ISRCTN18328134 https://doi.org/10.1186/ISRCTN18328134

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

Registration date
25/10/2000

Overall study status
Completed

Last Edited
13/10/2014

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Not Specified

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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
United Kingdom

England

Study participating centre
Department of Social Medicine
Bristol
United Kingdom
BS8 2PR

Sponsor information

Organisation
Medical Research Council (MRC) (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

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