Does Baby Check improve parental recognition of the severity of their child's illness: a pilot study of the revised Baby Check Symptom Diary

	 Prospectively registered
12/09/2003 No longer recruiting	☐ Protocol
Overall study status	Statistical analysis plan
Completed	Results
Condition category	Individual participant data
Neonatal Diseases	Record updated in last year
	Completed Condition category

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N0220111014

Study information

Scientific Title

Study objectives

Can parents safely and routinely use Baby Check (a parent administered infant illness severity score) and that they will seek professional medical attention for their infant more appropriately than parents without Baby Check? These hypotheses will be examined specifically in relation, accuracy of diary use and appropriateness of visits to the GP and hospital admissions.

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)

Other

Study type(s)

Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied

Neonatal Diseases

Interventions

This pilot study is confined to the residents of the South and South West PCTs in Sheffield. The participating Health Visitors will recruit Primips at 36 weeks at their routine ante natal visit. They will be enrolled by the Health Visitor 1-14 days postnatally. The CONI office (in Sheffield) will randomise families and send the appropriate symptom diary (and thermometer if randomised to Baby Check arm) to the family home enabling the Health Visitor to familiarise the family with the use of the symptom diary (and Baby Check) at this first post natal visit.

GPs will be informed and sent appropriateness of consultation forms at the time of the infants' enrolment.

The symptom diaries will be kept by the parents for a period of 3 months during which we would

expect from routine health care there would be around six contacts with either the Health Visitor or the GP. Once completed the diaries will be returned to the CONI office for analysis prior to being returned to the parents or being destroyed.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

The proposed pilot study to be undertaken in Sheffield is to test whether parents can use and complete the revised diary; whether when used in conjunction with Baby Check it influences the use of medical services (GP and hospital); whether following consultation with the GP the parents are more empowered and the GP perceives the consultation to be appropriate.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/06/2002

Completion date

30/09/2004

Eligibility

Key inclusion criteria

This pilot study is confined to the residents of the South and South West PCTs in Sheffield. The participating Health Visitors will recruit Primips at 36 weeks at their routine ante natal visit. They will be enrolled by the Health Visitor 1-14 days postnatally. For the pilot scheme only families with English as their first language will be recruited. We will recruit 120 families, randomised to 60 study infants and 60 controls.

Participant type(s)

Patient

Age group

Neonate

Sex

Both

Target number of participants

120 (60 study infants and 60 controls)

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

Date of final enrolment 30/09/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Sheffield Teaching Hospital Sheffield United Kingdom S10 2TH

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL

Sponsor type

Government

Website

http://www.doh.gov.uk

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Results and Publications

Publication and dissemination planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration