

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

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

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

N/A

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

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Screening

Participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/01/2002

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

Age group

Adult

Sex

Female

Target number of participants

1466

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

England

United Kingdom

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)

Sponsor details

Research and Development

Royal Victoria Infirmary

Queen Victoria Road

Newcastle upon Tyne

England

United Kingdom

NE1 4LP

Sponsor type

Hospital/treatment centre

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**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