

# Randomised controlled trial of a low-cost intervention to promote self-help smoking cessation in pregnancy

**Submission date**  
25/10/2000

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
25/10/2000

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
13/10/2014

**Condition category**  
Pregnancy and Childbirth

☐ Individual participant data

## 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

G9711788

# Study information

## Scientific Title

### Study objectives

The trial aims to identify the effectiveness of low cost self-help health education materials implemented within routine UK antenatal care in helping pregnant women quit smoking, using validated smoking status at the end of the second trimester of pregnancy (27 weeks) as the primary outcome measure. Secondary aims of the research will be (i) to collect data on birth weight, gestation at delivery and stillbirth and neonatal/infant mortality to contribute to the cumulative meta-analysis of the impact of smoking cessation on these outcomes; (ii) to assess the acceptability of the booklets to the women and (iii) to assess the feasibility and cost of incorporating self-help manuals dispatched by post into routine antenatal care

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Three NHS trusts agreed to participate in the study, and approval from relevant local research ethics committees were obtained

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Not Specified

### Participant information sheet

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

Public health, social medicine

### Interventions

Low cost self-help health education materials/control.

There will be two experimental groups: (i) participants receiving normal antenatal care only and (ii) participants receiving the programme of self-help booklets in addition to normal antenatal care. 112 participating midwives will be randomly allocated to the two groups: during the period of the trial, each of the midwives will deliver care according to their respective allocation to experimental group to all their patients satisfying the inclusion criteria.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Primary end point: smoking cessation rate (validated by urinary cotinine assay) at end of second trimester of pregnancy (27 weeks).

**Secondary outcome measures**

Secondary end points: birth weight and gestation at delivery. The acceptability of the intervention to participants and midwives, aspects of programme content and delivery and programme costs will also be assessed

**Overall study start date**

01/02/1998

**Completion date**

28/02/2001

**Eligibility****Key inclusion criteria**

Aged 16 years or above at their first appointment with one of 40 participating midwives. Participants will be those who are less than 16 weeks pregnant at that time and who were smokers immediately prior to pregnancy.

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

1500

**Key exclusion criteria**

Not provided at time of registration.

**Date of first enrolment**

01/02/1998

**Date of final enrolment**

28/02/2001

# Locations

## Countries of recruitment

England

United Kingdom

## Study participating centre

Department of Social Medicine

Bristol

United Kingdom

BS8 2PR

# Sponsor information

## Organisation

Medical Research Council (MRC) (UK)

## Sponsor details

20 Park Crescent

London

United Kingdom

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[clinical.trial@headoffice.mrc.ac.uk](mailto:clinical.trial@headoffice.mrc.ac.uk)

## Sponsor type

Research council

## Website

<http://www.mrc.ac.uk>

# Funder(s)

## Funder type

Research council

## Funder Name

Medical Research Council (UK)

## Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## 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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	Results	14/12/2002		Yes	No