

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

Submission date 12/09/2003	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 12/09/2003	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 27/11/2015	Condition category Pregnancy and Childbirth	☐ 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

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Quality of life

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(s)

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

Key secondary outcome(s)

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

Completion date

30/06/2004

Eligibility

Key inclusion criteria

Women with congenital abnormalities of their babies.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

England

Study participating centre

Birmingham Women's Hospital

Birmingham

United Kingdom

B15 2TG

Sponsor information

Organisation

Department of Health (UK)

Funder(s)**Funder type**

Government

Funder Name

Birmingham Women's Healthcare NHS Trust

Results and Publications**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