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An evaluation of the Family Talk intervention to support families where a parent has mental health difficulties: The PRIMERA Research Programme

Submission date
19/11/2018

Recruitment status
No longer recruiting

Registration date
05/02/2019

Overall study status
Completed

Last Edited
12/04/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Children of parents with mental health difficulties are at increased risk of having problems with mental health, social status, physical health and educational results. They are amongst the most vulnerable 'hidden' groups in society. Research suggests that up to one in five young people may live in families where a parent has mental health difficulties. Due to the way mental health services are organised in Ireland and other countries, the complex needs of these children and families often go unrecognised and untreated. For instance, most mental health services do not investigate the parenting status of service users because they are focused on the individual service user, adult and child/adolescent mental health services are separated, and staff might lack skills and resources in knowing how to deal with child welfare and protection. Many people have called for the treatment of mental health difficulties in parents of children to be more family-focused.
This study aims to investigate whether an approach called Family Talk can support the mental health of families where a parent has mental health difficulties. Research has shown that family-focused interventions can help parents and children cope with parental mental health difficulties. Family Talk (6-8 sessions) is a treatment with promising evidence for improving child mental health, child coping and resilience, parental mental health, coping and resilience, and family functioning. Family Talk is a strengths-based programme that can be used with any mental illness, and with scope for flexibility if required (for example, it can include a crisis plan). Family Talk involves parents, children and the whole family. Family Talk is attractive in an Irish context as it is similar to some previous, existing and proposed services in Ireland. Family Talk has freely available online training and resources. Family Talk has been used in Australia, Finland, Norway and Greece to support children and families when a parent has mental health difficulties.

Who can participate?
Parents aged over 18 years with children aged 5-18 years who are currently being treated or were treated in the last 18 months for a mental illness by a GP, psychiatrist or multidisciplinary team.

What does the study involve?
Families will be randomly allocated to receive Family Talk immediately or to go on waiting list to start Family Talk in 6 months' time. In both groups, people with mental health difficulties and their families will receive treatment and support as usual from mental health services.
Family talk involves 6-8 sessions over 6-10 weeks. A trained healthcare professional will meet with the parents, children and other family members. The first two sessions involve the family discussing their experience and knowledge of mental illness. In session 3, the healthcare professional meets with the children alone to assess them and to identify any questions which the child(ren) may have about their parent's mental health difficulties. Session 4 is a planning meeting between the healthcare professional and parents. Session 5 is a whole-family session to support family discussion and provide information on mental illness as needed. The follow-up meetings (after one week and after 3-6 months) are to check in and support the family going forward.

What are the possible benefits and risks of participating?
We hope that families will benefit from attending Family Talk, and that it will improve understanding and communication about mental health among family members. The data and feedback that families will give to the research team will be essential in informing government and funders about what is needed to provide better supports for other families when a parent has mental health difficulties.
There is a small risk during the study that families may experience some emotional distress either during or following questionnaires/interview. Safety measures and supports have been put in place in case this happens. If families experience any distress in attending Family Talk, they can discuss with their mental health worker who will support them.

Where is the study run from?
Maynooth University (Ireland) in collaboration with nine sites across Ireland (involving HSE, Tusla and Saint John of God organisations).

When is the study starting and how long is it expected to run for?
June 2017 to December 2021 (updated 06/08/2020, previously: September 2021)

Who is funding the study?
Health Service Executive Mental Health Division, Republic of Ireland

Who is the main contact?
1. Professor Sinéad McGilloway, Sinead.McGilloway@mu.ie
2. Dr Mairead Furlong, Mairead.Furlong@mu.ie

Study website
https://cmhcr.eu/primera-programme/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Nil known

Study information

Scientific Title

A randomised controlled trial evaluation, cost-effectiveness study and process evaluation of the Family Talk intervention to improve child and parent mental health in families where a parent has mental health difficulties: The Promoting Research and Innovation in Mental hEalth seRvices for fAmilies (PRIMERA) Research Programme

Acronym
PRIMERA

Study objectives
The research will comprise a randomised controlled trial, with embedded process evaluation and an economic appraisal. Hypotheses/objectives related to each of these three elements are outlined:

1. Randomised controlled trial
• Compared to a control group of usual services, does the Family Talk intervention improve:
o Child emotional wellbeing and behaviour?
o Child resilience/coping skills?
o Child understanding of parental mental health difficulties?
o Family functioning?
o Parent mental health symptoms?
o Parent resilience/coping skills?
o Parent understanding of impact of mental illness on children?
o Partner wellbeing?

• Do outcomes vary at 6- and 12-month follow-ups?

2. Process evaluation

• What are the experiences and views of families/stakeholders at each site in receiving /delivering Family Talk, including in particular, the barriers and facilitators to implementation. Some key questions here are:
o What do families, clinicians and service providers think about the content of the programme?
o How did programme delivery go? Were there any barriers in this respect?
o What could be improved?
o Was the programme delivered in the way it was intended?

• To what extent have 'think family'/family-focused practices become more embedded within mental health services in Ireland during the PRIMERA research (e.g. by seeking the views of clinicians/service providers and managers).

3. Economic appraisal
What is the cost effectiveness of Family Talk in improving child and family wellbeing compared with usual services? (e.g. Gather data on staff time and patterns of service-use amongst participants to calculate an Incremental Cost Effectiveness Ratio).

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. Health Service Executive Research Ethics Committee, 17/09/2018, no reference number provided
2. Maynooth University Social Research Ethics Committee, 20/09/2018, ref: SRESC-2018-100
3. Tusla Research Ethics Review Group, 07/11/2018, no reference number provided
4. Saint John of God Research Ethics Committee – approved 07/01/2019

Study design
Multicentre assessor-masked randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Families in which a parent has a mental illness

Interventions
Intervention: Family Talk
Family Talk (FT) is a manualised, strengths-based, 6-8 session programme (6-10 weeks) for families where a parent has mental health difficulties. Family Talk uses an individual family format and the trained clinician(s) meets with parents, children and the whole family. The first two sessions involve the clinician and parents and includes a discussion of the family's experience of mental illness and psycho-education, as required. In session three, the clinician meets with the children alone to conduct an assessment and to identify any questions which the child(ren) may have in relation to their parent's mental health difficulties. Next, a planning meeting between the clinician and parents is held, after which a whole family session is organised to support family discussion and provide information on mental disorders as needed. The intervention concludes with follow-up meetings (after one week and after 3-6 months) to check in and support the family going forward.

Control: Waitlist
The waitlist control group will receive services as usual. This will mean the parent will still receive individual treatment in Adult Mental Health Services (AMHS) for their mental health difficulties or, in a small number of cases, will be receiving medication/treatment from their GP. Waitlist families will be offered the FT intervention following the 6-month follow-up assessment period.

Randomisation procedure:
Baseline assessments will be conducted once suitable families have been identified, are considered eligible and have agreed to participate in the study. Participants will then be block-randomised by site location (using family as the unit of randomisation) and blindly and randomly allocated on a 2:1 basis to the intervention and control arms of the trial. Randomisation will be undertaken by an external research consultant/statistician using computerised random allocation procedures; an independent collaborator will conceal the allocation sequence until the grouping has been assigned. The use of block randomisation means that FT can be delivered in a staggered manner, with some participants beginning the intervention while further recruitment continues.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 06/08/2020:
1. Child psychosocial functioning - measured by Strengths and Difficulties questionnaire. Outcome will be reported by parents and children and measured at baseline (pre-intervention), and 6 and 12 months later
2. Family functioning - measured by SCORE 15 (Systematic Clinical Outcome and Routine Evaluation). Outcome will be reported by parents and children and measured at baseline (pre-intervention), and 6 and 12 months later

Previous primary outcome measure:
1. Child psychosocial functioning - measured by Strengths and Difficulties questionnaire, SCARED 5 (Screen for Child Anxiety Related Disorders) and RCADS child depression scale (Revised Children's Anxiety and Depression Scale). Outcomes will be reported by parents and children and measured at baseline (pre-intervention), and 6 and 12 months later
2. Family functioning - measured by SCORE 15 (Systematic Clinical Outcome and Routine Evaluation). Outcome will be reported by parents and children and measured at baseline (pre-intervention), and 6 and 12 months later

Secondary outcome measures
Current secondary outcome measures as of 06/08/2020:
1. Understanding and experience of parental mental health difficulties measured by the Understanding of Parental Mental Health questionnaire. Outcome will be reported by parents and children at baseline (pre-intervention), and 6 and 12 months later
2. Child internalising symptoms: anxiety using SCARED 5 (Screen for Child Anxiety Related Disorders) and depression using RCADS child depression subscale (Revised Children's Anxiety and Depression Scale). Outcome will be reported by parents and children at baseline (pre-intervention), and 6 and 12 months later
3. Child coping/resilience measured by the Children and Youth Resilience Measure reported by children at baseline (pre-intervention), and 6 and 12 months later
4. Parental mental health measured by the BASIS 24 (Behaviour and Symptom Identification Scale) reported by parents at baseline (pre-intervention), and 6 and 12 months later
5. Parental coping/resilience measured by the Coping Self Efficacy questionnaire reported by parents at baseline (pre-intervention) and 6 and 12 months later
6. Partner wellbeing assessed using the Warwick-Edinburgh Mental Wellbeing Scale reported by

the partner themselves at baseline (pre-intervention) and 6 and 12 months later
7. Service utilisation assessed using the Services Utilisation Questionnaire reported by parents at baseline (pre-intervention) and 6 and 12 months later

Previous secondary outcome measures:
1. Understanding and experience of parental mental health difficulties measured by the Understanding of Parental Mental Health questionnaire. Outcome will be reported by parents and children at baseline (pre-intervention), and 6 and 12 months later.
2. Child coping/resilience measured by the Children and Youth Resilience Measure reported by children at baseline (pre-intervention), and 6 and 12 months later.
3. Parental mental health measured by the BASIS 24 (Behaviour and Symptom Identification Scale) reported by parents at baseline (pre-intervention), and 6 and 12 months later.
4. Parental coping/resilience measured by the Coping Self Efficacy questionnaire reported by parents at baseline (pre-intervention) and 6 and 12 months later
5. Partner wellbeing assessed using the Warwick-Edinburgh Mental Wellbeing Scale reported by the partner themselves at baseline (pre-intervention) and 6 and 12 months later
6. Service utilisation assessed using the Services Utilisation Questionnaire reported by parents at baseline (pre-intervention) and 6 and 12 months later

Overall study start date
01/06/2017

Completion date
31/12/2021

Eligibility

Key inclusion criteria
Family participants:
1. Parent(s) aged over 18 – and with children aged 5-18 years - attending Adult Mental Health Services and who are under the care of a psychiatrist/multidisciplinary team (MDT) due to a formal (or working) diagnosis of mental difficulty
Or
2. Parent(s) with a mental difficulty episode in the last 18 months who had been under the care of a psychiatrist or MDT
Or
3. Parent(s) currently attending a GP for mental health issues (clinical responsibility will be provided by the GP and Family Talk clinician/service provider)
In all of the above cases, the parents' symptoms should be relatively well maintained (i.e. not in crisis).

Staff participants:
Clinicians, service providers, and managers will be identified in collaboration with the lead contact person in each site. There are no inclusion or exclusion criteria with regard to staff participation.

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
144

Total final enrolment
102

Key exclusion criteria
Family participants:
1. Parents/children with active psychosis
2. Parents with active substance misuse such that they cannot engage with the intervention
3. Parents or children who are in hospital
4. Families with acrimonious dispute over child custody
5. Urgent need for child protection services

Depending on the level of resources available to staff, some sites may be able to support patients who have some level of active psychosis or substance misuse but it is key that families are able to engage with the intervention and agree to take part in the research. Where hospitalization or relapse occur during the delivery of Family Talk, the clinician must make a judgment whether the intervention can be merely postponed or would be better delivered at a later stage when the patient is more stable. Clinicians can discuss with families.

There are no exclusion criteria for other participants (clinicians, service providers, managers).

Date of first enrolment
03/03/2019

Date of final enrolment
30/11/2020

Locations

Countries of recruitment
Ireland

Study participating centre
Cluain Mhuire Family Services
Cluain Mhuire Community Mental Health Services
Newtownpark Avenue
Blackrock
Co. Dublin
Dublin
Ireland
A94 H9T1

Study participating centre
Letterkenny Mental health Services
The Willows
Carnamuggagh
Letterkenny
Co. Donegal
Letterkenny
Ireland
F92 X2NT

Study participating centre
Crosslinx West Galway/Roscommon
Woodview/Unit 9A
Merlin Park University Hospital Campus
Galway
Galway
Ireland
H91 HP0N

Study participating centre
Mayo Mental Health Services
CAMHS
St. Mary's
Castlebar
Co. Mayo
Castlebar
Ireland
F23 HP58

Study participating centre
Louth Adult Mental Health Services
Singleton House
Saint Lawrence St
Drogheda
Co. Louth
Drogheda
Ireland
A92 F5DD

Study participating centre
Cherry Orchard AMHS/CAMHS/Tusla
Linn Dara Child & Adolescent Mental Health Services
Cherry Orchard Campus

Dublin
Ireland
D10 XR23

Study participating centre
Carlow AMHS with Recovery College South East
St Dympna's Hospital
Athy Road
Carlow
Carlow
Ireland
R93 DE62

Study participating centre
Tusla Louth Meath social work and Prevention Partnership and Family Support
Tusla
Enterprise Centre
Trim Rd.
Navan
Co. Meath
Navan
Ireland
C15 DF2X

Study participating centre
Tusla Mayo social work and Prevention Partnership and Family Support
Tusla
2nd Floor
Mill Lane
Bridge Street
Castlebar
Mayo
Castlebar
Ireland
F23 WP58

Study participating centre
CAMHS/YAMHS midlands
Unit 23B Lough Sheever Business Park
Robinstown
Mullingar
Ireland
N91 H529

Study participating centre
Primary Care Psychology
Harbour Primary Care Centre,
Harbour Street
Mullingar
Ireland
N91 V6R9

Study participating centre
Clare Adult Mental Health Services
East Clare Mental Health Services
HSE West
Ennis Day Hospital
Gort Road
Ennis
Ireland
V95 XP38

Sponsor information

Organisation
Maynooth University

Sponsor details
Department of Psychology
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psychology.dept@mu.ie

Sponsor type
University/education

Website
https://www.maynoothuniversity.ie/

ROR
https://ror.org/048nfjm95

Funder(s)

Funder type
Government

Funder Name
Health Service Executive Mental Health Division, Republic of Ireland

Results and Publications

Publication and dissemination plan
The research will be written up and presented in a series of summary reports/papers, presented at national and international conferences and will be published in scientific journals. A protocol of the trial will be submitted to Trials in 2019 and reports/articles from the study will be submitted for publication in 2020-2022. A copy of the research findings will be made available to participants upon request. Reports and other outputs will be uploaded to our study website https://cmhcr.eu/primera-programme/, We will also report findings from the process evaluation, costs, and a cost-effectiveness analysis of the Family Talk service compared with usual services.

Intention to publish date
28/02/2024

Individual participant data (IPD) sharing plan
Current Individual participant data (IPD) sharing statement as of 22/12/2021:
The datasets generated during and/or analysed during the current study will be stored in publically available repositorities, i.e. the Irish Qualitative Data Archive (IQDA; https://www.maynoothuniversity.ie/iqda) and the Irish Social Sciences Data Archive(ISSDA;https://www.ucd.ie/issda/). Where participants provided consent, anonymised versions of both their qualitative and quantitative data will be shared. The data will be available in December 2023, with no specified end date to its availability. Future researchers will require ethical approval from a third level institution in order to access and use the data.

Previous Individual participant data (IPD) sharing statement:
Where participants in the study provide consent, following the completion of the study (2021), we will place an anonymised version of their quantitative and qualitative data in the Irish Qualitative Data Archive (IQDA; https://www.maynoothuniversity.ie/iqda) and the Irish Social Science Data Archive (ISSDA;https://www.ucd.ie/issda/). These archives have been created to store anonymous data produced as part of social research projects conducted in Ireland, so that other researchers may be able to access and use these data in future studies. If any future research studies want to use this anonymised data, then the study will require approval from a research ethics committee. Once the data is deposited, there is no specified end date to its availability.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Interim results article	The Family Talk Programme in Ireland: A Qualitative Analysis of the Experiences of Families With Parental Mental Illness	15/11/2021	22/12/2021	Yes	No
Other publications	A Family-Focused Intervention for Parental Mental Illness: A Practitioner Perspective	23/11/2021	22/12/2021	Yes	No
Other publications	Covid-19 and Families With Parental Mental Illness: Crisis and Opportunity	27/07/2021	22/12/2021	Yes	No
Protocol article		01/04/2021	22/12/2021	Yes	No
Other unpublished results			16/02/2024	No	No
Results article		28/05/2024	12/04/2024	Yes	No