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Evaluation of a lengthened and multi-disciplinary consultation model in a socially deprived community

Submission date	Recruitment status
19/04/2007	No longer recruiting
Registration date	**Overall study status**
09/05/2007	Completed
Last Edited	**Condition category**
27/01/2011	Mental and Behavioural Disorders

[_] Prospectively registered
[X] 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

Protocol serial number
N/A

Study information

Scientific Title

Study objectives
The null hypothesis is that implementation of a lengthened and multidisciplinary primary care consultation will have no impact upon the psychological health of mothers in terms of anxiety and depression as measured by the Hospital Anxiety and Depression Scale (HADS).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Research Ethics Committee of the Royal College of Surgeons in Ireland (RCSI REC) on the 13th December 2004 (ref: REC115).

Study design
This is a randomised controlled trial.

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Depression of mothers in socially deprived area

Interventions
Families (with at least one child under the age of 16 years) with a history of social problems, substance misuse or depression will be identified by the general practices. Mothers of the families will be approached on behalf of the families and invited to participate in the research by letter and telephone follow up. Families agreeing to participate will be randomised into two equal sized non-stratified groups.

Intervention group:
A multidisciplinary lengthened primary care consultation will be given to the intervention families. The mothers and their families in the intervention group will be offered the multidisciplinary consultation with the Primary Health Care Team (PHCT) to assess their health and social needs. The General Practitioner (GP) will hold an initial discussion with the mother to discuss what her needs are, and this will guide the GP as to which members of the PHCT to invite to the trial consultation. The GP will invite up to other three members of the PHCT, who he or she feels will be able to give significant input, to help address the familys health and social problems. The health care professionals in attendance will actively participate in the consultation and offer advice and input where appropriate.

The GP will be in charge of running the consultation, and will have the whole PHCT from the Ballymun primary care project available to him or her. The GP will try to bring out all the health and social problems of the family so solutions may be worked out. Further lengthened consultations with the members of the primary care team may be required. The GP will arrange the appointments of the trial consultation for the families to attend. An allowance of up to an hour will be given for each case so that three consultations may be arranged per clinical session.

Control group:
The mothers and families in the control group will receive normal care from their GP and the PHCT.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The primary outcome of this study is the psychological health of mothers in terms of anxiety and depression as measured by the Hospital Anxiety and Depression Scale (HADS), measured at 0, 6 months and 12 months.

Key secondary outcome(s))
1. Service delivery:
1.1. Frequency of GP and PHCT visits
1.2. Time spent with GP and PHCT
1.3. Referrals to secondary care and other agencies
2. Medical measures:
2.1. Health status (36-item Short Form health survey [SF-36])
2.2. Smoking status
2.3. Alcohol consumption
2.4. Substance misuse
3. Social measures:
3.1. School truanting
3.2. Unemployment
3.3. Family income
4. Psychological measures (psychotropic prescribing)
5. Satisfaction with management

It is not possible at the outset to determine whether an increase or decrease of service measures is beneficial. An assessment of the trend in referrals and time spent with primary care professionals will be made as the study comes to completion. All secondary outcomes will be measured at time 0, 6 months and 12 months.

Completion date
31/01/2007

Eligibility

Key inclusion criteria
Inclusion - must be mothers who:
1. Have at least one child under 16 years old
2. Have multiple physical or mental health and/or social and/or alcohol and/or drug problems

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Mothers of the families who are under 18 years of age
2. English is not the first language
3. Mothers who have a learning disability or dementia
4. Have high financial income, i.e., non-General Medical Services (GMS) (means tested access to medical services in Ireland)

Date of first enrolment
07/02/2004

Date of final enrolment
31/01/2007

Locations

Countries of recruitment
Bahrain

Ireland

Study participating centre
RCSI-MUB
Manamsa
Bahrain
15503

Sponsor information

Organisation
Royal College of Surgeons in Ireland (RCSI) (Ireland)

ROR
https://ror.org/01hxy9878

Funder(s)

Funder type
Government

Funder Name
Health Research Board (Ireland) (ref: PC/2003/11)

Alternative Name(s)
HRB

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Ireland

Results and Publications

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:	24/01/2011		Yes	No
Protocol article	Protocol:	28/06/2007		Yes	No