Sigurdardottir, T., Steingrimsdóttir, T., Geirsson, R. T., Halldorsson, T. I., Aspelund, T., Bø, K. (2023). Postpartum pelvic organ prolapse and pelvic foor muscle training: secondary analysis of a randomized controlled trial of primiparous women. *International Urogynecology Journal, 34*, 1319-1326. http://dx.doi.org/10.1007/s00192-023-05502-8

Postpartum pelvic organ prolapse and pelvic floor muscle training

Secondary analysis of a randomized controlled trial of primiparous women

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Financial disclaimer/conflict of interest: none

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Abstract

Introduction and Hypothesis

Pelvic floor dysfunction is common after childbirth. We hypothesize that physiotherapist-guided pelvic floor muscle training (PFMT) is effective regarding pelvic organ prolapse (POP) symptoms during the first postpartum year.

Methods

This was a secondary analysis from a randomized controlled trial (RCT), carried out at a physiotherapy clinic, Reykjavik. Participants were eighty-four primiparous women with a singleton delivery. They were screened for eligibility 6-13 weeks postpartum. Women in a training group conducted 12 weekly individual sessions with a physiotherapist within an RCT, starting on average 9 weeks postpartum. Outcomes were assessed after the last session (short-term) and at approximately 12 months postpartum (long-term). The control group received no instructions after the initial assessment. Main outcome measures were self-evaluated POP symptoms by the Australian Pelvic Floor Questionnaire.

Results

Forty-one and 43 women were in the training and control groups, respectively. At recruitment, 17 (42.5%) of the training and 15 (37%) of the control group reported prolapse symptoms (p=0.6). Five (13%) from the training and nine (21%) controls were bothered by the symptoms (p=0.3).

There was a gradual decrease in the number of women with symptoms and no significant short-term (p=0.08) or long-term (p=0.6) differences between the groups regarding rates of women with POP symptoms. The difference between groups regarding bother in the short (p=0.3) or longer term (p=0.4) was not significant. Repeated measure analyses using Proc Genmod in SAS did not indicate a significant effect of the intervention over time, p>0.05.

Conclusions

There was an overall decrease in postpartum symptoms of POP and bother during the first year. Physiotherapist-lead PFMT did not change the outcomes.

Key words

Pelvic floor muscle training, pelvic floor muscles, pelvic organ prolapse, physiotherapy, postpartum, primiparity, quality of life.

Brief summary:

Pelvic floor muscle training during the first year after childbirth did not influence pelvic organ prolapse symptoms in primiparous women.

Abbreviations

AI, anal incontinence; APFQ, Australian Pelvic Floor Questionnaire; CG, control group; CI, confidence interval; IUC, The International Urogynecology Consultation; PFD, pelvic floor dysfunction; PFM, pelvic floor muscles; PFMT, pelvic floor muscle training; POP, pelvic organ prolapse; CS, cesarean section; RCT, randomized controlled trial; SD, standard deviation; TG, training group; UI, urinary incontinence; VD, vaginal delivery.

Introduction

Pelvic organ prolapse (POP) is a distressing and common symptom in the female population and has been reported in up to 10% of the adult female population when defined as a bulging sensation into the vagina [1].

However, the prevalence of anatomic POP is higher; a population-based study which included pelvic examinations showed a prevalence of 31% among women aged 20-59 [2]. In a recent review the prevalence of POP varied greatly, from 1-65% depending on type of diagnosis (questionnaires and/or physical examination), definition as well as geography [3].

Pelvic organ prolapse is defined as a loss of support for the vaginal walls, the uterus, bladder, colon and rectum resulting in partial or complete prolapse of the affected organs coming down or through the vagina [4]. Haylen et al [5] defined stages of POP from 0-4. Stage 0 as no prolapse, stage 1 with the most distal part of the prolapse more than 1 cm above the level of hymen, stage 2 with the most distal part of the prolapse between 1 cm above the hymen and 1 cm below the hymen, stage 3 with the most distal portion of the prolapse more than 1 cm beyond the plane of the hymen but everted at least 2 cm less than the total vaginal length and stage 4 showing complete eversion or at least eversion within 2 cm of the total length of the lower genital tract is demonstrated [5]. The prevalence of both anatomic and symptomatic POP in the early postpartum period has been sparsely investigated. According to Reimers et al [6] anatomic POP stages ≥2 was found in 9% of primiparous women six weeks postpartum with no significant difference between women after vaginal delivery (VD) or cesarean section (CS). In another study evaluating anatomic POP in primiparous women at 5-22 weeks postpartum stage 2 POP was noted in 35.5% of the women, of whom 7.6% had this after CS vs. 43% for VD [7].

Using the Australian Pelvic Floor Questionnaire we recently showed an overall prevalence of POP symptoms 6-10 weeks after first childbirth of 29%, with 33% in the VD- and 12% in the CS groups in an Icelandic population [8]. Prolapse symptoms in the immediate postpartum period have been found to be related to pre-labor maternal characteristics, such as a larger levator hiatal area, a longer distance from the urethral meatus to the anus and a more caudal position of the anterior vaginal wall at mid-pregnancy [6]. Later in life, POP has also been associated with a low body mass index, higher parity, higher birthweights, operative and instrumental VD, levator ani trauma and constipation [9–12].

Women with symptoms of prolapse may also suffer from other symptoms from pelvic organs such as urinary symptoms, sexual dysfunction, thereof obstructed intercourse in many cases, abdominal and low back pain and bowel complaints [13].

The International Urogynecology Consultation (IUC) concluded that there is high-level evidence for pelvic floor muscle training (PFMT) to be useful as first line treatment for POP stages I-III in the general population [14]. However, few high quality studies, including RCTs, were found on the effects of PFMT in the first year postpartum. The consensus group concluded that results from RCTs were needed to assess the value of early intervention after childbirth [14].

We aimed in the present study to evaluate the effects of an individualized, postpartum physiotherapist-guided PFMT program on the rate of symptomatic POP and perceived bother in primiparous women. We hypothesized that PFMT will reduce symptoms of POP when compared to no PFMT.

Materials and methods

Study design

This was a secondary analysis of a parallel-group, assessor-blinded randomized controlled trial (RCT) with the primary aim of examining the effects of postpartum PFMT on the rate of postpartum urinary incontinence (UI) and anal incontinence (AI) in primiparous women [15]. The trial was carried out at a Physiotherapy Clinic in the Reykjavik Capital Area, from March 2016 to January 2018. Baseline assessments and background data of participants were obtained at recruitment nine weeks postpartum (range 6-13 weeks). Short-term outcomes were completed at the end of treatment at around six months (range 5-7), and long-term outcomes were investigated at 12 months (range 11-14) postpartum.

The study was approved by the Icelandic National Bioethics Committee (Ref: VSN-13-189), the Icelandic Data Protection Authority (Ref: 2014030475TS/--) and registered at https://register.clinicaltrials.gov (NCT02682212). The study was conducted according to the Helsinki declaration on human experimentation. All participants provided a signed informed consent. Delivery and maternal data were obtained from the Icelandic Medical Birth Register.

Participants and randomization

Through 2016 and 2017, primiparous women with one live newborn were approached before discharge from the maternity ward of the Landspitali University Hospital in Reykjavik. Women who consented were sent an electronic questionnaire through e-mail about their experiences of pelvic floor dysfunction (PFD) 6-10 weeks postpartum which was published in a cross-sectional study [8]. Of all the women who answered the questionnaire, 95 were invited to participate in an RCT [15]. Eligibility criteria were established for that study, i.e., the presence of self-reported postpartum symptoms of UI according to the Australian Pelvic Floor Questionnaire. The women had to be generally healthy, aged ≥18 years, able to

understand Icelandic and to attend the treatment sessions. Women with a multiple birth, a gestational length of <32 weeks, a stillbirth or an unwell newborn or those who otherwise had conditions that could interfere with their ability to participate were excluded (inability to contract their pelvic floor muscles (PFM), neurological conditions, previous urogynecological and/or bowel surgery or cognitive disorders). The main outcome assessor (T.S.) evaluated participants initially and before randomization at an outpatient physiotherapy clinic.

At baseline, all the women received instructions about how to correctly contract their PFM, which was confirmed with an observation and vaginal palpation of PFM contractions defined as an inward movement of the perineum and a squeeze around the pelvic openings [16–18]. Subsequently, measurements of PFM variables were done with a vaginal manometer, the Myomed 932 (Enraf Nonius, Netherlands). The PFM measurements were repeated at short-term and long-term and have been reported elsewhere [15]. Following this clinical assessment, the clinics´ secretary allocated participants to either a training group (TG) or a control group (CG) using concealed random sequence numbers from an on-line generator (https://stattrek.com/statistics/random-number-generator.aspx). The Microsoft Excel document containing the randomization code was locked with a password and only accessible to the secretary. She was responsible for booking participants for the short-term and long-term appointments.

Outcome measures

In the present study we aimed to examine the effects of PFMT on rates of POP symptoms as well as bother from symptoms, as assessed by the Australian Pelvic Floor Questionnaire [19, 20] (APFQ, Icelandic translation). The questionnaire had previously been rigorously

translated and pre-tested [21] but the Icelandic version was not validated. It had, however, been validated in several other languages [22–27].

Pelvic organ prolapse was evaluated by the questions “Do you have a sensation of tissue protrusion or a lump or bulging in your vagina?” and “Do you experience vaginal pressure or heaviness or a dragging sensation?“ Women were considered to have no symptoms if they answered “never“ to both questions. Answers of “occasionally“, “frequently“ and “daily“ were considered signs of POP. Bother is a concept used in the APFQ and can in general be defined as trouble, nuisance, worry or something annoying. Bother was considered absent when the answer to the question “How much does your prolapse problem bother you?“ was “not at all“. Answers of “slightly, moderately and greatly“ were considered as bother. According to this approach, data were analyzed as categorical, 0 = no symptoms or no bother and 1 = signs of symptoms and/or of bother.

Intervention

The intervention entailed 12 sessions with a duration of 45-60 minutes for each visit. The exercise period lasted on average 3.7 (range 2.6-6.7) months. The participants met weekly with a physiotherapist. If they cancelled, a new appointment was given in order to accomplish 12 sessions.

The NeuroTrack Simplex® biofeedback device with electromyographic vaginal sensors (Quintet, Norway) was used to facilitate the PFMT. Treatment was customized to each woman´s capacity within a protocol encouraging 10 close-to-maximum contractions and five second holding periods with a 10 second rest between each contraction. The women were in the lithotomy position during the treatment sessions. During the first two appointments women were coached to do two exercise sets during every visit with a rest in between and thereafter three sets of 10 contractions if possible. The participants used the biofeedback

device to aid progress and to help with relaxation between each contraction. During visits 8-9, the women were asked to add three fast contractions at the end of each contraction and do so in the remaining sessions [28].

Women in the TG were asked to do home exercises of 10 close-to-maximum PFM contractions with five seconds holding time, three sets/day. They were also encouraged to use different positions from lying to standing as well as to use the "knack" (pre-contracting the PFM before coughing and sneezing) [29]. They were asked to adhere to the home training program and to register daily exercises in a written training diary. During each visit they were encouraged to adhere to the home exercises.

The short-term evaluation was done within a week after the last training session. Long-term assessment was one year after childbirth. At both time-points women answered the APFQ. During the long-term appointment participants also answered a questionnaire about PFMT adherence. The CG women had no further follow-up after recruitment, which included general instructions and assessment of PFM contractions, but they were not discouraged from doing PFM exercises. The main assessor was blinded to group allocation throughout the study.

Sample size calculation

Sample size was estimated for the primary study on UI and AI [15] and was based on outcomes from a previous study [28]. No further power calculation regarding POP symptoms was conducted for the present study.

Statistical analysis

We used SPSS, version 24 (IBM, Armonk, NY, USA) for all statistical analysis except for the repeated measure analyses by Proc Genmod which was done in SAS version 9.2.

Normally distributed continuous variables are presented as means with standard deviations (SDs). Other participants characteristics are reported as counts with percentages. Rates of POP and bother were analyzed with chi-squared tests. The study was analyzed by intention-to-treat. Significance levels were set to 0.05.

Results

Of 95 women invited, 84 Caucasian women entered the study, 41 to the training group and 43 controls, with the initial session occurring at a mean nine weeks postpartum (range 6-13 weeks). Baseline characteristics are shown in Table 1. Four women (three from the TG) withdrew after the initial evaluation (Figure 1). Characteristics and delivery outcomes did not differ between participating and non-participating women except that women who dropped out were slightly younger and had smaller babies. Five women randomized to the training group did not participate in any of the training sessions or did any home PFMT but contributed to the main outcome measures by answering the questionnaires throughout the study. Therefore, 33 of 41 women who attended the intervention completed all 12 sessions with the physiotherapist. No adverse treatment-effects were reported.

Short-term outcome measures

At recruitment 17 of 40 (42.5%) and 15 of 41 (37%) women in the TG and CG respectively reported POP symptoms (p=0.6). Short-term (5-7 months postpartum) and long-term (11-14 months postpartum) results of POP are shown in Table 2.

The differences in POP rates between the groups measured at six months postpartum was not significant leaving 8 of 36 in the TG and 3 of 38 from the CG symptomatic (p=0.08). There were no significant differences between groups in the rates of women who were bothered by POP symptoms at short-term with five TG women at baseline and six months postpartum being bothered by POP but reduced from nine to one woman being bothered in the CG (p=0.08).

Long-term outcomes

Prolapse rates at long-term (11-14 months after childbirth) revealed no significant differences between the groups, with 4 of 38 from the TG and 6 of 42 from the CG still symptomatic *(p*=0.6). The differences in the rates of women bothered by symptoms in the TG and CG respectively was not significant, with 1 of 37 and 3 of 42 in the TG vs. CG bothered by POP symptoms (*p*=0.4).

Repeated measure analyses using Proc Genmod in SAS did not indicate a significant effect of the intervention over time, $p>0.05$.

Discussion

Main findings

Pelvic organ prolapse symptoms were overall reduced considerably in this group of first-time mothers during the postpartum year, and the feelings of bother were in general mild and not common. Difference in the rate of symptoms and bother after the intervention between the two groups was not significant. The research hypothesis was therefore rejected.

This is in line with the results from a cohort study by Reimers et al (2016) which showed good recovery of POP symptoms with no treatment in primiparous women during the first year postpartum [30].

Limited data from RCTs are available regarding the treatment effects of PFMT for POP symptoms in the postpartum period despite the wide practice of advising and providing such treatment [14]. Bø et al (2015) did not find improvements for POP symptoms when assessing the effect of a 4-month group-lead PFMT at 6 months postpartum. However, that study included women with diagnosed major levator ani tears which might have reduced the odds for improvement [31]. Yang et al (2013) found significant differences in postpartum POP stages in favor of the two training groups when measured at three months postpartum, where one group included PFMT and the other involved PFMT combined with vaginal electrical stimulation. The combination treatment was superior to PFMT alone when compared to a control group [32]. Both studies had larger sample sizes than our study. A Chinese RCT with only the abstract available in English disclosed positive results regarding postpartum POP symptoms after PFMT with biofeedback combined with electrical stimulation when measured 12 weeks postpartum [33].

It is, however, difficult to evaluate the information given regarding how the treatment was conducted. Pelvic floor electrical stimulation can provoke the muscles to contract as well as

produce responses from the central nervous system, i.e., increase the awareness of the muscle contractions which could be important for women with a weak PFM [34]. Yet, use of electrical stimulation can be questioned in the early postpartum period and when women are breast-feeding. Low levels of estrogen and thinning of the vaginal epithelium may make electrical stimulation painful.

In our study, symptoms were in general mild, and women may well have had difficulties in distinguishing between never or occasionally (less than once a week). Women in the TG might also have been more aware of their symptoms during the intervention period as a result of the weekly contacts with a women´s health physiotherapist. Conversely, with no contact to treatment providers, women in the CG could have considered themselves as less symptomatic.

The steady decrease in the number of women with symptoms in the TG from recruitment to one year after childbirth did, however, follow a measured increase in PFM strength during the study period. As previously reported, this improvement was significantly better in the TG [15]. The low number of symptomatic women at 6 months postpartum in the CG seems to be an incongruity and most likely the result of small sample size. Another explanation may be that they also had learned during initial examination how to contract the PFM and were not discouraged from doing PFMT.

Adherence to PFM exercises at home which was encouraged by the physiotherapists for the participants in the TG during our study period has been previously published in the study reporting the effect of PFMT on postpartum UI and AI [15]. Adherence was in general poor, especially during the latter half of the year which may have influenced the results.

Future RCTs should address PFMT on women with persistent postpartum POP symptoms e.g., one year after birth. Studies on both anatomic and symptomatic POP in the postpartum period are warranted.

Strengths and limitations

Strengths of the study were the randomized and assessor-blinded design, concealed allocation, a supervised individually tailored program for each participant aiming at treating the symptoms and high adherence to the exercise sessions, even if POP was not a primary outcome object. Following the participants for one year was also a strength, because long-term results are lacking in published studies [35].

Limitations which also affected this secondary analysis were the higher drop-out rate in the TG and the low number of women reporting prolapse symptoms in both groups which may have caused a type II error due to small sample size. Five women who were in the TG and contributed to the main outcomes did not participate in the intervention, which also might have influenced the results. The low adherence to PFMT after cessation of the intervention was also a limitation.

Interpretation

Our results are in line with results from the few RCTs evaluating effect of PFMT in reduction of POP stage and symptoms in the postpartum period [35]. To date, all studies reported POP as secondary analyses and not all women included in the studies had POP. This may explain the negative results as well as the fact that the studies were conducted in the early postpartum period. Studies indicate that POP symptoms improve for most of primiparous women during the first postpartum year.[30, 36]

Conclusions

Postpartum symptoms of pelvic organ prolapse and bother decreased during the first year for both controls and exercisers but the difference between the PFMT and the control groups was non-significant.

Acknowledgements

The authors thank Hulda Magnusdottir for her work in registering and administering all clinical appointments for the participants of the study, physiotherapists Fanney Magnusdottir and Gudrun Magnusdottir for carrying out the training sessions. We express our gratitude for the permission given by Dr. Kaven Baessler and co-authors to translate and use the Australian Pelvic Floor Questionnaire.

Details of Ethics Approval

Ethical approval was obtained from Icelandic National Bioethics Committee (Ref: VSN-13-189), and Data Protection Authority granted permission as well (Ref: 2014030475TS/--). The study was conducted in accordance with the Helsinki Declaration on human experimentation.

Funding:

This study has received grants from following funds:

University of Iceland Research Fund, Public Health Fund, Icelandic Directorate of Health, Icelandic Physiotherapy Association Science Fund, Landspitali University Hospital Science Fund.

Clinical trial registration:

The trial was registered 30th of March 2015 at https://register.clinicaltrials.gov (NCT02682212). Initial participant enrolment was 16th of March 2016 and reported following CONSORT guidelines for RCTs.

Figure/table caption list

Figure 1

CONSORT flow diagram of participants.

Table 1

Characteristics of included participants at recruitment and delivery outcomes.

Table 2

Outcome measures at recruitment, short-term (6 months postpartum) and long-term (12 months postpartum).

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Table 1.

Characteristics of included participants at recruitment and delivery outcomes.

	Training group (n=41)	***Control group (n=43)***	***P-values***
Maternal and neonate characteristics			
Age (years), mean (SD)	28 (4.3)	29 (5.3)	*0.2*
BMI at recruitment, mean (SD)	26 (4.3)	27 (4.5)	*0.4*
Weeks from delivery to recruitment, mean (SD)	9 (1.3)	9 (1.6)	*0.4*
Breastfeeding, n (%)	38 (93%)	39 (91%)	*0.7*
Smoking, n (%)	0 (0%)	2 (5%)	*0.2*
Birth weight (g), mean (SD)	3547 (487)	3668 (544)	*0.3*
Head circumference (cm), mean (SD)	35 (1.3)	36 (1.4)	*0.2*
Delivery outcomes			
Vaginal delivery, n (%)	37 (90%)	42 (98%)	*0.2*
Cesarean delivery, n (%)			
Emergency*	2 (5%)	1 (2%)	
Elective	2 (5%)	0 (0%)	

Independent samples *t*-test for continuous normally distributed variables, Chi-squared test for nominal variables. * in each group one emergency cesarean delivery became necessary after induction of labor.

Table 2.

Outcome measures at recruitment, short-term and long-term.

	n training/control*	***Training group***	***Control group***	***P-value***
Outcomes at baseline		***n (%)***	***n (%)***	
Pelvic organ prolapse symptoms[1], n (%)	40/41	17 (42.5%)	15 (36.6%)	*0.6*
Prolapse-related bother[1], n (%)	38/42	5 (13.2%)	9 (21.4%)	*0.3*
Outcomes at short-term (5-7 months postpartum)				
Pelvic organ prolapse symptoms[1], n (%)	36/38	8 (22%)	3 (8%)	*0.08*
Prolapse-related bother[1], n (%)	36/38	5 (14%)	1 (3%)	*0.08*
Outcomes at long-term (11-14 months postpartum)				
Pelvic organ prolapse symptoms[1], n (%)	38/42	4 (10.5%)	6 (14.3%)	*0.6*
Prolapse-related bother[1], n (%)	37/42	1 (3%)	3 (7%)	*0.4*

[1] Chi-squared test * The participants answered different number of questions in the questionnaire each time.

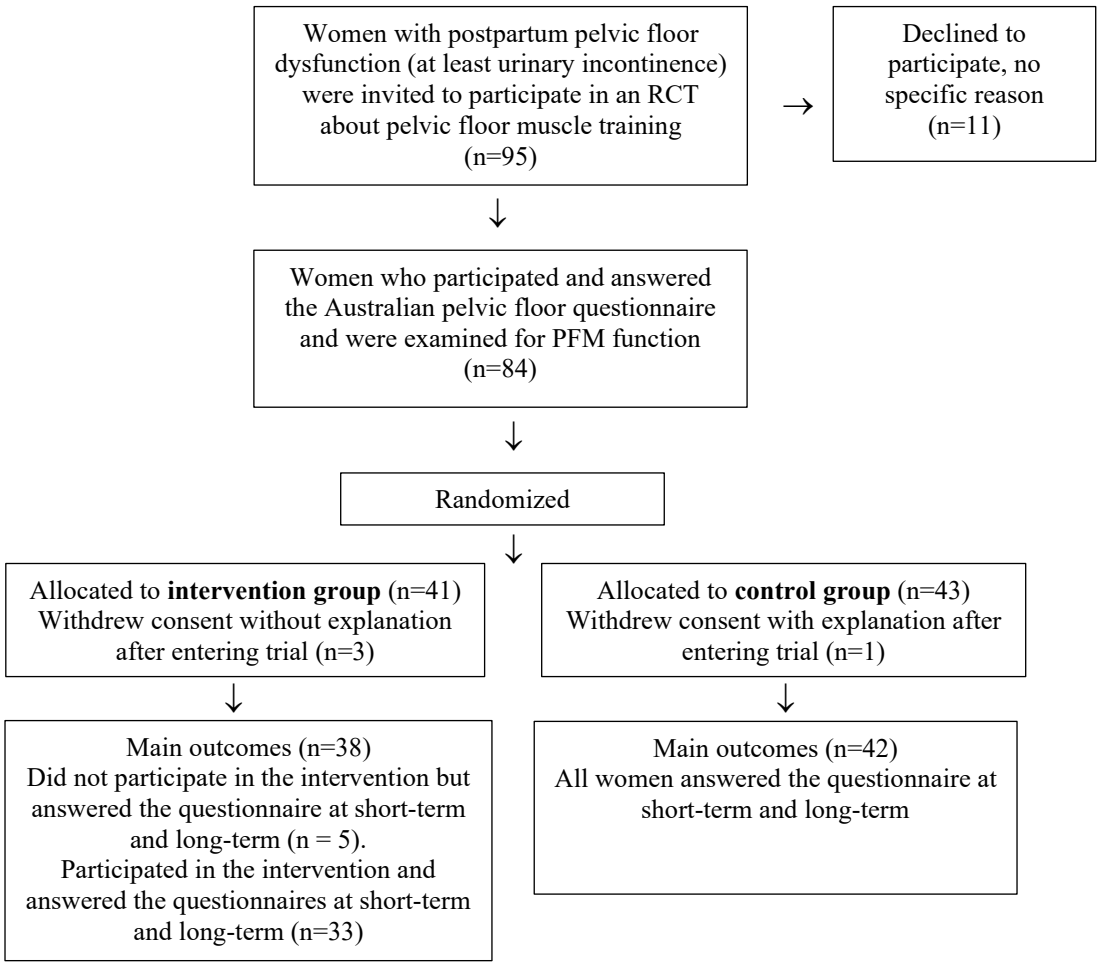

Figure 1.
CONSORT flow diagram of participants.