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# The MOMENTS Study: Improving the outcome of pregnancy and early infancy with an intervention using mentors in socially deprived areas of Belfast

**Submission date**
18/01/2008

**Recruitment status**
No longer recruiting

**Registration date**
27/03/2008

**Overall study status**
Completed

**Last Edited**
11/06/2010

**Condition category**
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**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
COM/182/02; RRG/3247/05

# Study information

### Scientific Title
Improving the outcome of pregnancy and early infancy with an intervention using mentors in socially deprived areas of Belfast

### Acronym
MOMENTS

### Study objectives
Main research question:
Can the use of peer group mentors improve outcomes of pregnancy and early infancy in first time mothers from socially deprived areas?

MOMENTS Qualitative Study: Peer-mentoring for first-time mothers from areas of socio-economic disadvantage: a qualitative study within a randomised controlled trial -
A qualitative study took place alongside the randomised controlled trial (RCT) (all details pertaining only to this qualitative study will be headed under the title MOMENTS Qualitative Study in the relevant sections). This qualitative study used thematic analysis of semi-structured interviews with women participants, mentors and research midwives, and took place from 01/09 /2004 to 31/08/2006. 24 participants were recruited to this qualitative study.

Hypothesis: To explore difficulties encountered in conducting a randomised controlled trial of a peer-mentoring programme for first-time mothers in socially disadvantaged areas, in order to provide information relevant to future research and practice.

The aims of the qualitative study are to assess:
1. Implementation and ongoing development of the programme
2. Internal dynamics and actual operations of the mentor programme
3. Quality and quantity of the activity undertaken by the mentors
4. Interactions between mothers and mentors
5. Strengths and weaknesses of the various programme components
6. Challenges and barriers to successful implementation
7. Mentors' and mothers' perspectives on programme effectiveness

We intend to employ a range of different qualitative methods including in-depth interviews with mentors, mothers and other key stakeholders, observations of both group and individual sessions and documentary analysis.

MOMENTS Follow-up Study: Can peer mentoring in first-time mothers from areas of socially deprived area, during pregnancy and the first year of the infant's life have sustained effects of child growth, health and development and maternal health and wellbeing?
In 2006 a follow-up study was added to this RCT (all details pertaining only to this qualitative study will be headed under the title MOMENTS Follow-up Study in the relevant sections). This follow-up study continued on from the original RCT with the same inclusion and exclusion

criteria, and the same interventions, but with a longer-term primary outcome. This follow-up took place from 01/09/2006 to 01/09/2008. 350 participants were followed-up from the original RCT.

Please note that the target number of participants on this ISRCTN record has been amended from 500 to 340 as of 20/02/2009. Recruitment was slower than anticipated and our sample size calculation was reviewed. This determined that a final sample size of 144 in each group would allow detection of a difference of 5 points in Bayley scores (SD 15) between the two groups at one year with 80% power and an alpha of 0.05. To achieve a final sample size of 144 in each group we aimed to recruit 170 subjects in each group, thus allowing for an attrition rate of about 15%.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Ethics approval received from the Office for Research Ethics Committees Northern Ireland (ORECNI) on the 30th April 2003 (ref: 124/03).

## Study design
Randomised controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Not specified

## Study type(s)
Quality of life

## Participant information sheet

## Health condition(s) or problem(s) studied
Infant development and maternal wellbeing

## Interventions
Participant calculation:
Our randomised study with 250 in each group of the trial will be capable (80% power; alpha 0.05) of detecting an improvement of Bayley score at one year of 5 points.

Intervention group:
The intervention will be carried out by specially trained peer group mentors from the same geographical areas as the subjects. Each mentor will be responsible for no more than 15 to 18 mothers during the course of this study. The intervention will begin with a home visit soon after booking followed by a minimum fortnightly contact (telephone, home visit or small group meeting, as deemed appropriate by mother and mentor together) thereafter throughout pregnancy. Initial data collected by questionnaire at recruitment by the research midwife will

identify known risk factors for pregnant women and their babies and enable targeting of subsequent interventions.

The mentors will provide education on diet, nutritional supplementation, personal hygiene, promotion of breast feeding and avoidance of adverse lifestyle factors such as smoking, alcohol or drug abuse. In addition they will try to involve relatives and close friends, and encourage participation in both local and hospital based services for first time mothers, including parentcraft and infant feeding classes. Linkage with other relevant support schemes such as Surestart will be offered. The mentors will provide information on welfare rights, housing, accommodation, social support and agencies for issues such as domestic violence if appropriate.

Small group meetings of a mentor and her group of mothers will be organised every four weeks to allow sharing of information and experiences. Another important part of the intervention will be stress management including alleviating, where possible, environmental stressors, relaxation training techniques, using tape recordings, meditating, and listening to music, and training in coping strategies and anger control. After birth the mentors will continue to provide information and support for these mothers monthly throughout the first year, based on the Child Development Programme and including advice on infant feeding, immunisations and self-esteem and confidence, as required. The intervention package will be tailored to the individual needs of each mother and family.

Control group:
The control group of first time mothers from deprived areas will have routine antenatal and postnatal care without any intervention from the trained peer group mentors. Contacts with health professionals will be recorded retrospectively from routinely collected child health surveillance data.

## Intervention Type
Other

## Phase
Not Specified

## Primary outcome measure
Differences in Bayley scores in infants and in maternal physical and mental well-being at one year between the intervention and non-intervention group. This assessment, in hospital, will take approximately 90 minutes. The Bayley Scales of Infant Development II assess performance on mental, motor and behavioural rating scales; raw scores will be converted to normalised scores representing the Mental Development Index and Psychomotor Development Index. The 36-item short form health survey (SF-36) will also be used to assess maternal physical and mental health.

MOMENTS Follow-up Study:
1. Bayley's Scales of Infant Development III at age 2.5 years and 4 years
2. Maternal quality of life by SF-36

## Secondary outcome measures
1. At booking (10 - 12 weeks): basic demographic data, mother's knowledge of pregnancy and infant development, current dietary habits, feeding intentions, lifestyle factors (smoking, alcohol and drugs), physical and mental health (SF-36)
2. At 22 weeks (when women attend hospital for an anomaly scan): foetal growth (biparietal

diameter, femur length and abdominal circumference) and a short questionnaire on stress levels (Speilberger State Trait Anxiety Questionnaire) and maternal feelings for the pregnancy
3. At 29 - 30 weeks: foetal growth and foetal behaviour. During a 45 minute ultrasound, the frequency and duration of movement and the foetus's startle reaction. A two-second vibroacoustic stimulus (Corometrics) will be presented to the foetus and the response noted in the following 10 seconds (whether the foetus responded and the strength of the foetus) scored on a 10 point scale. Both measures are useful indicators of neurological well-being. Maternal self-report of anxiety levels will be obtained.
4. At birth: Apgar scores at 1 and 5 minutes, growth measurements (birth weight, length and head circumference) in relation to gestation, Brazelton Neonatal Behavioural Assessment Scale at 24 - 72 hours, method of infant feeding
5. At 6 - 8 weeks: infant growth measurements by health visitors during routine visits in the community, details of method and amount of feeding will be noted
6. At 7 - 8 months: infant growth and feeding data will be recorded by health visitors at routine visits and infant temperament using the Revised Infant Temperament Questionnaire (RITQ). Temperament is considered to represent constitutionally based individual differences in reactivity and self-regulation which represent the core of developing personality. The RITQ involves questionnaire responses from the infant's mother which measure dimensions of activity, rhythmicity, approach, adaptability, threshold, mood, intensity, persistence and distractibility. The Parenting Stress Index short form will also be completed.
7. At 1 year: at a hospital clinic, in addition to Bayley Scores and maternal wellbeing, questionnaires will be used to assess anxiety and coping (Parenting Stress Index), hospital admissions, illnesses, use of medication, immunisation status and self-efficacy. Questionnaire data will be validated, with the subjects' consent, by consulting general practice records and hospital records.

### Overall study start date
01/02/2003

### Completion date
31/08/2006

## Eligibility

### Key inclusion criteria
We intend to recruit first time mothers aged 30 years or less from the antenatal clinics at Royal Maternity Hospital, Belfast at first booking (approximately 10 - 12 weeks). Women will be selected from small areas (electoral district equivalents) that are within the most deprived fifth of the Northern Ireland population. These women will be identified from postcodes on their hospital referral letter and when they attend the hospital booking clinic they will be invited to participate in the study.

MOMENTS Qualitative Study:
Purposive samples were selected for invitation to participate. Mentors were selected to include a range of age, locality, work experience, family composition and mentor experience.

### Participant type(s)
Patient

### Age group
Adult

### Sex
Female

### Target number of participants
340

### Key exclusion criteria
1. Women who had been pregnant previously (including miscarriage, termination, stillbirth, live birth)
2. Women with any significant ongoing medical condition which requires regular attendance with a health professional

### Date of first enrolment
01/02/2003

### Date of final enrolment
31/08/2006

## Locations

### Countries of recruitment
Northern Ireland

United Kingdom

### Study participating centre
**Perinatal Medicine**
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## Sponsor information

### Organisation
The Royal Group of Hospitals Trust (UK)

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**Sponsor type**
Hospital/treatment centre

**Website**
http://www.royalhospitals.org/

**ROR**
https://ror.org/02tdmfk69

# Funder(s)

**Funder type**
Government

**Funder Name**
The Research and Development Office of Northern Ireland (UK) - through Targeting Social Needs Initiative

**Funder Name**
MOMENTS Follow-up Study:

**Funder Name**
The Research and Development Office of Northern Ireland (UK) - through Recognised Research Group (RRG) Project Support

# 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

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/03/2011 | | Yes | No |