

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

<b>Submission date</b> 07/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 17/11/2005	<b>Overall study status</b> Stopped	<input type="checkbox"/> Protocol
<b>Last Edited</b> 21/02/2019	<b>Condition category</b> 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

### Contact name

Prof Steven Robson

### Contact details

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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