Long term effects of multidisciplinary assessment and pre-partum Pelvic Floor Muscle Group Treatment in adult gravid women with stress urinary incontinence compared to care-as-usual: a randomized controlled trial

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Objectives.The primary aims of this multicenter randomized clinical trial (RCT) are threefold1. to investigate whether a structured assessment and treatment program of intensive, supervised pre-partum pelvic floor muscle group training (PFMGT)...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Interventional

Summary

ID

NL-OMON47306

Source
ToetsingOnline

Brief title
motherfit pre-partum

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
pre-partum incontinence, urine loss during physical effort

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: group training, pelvic floor muscle training, pre-partum, stress urinary incontinence

Outcome measures

Primary outcome

-OUTCOME PARAMETERS/TIME (endpoints)

Primary: 18 months post partum

- ICIQ-UI-SF

at baseline, at 34 weeks gestation and post partum at 6 weeks, 6, and 18

months.

Secondary outcome

Secondary: 18 months post partum

- Patient global impression of severity (PGI-S),

- Incontinence Impact Questionnaire-7(IIQ-7); generic QoL (EQ-5D-5L)

- Costs, costs questionnaire

at baseline, at 34 weeks gestation and post partum at 6 weeks, 6, and 18 months.

- Patient satisfaction

at 34 weeks

Study description

Background summary

1 in 3 women will be affected by urinary incontinence (UI) during her life, evoking substantial individual morbidity, loss in quality of life (QoL)and socio-economic costs (1,2). The first pregnancy and childbirth are the most important causal and provocative factors for UI during lifetime (1).
UI impacts not only on the physiological but also on the psychological realms of a person*s life (3). The condition can have significant impact on her individual self-esteem and general wellbeing. It means that on top of losing bladder control, having to wear incontinence pads make young peri partum patients often crack their individuality and self-confidence (3). Studies have found that up to 50% UI sufferers will often avoid intimacy with their partners (4). Stress UI is UI in relation to physical exertion (5). Prevalence is 41% during pregnancy and up to 38% at 2-3 months after delivery (1). If SUI during pregnancy, 42% > risk UI in next 12 years (1). Stress UI can prevent people from participating in active pursuits such as sports because of anxiety regarding potential leakages. This tends to have knock-on impacts in terms of obesity and hence exacerbating UI so that this situation is self-perpetuating. All of these issues contribute to the enormous QoL effects on sufferers (1,3).
Despite all this, 3/4 of new mums say they have never sought help from a health care professional about their condition (6).
56% of women say they fell "embarrassed". Moreover, standard Dutch peri partum care hardly pays any attention to UI, while,at least on the short run, PFMT strongly reduces UI in advanced pregnancy and early post partum (1). PFMT improves generic QoL substantially > than control group at 3 months post partum (RR 7.2,95% CI 2.4-12.0)(1). Persistent pre-partum UI is accessible by PFMT, but may be initiated too late. One of the reasons may be that obstetricians and gynecologists are not (yet) convinced of persisting long-term results of PFMT (1). Another is that pre-partum women are not (yet)familiar with potential solutions for their UI problem (6). As only a minority of pregnant women are actively aware of the risk of UI (6)the Pelvic care Center Maastricht (PcCM) designed motherfit, which is more than only PFMT. It is a multidisciplinary strategy to treat women with UI and make them aware peri partum of PFM importance as requirement for a healthy lifestyle. The motherfit concept focuses also on integrated self-management long term. Our health-care system to support and increase adherence and durable motivation for the holistic training program will enable pregnant and post

partum women (and individuals of other age groups) to become co-managers of their health and wellbeing with the help of ICT, tools and personalised services. Public and individual awareness about the impact of pregnancy and vaginal delivery, their pathophysiological consequences on the pelvic floor, leading to UI and the possibilities to treat this health problem are starting points of the motherfit strategy. Adequate patient information and education and supervised, intensive PFMGT in the clinic will be followed by and the base of a home maintenance, personalized, self-management program.
In order to support maintenance of the home training program and lifestyle advices we will introduce a health-care system integrating a mobile App advising the user with accessible and functional training plans, instructive videos and relevant information, tips and lifestyle advices.
The tips and lifestyle advices will be in line with and support the midwife's information and education. Midwives promote a healthy lifestyle with information on adequate gestational weight gain, healthy diet, mental wellbeing and avoiding negative behaviours such as smoking and alcohol. Information on UI and how to prevent or treat this can be an integrative part of health education during the perinatal period aiming to support women in the self-management of their own health. Clinical validation of our health-care system as a home self-management device benefits the peri partum UI patient and clinical practice. This health-care system aims to stimulate the home maintenance training program, increasing adherence and compliance with PFMT. This strategy guides women through this extensive healing process and makes PFMT part of a healthy lifestyle. This concept is a major advantage in returning patients a sense of self again.
The App software integrates the training routine by visually translating the program into accessible and attractive short videos.
The motherfit home self-training is based on the motherfit protocol involving the high intensity, supervised program, described before.

Study objective

Objectives.
The primary aims of this multicenter randomized clinical trial (RCT) are threefold
1. to investigate whether a structured assessment and treatment program of intensive, supervised pre-partum pelvic floor muscle group training (PFMGT) including its home maintenance reduces 18 months post partum UI severity (frequency, amount, impact) in adult gravid women with stress urinary incontinence;
2. to study in adult gravid women with stress urinary incontinence the effect

of treatment with PFMGT on UI severity (frequency,
amount, impact) comparing baseline (12-20 (+max 4) weeks gestation) with end treatment (34 weeks gestation), and with 6 weeks and 6 months post partum (study I motherfit pre-partum);
3.whether intensive supervised pre-partum pelvic floor muscle group treatment (PFMGT) is cost-effective in adult gravid women with stress urinary incontinence.
Participant characteristics and specific aspects of obstetric history and PF function will be measured and used in the analyses
as possible predictors/confounders of a successful outcome on UI after PFMGT pre-partum.

Study design

-DESIGN
The design is a randomized controlled trial (RCT). At 12 weeks adult gravid women will be randomized to PFMGT or
CAU. Outcome measurement of (cost-)effects of PFMGT pre-partum compared to CAU. The primary endpoint is 18 months. Data will be analysed by the intention-to-treat procedure. This is a multicenter study with
participation of Maastricht University Medical Center (MUMC), Zuyderland MC, Heerlen/Sittard, Laurentius hospital, Roermond,
Maxima MC, Eindhoven and surrounding midwife/GP/PPT practices.
Except for Maxima MC all obstetric centers are part of the Obstetric Consortium Limburg, a first, second and third line obstetric
midwifery maternity care collaboration.
Feasibility of recruitment is high since in the region of Maastricht, Heerlen, Sittard, Roermond and Eindhoven/Veldhoven:
- potentially 3300 vaginal deliveries of adult gravid women take place per year
- the 5 hospitals and midwifery practices in these areas already have a cooperation in other obstetric and urogynecological
research projects and finally
- sufficient PPTs and ZwangerFit teachers are available to provide the training in all areas.

Intervention

-INTERVENTION DURING PREGNANCY
At 12 weeks gestation participants receive UI counselling by their midwife/obstetrician/gynaecologist. A short
assessment of a correct contraction of PFMs by observation and vaginal palpation of closing the vagina, in-and forward
movement of the perineum during contraction will be performed (26).
Women in de motherfit groep (PFMGT)not aware or not able to contract or relax their PFMs correctly will be referred to the PPT for individual instruction on PF anatomy and how to contract the PFMs correctly.

All women allocated to motherfit will receive a specially designed written or digital instruction booklet on pre- and post-partum
PFM Group Training.
Next, all women, those who are able and those who are able after instruction by the PPT to contract their PFMs, are referred to
8 intensive pre-partum group training sessions. PFMT includes instructions on PF anatomy and how to contract, relax and train
the PFMs correctly and is combined with general fitness exercises. The PFMGT starts from 20 weeks gestation and is
supervised by registered motherfit PT trainers. All women will receive via the mApp or webApp an individual PFM home training
program and general advices on physical activity considering the intensity and type of physical activity appropriate for pregnant
women for lifelong cure and prevention of UI and chronic diseases, and evidence based lifestyle advices both verbally and
written addressing constipation, alcohol use, smoking, obesitas, physical activity, etc) (12,13,14).
Performance of and adherence to PFMT will be reinforced by regularly sending *push* notifications on the mApp or webApp, as
forgetting is the most important cause of inadequate adherence. Performance of and adherence to PFMT will also be recorded
in women*s personal treatment diary. The diary will be available for the motherfit group trainers and used to discuss women*s
motivation to incorporate adequate PFMT and use of PFM in their daily activities (8,9).

-USUAL CARE/COMPARISON (CAU)
Participating midwifes/gynecologists/general practitioner give their normal advices and pregnant women make their own choices as usual whether or not to take part in any kind of pregnancy related pre- or post partum course. UI women will receive CAU by their midwife/gynecologist/general practitioner.

Study burden and risks

Based on the nature of the assessments and intervention no risks or adverse events are expected. Patients will have to fill out extra questionnaires and personal training diaries which is considered a burden of minor importance. There will be 5 outcome measurements including also at baseline one time digital vaginal palpation on behalf of the pelvic floor muscle functional assessment.
Patient will receive extensive information about their urinary incontinence problem and what can be done to solve the problem. Extra time investment for participation is limited.
Because we want to investigate adult gravid women with stress urinary incontinence women can only be recruited from this population (group

relatedness)

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* adult gravid woman
* urinary incontinence (stress or mixed with predominant stress UI factor)
* motivated for participation in the motherfit program
* signed informed consent
* competent to speak and understand Dutch language and to read and fill in forms independent
* mApps on tablet (Apple or Android) or webApp available

Exclusion criteria

* UI prior to pregnancy, still existing during pregnancy
* high-risk pregnancy giving, resulting in a contra-indication for performing intensive PFM exercises (f.i. placenta praevia, vaginal blood loss, partus prematurus imminens)
* suffering from significant exercise limitations or co-morbidities (physical or psychological) that would restrain a woman from participation in motherfit (group) training
* history of chronic neurological disorders or diseases related to UI (f.i. multiple sclerosis, cerebro-vascular accident, diabetes mellitus)
* urinary tract infection (urine-sediment, urine culture)
* history of anti-incontinence or urogynecological surgery
* women who are expected to be lost to follow-up (e.g. because of a planned change of residency)
* recent pelvic physiotherapy (< 6 months)
* refusal to use a mApp or webApp

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-03-2018
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	21-12-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	08-08-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL58776.068.16