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Pelvic (floor) Reminders (to) Explore Perinatal (women's) Acceptability (of) Reminders (to) Exercise (PREPARE) study

Submission date
26/08/2023

Recruitment status
No longer recruiting

Registration date
27/09/2023

Overall study status
Completed

Last Edited
09/04/2025

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Pelvic floor muscle dysfunction (PFMD) is a condition that affects up to one in three women at some point in their lifetime and can be commonly traced back to the perinatal period due to the physiological changes associated with pregnancy and childbirth. The most prevalent symptom of PFMD is stress urinary incontinence (SUI), defined as the involuntary loss of urine on effort or physical exertion (e.g., sporting activities), or on sneezing or coughing. The social, emotional, economic, and environmental impact of SUI is well documented and includes social isolation, difficulty returning to work, impaired sexual function and prevention of vigorous exercise. Supervised pelvic floor muscle training (PFMT) is the gold standard of treatment for symptoms of SUI. Pelvic floor muscle training is defined as exercise to improve pelvic floor muscle strength, endurance, power, relaxation or a combination of these parameters. Women are less likely to develop urinary incontinence during pregnancy or in the early post-natal period if they regularly complete PFMT. PFMT involves women completing supervised PFMT three times a day for a minimum of three months for it to be effective at reducing symptoms of PFMD; however, clinically, it is recognised women do not regularly adhere to this exercise prescription.
Health apps commonly use reminders for long-term conditions to promote self-management and have been proven effective in other long-term conditions. The use of digital technology, such as mobile apps, in maternity care can personalise the treatment individual women receive thus improving healthcare delivery and in particular the management of PFMD. Personalisation of PFMT may be enhanced by providing digital ‘nudges’ as reminders and encouragement to enhance adherence to exercises.

Who can participate?
Women between the ages of 18 and 45 years who have a viable pregnancy and have given birth once before

What does the study involve?
The feasibility trial will determine whether a future randomised controlled trial can be conducted. The feasibility trial will compare an intervention and a control group. The intervention group will receive a PFMT mobile app and digital nudges. The control group will

receive a leaflet on the role of the pelvic floor and how to complete PFMT developed by a UK-based professional network of clinical specialist physiotherapists. Perinatal women will have three telephone follow-ups lasting no longer than 30 minutes. The timing of these follow-ups will be at 9, 21 and 31 weeks. These follow-ups correspond to the late antenatal stage of gestation (36 weeks), around 1 month postnatal and 4 months postnatal.

What are the possible benefits and risks of participating?
The immediate advantage to participants is support with pelvic floor muscle training during pregnancy. Whilst the researchers do not anticipate any risks to participants there is a very small risk of emotional distress talking about pelvic floor-related symptoms. For those in the intervention group, there is a small but possible chance that participants find digital reminders a burden. There is a small but possible risk participants may find the statements in the digital nudges hard to understand. Participants randomised into a group they are not happy with may experience negative feelings.

Where is the study run from?
Bournemouth University (UK)

When is the study starting and how long is it expected to run for?
January 2023 to April 2025

Who is funding the study?
1. Bournemouth University (UK)
2. University Hospitals Dorset (UK)
3. National Institute for Health Research (NIHR) Applied Research Collaboration (ARC) Wessex (UK)

Who is the main contact?
Rosie Harper, rharper1@bournemouth.ac.uk

Contact information

Type(s)
Public

Contact name
Miss Rosie Harper

ORCID ID
https://orcid.org/0000-0003-3414-7580

Contact details
Faculty of Health and Sports Sciences
Bournemouth Gateway Building
12 St Paul's Ln
Bournemouth
United Kingdom
BH8 8GP
+44 (0)1202 969696
rharper1@bournemouth.ac.uk

Type(s)
Scientific

Contact name
Miss Rosie Harper

Contact details
Faculty of Health and Sports Sciences
Bournemouth Gateway Building
12 St Paul's Ln
Bournemouth
United Kingdom
BH8 8GP
+44 (0)1202 969696
rharper1@bournemouth.ac.uk

Type(s)
Principal investigator

Contact name
Prof Carol Clark

ORCID ID
https://orcid.org/0000-0002-9296-7141

Contact details
Faculty of Health and Sports Sciences
Bournemouth Gateway Building
12 St Paul's Ln
Bournemouth
United Kingdom
BH8 8GP
+44 (0)1202 969696
cclark@bournemouth.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
328225

Central Portfolio Management System (CPMS)
58654

Study information

Scientific Title
Pelvic (floor) Reminders (to) Explore Perinatal (women's) Acceptability (of) Reminders (to) Exercise (PREPARE)

Acronym

PREPARE

Study objectives
The principal research objective is to determine the feasibility of undertaking a randomized controlled trial that explores whether a physiotherapy-led digital intervention can increase pelvic floor muscle training adherence in women.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 19/12/2023, HRA REC South Central (South Central – Hampshire A, Southampton, SO17 1BJ, United Kingdom; +44 (0)207 104 8120, +44 (0)207 104 8210, +44 (0)207 104 8290; hampshirea.rec@hra.nhs.uk), ref: 23/SC/0407
2. Approved 12/01/2024, Bournemouth University (Faculty of Health and Sports Sciences, Bournemouth, BH8 8GP, United Kingdom; +44 (0)1202 524111; researchethics@bournemouth.ac.uk), ref: 52246

Primary study design
Interventional

Study design
Single-centre interventional mixed methods feasibility study

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Pelvic floor dysfunction

Interventions
Participants will be randomised between 26-28 weeks of pregnancy by assigning random numbers to each subject using permuted block randomisation in REDCapTM software. Participants will be randomised into one of two arms of the study: the intervention group or the control group. The researchers are unable to blind the participants in the study. It was not possible to blind data collectors in the study. The control group will receive a leaflet on the role of the pelvic floor and how to complete PFMT developed by a UK-based professional network of clinical specialist physiotherapists.

The intervention consists of 31 targeted digital PFMT ‘nudges’ and a pelvic floor muscle training mobile app. The digital nudges were co-designed as part of a larger research study to support perinatal women to complete regular pelvic floor muscle training. The total number of digital nudges is 31 to account for the number of weeks between 26 weeks of pregnancy and 4 months postnatal. The nudges target different stages of the perinatal period and have been divided into the following categories:
1. Late antenatal
2. Early postnatal
3. Late postnatal
The nudges will be in the form of push notifications. A digital nudge will be sent once a week to

each participant. Women will receive the first digital nudge between 26-28 weeks of pregnancy soon after they have been enrolled in the study. Each digital nudge is unique and the last digital nudge will be sent around 4 months post-natal.

The control group will receive a leaflet on the role of the pelvic floor and how to complete PFMT developed by a UK-based professional network of clinical specialist physiotherapists.

Intervention Type
Behavioural

Primary outcome(s)
Several outcome measures will be trialled in the study to determine whether the study design and intervention can be taken forward for an RCT. Primary outcome measures include:
1. Quality of life measured using EQ5D5L at baseline, 9 weeks, 21 weeks and 31 weeks
2. Severity of urinary incontinence symptoms measured using International Consultation of Incontinence Questionnaire of Urinary Incontinence- Short Form (ICIQ-UI) at baseline, 9 weeks, 21 weeks and 31 weeks
3. Self-efficacy around pelvic floor muscle training measured using the Broome pelvic muscle self-efficacy scale at baseline and 31 weeks
4. Adherence to pelvic floor muscle training measured using in-app adherence data that will be collected weekly throughout the study
5. Adherence to pelvic floor muscle training measured using online and paper diaries at 9 weeks, 21 weeks and 31 weeks
6. Participant engagement with the intervention measured using in-app algorithms e.g. interaction response time and will be collected continuously throughout the study

Key secondary outcome(s)
Secondary outcome measures will be used to add greater depth to the quantitative data collected in the study to explore participants' acceptability of the intervention.
The secondary outcome measures include:
1. Participant's views on the acceptability of the digital nudges and study processes will be measured using semi-structured interviews at just after 31 weeks
2. Participant's acceptability of the intervention will be captured using one open-ended questions ‘which nudges best supported you in your training and why’ at 9 weeks, 21 weeks and 31 weeks

Completion date
30/04/2025

Eligibility

Key inclusion criteria
Primiparous women over the age of 18 years with a viable pregnancy and the ability to send and receive e-mail

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Female

Total final enrolment
44

Key exclusion criteria
1. Under the age of 18 years
2. Haematuria
3. Difficulty passing urine or bladder emptying difficulties
4. Present malignancy of the pelvic area
5. A neurological disease that affects the urinary system
6. Pyelonephritis
7. Severe comorbidities in pregnancy (including placenta previa, threatened premature labour, pregnancy-induced hypertension)
8. Hyperactivity of the pelvic floor
9. Active urinary tract infection
10. History of stroke, diabetes or gestational diabetes
11. Use of another PFMT mobile app
12. Cannot read or understand written English

Date of first enrolment
23/02/2024

Date of final enrolment
23/05/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals Dorset NHS Foundation Trust
Management Offices
Poole Hospital
Longfleet Road
Poole

United Kingdom
BH15 2JB

Sponsor information

Organisation
Bournemouth University

ROR
https://ror.org/05wwcw481

Funder(s)

Funder type
University/education

Funder Name
Bournemouth University

Alternative Name(s)
Bournemouth Municipal College, Bournemouth College of Technology, Dorset Institute of Higher Education, Bournemouth Polytechnic, BU, DIHE

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
University Hospitals Dorset

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Rosie Harper (rharper1@bournemouth.ac.uk). Consent from participants will be required and obtained and participants will be pseudo-anonymised using a unique study identity code. All other details will be added to the study record at a later date.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol (preprint)		19/01/2024	13/05/2024	No	No