

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

Dr Laurence Moore

Contact details

Department of Social Medicine
University of Bristol
Canyng Hall
Whiteladies Road
Bristol
United Kingdom
BS8 2PR

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

W1B 1AL

+44 (0)20 7636 5422

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?
Results article	Results	14/12/2002		Yes	No