

# 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

<b>Submission date</b> 05/07/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 07/07/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 04/01/2008	<b>Condition category</b> 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

**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?
<a href="#">Results article</a>	Results	01/06/2003		Yes	No
<a href="#">Results article</a>	Cohort results:	01/09/2003		Yes	No
<a href="#">Results article</a>	Results	01/05/2005		Yes	No
<a href="#">Results article</a>	Results	29/07/2005		Yes	No
<a href="#">Results article</a>	Results	01/05/2006		Yes	No
<a href="#">Abstract results</a>		01/01/2005		No	No