# Home Blood Pressure Recording in Pregnancy - A Pilot Study for a Randomised Trial

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>		
23/01/2004		☐ Protocol		
Registration date 23/01/2004	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
21/01/2010	Pregnancy and Childbirth			

### Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

**Prof Jenny Hewison** 

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# Additional identifiers

Protocol serial number

HSR/037

# Study information

Scientific Title

#### **Study objectives**

The traditional model of antenatal care often involves 14 or more clinical visits but there is large practice variation. The detection of hypertension is an important function of antenatal care and, unless blood pressure can be monitored outside the clinic, this sets a lower limit on the frequency of visits. We propose a pilot study (prior to embarking on a larger trial) where women would be randomised to receive EITHER routine antenatal visits and clinic monitoring of blood pressure OR a reduced number of antenatal visits and home monitoring of blood pressure. The pilot will investigate what proportion and types of women are willing to take part in such a study and whether women use portable blood pressure monitors satisfactorily and at the prescribed times. It will also be sufficient to measure major effects on anxiety and number of attendances.

#### 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)

Screening

# Health condition(s) or problem(s) studied

Pregnancy and hypertension

#### **Interventions**

- 1. Routine antenatal visits and clinic monitoring of blood pressure
- 2. A reduced number of antenatal visits and home monitoring of blood pressure.

#### Intervention Type

Other

#### Phase

Not Applicable

## Primary outcome(s)

- 1. Recruitment
- 2. Total number of clinic visits
- 3. Frequency of blood pressure measurements
- 4. Schedule preference
- 5. Anxiety

#### Key secondary outcome(s))

Not provided at time of registration

#### Completion date

# **Eligibility**

#### Key inclusion criteria

Pregnant women

## Participant type(s)

**Patient** 

# Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

Female

#### Key exclusion criteria

- 1. Multiple pregnancies
- 2. Established hypertension
- 3. Previous early-onset pre-eclampsia
- 4. Serious medical disease
- 5. Previous pregnancy loss after 24 weeks

#### Date of first enrolment

25/03/1996

#### Date of final enrolment

24/09/1997

# Locations

#### Countries of recruitment

**United Kingdom** 

England

# Study participating centre Academic Unit of Psychiatry and Behavioural Sciences

Leeds United Kingdom LS2 9LT

# Sponsor information

## Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

# Funder(s)

## Funder type

Government

#### Funder Name

NHS Executive Northern and Yorkshire (UK)

# **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	01/02/2000		Yes	No