

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

Protocol serial number

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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

Trinity College Dublin

ROR

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

Funder(s)

Funder type

Government

Funder Name

Enterprise Ireland (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request