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The effectiveness of theory based intervention using social media to reduce urinary incontinence among postpartum women in Hebron city hospitals

Submission date
26/07/2018

Recruitment status
No longer recruiting

Registration date
01/08/2018

Overall study status
Completed

Last Edited
12/03/2019

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Urinary incontinence (UI) is common and strongly associated with childbirth. Women who give birth are at higher risk of developing UI and should undertake a pelvic floor muscle exercise (PFME) program to maintain or improve pelvic floor muscle function. PFME has been considered the first line of treatment for UI by the International Continence Society, and has an essential role for prevention and treatment of UI. Practicing PFME regularly is a key factor in its effectiveness. The aim of this study is to test a social media intervention to reduce UI among women in Hebron city hospitals.

Who can participate?
Women with urinary incontinence after child delivery

What does the study involve?
Participants are randomly allocated to the intervention group or the control group. Every week a message is sent via whatsapp to the intervention group to remind and encourage the participant to do PFME. Information includes how to find the pelvic floor muscles using graphics showing the location of the muscles and how to contract them correctly. Participants are prescribed a maximum of 45 PFM contractions per day (15 PFM contractions, 3 times per day). The control group do not receive any material included in the app during the study period. After completing the 6-months follow-up, they receive the intervention. A whatsapp-based questionnaire is sent to both groups after 3 and 6 months with follow-up questions on PFME and symptom severity.

What are the possible benefits and risks of participating?
This study will motivate participants to do PFME at home regularly, and increase their knowledge and ability to practice these exercises. They can consult expert physiotherapists and ask them any question related to UI and PFME. There is no risk of participating in this study

Where is the study run from?
Al-Ahli Hospital (Palestinian Territory)

When is the study starting and how long is it expected to run for?
August 2018 to April 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Mrs Zeenat Mesk
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
The effectiveness of theory based intervention using social media to reduce urinary incontinence among postpartum women in Hebron city hospitals

Acronym
TBIUI

Study objectives
1. There are significance differences between and within groups at baseline and three and six months after the intervention regarding the practice of pelvic floor exercises
2. There are significance differences between and within groups at baseline and three and six months after the intervention regarding the severity of urinary incontinence
3. There are significance differences in the level of beliefs (perceived severity, perceived

benefits, perceived barriers, self efficacy, cue to action) between and within groups at baseline after intervention at three and six months
4. There is a significant effect of theory-based intervention using social media in improving the practice of PFME among the intervention group
5. There is a significant effect of theory-based intervention using social media in reducing urinary incontinence among the intervention group

Ethics approval required
Old ethics approval format

Ethics approval(s)
University Putra Malaysia ethics committee, 22/12/2017, ref: UPM/TNCPI/RMC/1.4.18.2(JKEUPM)

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Urinary incontinence after childbirth

Interventions
Participants are randomised by permuted block randomization to the intervention group or the control group.

The intervention will be a theory-based intervention with a treatment program for UI, focused on PFME. During the development process, the intervention will be reviewed by the researchers and a test group, until a final version will be accepted. Every week, the women will receive a whatsapp message to remind them to practice PFME and ask them whether they have experienced any problems. The intervention will focuses on PFME but also contains information that described SUI, the pelvic floor, and lifestyle.

This study incorporate constructs of the health belief model to promote change in behaviour which increase the practice of pelvic floor muscles exercises. Four constructs of the HBM will be addressed during this study, including perceived benefits of practicing PFME regularly, perceived barriers performing PFME behaviors related to emotional, social, and physical barriers, cues to action/motivation, and self-efficacy. Perceived barriers to an anticipated behavior to reduce the problem, maintain health, and improve disease may include pain, money, change of habits, embarrassment, inconvenience, and side effects. Health motivation was defined as one's state of concern about general health matters, resulting in positive health activities and behaviors to decrease disease.

The health belief model conceptualizes that a person's perceptions of susceptibility, seriousness, barriers and benefits are affected by the cues to action and self-efficacy, and this has the potential to affect or change a person's behavior (Wilkinson & McIntyre, 2012). Perceived benefits, perceived barriers, cues to action, motivating factors, and self-efficacy, and all four constructs will be used to design interventions programs to maintain behaviors (do PFME

regularly) to reduce UI. The health information will include the benefits of maintaining or improving PFM function and cues to action for practicing pelvic floor muscle exercises in order to reduce perceived barriers for practicing PFME and prevent the consequences of developing chronic UI.

The intervention includes PFME, the exercises included different combinations and repetitions of commonly used contractions: a basic contraction to identify the correct muscles, contractions to improve strength and endurance, quick contractions, and contractions prior to coughing. The treatment program prescribes exercises three times daily. Each exercise description will include graphics showing the duration and intensity of each contraction with concomitant relaxation. Every week a message via whatsapp will be sent to the intervention group to remind and encourage the participant to do exercises. Information on pelvic floor muscles and how to find them using the graphics showing the location of the muscles and how to contract them correctly will be send to intervention group. Information on urinary incontinence (seriousness, long term effect) will also be sent to the participant via whatsapp throughout the intervention phase, and the participants will be prescribed a maximum of 45 PFM contractions per day (15 PFM contractions, 3 times per day).

The control group will be a postponed treatment group and will not receive any material included in the app during the study period. After completing the 6-months follow-up, they will receive the intervention.

A whatsapp based questionnaire will be send to the both groups 3 months and 6 months after randomization with follow-up questions on PFME and symptom severity.

Intervention Type
Behavioural

Primary outcome(s)
Severity of urinary incontinence measured by International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form (ICIQ-UI SF) at baseline, 3 and 6 months

Key secondary outcome(s)
Level of practice of PFME, measured subjectively using Exercise Adherence Rating Scale (EARS) at baseline, 3 and 6 months

Completion date
15/04/2019

Eligibility

Key inclusion criteria
Women with urinary incontinence after child delivery

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Sex
Female

Total final enrolment
120

Key exclusion criteria
1. Chronic obstructive pulmonary disease
2. Neurological disease
3. Diabetes mellitus
4. Arterial hypertension
5. Urinary tract infection
6. History of pelvic surgery
7. Kidney stones

Date of first enrolment
15/08/2018

Date of final enrolment
01/03/2019

Locations

Countries of recruitment
Palestine, State of

Study participating centre
Al-Ahli Hospital
Hebron wadi abu ktelelah
Hebron
Palestine, State of
715

Sponsor information

Organisation
University Putra Malaysia

ROR
https://ror.org/02e91jd64

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date