

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

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/11/2015	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

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