMT is proposed as a more affordable intervention option for women with UI.[17–19] However, economic evaluations of group-based PFMT programs are scarce, and evidence is lacking on its cost-effectiveness compared with standard individual PFMT.

Therefore, the study question for this economic evaluation conducted alongside a randomised clinical trial[20] was:

How cost-effective is group-based PFMT for treating urinary incontinence in older women?

Method

Design

This was a planned secondary analysis of the Group Rehabilitation Or IndividUal Physiotherapy (GROUP) trial, which was an assessor-blinded, multicentre, randomised non-inferiority trial comparing standard individual (one-on-one) with group-based PFMT (one physiotherapist for eight patients) for the treatment of stress and mixed UI in older women.[19,20]

Participants, therapists, centres

Eligible participants were women aged $\geq$ 60 years, who reported at least three UI episodes per week during the preceding 3 months.[21] Stress/mixed UI was confirmed with the validated Questionnaire for Incontinence Diagnosis.[22] Women were excluded if they had reduced mobility or comorbidities that would interfere with the study. Additional details of the trial's eligibility criteria are provided in the trial protocol.[20]

Women who met the eligibility criteria and consented to participate were randomly assigned (1:1) to either group-based PFMT or individual PFMT, with random block sizes (four to six), stratified by centre (Montreal and Sherbrooke) and by UI type (stress and mixed). Participants were each assigned a random computer-generated sequence, which was provided by a statistician external to data collection (allocation concealed). Outcome assessors remained blinded to the participants' intervention allocation.

Intervention

Participants from both study arms attended an individual session with a physiotherapist to learn how to effectively contract their pelvic floor muscles using vaginal palpation. This was followed by 12 1-hour PFMT sessions delivered once per week, either individually (one-on-one) or in groups of six to eight women. The training protocol for both interventions comprised the same standardised educational and exercise components, including home pelvic floor muscle exercises assigned for 1 year. Only those who attended 10 or more of the 12 sessions were included in the analysis.

In addition to the standard protocol, the individual arm used electromyography biofeedback as per usual practice. Participants in the group-based arm were offered up to three short one-on-one assessment sessions with a physiotherapist to confirm correct PFM contractions, if necessary.

Outcome measures

Cost outcomes

UI-related annual costs per woman were estimated from participant and provider perspectives in each trial arm and reported in 2019 Canadian dollars. Therefore, all dollar values reported in this manuscript are in Canadian dollars, unless specifically stated otherwise. For each perspective, total cost included the estimated intervention cost plus UI-related additional costs to participants or providers collected over the course of the study. Details of the cost are presented in Figure 1.

Participant perspective: Intervention cost was based on values customarily applied in private physiotherapy clinics in the study area. For the individual arm in particular, each participant's intervention cost was based on the average cost per initial individual assessment ($100) and PFMT sessions ($100 each) multiplied by their attendance. Group-based intervention cost was considered as a treatment package ($260), including the initial individual assessment and the twelve treatment sessions (independent of their attendance to each session). Additional costs from both arms were derived from participants' reports on the Dowell Bryant Incontinence Cost Index, which were acquired at baseline, after treatment and at the 1-year follow-up. These costs included UI-related expenses from incontinence care products and other UI treatments undertaken during the study period. Annual cost estimates per participant were based on reported event frequency and mean unit costs applied to the study area. When sources from prior to 2019 were used to derive costs, inflation was calculated for an equivalent price in 2019.

Provider perspective: Provider intervention cost was estimated from the current mean labour hour of a specialised physiotherapist (market value),[23] in addition to room cost (including staff time, consumables and all equipment necessary for PFMT clinical practice, and specific to each trial arm). For group-based PFMT, intervention cost

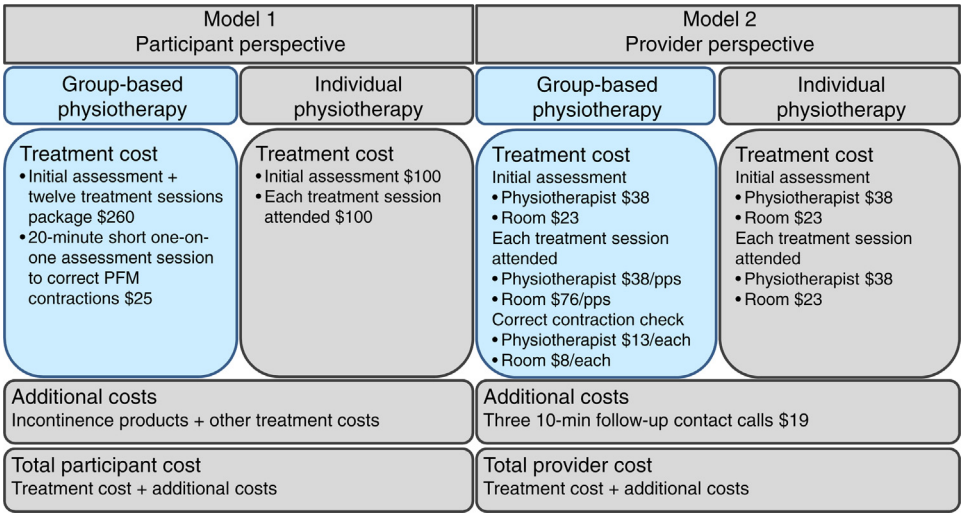

Figure 1. Outline of cost calculation, including primary clinical costs and extra costs from the participant and provider perspectives. Values are presented in Canadian dollars, based on the current (2019) practice in the study area. Room cost includes staff time, consumables and all reusable equipment, comprising biofeedback-related expenses for the individual sessions and extra room space and reusable equipment for the group sessions. pps = number of participants per session.

Table 1
Baseline demographic characteristics and effectiveness outcomes.

Characteristic	Group (n = 154)	Individual (n = 165)
Age *(y)*, mean (SD)	68.4 (5.9)	68.1 (5.9)
BMI *(kg/m²)*, mean (SD)	27.1 (4.5)	27.1 (4.7)
Parity, median (IQR)	2 (1 to 3)	2 (1 to 2)
Type of UI, n (%)		
Stress UI	31 (20)	24 (15)
Mixed UI	123 (80)	141 (85)
Duration of symptoms *(y)*, mean (SD)	8.8 (8.7) (n = 151)	10.3 (10.3) (n = 162)
Leakage *(episodes/d)*, median (IQR) [a]		
Baseline	1.43 (0.86 to 2.00)	1.57 (0.86 to 2.79)
Follow-up	0.43 (0.14 to 1.07) (n = 153)	0.43 (0.14 to 1.00)
HRQoL *(ICIQ-LUTSqol)*, median (IQR) [b]		
Baseline	32 (27 to 40) (n = 154)	32 (28 to 38) (n = 163)
Follow-up	23 (21 to 28) (n = 151)	23 (21 to 27) (n = 163)

BMI = body-mass index, HRQoL = health-related quality of life, n = number used in the analysis, UI = urinary incontinence.
[a] As reported on the 7-day bladder diary.
[b] As reported on International Consultation on Incontinence Modular Questionnaire - Lower Urinary Tract Symptoms Quality of Life (ICIQ-LUTSqol); scores ranging 19 to 76, greater values indicate an increased impact on quality of life (minimum clinically important difference, 3.71 points; incremental improvement, 6.63 points).[29]

was based on the number of participants attending per session. Occasional short one-on-one vaginal palpation assessments were estimated to cost one-third of the hour-long individual assessments based on their mean duration of 20 minutes. For both arms, additional costs included follow-up calls to the participants undertaken at 3 and 6 months after intervention. These calls were estimated to cost one-sixth of the physiotherapist labour hour, based on their mean duration of 10 minutes. Repeated attempts to contact participants were also considered.

Effectiveness outcomes

Effectiveness of the two PFMT interventions were acquired at 1 year and included leakage reduction and health-related quality of life (HRQoL).

Leakage reduction: Leakage reduction data were derived from participants' self-reports on a 7-day bladder diary. The number of participants with a minimum clinically important difference in UI episodes ($\geq$ 50%)[24] at the 1-year follow-up relative to the pre-treatment baseline was considered for analysis.

Health-related quality of life: HRQoL was derived from a condition-specific measure, the International Consultation on Incontinence Modular Questionnaire - Lower Urinary Tract Symptoms Quality of Life (ICIQ-LUTSqol) assessed at the 1-year follow-up. This choice was based on previous assumptions that generic health-state measures usually used in economic evaluations (such as the EQ-5D-5L) would not be sensitive enough to capture clinically important differences related to UI on quality of life.[25,26] Furthermore, the ICIQ-LUTSqol is a recommended questionnaire with which to assess the impact of UI on quality of life (Grade A+).[27] For the cost-effectiveness analysis, full scores were converted into a utility index (from 0 [worst imaginable health state] to 1 [best imaginable health state]) using a published algorithm.[25]

Cost-effectiveness outcomes

Incremental cost-effectiveness ratios were calculated for each of the effectiveness outcomes and the two perspectives (ie, participant and provider). The incremental cost-effectiveness ratio was defined by the difference in cost, divided by the difference in effect for the group-based versus individual PFMT. Incremental net benefits of each intervention were calculated using the usual willingness-to-pay threshold of $50,000 per quality-adjusted life years (QALY)[28]:

$$([\mathrm{HRQoL}_{\mathrm{group}} - \mathrm{HRQoL}_{\mathrm{individual}}] * \$50{,}000 - [\mathrm{Cost}_{\mathrm{group}} - \mathrm{Cost}_{\mathrm{individual}}])$$

Data analysis

Analyses were focused on outcomes at 1 year following guideline recommendations,[12] and only women who completed the 1-year assessment were included. Baseline characteristics of the study arms were summarised with descriptive statistics. Spearman's correlation was carried out between cost and effectiveness in order to choose an estimation method. If cost and effectiveness were correlated, then a seemingly unrelated regression was used. If there was no evidence of a correlation, ordinary least squares was used. Cost and effectiveness data were resampled 1,000 times with non-parametric and univariate parametric bootstrapping to estimate 95% CIs around the mean difference in costs and effects between study arms.

Results

A total of 362 women were randomised to either individual (n = 184) or group-based PFMT (n = 178). Overall, 337 of 362 (93%) participants completed the intervention and 319 of 362 (88%) completed the follow-up assessment and were included in this study. Table 1 provides clinical and demographic characteristics of the participants. No important baseline imbalances were found between study arms. Adherence to treatment sessions was high (98% for group-based and 95% for individual PFMT). Loss to follow-up until the end of the intervention was low, similar between arms and unrelated to treatment allocation: 12 of 178 (7%) of the group-based and 13 of 184 (7%) of the individual PFMT participants. Details are presented in Appendix 1 on the eAddenda.

Estimates for the average UI-related costs per woman in each study arm and perspective are presented in Table 2. The main cost

Table 2
Estimated average urinary incontinence-related annual cost per woman from participant and provider perspectives.

Cost categories	Participant perspective mean (SD)		Mean difference (95% CI)[a]	Provider perspective mean (SD)		Mean difference (95% CI)[a]
	Group (n = 154)	Individual (n = 165)		Group (n = 154)	Individual (n = 165)	
Initial assessment (A)	100	100	–	64	64	–
Treatment sessions (B)	261 (6)	1,173 (68)	−911 (−921 to −900)	238 (72)	747 (43)	−509 (−523 to −496)
Primary treatment cost (C) (A+B)	361 (6)	1,273 (68)	−911 (−921 to −900)	302 (72)	811 (43)	−509 (−523 to −496)
Incontinence products[b] (D)	172 (230)	177 (240)	−5 (−60 to 43)	–	–	–
Follow-up contact calls (E)	–	–	–	19	19	–
Other treatments[c] (F)	6 (34)	3 (26)	2 (−4 to 9)	–	–	–
Additional costs (G)(D/E + F)	177 (234)	180 (241)	−3 (−57 to 48)	19	19	–
Total cost (C+G)	539 (233)	1,453 (246)	−914 (−970 to −863)	321 (72)	830 (43)	−509 (−523 to −496)

All costs are reported in 2019 Canadian dollars.
[a] Bootstrapping was used to estimate the 95% CI around the mean difference.
[b] Annual costs were estimated using self-reported data acquired at baseline (T0), post treatment (T1) and 1 year (T2) as T0*3+T1*3+T2*6; costs were no different between study arms at either time point (T0: $24 [SD 33] group versus $25 [SD 32] individual, mean difference [MD][95% CI]: −0.3 [−7.1 to 6.4]; T1: $10 [SD 16] group versus $11 [SD 19] individual, MD [95% CI]: −1.2 [−5.0 to 2.6]; T2: $12 [SD 21] group versus $12 [SD 21] individual, MD [95% CI]: −0.3 [−4.9 to 4.3]).
[c] Other treatment costs were based on the participants' reported frequency and their mean current unitary cost (specific to this population in the study area).

Table 3
Cost-effectiveness outcomes.

Outcome	Intervention	Total cost mean (SD)	Effect mean (SD)	Δ cost mean (95% CI)	Δ effect mean (95% CI)	ICER (95% CI)	
						NPB	UPB
Participant perspective							
Reduction in UI episodes *(%)*	Group (n = 153)	536 (232)	74 (44)	−917	2 (1.8 to 2.4)	–	–
	Individual (n = 165)	1,453 (246)	72 (45)	(−918 to −915)			
QALY	Group (n = 151)	537 (230)	0.9815 (0.018)	−916	−0.00006	1,958,228	1,571,525
	Individual (n = 163)	1,453 (248)	0.9820 (0.018)	(−918 to −915)	(−0.00080 to −0.00056)	(−2,381,108 to 6,297,564)	(−630,539 to 3,773,589)
Provider perspective							
Reduction in UI episodes *(%)*	Group (n = 153)	321 (72)	74 (44)	−509	2 (1.8 to 2.4)	–	–
	Individual (n = 165)	830 (43)	72 (45)	(−507 to 512)			
QALY	Group (n = 151)	322 (72)	0.9815 (0.018)	−508	−0.0006	1,098,535	855,423
	Individual (n = 163)	830 (43)	0.9820 (0.018)	(−510 to −507)	(−0.00080 to −0.00056)	(−1,339,830 to 3,536,899)	(−239,281 to 1,950,128)

All costs are reported in 2019 Canadian dollars.
Δ = incremental (group − individual) cost and effect, ICER = incremental cost-effectiveness ratio (Δ cost/ Δ effect), NPB = nonparametric bootstrapping (1,000 iterations), QALY = quality-adjusted life years, UI = urinary incontinence, UPB = univariate parametric bootstrapping (1,000 iterations).

driver from both perspectives was the *intervention cost*, which was at least 60% less costly in the group-based PFMT. Regardless of the perspective, *additional costs* were similar between study arms.

No important differences were found in effectiveness between the study arms (Table 1). At the 1-year follow-up, > 70% of participants from both group-based and individual PFMT demonstrated minimum clinically important differences (≥ 50% reduction) in the number of UI episodes. HRQoL also reached incremental clinically important differences in both study arms: ICIQ-LUTSqol > 6.63 points;[29] mean difference 9.0 (95% CI 7.6 to 10.3) and 8.9 (95% CI 7.7 to 10.2) for the group-based and individual PFMT, respectively.

The estimated average UI-related annual cost per woman from participant and provider perspectives are shown in Table 2, while cost-effectiveness outcomes are shown in Table 3. Total cost per woman was on average lower for group-based PFMT, with an average gap of $914 from participant and $509 from provider perspectives. Bootstrapped incremental cost-effectiveness ratios showed convergent results for each perspective and effect. From the participant's perspective, a variable correlation between participant costs and effects was found, and therefore a seemingly unrelated regression model estimation was used, while an ordinary least squares was used for the provider's perspective. When the effectiveness outcome was the reduction in UI episodes, the incremental costs and effects indicated that individual PFMT was inferior, as the group-based arm had lower costs and slightly more people with a 50% reduction in UI episodes. On the other hand, when average QALY was considered, individual PFMT was slightly more effective. However the incremental cost-effectiveness ratios were in excess of $800,000 per additional QALY gained for individual compared with group-based PFMT, which was much higher than the pre-established $50,000 threshold for willingness to pay.[28]

Figure 2 shows the probability of cost-effectiveness for various cost thresholds per unit of effectiveness gained, while distribution of costs and effects are illustrated in Figure 3. Over the range of society's willingness to pay, group-based PFMT had no more than 87% and 94% probability of being considered cost-effective for a 50% reduction in UI episodes, or 38% and 40% for a QALY gain from participant and provider perspectives, respectively. Table 4 shows the net monetary benefit of each intervention based on a society willingness to pay threshold of $50,000 per QALY gain, again favouring group-based PFMT in both perspectives.

Discussion

Group-based PFMT is a cost-effective approach for treating UI: it incurred low costs, sustained reduction in UI episodes over 1 year and improved HRQoL. When compared with the standard individual treatment, group-based PFMT provided at least 60% in cost savings, regardless of who paid for the treatment, while differences in effects

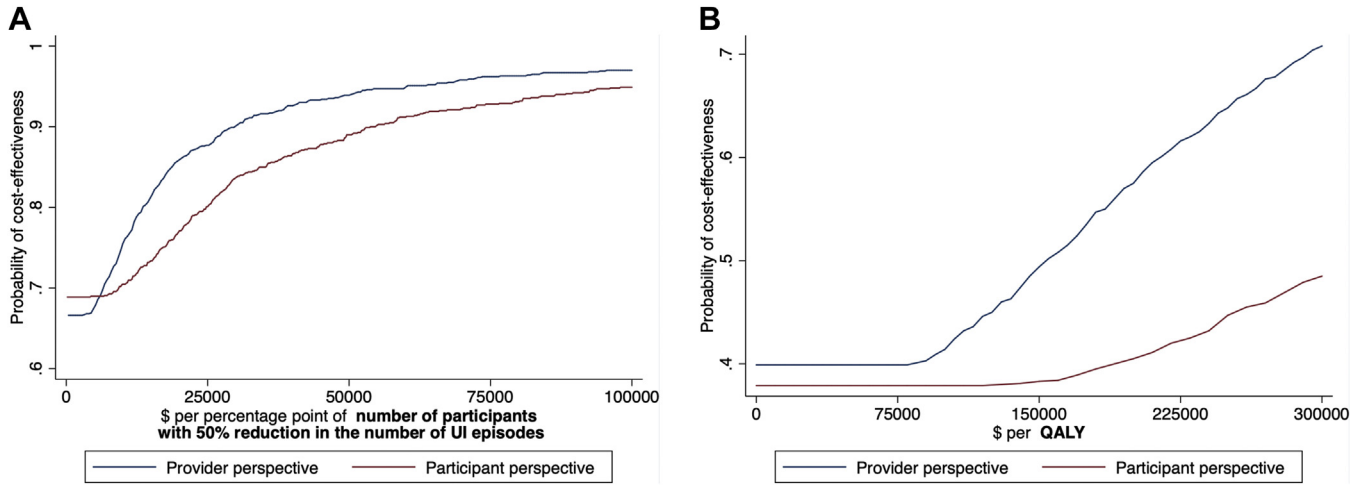

Figure 2. Cost-effectiveness acceptability curve of maximum willingness to pay for group-based versus individual pelvic floor muscle training.

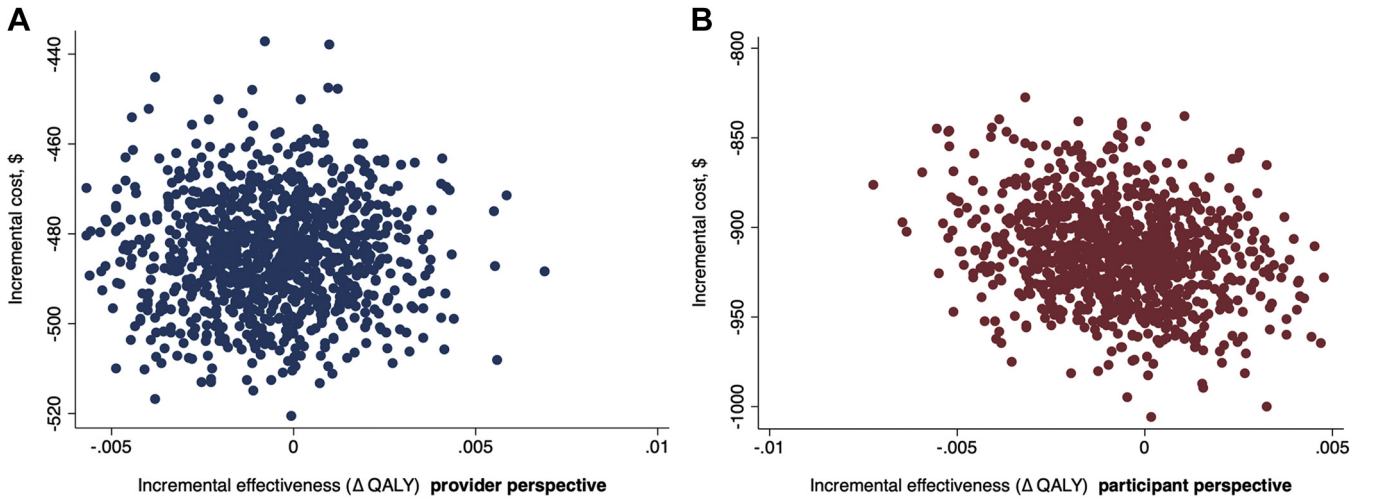

Figure 3. Joint density of the incremental costs and benefits of each of the 1,000 simulated cost-effectiveness ratios.

were negligible.[25] Adherence to treatment sessions was high and loss to follow-up low, indicating acceptability of both interventions. Of interest, participants in the group-based treatment reported benefits from peer support, and perceived the group classes as a safe space to share their experiences.[30,31]

From the provider perspective, with budget constraints in healthcare worldwide, innovative ways of managing and stretching budgets are greatly needed.[26] Even when available, PFMT currently involves long wait times, leading to under-treatment,[3,15,16] or the frequent use of surgery as first-line therapy, despite serious adverse effects.[3] Group-based PFMT could be a cost-effective strategy for reducing costs and optimising rehabilitation services. For instance, the cost for treating three women individually would be equivalent to eight women treated in a group-based PFMT approach. This is of particular importance when considering the combination of an aging world population and the tendency for UI to become more prevalent with age.[32] Addressing UI earlier and more comprehensively amongst seniors could go a long way to reduce related downstream health outcomes.[3,7]

From the participant perspective, the burden of UI has been compared with many other chronic diseases in women; however, unlike most chronic diseases, UI-related healthcare costs are often fully covered out-of-pocket.[3,33] The average cost gap for choosing group-based over the standard individual PFMT ($914) may seem small, but represents as much as 3% of the average annual income for an older woman living in the community (Canada, 2018).[34] With the benefits of peer support and lower costs, group-based PFMT could be a way of promoting access to care and encouraging women to pursue and adhere to treatment.

It is believed that this is the first cost-effectiveness analysis conducted alongside a robust clinical trial involving supervised group-based versus standard individual PFMT over 1 year for the treatment of UI in older women. Furthermore, the high rate of participants who completed the study (88%) and the lack of baseline differences between completers and non-completers support the assumption that data were missing at random, which is unlikely to cause bias. Although the QALY gains (0.021) that were obtained were relatively small, they reached incremental clinical differences and were comparable or higher than those found in other conservative management studies treating adult women with UI (0.01 to 0.02).[35,36] Finally, the results were consistent between both participant and provider perspectives, and also considering both UI leakage reduction and HRQoL.

Limitations of this study included disregarding costs related to accessing care (such as laundry costs or time and travel costs). Although all relevant costs should be accounted for in a complete analysis, this exclusion should not impact the study results, as both study arms followed the same training program delivered in the same location. In addition, the 1-year follow-up assessment revealed excellent adherence to treatment and improvement in symptoms. However, a longer-term follow-up should be considered in future research. Further, although generic quality of life measures (such as the EQ-5D) are the recommended instrument with which to calculate QALY, they have often been considered not sensitive enough to assess UI-specific outcomes.[26] Here, the choice for a recommended UI-specific quality of life measure (ICIQ-LUTSqol)[27] proved to be accurate to capture small but clinically important differences related to PFMT. Finally, since effect variables (ie, UI episodes, QALY) were correlated with cost variables, it was decided to run the two regressions simultaneously using the seemingly unrelated regression method; this enabled error terms correlation to be taken into account and bias to be avoided.

In conclusion, compared with standard individual PFMT, group-based PFMT was less costly and as clinically effective and widely accepted. The implementation of group-based interventions to treat UI could optimise the use of common resources, help unburden

Table 4
Net monetary benefit.

Intervention	Total cost mean (SD)	QALYs mean (SD)	Net monetary benefit (95% CI)	Incremental net monetary benefit (95% CI)	
				NPB	UPB
Participant perspective					
Group (n = 151)	$537 (230)	0.9815 (0.018)	$48,537 (48,376 to 48,698)	$828 (821 to 834)	$887 (880 to 894)
Individual (n = 163)	$1,453 (248)	0.9820 (0.018)	$47,649 (47,498 to 47,799)		
Provider perspective					
Group (n = 151)	$322 (72)	0.9815 (0.018)	$48,752 (48,606 to 48,899)	$458 (452 to 464)	$451 (444 to 457)
Individual (n = 163)	$830 (43)	0.9820 (0.018)	$48,272 (48,136 to 48,408)		

All costs are reported in 2019 Canadian dollars. Willingness to pay established at $50,000 per QALY. Net monetary benefit = HRQoL * $50,000 – cost; Incremental net benefit = ($HRQoL_{group}$ PFMT – $HRQoL_{individual}$ PFMT) * $50,000 – ($cost_{group}$ PFMT – $cost_{individual}$ PFMT).
HRQoL = health-related quality of life, NPB = non-parametric bootstrapping (1,000 iterations), QALY = quality-adjusted life years, UPB = univariate parametric bootstrapping (1,000 iterations).

primary care, and facilitate access to care for women seeking an effective and more affordable UI treatment.

What was already known on this topic: The combined high prevalence and hidden nature of incontinence leads to a large direct economic burden on individuals and high healthcare costs. Clinical practice guidelines recommend supervised pelvic floor muscle training, which is usually delivered individually but group-based programs are effective.
What this study adds: Compared with standard individual PFMT, group-based PFMT was less costly and as clinically effective and widely accepted.

Ethics approval: The research centre of the Institut universitaire de gériatrie de Montréal and the research centre of the Centre hospitalier universitaire de Sherbrooke, Canada, Ethics Committees approved this study. All participants gave written informed consent before data collection began.

Competing interests: Nil.

eAddenda: Appendix 1 can be found online at https://doi.org/10.1016/j.jphys.2022.06.001

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