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Postal questionnaire data collection pilot study - APPEAL pilot study

Submission date
20/08/2018

Recruitment status
No longer recruiting

Registration date
10/09/2018

Overall study status
Completed

Last Edited
06/12/2018

Condition category
Urological and Genital Diseases

[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
Pregnancy and childbirth are important risk factors for Urinary Incontinence (UI) in women. Between two-thirds to three-quarters of women may still experience UI symptoms 12 years after childbirth. Incontinence places a large burden on women's health and impacts on physical, mental and social quality of life with associated pressure on NHS resources. This study is being undertaken as part of a programme that aims to prevent child-birth related UI by increasing the number of women doing pelvic floor muscle exercises (PFMEs) during pregnancy. The aim of this study is to try out two postal questionnaire data collection methods in order to provide estimates for UI rates and find the postal method with the best response rate to be used in the main trial.

Who can participate?
Women aged over 16 who have delivered under the care of a participating community midwife team during a defined period

What does the study involve?
Participants are randomly allocated to receive either a long form or short form postal questionnaire.
The questionnaires assess stress urinary incontinence, bowel incontinence, effectiveness of PFMEs and general health, as well as some questions about advice and information that the women received on PFMEs in their pregnancy and their own practice of PFME. Should the completed questionnaire (of either type) not be received at two weeks from the date of initial posting, then the initial questionnaire is sent again. Should no response be forthcoming then no further questionnaires are sent.

What are the possible benefits and risks of participating?
The benefits to the women are assisting with improving continence in future generations of women. The first questionnaire is accompanied by a £10 voucher which is redeemable in many High Street shops and online as a gratuity for the woman's time in completing and returning the questionnaires. There are no risks of participating in this study.

Where is the study run from?
1. Birmingham Women's & Children's NHS Foundation Trust (UK)
2. Heart of England NHS Trust (UK)
3. Sandwell & West Birmingham Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
March 2018 to November 2018

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

Who is the main contact?
Mrs Sara Webb
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
39050

Study information

Scientific Title

Postal questionnaire data collection pilot study: Antenatal Preventative Pelvic Floor Exercises and Localisation (APPEAL) programme

Acronym
APPEAL

Study objectives
Pregnancy and childbirth are important risk factors for Urinary Incontinence (UI) in women. Between two-thirds to three-quarters of women may still experience UI symptoms 12 years after childbirth. Incontinence places a large burden on women's health and impacts on physical, mental and social quality of life with associated pressure on NHS resources.

This postal questionnaire data collection pilot study is being undertaken as part of a five year NIHE funded Antenatal Preventative Pelvic Floor Exercises and Localisation (APPEAL) programme that aims to prevent child-birth related UI (Urinary Incontinence) by increasing the number of women doing pelvic floor muscle exercises during pregnancy. This pilot study is necessary to try out two postal questionnaire data collection methods in order to provide estimates for UI rates and find the postal method that optimises response rates that can be used in the subsequent trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Brighton & Sussex Research Ethics Committee, 18/05/2018, ref: 18/LO/0934

Study design
Multicentre randomised controlled open-label parallel-group two-arm pilot trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Specialty: Reproductive Health and Childbirth, Primary sub-specialty: General Gynaecology; Health Category: Renal and Urogenital; Disease/Condition: Other diseases of urinary system

Interventions

In this pilot study the intervention is type of postal questionnaire design (long form or short form) which is provided to the women.

The question set for the pilot study consists of a number of validated questionnaires to assess stress urinary incontinence (ICIQ-UI SF), bowel incontinence (RFIS), efficacy of PFME (PFMSES) and general health (SF-12) as well as some questions about advice and information that the women received on PFME in their pregnancy and their own practice of PFME. In order to investigate the most efficacious way of receiving these data back from the women this pilot study will send out the questionnaires in two configurations:

Long form questionnaire
This includes all of the questions necessary to satisfy both the primary and secondary outcome measures for the subsequent cluster randomised controlled trial (APPEAL) and to provide estimates for urinary stress incontinence rates for use in sample size calculation and intra-cluster correlation co-efficient (ICC)
This questionnaire will include a tick box to allow the women to give consent to access her maternity hospital records for the relevant maternity data, alongside tick boxes to request the study results and whether she agrees to be contacted in the future for further research.

Short form questionnaire
In the short form (two part) version of the questionnaire the first part (Part A), contains the questions necessary to address the primary outcome of the subsequent cluster randomised controlled trial alongside secondary outcomes of bowel incontinence as well as questions about advice and information that the woman received on PFME in their pregnancy and their own practice of PFME.
Part A of the short form questionnaire will include a tick box option to allow the woman to give consent to access her hospital records for relevant maternity data, alongside tick boxes to request the study results and whether she agrees to be contacted in the future for further research.
The second part of the short form questionnaire (Part B) includes the PFMSES and SF-12 questionnaires. This will only be sent out to the participants in the short form questionnaire arm following receipt of the completed Part A questionnaire.

Should the completed questionnaire (of either type) not be received at two weeks from the date of initial posting, then the initial questionnaire will be sent again. Should no response be forthcoming then no further questionnaires will be sent. The questionnaires will be sent to the eligible woman in both arms by members of the local team employed by the trust who were responsible for the woman's care during her pregnancy and birth. The first questionnaire will be accompanied by a £10 voucher which is redeemable in many High Street shops and online as a gratuity for the woman's time in completing and returning the questionnaires.

Intervention Type
Other

Primary outcome measure
The response rate for completion of urinary stress incontinence to the full and split questionnaire processes. The process that optimises the response rate for collection of urinary stress incontinence rates will then be used in the subsequent cluster randomised controlled trial (APPEAL).

Secondary outcome measures

1. Stress urinary and bowel incontinence rates at questionnaire completion (10-12 weeks postnatal), the former for use in sample size calculation for the subsequent cluster randomised controlled trial
2. Intra-cluster correlation co-efficient (ICC) for primary outcome for use in the subsequent cluster randomised controlled trial

Overall study start date
01/03/2018

Completion date
30/11/2018

Eligibility

Key inclusion criteria
Women who have delivered under the care of a participating community midwife team during a defined period

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Planned Sample Size: 800; UK Sample Size: 800

Key exclusion criteria
Women who:
1. Are under 16 years of age at the point their notes are reviewed
2. Have a non-live baby on discharge home after birth
3. Have informed the study team that they do not wish to receive the questionnaire

Date of first enrolment
08/10/2018

Date of final enrolment
05/11/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Birmingham Women's & Children's NHS Foundation Trust
Mindlesohn Way
Edgbaston
Birmingham
United Kingdom
B15 2TG

Study participating centre
Heart of England NHS Trust
Birmingham Heartlands Hospital
Bordesley Green East
Birmingham
United Kingdom
B9 5SS

Study participating centre
Sandwell & West Birmingham Hospitals NHS Trust
Department of Research & Development
D46, 2nd Floor Sheldon Block,
City Hospital, Dudley Road
Birmingham
United Kingdom
B18 7QH

Sponsor information

Organisation
Birmingham Women’s & Children’s NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/056ajev02

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-0514-20002

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal with intent for publication around one year after overall trial end date.

Intention to publish date
30/11/2019

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No