Feasibility study of a coping Intervention for recurrent miscarriage

Submission date	Recruitment status	Prospectively registered		
18/02/2014	No longer recruiting	[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
18/02/2014	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
19/05/2020	Pregnancy and Childbirth			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

Randomised; Interventional and Observational; Design type: Qualitative

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

Not provided at time of registration

Overall study start date

17/01/2014

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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

Planned Sample Size: 50; UK Sample Size: 50

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

England

United Kingdom

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)

Sponsor details

Tremona Road Southampton England United Kingdom SO16 6YD

Sponsor type

Hospital/treatment centre

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

Publication and dissemination plan

2017 results published in thesis: https://eprints.soton.ac.uk/422273/

Intention to publish date

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?
Protocol article	protocol	15/04/2015		Yes	No
Results article	qualitative results	01/06/2019	19/05/2020	Yes	No
HRA research summary			28/06/2023	No	No