motherfit

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23435

Source
Nationaal Trial Register

Brief title
motherfit

Health condition

stress urinary incontinence, pelvic floor muscle training, peri-partum, pre-partum, post partum, grouptraining, randomized
clinical trial, pregnancy

Sponsors and support

Primary sponsor: Maastricht University Medical Centre, Maastricht, The Netherlands
Source(s) of monetary or material Support: ZonMw DoelmatigheidsOnderzoek SA / DoelmatigheidsOnderzoek GA

Intervention

Outcome measures

Primary outcome

Study I and II primary: 18 months post partum

- ICIQ-UI-SF

Secondary outcome

18 months post partum

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

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

- Costs

- Patient satisfaction

Study description

Background summary

RESEARCH QUESTION

In adult women with stress urinary incontinence (SUI) during pregnancy (study I) or after first delivery (study II), is a multidisciplinary strategy of assesment and intensive, supervised peri-partum Pelvic Floor Muscle Group Treatment (PFMGT) more (cost)effective than care-as-usual (CAU) 18 months post partum

-HYPOTHESIS

PFMGT in pre (Studie I) and post partum SUI (Studie II) women is more cost(effective)than care-as-usual

-STUDY DESIGN

This study is a Randomized Clinical trial with starting point superiority of PFMGT compared with care-as-usual

-STUDY POPULATION

Adult primi gravid (study I) or after the first vaginal (study II) delivery women with SUI

-INTERVENTION

Study I: 8 pre-partum sessions PFMGT from 20 weeks gestation. Individual daily home training program, supported by a mApp or webApp.

Study II: From 12 weeks post partum, 8 sessions PFMGT. Individual daily home training program, supported by a mApp or webApp.

-USUAL CARE/COMPARISON

Pre- (study I) and post- (study II) partum CAU. This means the health care normally provided by the gynaecologist, midwife or general practitioner

-OUTCOME MEASURES

Primary outcome is UI prevalence 18 months post partum (ICIQ-UI SF), secondary outcomes are Patient Global Impression of Severity of incontinence (PGI-S), costs, patient satisfaction

-SAMPLE SIZE/DATA-ANALYSIS

Assuming a loss to follow up of 20%, to proof superiority of the intervention we will need to include 240 SUI women (150 (study I, 2 groups of 75) / (90 (study II), 2 groups of 45). Data-analysis according to intention-to-treat.

-COST EFFECTIVENESS ANALYSIS /BUDGET IMPACT ANALYSIS

The cost-analysis will be performed from multiple perspectives, e.g. societal, health care, health care insurance and patient perspective. Cost utility of the PFMGT program and costs of the use of the health-care system (mApp, webApp, underwear) will be estimated. compared to care-as-usual. Non-healthcare and patient and family costs will be collected. The budget impact analysis addresses the financial stream of consequences related to the implementation of PFMGT programme and thus its affordability. The analyses will be performed from different perspectives, including a health care budgetary perspective and a health insurers’ perspective.

-KEYWORDS

stress urinary incontinence, pelvic floor muscle training, peri-partum, pre-partum, post

partum, group training, randomized clinical trial, pregnancy

Study objective

Pelvic Floor Muscle Group Training in pre (Studie I) and post-partum SUI (Studie II) women is more cost(effective) than care-as-usual

Study design

All data (baseline, EPF) of the participating women, health care professionals and researchers will be collected in a (web-based) central database. Demographic variables and personal characteristics will be registered at baseline in study I at 12 weeks gestation (max + 4 weeks) and for study II at 6 weeks (max + 4 weeks) post partum.

Frequency, intensity and type of physical activity, including PFMT, will be recorded for all groups at inclusion and at follow-up by self-report in a questionnaire. In addition, women in the PFMGT register PFMT in the personal training diary adapted from Mørkved (2003)(2,29).

Risk- and prognostic factors that can change over time such as BMI and all other outcomes (ICIQ-UI-SF; PGI-S; EQ-5D-5L;
Pelvic Floor Muscles Functional Assessment; NVOG-Questionnaire; IIQ-7; training diary) will be assessed at baseline, at 34 weeks gestation and post partum at 6 weeks, 6, and 18 months (Study I) and at 6 weeks (baseline), 4 months (end training), 9, and 18 months (Study II). Patient satisfaction at 34 weeks (Study I) and at 4 months (Study II).

Intervention

INTERVENTION DURING PREGNANCY

Study I: At 12 weeks gestation participants receive UI counselling by their midwife/obstetrician/gynaecologist or general practioner (GP). 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 not aware or not able to contract or relax their PFMs correctly will be referred to the pelvic physiotherapist (PPT) for individual instruction on pelvic floor (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 mobile app (mApp) 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).

INTERVENTION POST PARTUM

Study II: At 6 weeks post-partum routine control all women with UI besides those women who (still) participate in study I of motherfit are counselled by their
midwife//gynaecologist/general practitioner on presence of UI. The same individual assessment and referral procedure to 8 intensive, in this case post partum, (group) training sessions will be followed as for the intervention during pregnancy. All women will receive an individual PFM home training program and general advices on physical activity considering the intensity and type of physical activity appropriate for post-partum women and building up towards optimal PFM and optimal physical activity for adults for lifelong cure and prevention of UI and chronic diseases (9, 12,13). Strong emphasis will be given to factors which might predict long-term motivation for adherence to PFMT (14). Also
here adherence and compliance will be stimulated using 'push' notifications and the women's personal diary

-USUAL CARE/COMPARISON (CAU)

Participating midwifes/gynaecologists/general practitioner give their normal advices and pregnant and post partum 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/gynaecologist/general practitioner. Preceding interviews and focus groups demonstrate that usual policy is to wait and see post-partum for 3-6 months as an expectative policy and, when UI complaints do persist, to consult the GP. The GP often advices to first recover from pregnancy before referral. Also because in some of the women the problem solves itself automatically. GPs would use the NHG-guideline UI, in case of SUI often only perscription of pads, sometimes lifestyle advices or referral to PPT (27).

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

• primi gravid woman

• urinary incontinence (stress or mixed with predominant stress UI factor, according to Haylen (2010)(5)

• motivated for participation in the motherfit program

• written 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

A potential subject who meets any of the following criteria will be excluded from participation

in this study:

• 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 minimal 1 year hbac1 > 10 mmol/l)

• 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 type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	01-12-2016
Enrollment:	240
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL5816
NTR-old	NTR5971
Other	Dossier number: 80-84300-98-72001 : ZonMw

Study results

Summary results
Moossdorff-Steinhauser HF, Albers-Heitner P, Weemhoff M, Spaanderman ME, Nieman FH, Berghmans B. Factors influencing postpartum women's willingness to participate in a preventive pelvic floor muscle training program: a web-based survey. Eur J Obstet Gynecol Reprod Biol. 2015 Oct 23;195:182-187

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