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# 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

**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

## Study design
Randomised controlled trial

## Primary study design
Interventional

## 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 |