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Pelvic floor muscle group therapy for the treatment of urinary incontinence during pregnancy and post-partum: a randomized controlled trial

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ABSTRACT

Objective: Pelvic Floor Muscle Group Therapy (PFMGT) is an effective treatment option in the general population. However, the effect of therapy during pregnancy and shortly thereafter is unclear. Therefore, this study investigates the effect of PFMGT in peri-partum women with UI compared to care-as-usual.

Materials and Methods: Two randomized controlled trials: study 1: pregnant women and study 2: 6 weeks post-partum women, were performed. The primary outcome was UI severity based on the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short form (ICIQ-UI SF). Secondary outcomes were the Global Impression of Severity (GPE) measuring patient's self-reported improvement and the Incontinence Impact Questionnaire-7 (IIQ-7), measuring UI impact. Descriptive and univariate analysis were reported and the non-parametric Mann-Whitney U test was used to compare differences between groups.

Results: Inclusion numbers could not be met, and therefore all women received individual Pelvic floor muscles training (PFMT). Study 1 showed no significant results regarding the prevalence of UI (ICIQ-UI SF), GPE and IIQ-7 at any measurement moment. As compared to baseline, study 2 showed a significant improvement for prevalence of UI and impact of UI at 4 months post-partum, however there was no significant difference between groups at other measurement moments. Significant subjective improvement was seen at 4th and 9th months post-partum, in favor of the PFMT group ($p=0.02$).

Conclusion: PFMT, started after childbirth, demonstrated improved UI and quality of life with a lower number of complaints at the 4 months post-partum assessment. However, the full potential of effectiveness of PFMT could not be established due to insufficient inclusions.

Keywords: Pelvic floor muscle group therapy; physical therapy; post-partum; pregnancy; pre-partum; urinary incontinence

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INTRODUCTION

Urinary incontinence (UI) is the complaint of involuntary loss of urine.¹ The reported overall prevalence of UI varies between 25 and 46.4%.^{2,3} Stress urinary incontinence (SUI), the complaint of involuntary loss of urine on effort or physical exertion or on sneezing or coughing,¹ is the most prevalent type among peri-partum women.²⁻⁴ During pregnancy prevalence of UI is reported between 9 and 75%, and post-partum between 10 and 63%.⁵⁻⁸ UI reduces quality of life (QoL) but nonetheless, many women tend to accept their problems because they are embarrassed, think it is normal and will diminish by itself.⁸⁻¹⁰

The development of UI peri-partum might be due to several reasons, including childbirth or physiological weight gain resulting in an increase of intra-abdominal pressure transmitted to the bladder and bladder neck, leading to urethral mobility and pelvic floor muscles (PFM) activity problems.¹¹⁻¹³ The PFMs of women with UI during pregnancy are weaker and thinner.¹⁴

PFM training (PFMT) aims to improve the supportive system and is a first-line treatment option for UI.^{15,16} As the costs for healthcare are rising, it is important to provide cost-effective therapies.¹⁷ PFMT can be provided as individual, but also as group therapy (PFMGT). PFMGT appeared to be equally effective in the treatment of UI in women in the general or older population.^{18,19} A recent Cochrane systematic review concluded that it is uncertain whether PFMT is an effective treatment option for women with UI during pregnancy and post-partum.²⁰ Also, information on cost-effectiveness of PFMT and long-term effects is lacking.²⁰

Therefore, the primary aim of this study was to investigate whether a structured assessment and treatment program of intensive, supervised PFMGT, including a home maintenance program, reduces 18 months post-partum UI severity (frequency, amount, and impact) compared to care-as usual (CAU) in adult pregnant (study 1) and post-partum women with SUI (study 2). The secondary aim was to investigate whether PFMGT is cost-effective compared to CAU.

MATERIALS AND METHODS

Study design

In two randomized controlled multicenter trials, PFMGT (intervention group) was compared to CAU (control group). The two studies were registered as one trial in The Netherlands National Trial Register (NTR5971). The Medical Ethics Committee (METC) of the Maastricht University Medical Center (MUMC+) has approved study 1 (METC162038) and study 2 (METC162051). The ethics boards of the participating four hospitals, Zuyderland Medical Center (two locations), Laurentius hospital and Maxima Medical Center, approved the trial, indicating also coverage for 13 local midwifery practices. The study protocol was published previously.²¹

Participants

The women were recruited in the southern part of The Netherlands between December 1st 2017 and August 1st 2019 by midwives and physicians (case managers). Women were included if they met amongst others the following criteria: (1) ≥ 18 years, (2) UI (stress or mixed with predominant SUI factor, according to Haylen et al.²²), and (3) a score of >3 on the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF).²³ Exclusion criteria included: (1) UI prior to first pregnancy, still existing during pregnancy, (2) high-risk pregnancy, resulting in a contra-indication for performing intensive PFMT (e.g., placenta praevia, vaginal blood loss, preterm uterine contractions), (3) suffering from significant exercise limitations or co-morbidities (physical or psychological) that would restrain a woman from participation in the group therapy. A full description of inclusion and exclusion criteria is published elsewhere.²¹

Randomization and blinding

During a regular planned consultation with their case manager, women meeting the eligibility criteria and interested to participate, received a short vaginal examination to check the ability to contract the PFMs. The candidate participant received an email with a link to the electronic baseline questionnaire after signing the informed consent. Once the questionnaires were completed, blocked randomisation was done by a computer-generated sequence in a 1:1 ratio on patient and location level. Allocation in blocks of four was concealed and done using a central computer. Participants in the intervention group, who could not contract their PFMs correctly, were referred to a specialized (pelvic) physical therapist (PT) for individual instruction before joining PFMGT (Figure 1).

The participants, specialized PT and coordinating researcher could not be blinded. However, once the participant completed the questionnaires, they were blocked from making alterations. Before the statistical analyses all participants were appointed a new study number for which the coordinating researcher was blinded. Therefore, analyses were done blinded for treatment allocation.

Intervention

The intervention was provided by one specialized PT in every region. In Netherlands, pelvic PT is a specialisation within the field of physical therapy and has its own registration in order to guarantee quality.²⁴ The specialized PT's were instructed on the PFMGT protocol which consisted of eight once weekly PFMGT sessions of 60 minutes each. Pregnant and post-partum women

could participate as soon as they were randomized in the same intervention group, with a maximum of four per group.

The intervention included instructions on pelvic floor anatomy and how to contract, relax and train the PFM's correctly in combination with general physical exercises with a strong focus

on self-management. The PFMGT protocol has been published previously.²¹ The women in the intervention group received a mApp (iPelvis),²⁵ which is an application with individualized pelvic PT exercises to reinforce adherence to and compliance with a home maintenance program.

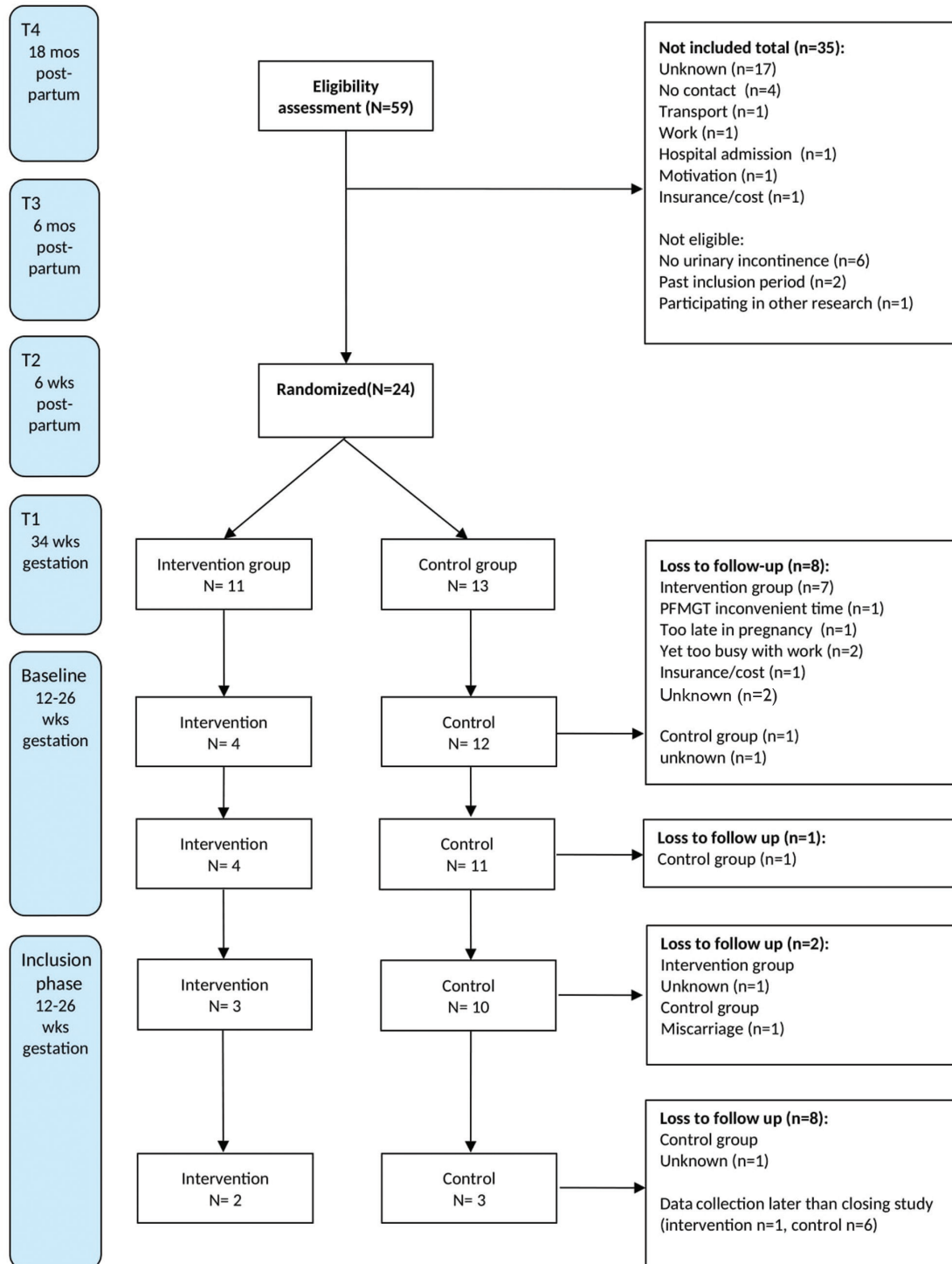


Figure 1. Flowchart study 1

T: measurement, wks: weeks, mos: months, N: number, PFMGT: pelvic floor muscle group therapy

Care-as-usual

Participants in the CAU group received regular advice from their case managers and were free to participate in any pregnancy-related course or visit a health care professional for their UI.

Measurements

Besides the measurement of the baseline characteristics in both studies the women were asked to fill in the questionnaires multiple times (Figure 1 and 2).

Primary outcome measure

The primary outcome is based on the ICIQ-UI SF. This is a validated brief (four questions) measure for evaluating the frequency, severity and impact on QoL of UI.²⁶ The total score ranges from 0 (not affected) to 21 (severely affected). The questionnaire is translated in Dutch.²⁷ Therapy success is defined as absence of UI or change from baseline of at least three points on the ICIQ-UI SF at 18 months post-partum.²⁸

Secondary outcome measures

The Patient Global Impression of Severity (GPE) questionnaire was used to assess the patients' self-reported improvement.²⁹ It is a reliable scale for incontinence, consisting of one question and seven response options ranging from very much improved to very much deterioration.^{30,31}

The validated Incontinence Impact Questionnaire-7 (IIQ-7) was used to determine the UI impact on four domains: mobility, physical functioning, emotional health and embarrassment.³² The total score ranges from 0 to 100, 0 meaning no impact and 100 extreme impact.

Sample size

The total sample size estimate for study 1 was 150, and study 2 was 90. These numbers are based on a significance level of 0.05, a power of 90%, and a 20% drop-out rate. Further justification has been described elsewhere.²¹

Statistical analysis

The Consolidated Standards of Reporting Trials (CONSORT) statement was followed for reporting the trial.³³ Data was analysed according to the intention-to-treat principle.

Descriptive and univariate analysis were reported as means and standard deviations or 95% confidence intervals. The non-parametric Mann-Whitney U test was performed to compare differences between the two groups. A p-value <0.05 is considered to be statistically significant. Data analyses are carried out using IBM SPSS Statistics for Windows, version 25.0 (IBM Corp., Armonk, N.Y., USA).

RESULTS

Recruitment took place between 01.06.2017 and 01.08.2019.

Participants

In study 1, 59 women were eligible for participation, of which 24 women were randomized (intervention group=11, control group=13) (Figure 1). Four participants completed the study (Figure 1). In study 2, 116 women were eligible of which 23 were randomized (intervention group=10, control group=13), 14 participants completed the study (Figure 2). Characteristics of the participants for study 1 and 2 are shown in Table 1.

Outcomes

The results are based on individual PFMT instead of PFMGT, as groups did not fill sufficiently (therefore, from this point on the term PFMT will be used). However, the original PFMGT protocol was followed. Study 1 showed no statistically significant differences between groups at any point regarding the ICIQ-UI SF total score, GPE and IIQ-7 (Table 2), although both groups showed improvements on all outcomes post-intervention.

In study 2, the intervention group improved significantly compared to the control group ($p=0.012$) at four months post-partum with regard to the ICIQ-UI SF score of ($p=0.012$) and IIQ-7 ($p=0.04$). Moreover, the GPE of the intervention group improved significantly at T1 and T2 ($p=0.02$). T3 showed no statistically significant difference between groups (Table 2).

The mean number of days per week the participants performed PFM exercises during the eighth week PFMGT was 5.9 (median 6.0) and 5.0 (median 5.3) in study 1 and 2, respectively.

Cost-effectiveness outcomes have not been calculated because both studies were underpowered.

DISCUSSION

The cost-effectiveness of PFMT, for pregnant (study 1) and post-partum women (study 2) with SUI could not be established as planned, due to the small number of included women in both studies. As a consequence of the small numbers, all women in the intervention group received individual PFMT. Therefore, the reported results should be interpreted with great caution and no conclusions regarding the original hypothesis can be made.

PFMT started during pregnancy showed no significant results regarding the effect on UI, impact, and self-perceived impression of severity of symptoms at any point. This is in line with a recent Cochrane systematic review, reporting no evidence of the treatment effect of PFMT on UI in late pregnancy.²⁰ Most likely our findings must be explained by the fact the study is underpowered. In addition, during pregnancy the continence

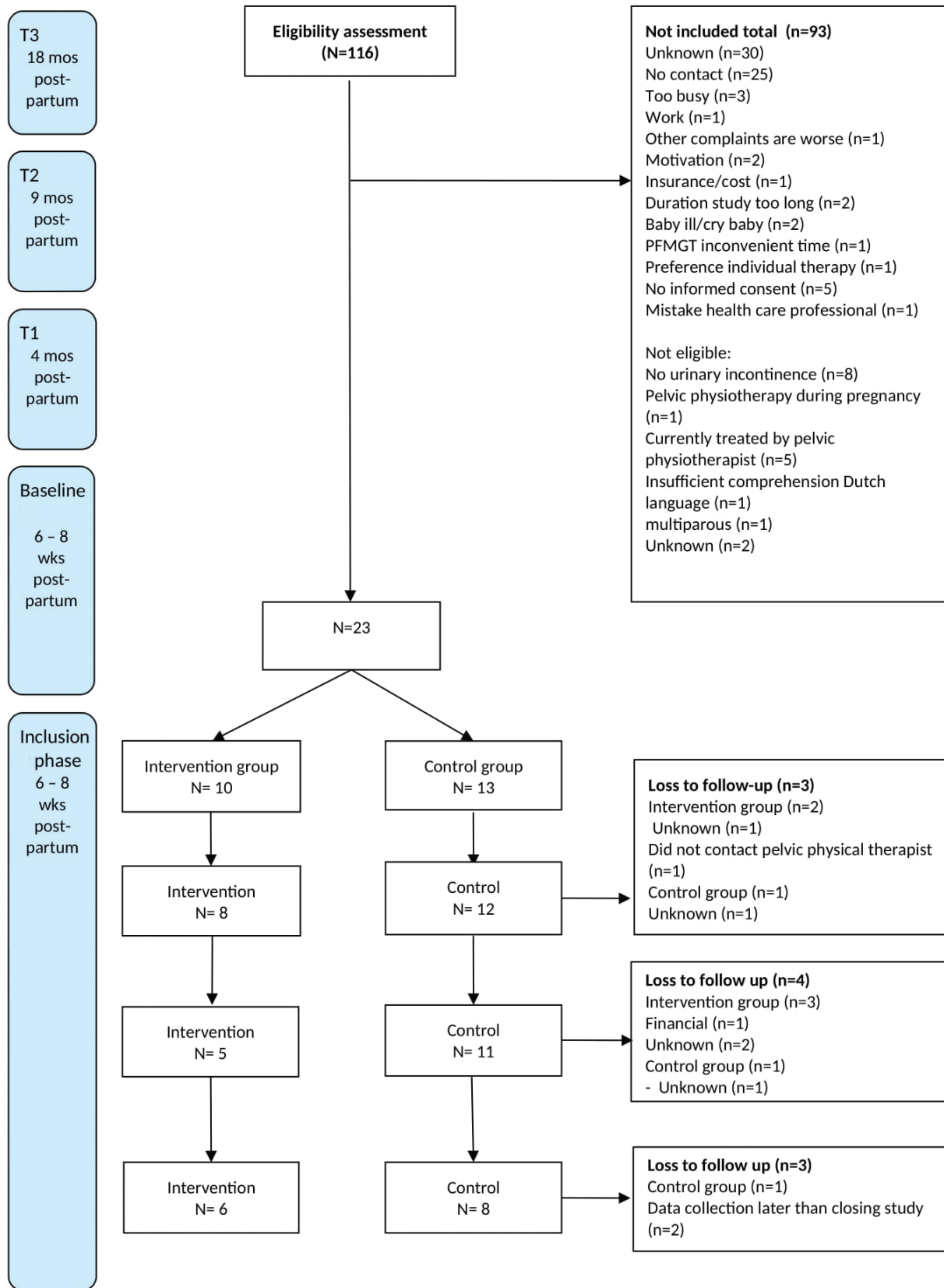


Figure 2. Flowchart study 2
T: measurement, wks: weeks, mos: months, PFMGT: pelvic floor muscle group therapy

mechanism is challenged by a multitude of factors of which some are non-modifiable. Physiological weight gain,² and changes in the neuromuscular function of the urethral sphincter are considered examples of non-modifiable factors.³⁴ However, PFMT in the general female population is a proven effective intervention.³⁵

PFMT post-partum revealed a positive effect directly after PFMT regarding UI, impact and self-perceived impression of severity. However, this effect was not maintained at later follow-up, except for subjective improvement. Although this study focused on adherence strategies for PFMT, the effect did not last.

Table 1. Participants' characteristics

		Study 1 n (%)			Study 2 n (%)		
		I (11)	C (13)	Total (24)	I (10)	C (13)	Total (23)
Age (mean, range)		32.1 (24-38)	32.9 (23-42)	32.5 (23-42)	32.3 (27-37)	30.2 (24-37)	31.0 (24-37)
Education	Secondary	4 (36.4)	4 (30.8)	8 (33.3)	3 (30.0)	5 (38.5)	8 (34.8)
	Tertiary	7 (63.6)	9 (69.2)	16 (66.7)	7 (70.0)	8 (61.5)	15 (65.2)
Parity	0	4 (36.4)	4 (30.8)	8 (33.3)	-	-	-
	1	7 (63.6)	7 (53.8)	14 (58.3)	2 (20.0)	5 (38.5)	7
	≥2	0 (0)	2 (15.4)	2 (4.2)	1 (10.0)	1 (7.7)	2
	Missing				7	7	14

n: number, I: intervention group, C: control group

Table 2. Results ICIQ-UI SF, GPE and IIQ-7

Study 1	Baseline 12-26 weeks gestation			T1 34 weeks gestation			T2 6 weeks post-partum			T3 6 months post-partum		
	I (11)	C (13)	T (24)	I (4)	C (12)	T (16)	I (4)	C (11)	T (15)	I (3)	C (10)	T (13)
	ICIQ-UI SF (range 0-21)	11.2 (2.0) (8-14)	9.5 (3.2) (5-15)	10.3 (2.8) (5-15) p=0.17 ^Ø	6.8 (2.2) (4-9)	8.6 (3.8) (4-14)	8.1 (3.5) (4-14) p=0.46	6.8 (2.2) (4-9)	6.1 (3.9) (0-11)	6.3 (3.5) (0-11) p=0.84	7.3 (1.5) (6-9)	5.9 (3.8) (0-11)
GPE (range: 1-7)	-	-	-	2.3 (0.3)	3.5 (0.5)	3.2 (1.5) p=0.10	2.8 (1.7)	2.6 (1.5)	2.7 (1.5) p=0.89	3.3 (1.5)	2.9 (1.1)	3.0 (1.2) p=0.66
IIQ-7 (range: 0 - 100)	14.3 (0-57.1)	16.8 (0-57.1)	p=0.84	13.1 (0-19.0)	15.9 (0-57.1)	p=0.95	10.7 (0-28.5)	9.9 (0-38.1)	p=0.74	7.9 (0-14.3)	4.8 (0-23.8)	p=0.40
Study 2	Baseline 6 weeks post-partum			4 months post-partum			9 months post-partum			18 months post-partum		
	I (10)	C (13)	T (23)	I (8)	C (12)	T (20)	I (5)	C (11)	T (16)	I (6)	C (8)	T (14)
	ICIQ-UI SF (range: 0-21)	8.3 (1.9) (5-11)	8.6 (2.5) (6-13)	8.5 (2.2) (5-13) p=0.88	5.3 (3.0) (0-11)	8.7 (2.9) (5-13)	7.2 (3.3) (0-13) p=0.01*	4.2 (2.6) (1-8)	7.5 (3.8) (0-13)	6.4 (3.7) (0-13) p=0.09	4.3 (5.2) (0-13)	8.4 (3.6) (1-12)
GPE (range: 1-7)	-	-	-	2.3 (0.89)	3.3 (0.99)	2.90 (1.07) p=0.02*	2.00 (0.71)	3.55 (1.21)	3.06 (1.29) p=0.02*	2.0 (1.55)	3.63 (1.30)	2.93 (1.59) p=0.08
IIQ-7 (range: 0 - 100)	14.3 (0-38.1)	19.1 (0-57.1)	p=0.90	6.0 (0-19.1)	23.0 (0-57.1)	p=0.04*	13.3 (0-47.6)	20.3 (0-66.7)	p=.32	7.1 (0-33.3)	18.5 (0-47.6)	p=0.09

I: Intervention group, C: Control group; T: Total group, T1: Follow-up 1; T2: Follow-up 2; T3: Follow-up 3; T4: Follow-up 4; ICIQ-UI SF: International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form; GPE: Global perceived effect; IIQ-7: Incontinence Impact Questionnaire-7; *: significant, Ø: between groups.

We anticipated no major problems in recruiting the necessary number of participants for both studies due to a number of reasons. Firstly, the recruitment was done by case managers covering the majority of maternal care (pre- and post-partum care) in the southern part of The Netherlands, in which over 8,500 babies were born in 2019.¹⁷ Secondly, high prevalence rates of SUI during pregnancy and post-partum are reported in numerous studies and thirdly,⁶⁻⁸ other studies on PFMT peri-partum in northern Europe reported high inclusion and participation rates.³⁶ Nonetheless, recruitment proved to be problematic.

In order to improve the number of inclusions several alterations to the eligibility criteria of the study were proposed and granted. The changes were: 1. inclusion of all women regardless of parity instead of only primigravid and primiparous women. 2. extending the inclusion period from 12 to 20 weeks up to 26 weeks of gestation. Other strategies to improve the inclusion rate were: regular presentations in the participating hospitals, visits to midwifery practices, attending clinics and regular phone conversations with midwives and research assistants of the hospitals. Also, a monthly newsletter informing the healthcare professionals was sent.

Several factors might explain the disappointing inclusion numbers, which might also be useful for other researchers in the field to plan their studies or optimize their recruitment strategies. Firstly, our studies were so called 'efficiency studies' in which two different treatments are compared with regard to effect and financial costs, with the objective to discourage use of inefficient interventions.³⁷ Due to this design, participants were only allowed to be included by a case manager like a midwife or obstetrician, which might have influenced the disappointing inclusion numbers. In the study of Mørkved et al.³⁶ on the effect of PFMT to prevent UI during pregnancy, all women were asked to participate through a letter which they received in combination with the invitation for their standard appointment with their case manager. Secondly, a standard question on UI is lacking in electronic patient following systems in The Netherlands for case managers reporting peri-partum care. This digital reminder to ask for UI might have influenced the inclusion numbers. Thirdly, case managers involved in these studies mentioned their lack of attention as a major barrier to recruit participants together with lack of time and a difficult to implement protocol in usual clinical practice. These are well known barriers in clinical research.^{38,39} Moreover, the case managers also mentioned that the standard internal assessment of the PFM in the protocol was a barrier due to lack of time. The number of drop-outs in study 1, once randomized, and in the initial inclusion phase in study 2, can be explained by known barriers for patient participation

like inconvenience due to extra appointments, travel problems, costs and a preference for a specific study arm.

Fourth, the sample size calculation for both studies was based on reported high UI prevalence numbers. However, the experienced bother was not taken into account. This might have resulted in an overestimation of the crude prevalence of UI, because level of experienced bother is associated with help-seeking behavior.⁴⁰

Our result regarding PFMT post-partum may justify and therefore support the recommendation of Woodley et al.²⁰ for the development of a new RCT on this subject. However, it is advisable to recruit women through for instance (social) media because questions on UI are not standardly asked by health care professionals.⁴¹

Strengths of this study include that the intervention offered in both studies is protocol- and evidence based and the ability to contract the PFM is checked.²¹ Women who did not know how to contract the PFM received an individual session by a specialized PT in order to learn how to contract and relax, before joining PFMT; in addition to the protocol has a strong emphasis on adherence with the use of a mApp. A mApp has shown to have a beneficial effect on adherence.^{42,43} The original design includes a long follow-up period and cost-effectiveness calculation.

In conclusion, PFMT, started post-partum, demonstrated statistically significant improvements in UI and QoL with a lower number of complaints at the 4 months post-partum assessment. However, the full potential of effectiveness of PFMGT could not be established due to insufficient inclusions, the latter most likely due to accepted bother from UI rather than the presence of UI itself.

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Contributions

Surgical and Medical Practices: H.F.A.M., E.M.J.B., B.C.M.B., Concept: B.C.M.B., M.E.A.S., Design: H.F.A.M., E.M.J.B., M.E.A.S., B.C.M.B., Data Collection or Processing: H.F.A.M., E.M.J.B., Analysis or Interpretation: H.F.A.M., E.M.J.B., Literature Search: H.F.A.M., Writing: H.F.A.M., E.M.J.B., B.C.M.B., M.E.A.S.

Ethics

Ethics Committee Approval: This study was approved by Maastricht University (no: METC162038).

Informed Consent: Informed consent was obtained.

Peer-review: Externally peer-reviewed.

DISCLOSURES

Conflict of Interest: No conflict of interest was declared by the authors

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