

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

Submission date
19/04/2007

Recruitment status
No longer recruiting

☐ Prospectively registered

☒ Protocol

Registration date
09/05/2007

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
27/01/2011

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Quality of life

Participant information sheet

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 family's 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 measure

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.

Secondary outcome measures

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 truancy
 - 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.

Overall study start date

07/02/2004

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

Age group

Adult

Sex

Female

Target number of participants

92 families

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)

Sponsor details

123 St Stephens Green
Dublin
Ireland
2

Sponsor type

University/education

Website

<http://www.rcsi.ie>

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

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