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

| Submission date | Recruitment status No longer recruiting | Prospectively registered | | |
|-------------------------------|--|--------------------------------|--|--|
| 25/04/2003 | | ☐ Protocol | | |
| Registration date 25/04/2003 | Overall study status Completed | Statistical analysis plan | | |
| | | [X] Results | | |
| Last Edited 08/11/2022 | Condition category Mental and Behavioural Disorders | [] Individual participant data | | |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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

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