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APPEAL: Antenatal preventative pelvic floor muscle exercise intervention led by midwives to reduce postnatal urinary incontinence

Submission date
25/10/2019

Recruitment status
No longer recruiting

Registration date
09/03/2020

Overall study status
Completed

Last Edited
27/01/2025

Condition category
Urological and Genital Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Pregnancy and birth are the main risk factors for women to develop urinary incontinence. Despite experiencing symptoms of UI, many women 'suffer' in silence as they are embarrassed about their condition, or accept symptoms as 'normal' after having a baby, despite evidence that pelvic floor muscle exercises (PFME), if performed correctly in pregnancy, can reduce women's risk of developing urinary incontinence after giving birth. Guidelines recommend that midwives provide specific advice about PFME at the woman's antenatal booking appointment, but this very often doesn't happen, or if it does advice is often scant and insufficient for the woman to undertake effective exercises.

The APPEAL pilot trial will train teams of midwives to better explain and encourage pregnant women to undertake their pelvic floor muscle exercises. It will consider whether it would be feasible to undertake a future definitive trial to see if this training reduces the incidence of urinary incontinence in women under their care.

Who can participate?
All women who have antenatal care under the care of each of the community midwifery teams (clusters) in the two NHS trusts.

What does the study involve?
Teams of community midwives will be randomised to either continuing with their usual practice of providing advice and encouragement to the women under their care, or receiving a specially devised training package to better encourage women under their care to undertake pelvic floor muscle exercises (PFME).
At around 3 months after they have given birth, the women under the care of these midwifery teams during the period of this study will be asked to complete a questionnaire to determine whether they had advice from their midwife about PFME, whether they undertook PFME themselves and whether they experienced of any incontinence they may suffer after giving birth.

What are the possible benefits and risks of participating?
As the intervention is to encourage midwives to deliver best practice, we can foresee no risks, potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle to the women receiving antenatal care from the midwifery teams in the intervention arm. Nor can we see any potential risk or burden to the midwives in each cluster who participate in the study

Where is the study run from?
Birmingham Women's and Children's Hospital NHS Foundation Trust, UK

When is the study starting and how long is it expected to run for?
March 2020 to September 2022

Who is funding the study?
National Institute for Health Research (NIHR)

Who is the main contact?
Dr William McKinnon
w.mckinnon@bham.ac.uk

Contact information

Type(s)
Public

Contact name
Dr William McKinnon

Contact details
Birmingham Clinical Trials Unit
University of Birmingham
Birmingham
United Kingdom
B15 2TT
+44 (0)121 414 8335
w.mckinnon@bham.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
272603

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
0.9, CPMS 43784, IRAS 272603

Study information

Scientific Title
Antenatal preventative pelvic floor muscle exercise intervention led by midwives to reduce postnatal urinary incontinence (APPEAL): A feasibility and pilot cluster randomised controlled trial

Acronym
APPEAL

Study objectives
The aim of this feasibility and pilot cluster trial is to assess the potential to undertake a future definitive cluster trial to compare clinical and cost-effectiveness of a midwifery-led antenatal pelvic floor muscle exercise (PFME) intervention to reduce urinary incontinence in postnatal women. Specific objectives include assessment of the acceptability of the trial intervention and procedures to midwives, questionnaire return rates and prevalence of UI and other outcomes at 10 – 12 weeks postnatal

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/02/2020, West Midlands - Edgbaston Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)2071048193; NRESCommittee.WestMidlands-Edgbaston@nhs.net), REC ref: 19/WM/0368

Study design
Two centre feasibility and pilot cluster randomized controlled trial with nested process evaluation

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Postpartum urinary incontinence

Interventions
The intervention in this pilot and feasibility cluster randomized controlled trial comprises an antenatal midwife training package aimed at enhancing midwife ability and motivation to inform and support women in their practice of PFME.

Midwives in the community midwifery teams randomly allocated to the intervention will be trained how to teach PFME Following training, midwives in intervention clusters will be asked to provide verbal information and a resource pack to all women in their care to assist them in performing PFME. The midwifery-led intervention will be introduced to the women at their antenatal booking, with support and advice to undertake PFME included as part of each subsequent follow-up appointment throughout the rest of the pregnancy. Midwives will also be

given resource packs to give to each woman to assist them in performing PFME, which will include recommended ‘apps’, a specially prepared leaflet and other reminders.

Women whose community midwifery teams are allocated to the control will receive standard antenatal care only. The current NICE antenatal care guideline (NICE 2010) recommends that midwives give women advice about exercise, including PFME, at the antenatal booking visit but research suggests that this either does not happen at all, or not in a manner likely to result in sufficient PFME practice.

Fourteen community midwifery teams in two participating NHS trusts will comprise the trial clusters. Midwifery teams will be randomised in a 1:1 ratio to either standard care only or intervention using a dedicated computer programme supplied by BCTU. As randomisation will be by cluster, and the number of clusters allocated to trial arm will be small, it is important to balance the allocation to trial arms according to any factors known or believed to be associated with the study outcomes. A minimisation algorithm will be used within the randomisation system to ensure approximate balance in the treatment allocation over the following variables:
- Midwifery team size as defined by number of births (‘small’ versus ‘large’)
- Trust (BWCH or UHB)

At the first postnatal home visit women will be informed by their community midwife that they will receive a questionnaire at 10-12 weeks after their birth asking that they will receive a postal questionnaire at 10-12 weeks postpartum asking about advice on, and performance of, PFME and about any urinary and faecal incontinence they may have had

Midwives in the participating teams will provide antenatal care to around 1400-1500 women during the study period, of whom a proportion will return questionnaires.

Intervention Type
Behavioural

Primary outcome(s)
1. Dichotomous feasibility measures, such as recruitment and questionnaire return rates, as well as data completeness, will be reported as numbers and percentages
2. The feasibility and pilot cluster trial questionnaire will provide data to facilitate estimation of the sample size required for a future RCT
3. Outcome data on urinary incontinence and PFME will be collected from women at 10-12 weeks postnatally

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
30/09/2022

Eligibility

Key inclusion criteria
All women who receive antenatal care from a participating community midwifery team (cluster) during the trial period

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
15/12/2020

Date of final enrolment
31/03/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Birmingham Women's and Children's Hospital NHS Foundation Trust
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2TG

Sponsor information

Organisation
Birmingham Women's and Children's NHS Foundation Trust

Funder(s)

Funder type

Government

Funder Name
National Institute for Health 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

Results and Publications

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		20/01/2025	27/01/2025	Yes	No
Protocol article		22/10/2022	24/10/2022	Yes	No
HRA research summary			26/07/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes