

Postnatal Leaking, Exercise and Activity Shorts Evaluation (PLEASE) study

Submission date 14/01/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/02/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 01/10/2015	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

In 2012, we started the MAMMI study to find out about the health and health problems experienced by first-time mothers during pregnancy and up to 1 year after their baby's birth. According to the early results from this study, one in two women leak urine 3 months after their baby's birth and one in five leak urine 6 months after their baby's birth. Some women stop exercising because they leak urine and are concerned that the leakage will show on their outer clothing and be seen by others. The aim in the PLEASE study is to test two different kinds of sports shorts in women who leak urine.

Who can participate?

Women who leak urine while exercising

What does the study involve?

Women will be randomly allocated to either the intervention shorts or the other shorts group for 3 weeks. They will return their shorts and will be sent the other type of shorts to test similarly for a further 3 weeks. The shorts can be worn on their own or under track-suit bottoms or other sports clothes.

What are the possible benefits and risks of participating?

The benefits are feeling secure, comfortable and confident while exercising. Risks were not provided at the time of registration.

Where is the study run from?

Trinity College Dublin (UK)

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

From September 2014 to August 2015

Who is funding the study?

Enterprise Ireland (UK)

Who is the main contact?
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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
N/A

Study information

Scientific Title

Postnatal Leaking, Exercise and Activity Shorts Evaluation (PLEASE): a randomised cross over study

Acronym

PLEASE

Study objectives

Two different kinds of sports shorts will be tested to see if either, or both, help women who have postnatal urine leakage feel secure, comfortable and confident while exercising.

04/08/2015: Overall trial end date extended to 30/04/2016 from 31/08/2015. Additionally, the age range of participants at the time of recruitment has been changed from 3-6 month to 3-12 months.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Research Ethics Committee, Faculty of Health Sciences, Trinity College Dublin, 29/09/2014

Study design

Single centre randomised double-blind cross over trial

Primary study design

Interventional

Secondary study design

Randomised cross over trial

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet**Health condition(s) or problem(s) studied**

Urine leakage during exercising after giving birth

Interventions

1. Women will be randomly allocated to either the intervention shorts or the other shorts group for 3 weeks.
2. At the end of the 3 weeks, women using the first type of shorts will be asked to document the exercise type and amounts and satisfaction with the product for that time using a standardised tested survey form.
3. Women will return their shorts and will be sent the other type of shorts to test similarly for a further 3 weeks. At the end of the second 3 weeks of using the second type of shorts, women will be asked to document the exercise type and amounts and satisfaction with the product for that time using the same standardised tested survey form.

4. Neither women nor researchers will be aware of which shorts have been sent until the coding is revealed at the end of the trial to avoid bias.
5. When women return the second pair of shorts, with their data, both pairs of shorts will be returned to them.

Intervention Type

Mixed

Primary outcome measure

Measured with a standardised tested survey form at the end of 3 weeks:

1. Security while wearing and exercising with sports shorts
2. Comfort while wearing and exercising with sports shorts
3. Confidence while wearing and exercising with sports shorts
4. Satisfaction with the product

Secondary outcome measures

Measured with a standardised tested survey form at baseline:

1. Characteristics of women (age and body-mass index [BMI]) and frequency and severity of urinary leakage
2. Type, frequency and severity of leakage (urge, stress or mixed)
3. Type of exercise taken

Overall study start date

01/09/2014

Completion date

30/09/2016

Eligibility**Key inclusion criteria**

1. Taking part in the MAMMI (Maternal health And Maternal Morbidity in Ireland, <http://www.mammi.ie/>) study
2. Gave consent to being contacted about taking part in future research related to the MAMMI study
3. Not pregnant or planning a pregnancy during the study
4. Baby's age is between 3 months and 12 months at study start
5. Do at least 30 minutes of vigorous exercise twice a week and are willing to continue doing this amount of exercise for at least 2 months during the study

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

40 women

Key exclusion criteria

1. Not taking part in the MAMMI study at the time of recruitment to the PLEASE study
2. Did not provide consent to take part in future research related to the MAMMI study
3. Pregnant or planning a pregnancy
4. Not exercising for at least 30 minutes, twice a week
5. Less than 3 months and more than 9 months postpartum
6. Ill

Date of first enrolment

16/02/2015

Date of final enrolment

30/04/2016

Locations

Countries of recruitment

Ireland

Study participating centre**Trinity College Dublin**

School of Nursing and Midwifery

24 D'Olier Street

Dublin

Ireland

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Sponsor information

Organisation

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Sponsor type

University/education

ROR

<https://ror.org/02tyrky19>

Funder(s)

Funder type

Government

Funder Name

Enterprise Ireland (UK)

Results and Publications

Publication and dissemination plan

1. The main findings of the PLEASE study, women's feeling of security, comfort and confidence while exercising using two different type of sports shorts, and satisfaction with product will be published in a peer-reviewed journal and presented at relevant national and international conferences.

2. The current intention is that the analyses for the participating women will be published following collection of the final outcome data for all of those women.

Intention to publish date

30/06/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request