ISRCTN97337545 https://doi.org/10.1186/ISRCTN97337545

Psychosexual factors and well-being in women receiving a specialist ultrasound scan

Submission date	Recruitment status	[ ] Prospectively registered
12/09/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2003	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/11/2015	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
N0047111222

Study information

Scientific Title
Psychosexual factors and well-being in women receiving a specialist ultrasound scan

Study objectives
How do different ways of providing information about a specialist ultrasound scan (interview, letter, audiotape, and a combination of these) affect accuracy of recall and psychological wellbeing in pregnant women?

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)
Other

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Psychological wellbeing in pregnant women

Interventions
Randomised controlled trial. All women attending the clinic for a specialist scan will be invited to participate in the study. They will be provided with an information sheet outlining the details of the study. Women agreeing to participate will complete a questionnaire before their scan. Participants will be randomly assigned to one of four experimental groups using a pre-arranged randomised schedule. These groups will comprise:
1. A control group - receiving the standard care package of an interview and copy of the scan report
2. In addition to the above, group two will receive an audiotaped copy of the interview
3. In addition to the standard care package of an interview and copy of the scan report, group three will be sent a written summary of their interview
4. In addition to the standard care package, group four will receive both a taped copy of the interview and will be sent a written summary.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. State anxiety measured using the self-report State-Trait Anxiety Inventory (STAI) at baseline and 2 weeks post scan
2. Depression measured using the Beck Depression Inventory (BDI) at baseline and 2 weeks post scan

Secondary outcome measures
Information recall measured using a structured telephone interview 2 weeks post scan.

Overall study start date
04/05/2000

Completion date
30/06/2004

Eligibility

Key inclusion criteria
Women with congenital abnormalities of their babies.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
550

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
04/05/2000

Date of final enrolment
30/06/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Birmingham Women's Hospital
Birmingham
United Kingdom
B15 2TG

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Birmingham Women's Healthcare NHS Trust

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 provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	30/12/2003		Yes	No