

Feasibility study of a coping Intervention for recurrent miscarriage

Submission date 18/02/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 18/02/2014	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 19/05/2020	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
15894

Study information

Scientific Title
A feasibility and acceptability study and a qualitative process evaluation of a coping intervention for women with recurrent miscarriage

Study objectives

Some women experience the pain of miscarriage on numerous occasions. Studies show that these women experience feelings of anxiety and distress during the early stages of a new pregnancy as they worry another miscarriage will occur. This study will investigate whether a coping strategy, developed for a similar group of women, would be acceptable and useful to women suffering recurrent miscarriage, and reduce the anxiety and worry they experience. A secondary aim of the study is to develop a deeper understanding of the experiences and feelings of women in the early stages of a new pregnancy following multiple miscarriages.

Women who have experienced three or more first trimester miscarriages will be eligible and invited to take part in the study. The study will take place within two recurrent miscarriage referral hospitals in the South of England.

Ethics approval required

Old ethics approval format

Ethics approval(s)

13/SC/0506

Primary study design

Interventional

Study design

Randomised; Interventional and Observational; Design type: Qualitative

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Reproductive Health and Childbirth; Subtopic: Reproductive Health and Childbirth (all Subtopics); Disease: Reproductive Health & Childbirth

Interventions

PRCI, The Positive Reappraisal Coping Intervention (PRCI) consists of a small card that contains 10 positive reappraisal statements and aims to encourage women who have experienced recurrent miscarriage to redefine the waiting period of a subsequent pregnancy more positively.

Intervention Type

Behavioural

Primary outcome(s)

This study is a mixed method feasibility study; it is not powered to demonstrate clinical outcomes

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/12/2014

Eligibility

Key inclusion criteria

1. Women who have experienced three or more first trimester miscarriages.
2. Women aged 18 years and over.
3. Women who are willing and able to give written consent.; Target Gender: Female ; Lower Age Limit 18 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

Key exclusion criteria

Women will be excluded from this study if they do not speak English well enough to understand and complete study materials. This criterion is in place because the study materials (including the PRCI) are not currently available in translation.

Date of first enrolment

17/01/2014

Date of final enrolment

30/04/2016

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

University Hospital Southampton NHS Foundation Trust

Southampton

United Kingdom

SO16 6YD

Study participating centre

Portsmouth Hospitals NHS Trust
Portsmouth
United Kingdom
PO6 3LY

Sponsor information

Organisation

Southampton University Hospitals NHS Trust (UK)

ROR

<https://ror.org/0485axj58>

Funder(s)

Funder type

Government

Funder Name

NIHR Clinical Doctoral Research Fellowship; Grant Codes: CDRF-2012-03-004

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	qualitative results	01/06/2019	19/05/2020	Yes	No
Protocol article	protocol	15/04/2015		Yes	No
HRA research summary			28/06/2023	No	No