

A cluster randomised controlled trial of selective consent for the second trimester ultrasound scan

Submission date 07/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 17/11/2005	Overall study status Stopped	☐ Protocol
Last Edited 21/02/2019	Condition category Pregnancy and Childbirth	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Study information

Scientific Title

A cluster randomised controlled trial of selective consent for the second trimester ultrasound scan

Acronym

USS & You

Study objectives

Women given detailed information about the content and effectiveness of the second trimester fetal abnormality scan would experience no additional anxiety after their scan than women given standard information and care.

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)

Screening

Health condition(s) or problem(s) studied

Second trimester ultrasound scan

Interventions

1. A structured face to face discussion with a research midwife or research sonographer about the purpose of and effectiveness of the second trimester fetal anomaly scan followed by the opportunity to accept or decline 5 separate components of the procedure
2. Standard information and care

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Maternal anxiety two weeks post scan as measured by the State Trait Anxiety Inventory (STAI) (Spielberger, 1983)

Key secondary outcome(s)

1. Maternal anxiety (STAI) at baseline and immediately following scan
2. Maternal knowledge about the purpose and effectiveness of the second trimester scan
3. Maternal anxiety measured by the anxiety subscale of the Hospital Anxiety and Depression Scale (Zigmond and Snaith, 1983)
4. Uptake for the 5 separate components of the second trimester scan
5. Maternal anxiety (STAI) following a subnormal result from the second trimester scan at 30 weeks gestation and 6 weeks postnatal

Completion date

20/11/2002

Reason abandoned (if study stopped)

Objectives no longer viable

Eligibility

Key inclusion criteria

1. Pregnant women booked at the Royal Victoria Infirmary (RVI) attending for a 'routine' second trimester anomaly scan
2. Aged 16-50
3. Able to communicate verbally in English

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Known twin pregnancy
2. Women who have been given a risk positive result from an earlier scan

Date of first enrolment

01/01/2002

Date of final enrolment

20/11/2002

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Department of Obstetrics and Gynaecology

Newcastle upon Tyne

United Kingdom

NE1 7RU

Sponsor information

Organisation

Newcastle upon Tyne Hospitals NHS Trust (UK)

ROR

<https://ror.org/05p40t847>

Funder(s)

Funder type

University/education

Funder Name

University of Newcastle upon Tyne (UK) - an own account trial

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration