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How are you feeling? Improving communication between health visitors and women from ethnic minority communities

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 29/09/2006	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 12/05/2017	**Condition category** Other	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0071173444

Study information

Scientific Title
How are you feeling? Improving communication between health visitors and women from ethnic minority communities

Study objectives
The pilot will be used to address the following question under four key research themes:
Use of the booklets
1. What is the most appropriate way of training the staff to use the booklets?
2. How do staff use the booklets in their decision making?
3. What are staff perspectives on the use of the tool (utility, ease of use, etc)?
4. Can the booklets be used as effectively by different staff groups (health visitors, link workers and support workers)?

Impact on the service user
5. How satisfied are mothers with the encounter with staff with and without the use of the booklets?
6. Identify whether, and how, the needs of women are currently being met.

Impact on staff
7. How satisfied are the staff with their encounter with the mother, with and without the booklet?

Research to inform future trial
8. Does the use of the booklet impact on the different health outcome measures used in the study?
9. What are the most appropriate health outcomes measures for this population?
10. Based on the primary outcome measure, what sample size is required for the main study?
11. How effective are the data collection tools at capturing the information required to determine the study outcomes?

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)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Communication between health visitors and women from ethnic minority communities

Interventions
The trialists propose to undertake the pilot within three UK regions: Sheffield, Glasgow and Camden.

The unit of randomisation for the purpose of this trial will be the practices that provide health services in areas with high proportions of women from the target population groups. The practices will be randomized using a computer-generated randomisation list. In total each region will be asked to identify eight practices that are willing to participate in the trial.

The eight practices from each region will be randomly allocated into one of four groups:
1. Group 1: Control: Routine treatment* (no use of the booklets)
2. Group 2: Use of booklets with no training*
3. Group 3: Use of booklets with a training pack
4. Group 4: Use of booklets with a training pack and workshop training.

*All participants in groups 1 and 2 will be offered the opportunity for training in the use of the booklets following completion of the trial.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The main outcomes of interest from this phase of the research are:
1. User satisfaction with their interaction, measured by a generic satisfaction tool
2. HV satisfaction with their interaction with the client, measured using the Agnew Relationship Measure, and qualitatively through the focus groups
3. Change in health status of the participant
4. Diagnosis of PND during the trial period

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/10/2005

Completion date

30/09/2006

Eligibility

Key inclusion criteria
All mothers who have a baby that is up to one year of age during the recruitment period, with English as a second language will be invited to participate in the trial. However, particular attention will be paid to the selection of participating health visitors to ensure that the areas of greatest racial diversity are included in the trial. On average, each practice will need to recruit around 10 mothers to ensure a total recruitment of 60 women into the control arm and 180 into the intervention arm. To reduce the possibility of selection bias, HVs will be asked to invite all consecutive eligible women to participate in the trial until they have reached the target number per site. The use of the booklets will be based on the clinical judgement of the HVs. All postnatal Arabic, Chinese, Urdu, Bengali, Somali speaking women in the identified practices will be approached.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
240 women

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/10/2005

Date of final enrolment
30/09/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

University of Sheffield
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Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
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Sponsor type
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Funder(s)

Funder type
Government

Funder Name
Sheffield Health and Social Research Consortium (UK)

Funder Name
NHS R&D Support Funding (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration