

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Point prevalence abstinence, self-reported abstinence.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

England

Study participating centre

Department of Primary Care & General Practice

Birmingham

United Kingdom

B15 2TT

Sponsor information

Organisation

University of Birmingham (UK)

ROR

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

Funder(s)

Funder type

Government

Funder Name

West Midlands Health Authorities (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	01/06/2003		Yes	No
Results article	Cohort results:	01/09/2003		Yes	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
Abstract results		01/01/2005		No	No