

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

Submission date 25/04/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 25/04/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/11/2022	Condition category 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Prevention

Participant information sheet

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 measure

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

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/09/1998

Completion date

31/08/2001

Eligibility**Key inclusion criteria**

Families with infants living in a disadvantaged inner city area

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

731

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**

England

United Kingdom

Study participating centre
Social Science Research Unit
London
United Kingdom
WC1H 0NR

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Quarry House
Quarry Hill
Leeds
United Kingdom
LS2 7UE
+44 (0)1132 545 843
Sheila.Greener@doh.gsi.gov.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/en/index.htm>

ROR

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

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Results article	HTA monograph	01/08/2004		Yes	No