

# Randomised controlled trial and economic evaluation of two alternative strategies of providing support for socially disadvantaged inner city families with infants

<b>Submission date</b> 25/04/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 25/04/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 08/11/2022	<b>Condition category</b> Mental and Behavioural Disorders	<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**  
Prof Ann Oakley

**Contact details**  
Social Science Research Unit  
London University Inst of Education  
18 Woburn Square  
London  
United Kingdom  
WC1H 0NR  
+44 (0)20 7612 6391  
a.oakley@ioe.ac.uk

## Additional identifiers

**Protocol serial number**  
HTA 95/07/19

## Study information

**Scientific Title**

Randomised controlled trial and economic evaluation of two alternative strategies of providing support for socially disadvantaged inner city families with infants

**Study objectives**

The proposed study will quantify the effectiveness and cost effectiveness of two alternative strategies of providing support for socially disadvantaged inner city families with infants. Families with infants living in a disadvantaged inner city area will be randomly allocated to receive either a home based support programme delivered by a research health visitor, a support programme provided by community based family support organisations, or standard services. The intervention will start when infants are approximately six weeks old and will continue for one year. The primary outcome measures (child injury, parental smoking, maternal psychological ill health) are important causes of mortality, morbidity and costs to the NHS.

**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)**

Prevention

**Health condition(s) or problem(s) studied**

Mental and behavioural disorders

**Interventions**

1. Home based support programme delivered by a research health visitor
2. A support programme provided by community based family support organisations
3. Standard services

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

The primary outcome measures (child injury, parental smoking, maternal psychological ill health) are important causes of mortality, morbidity and costs to the NHS.

**Key secondary outcome(s)**

Not provided at time of registration

**Completion date**

31/08/2001

## Eligibility

**Key inclusion criteria**

Families with infants living in a disadvantaged inner city area

**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**

01/09/1998

**Date of final enrolment**

31/08/2001

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

Social Science Research Unit

London

United Kingdom

WC1H 0NR

## Sponsor information

**Organisation**

Department of Health (UK)

ROR

<https://ror.org/03sbpja79>

## Funder(s)

**Funder type**

Government

**Funder Name**

NIHR Health Technology Assessment Programme - HTA (UK)

## Results and Publications

**Individual participant data (IPD) sharing plan**

Not provided at time of registration

**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>	HTA monograph	01/08/2004		Yes	No