A randomised controlled trial of a preconception clinic in Barnsley

Submission date	Recruitment status	Prospectively registered
23/01/2004	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
23/01/2004	Completed	Results
Last Edited	Condition category	Individual participant data
07/09/2015	Pregnancy and Childbirth	Record updated in last year

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

RBH 97XX5

Study information

Scientific Title

A randomised controlled trial of a preconception clinic in Barnsley

Study objectives

What is the clinical effectiveness of providing preconception care in Barnsley to couples with a history of adverse pregnancy outcomes?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Pregnancy and childbirth: Pregnancy

Interventions

- 1. Preconception care
- 2. No care

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

An effective means of delivering a package of preconception care, incorporating interventions of known effectiveness, which reduces the risk of adverse outcomes to pregnancy saying costs short and long term for an acceptable initial expenditure. Publication of papers in peer reviewed journals Local regional and national seminars describing the findings to clinicians and health

educators in primary and secondary care. Representations to health authority to implement findings.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/03/1998

Completion date

28/02/2001

Eligibility

Key inclusion criteria

Couples where woman has a recent history of miscarriage, small for dates baby, premature birth, stillbirth or congenital defect

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

100 in each group

Key exclusion criteria

Women aged under 18 at the time of study

Date of first enrolment

01/03/1998

Date of final enrolment

28/02/2001

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

The Health Centre

Barnsley United Kingdom S75 5HQ

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

http://www.doh.gov.uk

Funder(s)

Funder type

Government

Funder Name

NHS Executive Trent (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available