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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

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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