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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

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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