

An evaluation of the relative effectiveness of interventions based on the transtheoretical model (TTM) of behaviour change (stages of change) compared with standard care in helping women to stop smoking in pregnancy

Submission date 05/07/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 07/07/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 04/01/2008	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Paul Aveyard

Contact details
Department of Primary Care & General Practice
University of Birmingham
Birmingham
United Kingdom
B15 2TT
+44 (0)121 414 8529
p.n.aveyard@bham.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

MREC 99/7/50

Study information

Scientific Title

Study objectives

That interventions based on the TTM would help more pregnant smokers stop smoking than standard 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)

GP practice

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Smoking in pregnancy

Interventions

A cluster randomized trial of three interventions:

1. Standard care
2. Self-help manual and enhanced stage-based counselling
3. Self-help manual, enhanced stage-based counselling and use of an interactive computer program

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Biochemically confirmed continuous abstinence for 10 weeks at the end of pregnancy.

Secondary outcome measures

Point prevalence abstinence, self-reported abstinence.

Overall study start date

01/03/1999

Completion date

31/03/2001

Eligibility

Key inclusion criteria

Pregnant, aged at least 16 years of age, smoking at the time of booking for maternity care, able to read English.

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

918

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/03/1999

Date of final enrolment

31/03/2001

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Department of Primary Care & General Practice
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
Dr Brendan Lavery
Research & Enterprise Services
University of Birmingham
Birmingham
England
United Kingdom
B15 2TT
+44 (0)121 414 7618
b.w.lavery@bham.ac.uk

Sponsor type
University/education

ROR
<https://ror.org/03angcq70>

Funder(s)

Funder type
Government

Funder Name
West Midlands Health Authorities (UK)

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	01/06/2003		Yes	No
Results article	Cohort results:	01/09/2003		Yes	No
Abstract results		01/01/2005		No	No
Results article	Results	01/05/2005		Yes	No
Results article	Results	29/07/2005		Yes	No
Results article	Results	01/05/2006		Yes	No