

An evaluation of a wraparound intervention for families whose children are at risk of abuse and /or neglect

Submission date 31/05/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 03/06/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/02/2021	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Freedom from abuse, neglect and violence is a basic right for all children. However, child maltreatment remains all too common and in 2013, over 40,000 referrals of child abuse or neglect were reported to the Health Service Executive in Ireland. Child maltreatment has negative social, psychological and economic impacts on those affected; these include poor physical and mental health in children and families, low levels of educational attainment, and greater use of mental health, law enforcement, judicial and social services. Prevention of physical abuse or neglect (or further abuse/neglect), is clearly preferable to attempting to alleviate its consequences. The establishment of the Child and Family Agency (Tusla) in Ireland in January 2014 brings a renewed and dedicated focus to the early prevention of child maltreatment. A considerable body of research undertaken both in Ireland and elsewhere demonstrates that early intervention (treatment) and prevention programmes, particularly those that focus on parenting skills, can significantly benefit parent and child relationships. Nevertheless, such stand-alone interventions do not address all the needs of the most vulnerable children and families, and particularly children at risk of abuse and neglect, where common problems include: attachment and parenting issues, child emotional and behavioural difficulties, parental mental health and addiction issues, and so forth. Wraparound interventions can provide an integrated, preventive and tailored service which may be more appropriate when working with 'at risk', multi-need families. The available evidence suggests that wraparound interventions that target parenting and involve home visiting, as well as providing other necessary supports, may be particularly helpful in reducing child maltreatment. The Children At Risk Model (ChARM) combines a range of supports for families whose children (3-10 years) are at risk of abuse or neglect, and is aimed at improving parenting skills and parent-child relationships, improving child and parent wellbeing, and reducing the risk of child maltreatment. It involves a 'core' programme which includes parent-training, a life skills programme, and home visiting by a family support worker, incorporating both practical support and scaffolding in parenting skills. Other additional supports will also be provided as necessary (e.g. substance abuse clinic; housing advice, referral of child to Child and Adult Mental Health Services). In this study, we want to test how well the wraparound intervention works compared to the usual services being offered, investigate how cost effective it is and also do a process evaluation.

Who can participate?

Children aged 3-10 years identified as being at risk of abuse and/or neglect and their parents /caregivers.

What does the study involve?

Parents who agree to participate in the study are asked to fill in questionnaires and be observed interacting with their child during the data assessment at the start of the study. Following this, parents are randomly allocated into one of two groups. Those in group 1 receive the intervention straight away. Those in group 2 receive the intervention after six months. Those who have to wait receive usual services in the meantime. The intervention involves a positive life skills programme, the Incredible Years BASIC parenting programme, home visits, and any other additional wraparound supports and services that the family may require. Follow-up data assessments take place at 6, 12, and 18 months into the study where parents and children are asked to partake in interviews, questionnaires, and observations.

What are the possible benefits and risks of participating?

It is hoped that the intervention will benefit participants in: reducing the risk of child abuse potential and incidences of child maltreatment, improvement in child wellbeing and behaviour, in parental mental health (including substance abuse issues), as well as improvement in parent-child relationships and in parenting competencies. We do not foresee any risks for families in participating in the study.

Where is the study run from?

A number of social work agencies in Ireland

When is the study starting and how long is it expected to run for?

February 2014 to December 2018

Who is funding the study?

Health Research Board (Ireland)

Who is the main contact?

Dr Sinead McGilloway

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Study website

<http://enrichireland.com>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Collaborative Applied Research Grants 2012 (CARG/2012/17)

Study information

Scientific Title

A randomised controlled trial evaluation, cost-effectiveness study and process evaluation of a wraparound programme to improve psychosocial outcomes for families whose children at risk of abuse and/or neglect.

Study objectives

This research will be carried out in line with UK Medical Research Council's (MRC) five-stage process for complex interventions and will use mixed methodologies and appropriate statistical and economic analyses. The research will comprise three key elements including:

1. An impact evaluation which will assess the effectiveness of the wraparound intervention compared to usual services
2. A process evaluation
3. A cost-effectiveness study.

Key questions within each element of the study include:

1. Impact evaluation
 - 1.1. Does the wraparound model reduce child abuse potential when compared to families who receive usual care?
 - 1.2. To what extent does the wraparound model reduce incidences of child maltreatment when compared to the control group?
 - 1.3. How effective is the intervention in improving child wellbeing and behaviour?
 - 1.4. Does the model improve parent-child relationships, and parental competencies?
 - 1.5. How effective is the model in improving parental/caregiver mental health and family functioning when compared to a control group?
 - 1.6. To what extent does the model affect addiction problems?
 - 1.7. To what extent are improvements (if any) maintained over time?
2. Process evaluation
 - 2.1. What are the experiences of parents, children and service providers in receiving/ delivering the wraparound intervention?
 - 2.2 What are the key facilitators and barriers identified by stakeholders in implementing the

programme?

2.3. Do some elements of the wraparound programmes work better than others (either singly or in combination)?

2.4. What are the key facilitators and barriers involved in disseminating the roll out of the model, if found to be effective?

3. Economic appraisal/Cost Analyses (including health and social service utilisation)

3.1. What are the costs associated with delivering the intervention compared with usual services?

3.2. What are the patterns of health and social service use amongst participants (child, parent and carer) in both the intervention and control groups?

3.3. How cost-effective is the intervention compared with usual services when costs are linked to outcomes of reducing child abuse potential and child wellbeing?

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Social Research Ethics Sub-committee in Maynooth University, Ireland, 06/02/2015, ref: SRESC-201x-xxxxx)

Study design

Randomised controlled trial, process evaluation and analysis

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Child abuse and neglect

Interventions

The Children At Risk Model (ChARM) is a wraparound programme that combines a range of supports to address the health and social care needs of families where children (3-10 years) are at risk of abuse and/or neglect. The supports involve a 'core' programme which comprises a life skills programme, parent-training, and home visiting by a mental health professional. Other additional services will also be provided as necessary (e.g. substance abuse clinic; referral of child to Child and Adult Mental Health Services, and so forth).

Intervention Type

Behavioural

Primary outcome measure

1. Improvement in child wellbeing and behaviour - measured by the Strengths and Difficulties questionnaire (SDQ), completed by parent (and child, where appropriate) at baseline, 6-, 12- and 18-month follow up
2. Reduction in incidences of child abuse and neglect - Conflict Tactics Scale Parent Child, completed by parent at baseline, 6-, 12- and 18-month follow up
3. Reduction in child abuse potential - measured by the Brief Child Abuse Potential Inventory, completed by parent/caregiver at baseline, 6-, 12- and 18-month follow up

Secondary outcome measures

1. Improvement in parental mental health - measured by the Depression, Anxiety and Stress scale (DASS) and the Parenting Stress Index, both completed by parent at baseline, 6-, 12- and 18-month follow up
2. Improvement in parental alcohol and drug use - measured by the CAGE and Drug Abuse Screening Test (DAST-10) questionnaires, both completed by parent at baseline, 6-, 12- and 18-month follow up
3. Improvement in the relationship between parent and children - measured by the Parenting Stress Index (PSI) and the HOME observation. The PSI is completed by parents. The HOME is conducted by researchers observing parent-child interaction. Both measures are administered at baseline, 6-, 12- and 18-month follow up
4. Improvement in parenting competencies - measured by the HOME observation, completed by researchers observing parent-child interaction at 6-, 12-, and 18-month follow up

Overall study start date

10/02/2014

Completion date

10/12/2018

Eligibility

Key inclusion criteria

1. Participants are parents/caregivers (both genders) of children aged 3-10 years (both genders) where:
 - 1.1. The child has been identified by a child welfare professional within a collaborating agency (e.g. social work team) as being at risk of abuse or neglect; or
 - 1.2. Where it is known by the social work team that a level of child maltreatment has occurred, but the child is still living within the home (i.e. not placed in state care)

The child's level of risk will be judged according to Levels 2 to 4 in line with the guidance contained in the document entitled 'Thresholds for referral to Tusla Social Work services'. This document is based on the Hardiker model.

2. Parents/caregivers must be judged by the social work team to be stable in terms of substance use, domestic violence or mental illness so that they have the capacity to engage for the duration of the intervention
3. In cases where families, and particularly high risk families, are on mandatory child protection plans and are allocated to the control group, they must be provided with interim support from their allocated social care leader/key worker until they receive the wraparound intervention. This support may involve usual services such as individual therapy, as well as referral to services

that are not part of the 'core' wraparound intervention

4. Parents/families must be willing and able to attend the services offered

5. Parents/families must agree to participate in the research

Participant type(s)

Patient

Age group

Mixed

Sex

Both

Target number of participants

150

Total final enrolment

41

Key exclusion criteria

1. Families who display unstable substance use or mental illness will be excluded as will those who are considered to be unstable due to domestic violence issues

2. Families who have had prior exposure to an evidence-based parenting programme will be excluded

Date of first enrolment

15/05/2015

Date of final enrolment

01/08/2016

Locations

Countries of recruitment

Ireland

Study participating centre

Child Welfare Team

Dublin South West

Dublin

Ireland

-

Study participating centre

Social Work Department Cherry Orchard

Dublin South Central

Dublin

Ireland

-

Study participating centre
Naas Social Work Department
Kildare
West Wicklow
Naas
Ireland

-

Sponsor information

Organisation
Maynooth University

Sponsor details
Maynooth
Co. Kildare
Ireland

-

Sponsor type
University/education

Website
<https://www.maynoothuniversity.ie/>

ROR
<https://ror.org/048nfjm95>

Funder(s)

Funder type
Government

Funder Name
Health Research Board

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

We intend to publish the protocol in Trials, which will be submitted in 2015. We also intend to publish reports and journal articles on our short-term and longer-term results, from the latter half of 2016 up until and beyond the end of funding in December 2018. These publications will include results from the RCT, the costs studies, and the process evaluation. Our reports (and journal articles) will be disseminated to the Child and Family Agency in Ireland, as well as to other relevant agencies nationally and internationally. We will also hold conferences, and other media events, to launch our findings.

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	05/04/2018	03/02/2020	Yes	No
Basic results		05/02/2021	08/02/2021	No	No