STUDY PROTOCOL

A community-based parent-support programme to prevent child maltreatment: Protocol for a randomised controlled trial [version 1; peer review: 1 approved, 1 approved with reservations]

Mairead Furlong[1], Sinead McGilloway [1], Ann Stokes [1], Grainne Hickey[1], Yvonne Leckey[1], Tracey Bywater[2], Ciaran O'Neill [3], Chris Cardwell[3], Brian Taylor [4], Michael Donnelly[3], ENRICH Research Team

[1]Centre for Mental Health and Community Research, Department of Psychology, John Hume Building, National University of Ireland Maynooth, Maynooth, Co. Kildare, Ireland
[2]University of York, York, UK
[3]Queens University Belfast, Belfast, UK
[4]Ulster University, Derry, UK

v1 **First published:** 05 Apr 2018, **1**:13 (https://doi.org/10.12688/hrbopenres.12812.1)
Latest published: 21 Sep 2018, **1**:13 (https://doi.org/10.12688/hrbopenres.12812.2)

Abstract

The prevention of child abuse and neglect is a global public health priority due to its serious, long-lasting effects on personal, social, and economic outcomes. The Children At Risk Model (ChARM) is a wraparound-inspired intervention that coordinates evidence-based parenting- and home-visiting programmes, along with community-based supports, in order to address the multiple and complex needs of families at risk of child abuse or neglect. The study comprises a multi-centre, randomised controlled trial, with embedded economic and process evaluations. The study is being conducted in two child-welfare agencies within socially disadvantaged settings in Ireland. Families with children aged 3-11 years who are at risk of maltreatment (n = 50) will be randomised to either the 20-week ChARM programme (n = 25) or to standard care (n = 25) using a 1:1 allocation ratio. The primary outcomes are incidences of child maltreatment and child behaviour and wellbeing. Secondary outcomes include quality of parent-child relationships, parental stress, mental health, substance use, recorded incidences of substantiated abuse, and out-of-home placements. Assessments will take place at pre-intervention, and at 6- and 12-month follow-up periods. The study is the first evaluation of a wraparound-inspired intervention, incorporating evidence-based programmes, designed to prevent child abuse and neglect within intact families. The findings offer a unique contribution to the development, implementation and evaluation of effective interventions in the prevention of child abuse and neglect.
The trial is registered with the International Standard Randomised Controlled Trial Number Register (DOI 10.1186/ISRCTN13644600, Date of registration: 3rd June 2015).

Keywords

Child maltreatment, child abuse and neglect, family, parenting, wraparound

Open Peer Review

Reviewer Status ? ✓

	Invited Reviewers	
	1	**2**
REVISED **version 2** published 21 Sep 2018		✓ report
version 1 published 05 Apr 2018	? report	✓ report

1 **Marie-Josée Letarte**, University of Sherbrooke, Sherbrooke, Canada
Isabelle-Ann Leclair Mallette, University of Sherbrooke, Sherbrooke, Canada
Caroline Temcheff, McGill University, Montreal, Canada

2 **Nuala Connolly**, Barnardos Ireland, Dublin, Ireland
EU-CoE Youth Partnership Pool of European Youth Researchers, Dublin, Ireland

Any reports and responses or comments on the article can be found at the end of the article.

Corresponding author: Ann Stokes (ann.stokes@mu.ie)

Author roles: Furlong M: Conceptualization, Funding Acquisition, Investigation, Methodology, Project Administration, Resources, Supervision, Writing – Original Draft Preparation, Writing – Review & Editing; **McGilloway S**: Conceptualization, Funding Acquisition, Investigation, Methodology, Project Administration, Resources, Supervision, Writing – Original Draft Preparation, Writing – Review & Editing; **Stokes A**: Conceptualization, Investigation, Methodology, Project Administration, Resources, Supervision, Writing – Original Draft Preparation, Writing – Review & Editing; **Hickey G**: Conceptualization, Funding Acquisition, Investigation, Methodology, Project Administration, Resources, Supervision, Writing – Original Draft Preparation, Writing – Review & Editing; **Leckey Y**: Conceptualization, Funding Acquisition, Investigation, Methodology, Project Administration, Resources, Supervision, Writing – Original Draft Preparation, Writing – Review & Editing; **Bywater T**: Conceptualization, Funding Acquisition, Methodology, Supervision; **O'Neill C**: Conceptualization, Funding Acquisition, Methodology, Supervision; **Cardwell C**: Conceptualization, Funding Acquisition, Methodology, Supervision; **Taylor B**: Conceptualization, Funding Acquisition, Methodology, Supervision; **Donnelly M**: Conceptualization, Funding Acquisition, Methodology, Supervision;

Competing interests: No competing interests were disclosed.

Grant information: The study is funded by the Health Research Board in Ireland under its new 'Collaborative Applied Research Grants in Population Health and Health Service Research 2012' awarded to Professor Sinead McGilloway as the Principal Investigator (CARG/2012/17).
The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

How to cite this article: Furlong M, McGilloway S, Stokes A *et al.* **A community-based parent-support programme to prevent child maltreatment: Protocol for a randomised controlled trial [version 1; peer review: 1 approved, 1 approved with reservations]** HRB Open Research 2018, **1**:13 (https://doi.org/10.12688/hrbopenres.12812.1)

First published: 05 Apr 2018, **1**:13 (https://doi.org/10.12688/hrbopenres.12812.1)

Introduction

It is widely acknowledged that child abuse and neglect (also called child maltreatment [CM]) has serious and far-reaching effects on child health outcomes (including mental health), educational and employment prospects, criminality, life expectancy, intergenerational transmission of maltreatment, and expenditure on health, judicial and social welfare services (Sethi *et al.*, 2013). Thus, the prevention of child abuse and neglect is an important human rights and global public health priority. Recent meta-analyses of self-reported incidences of CM have indicated that emotional abuse is the most common type of CM (36.3%), followed by physical abuse (22.6%), neglect (16.3% physical and 18.4% emotional) and sexual abuse (18.0% [girls] and 7.6% [boys]) (Stoltenborgh *et al.*, 2012; Stoltenborgh *et al.*, 2013a).

Importantly, despite a ratio of investment of 90 to 1 in child protection versus prevention services in the US and Europe (Gilbert *et al.*, 2009), attempts to treat the consequences of CM are less effective, more costly, and ethically inferior to investing in programmes to prevent CM and family breakdown (Leventhal, 2005). Furthermore, prevalence rates of CM are even higher in low and middle-income countries than in high-income countries, thereby making CM a truly global phenomenon (Sethi *et al.*, 2013).

Due to unreliable detection and surveillance systems in most countries, official statistics of substantiated abuse are widely believed to seriously underestimate the occurrence of CM, with reports suggesting that 90 per cent of child abuse and neglect goes unnoticed (Munro, 2011; Stoltenborgh *et al.*, 2013a; Stoltenborgh *et al.*, 2013b). Self-reports are considered more accurate, but are still likely to underestimate true prevalence rates (Gilbert *et al.*, 2009). Incidences of substantiated abuse vary between countries, but studies indicate that children of all ages (but especially those who are younger) are at risk of abuse and neglect (Akmatov, 2011). For instance, in the US in 2013, children under three years had a CM rate of 14.3 per 1000, compared with 10.3 per 1000 for children ages four to seven, 7.6 for children ages eight to 11, 6.7 for children ages 12 to 15, and 4.5 per 1000 for children ages 16 to 17 (U.S. Department of Health and Human Services, Administration on Children, Youth and Families, 2013). In Ireland, over 40, 000 referrals of child welfare and abuse cases were made to social work annually during 2012-2014, which represents a rate of 35 per 1000 children; this was almost double the number referred in 2007 (Tusla Quarterly National Performance Activity Report, 2015). These figures (although unlikely to be all confirmed cases) are a source of considerable concern and may be related, at least in part, to the impact of the economic recession in Ireland, including unemployment, financial difficulties and homelessness, all of which have been a feature of life in Ireland in recent years (Williams *et al.*, 2016).

The most significant risk factors for child abuse and neglect may be best understood within an ecological risk framework (MacKenzie *et al.*, 2011); these relate to poor parenting behaviours and parental stress, parental mental illness, parental experience of being maltreated as a child, parental substance abuse, family conflict, child misbehaviour and disability, and social disadvantage (e.g. young, single parents with low education and income levels) (Stith *et al.*, 2009). Research on protective factors to prevent CM is less developed than studies which have focused on identifying and understanding risk factors (Sethi *et al.*, 2013). Nevertheless, the available evidence indicates that several protective factors may prevent CM and promote child well-being including: knowledge of parenting and child development, nurturing parenting skills, parental resilience, a strong social network, community supports (e.g. housing, transport services), and building child behavioural, social and emotional competencies (Afifi & MacMillan, 2011). Therefore, there is increasing international recognition of the need to coordinate services and supports in order to address the complex needs of vulnerable families at risk of CM, who are often involved in multiple, 'siloed' systems of care (Burns *et al.*, 2000; Sethi *et al.*, 2013).

The wraparound (WA) model of care, developed in the US in the 1980s, is a family-focussed and strengths-based intervention approach which involves coordinating available formal and informal supports to meet the multiple needs of families. WA has demonstrated effectiveness in improving placement stability and psychosocial functioning among youths with serious mental health and behavioural disorders (Suter & Bruns, 2008; Suter & Bruns, 2009). WA individualizes a combination of services selected to be "wrapped around" families in contrast to standalone, standardized intervention approaches (Winters & Metz, 2009). Due to its individualized nature, the effectiveness of WA programmes is influenced by the 'fit' between family needs and the quality of services available within the local community system (Bruns *et al.*, 2008). WA is not based on any single theory of change; instead, it is consistent with several influential psychosocial theories of child development and behaviour, including the social-ecological approach, social learning theory, and systems theory (Walter & Petr, 2011).

Preliminary evidence from a retrospective cohort study indicated that both intact and foster care families who received the Brevard C.A.R.E.S (Coordination, Advocacy, Resources, Education and Support) wraparound intervention had reduced incidences of verified maltreatment compared to usual services (Schneider-Muñoz *et al.*, 2015). By contrast, a randomised controlled trial of WA versus standard services for maltreated children within both intact families and in out-of-home placements reported no differences in child and carer wellbeing (Browne *et al.*, 2014). It has been noted that, while WA improves placement stability and is perceived as being a highly transportable and acceptable approach to working with families within current care systems, it tends to have less support than evidence-based programmes (EBPs) in improving clinical outcomes (Bernstein *et al.*, 2015). Conversely, EBPs may lack feasibility and generalizability (Bruns *et al.*, 2014). There is increasing recognition, therefore, that a WA approach, or indeed an approach inspired by wraparound principles, that incorporates evidence-based CM prevention programmes, while also coordinating other tailored community-based supports, may offer a useful model of care in enhancing both clinical outcomes and programme feasibility (Bernstein *et al.*, 2015).

Evidence from meta-reviews has indicated that, of available EBPs, home visiting and parent training appear most successful in improving risk factors associated with CM, and to a far lesser extent, in reducing incidences of CM (MacMillan & Wathen, 2014; Mikton & Butchart, 2009). Nevertheless, stand-alone parenting or home visiting programmes are not sufficient to prevent CM in more high risk, disadvantaged families. For example, many 'real world' implementation studies have shown that less than 30–50 per cent of vulnerable families will attend a centre-based parenting programme me and that more than half of these will drop out during delivery (Axford *et al.*, 2012; Furlong & McGilloway, 2015). Such failure to engage parents is unsurprising as stand-alone parent programmes are typically not equipped to address the multiple and complex needs of families at risk of CM, which as outlined earlier, include addiction and mental health problems, housing and financial concerns, and so forth.

Home-visiting interventions, on the other hand, appear to have more capacity than parenting programmes to engage with vulnerable families due to meeting within the family home and addressing other material and support needs besides coaching of parenting skills (Macdonald *et al.*, 2010). Nevertheless, reviews report mixed results, particularly if home visitors have heavy caseloads, do not adopt a collaborative approach, and fail to coordinate the provision of necessary supports (e.g. mental health and addiction services) (Gomby, 2005). Additionally, a meta-review indicated that there is little evidence that stand-alone home visiting is effective in reducing incidences of CM (it is more successful in addressing risk factors for CM) (Mikton & Butchart, 2009). Moreover, it should be noted that, to date, most evaluations of preventive home-visiting programmes target families with very young children (0–3 years) and, therefore, there is a lack of evidence for their effectiveness in reducing CM among families with children older than three years (Selph *et al.*, 2013). The scarcity of evidence for home-visiting interventions targeted at older children is unexpected in light of: (1) reports that indicate that CM may remain undetected for years and only manifest at a later age (Sethi *et al.*, 2013); (2) substantiated and self-reports that indicate a high occurrence of CM in children aged between three and 11 years (Stoltenborgh *et al.*, 2013a; Stoltenborgh *et al.*, 2013b); and (3) the availability of home-visiting supports in many countries for families where the child is older than three years (Children and Young People Now Jobs, 2017; Tusla, 2017).

Arguably, therefore, home visiting and parenting programmes are not sufficient, when delivered as stand-alone interventions, to meet the complex needs of vulnerable families. Preliminary evidence from meta-analyses of parenting supports to prevent child abuse has indicated that interventions which combine home-visiting elements and group-based parent training may be more effective in improving risk factors associated with CM than either component delivered on its own (Chen & Chan, 2016; Lundahl *et al.*, 2006). Therefore, despite their limitations as stand-alone interventions in engaging high-risk families, it may be advisable to incorporate evidence-based home visiting and parenting programmes within a WA intervention. A WA-inspired approach that coordinates home visiting and parent training with other tailored formal and informal supports may also address family needs not otherwise met, such as parental and child mental health, substance misuse, domestic abuse, resilience and social skills competencies, and housing and financial difficulties. If found to be effective in preventing risk factors and incidences of CM, an intervention inspired by WA principles may achieve considerable cost savings in terms of reduced utilization of child welfare services, foster and residential home placements, criminal justice, mental health, prison service and other long-run costs that are typically incurred when children are exposed to abuse and neglect (Corso & Lutzker, 2006).

The development and implementation of a WA model of care for child and family services in Ireland is currently undergoing a period of transition and is at a different stage of advancement to WA as established in the National Wraparound Initiative (NWI) in the US (NWI, 2017). In recent years, a number of policy initiatives in Ireland have emphasized the importance of interagency collaboration and service coordination in order to improve outcomes for children and families (Better Outcomes Brighter Futures, 2014; Tusla, 2015). Stand-alone interventions, such as group-based parent training, have struggled to engage more vulnerable families (McGilloway *et al.*, 2012). Therefore, child welfare organizations have been inspired by a 'wraparound' model of care that would coordinate a number of tailored supports to meet the multiple needs of families. Meitheal is a recent 'wraparound-inspired' national policy initiative that has involved considerable restructuring of services for children in Ireland since 2014; Meitheal is an Irish word that equates to the concept of 'team around the child' (Tusla, 2015). Meitheal is a nine-step model designed to identify child and family needs and strengths and brings together a team around the family to deliver support that is outcomes-focussed, planned, documented and reviewed over time. The support is planned in a highly participatory manner and directed by the family (Tusla, 2015). As such, Meitheal is similar to the NWI model of care in implementing the ten core wraparound principles. The implementation of Meitheal is also influenced by the Common Assessment Framework in England and Wales, and by the My World Triangle and National Practice Model as part of Getting it Right for Every Child in Scotland (Tusla, 2015).

While significant progress was made in the implementation of Meitheal within Ireland during 2016 (Cassidy *et al.*, 2016), it has not yet been sufficiently embedded to have allowed time to restructure the current intervention within its wraparound framework. Therefore, the wraparound-inspired model to be evaluated in this study (and described below) was developed at an earlier stage (2012 to 2014) than Meitheal and does not contain all WA elements as indicated in the NWI. While it is similar to the NWI wraparound model in terms of utilizing a family-focussed, multi-disciplinary, tailored approach to meet the multiple needs of families, it is different in two important ways. Firstly, there is less flexibility and choice in the current model, as it comprises core components of home visits, parent training and a positive life skills programme (as well as any other supports desired by families). Therefore, the model is targeted towards

those families whose needs are best met by such programmes and who agree to engage with them. The US (and Meitheal) model, on the other hand, does not require any mandatory component and allows the family to select any service provider on their team. Secondly, the current model does not involve formal team meetings in which the family and selected service providers are present; rather the family collaborates with a caseworker to produce a coordinated plan of care that is tailored to meet family needs. The plan will include the core components as well as any other requested supports, although access to the latter may depend on availability. Therefore, the current intervention involves an intensive package of supports for families that has been inspired by a wraparound philosophy of care but is not identical to it.

Given the ongoing national implementation of Meitheal, we believe that the current intervention, if shown to be effective, can operate within its framework. Moreover, the current evaluation can inform whether a package of comprehensive community-based supports can prevent child abuse and neglect in high-risk families. For instance, one of the key concerns in establishing Meitheal is that it has developed a WA model of care, but there is a lack of evidence with regard to the types of supports that are most suitable in addressing particular family needs, and the resources and processes required to implement, embed and sustain such supports (Cassidy *et al.*, 2016).

This study involves the evaluation of a 'wraparound inspired' intervention that provides comprehensive parenting and family supports – ChARM (Children At Risk Model) – and which aims to prevent CM and improve child wellbeing within high risk families whose children are aged 3–11 years. The ChARM programme me incorporates evidence-based CM prevention programme s (i.e. home visiting and the Incredible Years BASIC group-based parenting programme me), and a positive life-skills programme, while also coordinating other community-based supports, which are provided as necessary to address specific family needs. The ChARM programme me is the first evaluation of a wraparound-inspired approach, incorporating evidence-based programme me, in the prevention of child maltreatment within intact families.

The objectives of the study are to evaluate the effectiveness, cost effectiveness and process mechanisms of the ChARM programme for vulnerable families whose children (age 3–11 years) are at risk of maltreatment, as compared to standard services. The primary hypotheses underpinning this randomised controlled trial (RCT) are: (1) the ChARM programme me will reduce parent-reported incidences of child maltreatment; and (2) will improve child wellbeing and behaviour. Secondary hypotheses are that the ChARM programme me will improve the quality of the parent-child relationship and parenting competencies, reduce parental stress and mental ill health as well as parental alcohol and drug use, and lead to a decrease in recorded incidences of substantiated abuse and out-of-home placements. The embedded process evaluation will investigate programme acceptability and engagement, enablers and barriers to implementation, and mechanisms of impact, while the costs analyses will explore whether the intervention warrants investment compared to standard services. The protocol has followed the SPIRIT guidelines for reporting protocols of clinical trials (Chan *et al.*, 2013).

Methods

Participants

The ChARM programme will be delivered within a social work department and a family resource centre in socio-economically deprived disadvantaged areas of Dublin and Co. Kildare, Ireland. These areas are designated as disadvantaged according to information on demographic profile, academic performance, social class composition, and labour market situation (Haase *et al.*, 2014).

Inclusion criteria

Participants are parents/caregivers of children aged 3–11 years where the child has:

- Been identified by a child welfare professional (social worker, family resource worker) as being at risk of abuse/neglect; or
- Where it is known by child welfare professionals 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 3 in line with the guidance contained in the document entitled '*Thresholds for referral to Tusla Social Work services*' (Tusla, 2014). This document is based on the Hardiker model, which is widely used as a planning framework in child welfare and protection services in both the UK and the Republic of Ireland (Hardiker *et al.*, 1991; see Supplementary Figure 1).
- Parents must be judged by child welfare professionals to be stable in terms of substance use or mental illness, i.e. parents must have a capacity to engage with the intervention.
- Parents/families must be willing and able to attend the services offered.
- Parents/families must agree to participate in the research. Children between 7–11 years must give assent to providing data; children below seven years are too young to provide data.

Exclusion criteria

- Families who display unstable substance use/mental illness.
- Parents who have had previous exposure to an evidence-based parent-training programme.
- Child is living in temporary or permanent out-of-home placement.

Eligibility of programme providers
In order to promote consistency of intervention delivery across sites and personnel, staff must:

- Have considerable experience in working within the child welfare and protection system in Ireland.
- Be trained and experienced in the delivery of the key components of the ChARM programme.

Recruitment

We aim to recruit approximately 50 families over a period of 24 months (2015–2017) at the two participating centres. Referrals of potentially eligible families will be accessed through existing waitlists within each site, as well as through liaison with a range of other statutory and community-based services in the area, who may also refer potential participants to the participating sites. Voluntary self-referrals will be accepted if the participating site deems that the family meets the inclusion criteria for the study. Many of the families involved in the study will most likely have an allocated social worker. Each site will meet with eligible families to discuss the intervention and the research evaluation. Families will be given a brief information sheet inviting them to receive further information about the study, and requesting that they provide their consent to forward their contact details to the research team. Participants will then be contacted by telephone to arrange for the research interviewer to visit them at home and to inform them about the study and obtain their written informed consent. Written informed consent will be obtained before any study-specific procedures, including collection of baseline data. Families will be thanked for their time e and given a shopping voucher worth €20 at each data-collection visit. Collectively, the research team have considerable experience of working with vulnerable and difficult-to-engage populations and their expertise, in conjunction with the advice and support of the collaborators, will be important in managing the recruitment process.

Procedure

Study design. The ChARM study is a randomised controlled, parallel group, investigator-blinded, superiority trial (n = 50) comparing the ChARM intervention with usual services (1:1 allocation ratio), and a primary endpoint of incidences of child maltreatment and child wellbeing at six-month follow up. Data will be collected at three time points: T1 (pre-intervention), at six-month follow up (T2; one-month post intervention), and at 12-month follow up (T3). Assessment of the control group will continue to T2, after which they will receive the ChARM programme. Assessment of the intervention group alone will continue to T3. We will follow CONSORT guidelines for reporting parallel group randomised trials (Moher *et al.*, 2010). Figure 1 shows the study flow diagram.

The embedded process evaluation - in line with the guidelines of the Medical Research Council (MRC) - aims to develop a logic model of the ChARM programme, elucidating key processes in programme development and implementation, impacts and outcomes (Moore *et al.*, 2014; see Supplementary Figure 2). Specifically, it will aim to:

- Identify key programme content and perceived mechanisms of change;
- Assess enablers and barriers to programme development and implementation within the trial;
- Evaluate fidelity of delivery and participant engagement; and
- Investigate the feasibility of implementing the programme among services not involved in the trial

The embedded costs analyses will include a cost effectiveness analysis (CEA) and a cost-benefit analysis (CBA). The CEA will be based on a societal perspective (involving public sector costs, and costs incurred by participants in attending the programme) and will assess the costs of delivering the ChARM programme compared to usual services. If the intervention demonstrates effectiveness, the CBA will investigate the down-stream impact of the intervention on later costs, such as generating savings in relation to reduction in child welfare services, foster and residential placements, health and mental health service utilization, crime, education and unemployment.

Randomisation and blinding

Participants will be randomly assigned by an independent statistician (in the Northern Ireland Clinical Trials Unit [NICTU]) to either the ChARM programme or to standard services with a 1:1 allocation using a computer-generated randomisation schedule stratified by site using permuted blocks of random sizes. The NICTU will use sequentially numbered, opaque, sealed envelopes to conceal the randomisation code until the participant has been recruited into the trial, which will take place following completion of baseline assessments. Block sizes will be concealed throughout the duration of the study. Throughout the study, randomisation will be conducted by the NICTU in order to keep the data management and the statistician blind against the study condition as long as the data bank is open. The randomisation list remains with the NICTU for the duration of the study. Thus, randomisation will be conducted without any influence of the principal investigator, data collectors or practitioners delivering the intervention.

Follow-up assessments at T1 and T2 will be performed by research staff blinded to study arm. At T3, we will only collect data from intervention families so blinding will not be relevant. At T2, participants will be requested not to disclose their group allocation to the researcher. If unblinding occurs, another assessor will be brought in to re-establish blindness. Any evidence of unmasking of blinding will be taken into account at the analysis stage. Due to the nature of the intervention, neither participants nor practitioners can be blinded to allocation.

Contamination

To reduce the risk of contamination between the intervention and control participants within sites, staff who deliver the

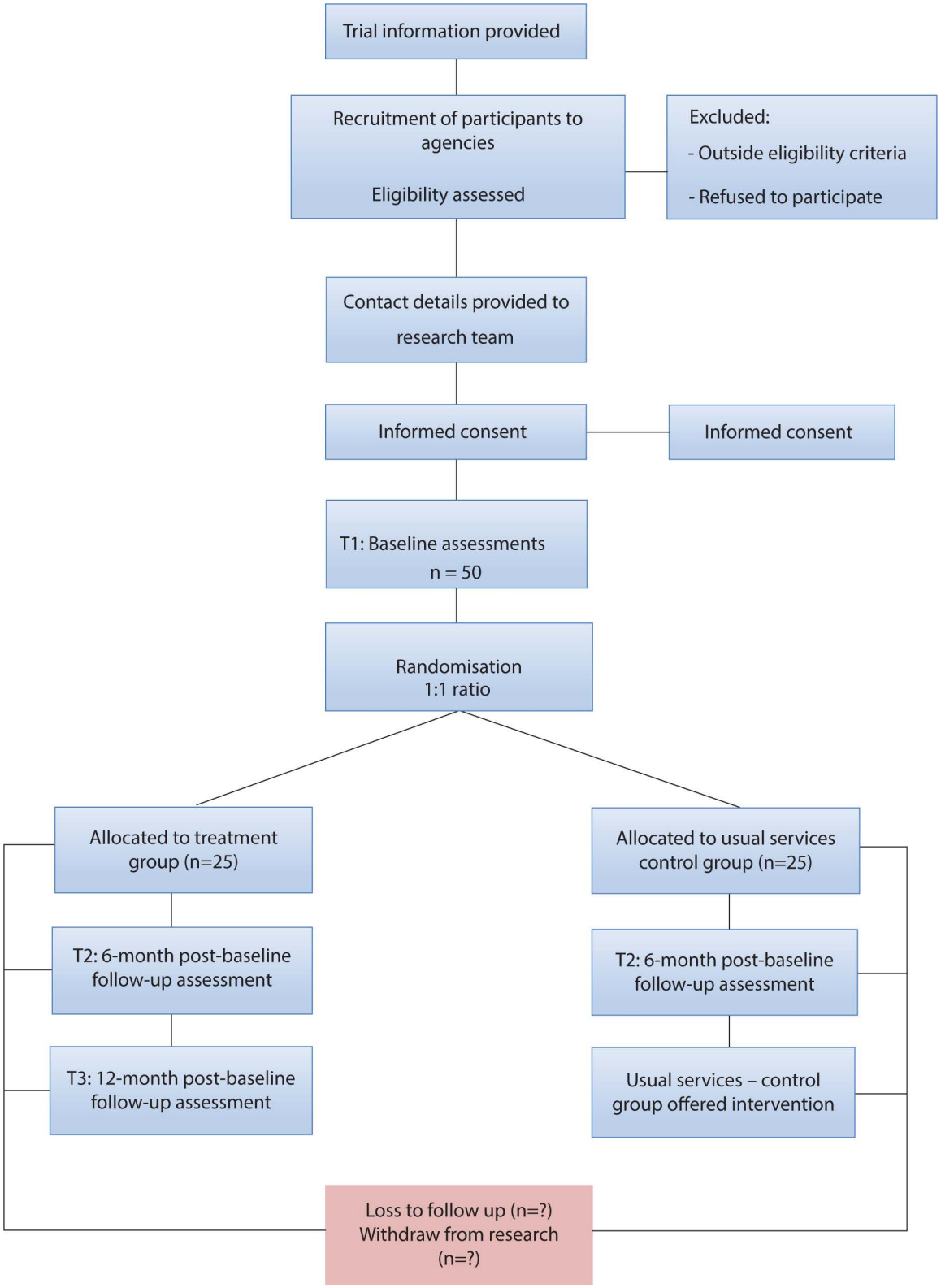

Figure 1. Study Flow Diagram. Outlines the flow of participants through the randomised controlled trial in which the impact of the ChARM intervention on incidences of child maltreatment and well-being will be compared with usual services. Data will be collected at three time points: T1 (pre-intervention), at six-month post intervention), and at 12-month follow-up (T3).

ChARM intervention will not be involved in delivering usual services to families in the control group. In addition, practitioners in both the intervention and control groups will be asked about the extent to which they shared with each other/learned of content from the ChARM programme and passed this information to families in the control group. If levels of contamination are found to be high in the control group, an extra confounder variable denoting contaminated controls will be added to the analysis and the effects of this contamination investigated.

Intervention

The ChARM programme involves the coordination of three 'core' components, as well as additional services and supports (formal and informal) that will be provided to families, as necessary (See Figure 2). The core components include: (1) the Positive Life Skills Programme (PLSP); (2) the Incredible Years Parenting Programme (IYPP); and (3) home visits. Both the PLSP and home visits may be used to initially engage families, although not all families will require home visiting as a means of engagement. Home visits will be conducted concurrently with the delivery of the PLSP and the IYPP. The programme will last 20 weeks. More details on the programme components are provided below.

Coordination of supports. Each family will be already linked to a caseworker (social worker, family support worker) informed of the wraparound approach. The caseworker will discuss the suitability of the ChARM intervention with the family. Families must consent to engage with the three core components of the programme. Family strengths and needs will be examined and families will have an opportunity to identify other services and supports, besides the three core components, that may help them to achieve their goals. If any issues emerge during the family's participation in the ChARM, additional services will be provided/recommended. The caseworker for intervention families in this study will also be a facilitator of the group programme s within the intervention.

The Positive Life Skills Programme - PLSP. The PLSP is a manualised four-week, two-hour, parent-group programme, developed as a brief intervention to encourage vulnerable, hard-to-reach parents to engage with services. Many 'at risk' families suffer from mental health, addiction and other issues and consequently, parents may not possess the skills and self-esteem to engage constructively with needed services and supports. Sessions are delivered by two group facilitators who are trained in programme delivery. The four sessions help parents to: engage

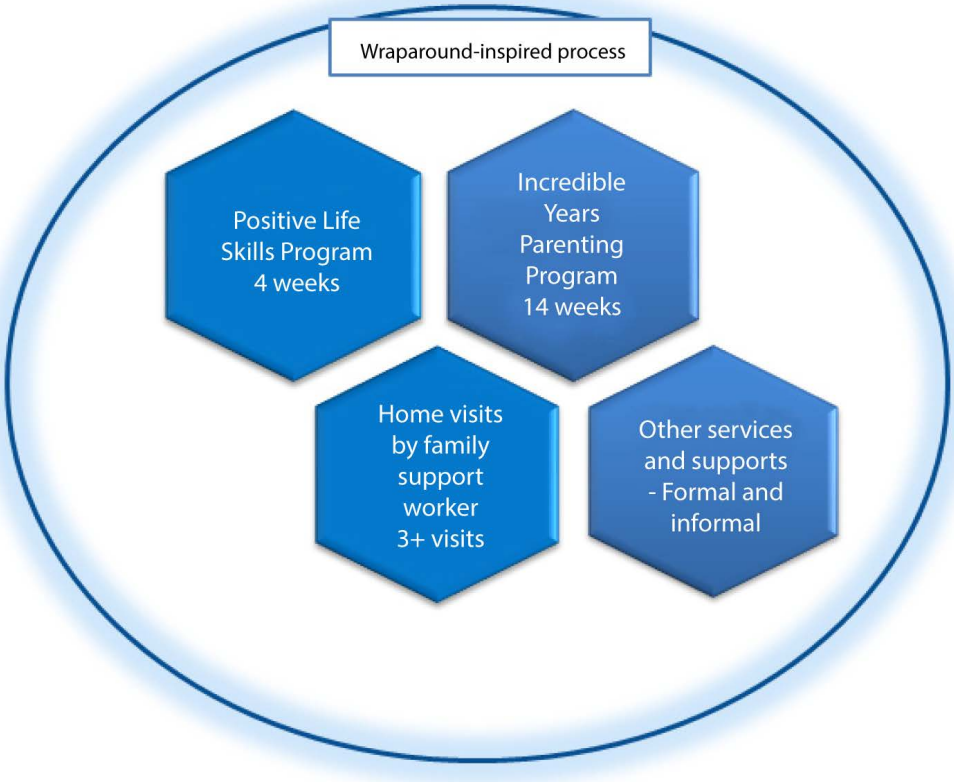

Figure 2. Core Components of ChARM Programme. ChARM involves an intensive package of supports for families inspired by a wraparound philosophy of care. It comprises core components of parent training, home visits, a positive life skills programme and additional supports as desired by families.

in a group setting with other parents and with service providers in a therapeutic space that allows sharing of personal issues; develop confidence, self-esteem and resilience in engaging with services; and build skills for daily living, including developing communication, stress and conflict management skills.

The Incredible Years Parenting Programme – IYPP. The IYPP is a well-known evidence-based parenting programme that has demonstrated effectiveness in improving child emotional and behavioural problems, and parental mental health, within high-risk populations (Furlong *et al.*, 2012). Recent studies of a clinically-informed adaption of the programme for families within the child welfare system have indicated preliminary evidence for improved parenting practices (Hurlburt *et al.*, 2013; Letarte *et al.*, 2010). The IYPP consists of 14 weekly, 2-hour, parent-group training sessions, and topics include: learning to play with the child; social and emotional coaching methods; increasing positive behaviour through praise and incentives; problem-solving; and managing non-compliance and aggression through limit setting, ignoring, and other strategies. The sequence of topics for child welfare populations is similar to standard IYPP protocols, but has a greater focus on parent-child attachment, emotional and social coaching, parental attributions and self-talk, monitoring and self-care, along with increased dosage and home visits, if necessary (Webster-Stratton & Reid, 2010). Sessions use dvds, role-play, modelling, group discussions, homework assignments and mid-week phone-call support to help parents rehearse and adopt positive parenting strategies. The IYPP addresses access issues and advocates provision of transportation, childcare and meals to parents. The programme also encourages parents to set up peer networks outside of group sessions in order to promote connections to the community and to increase the self-sufficiency of parents (Webster-Stratton & Hancock, 1998). Within the ChARM programme, the IYPP will be delivered following the PLSP.

Home visits. Home visits will be provided in parallel to the delivery of the PLSP and the IYPP, although in some cases, families will receive home visits before the PLSP in order to engage them to the ChARM programme. Family support workers will visit family homes and coach parents in positive parenting practices. Home-visiting sessions will reinforce the positive parenting principles taught in the IYPP using similar content, role-play and vignette strategies, as outlined in the IY home-visiting coaching model (Lees *et al.*, 2014). They may also link families into other services, teach them how to complete housework or to seek social support when necessary, such as in transporting children to activities. The number of home visits per family will vary, as some families will require significantly more assistance than others. We will document the number of home visits received by families.

Additional supports. Families at risk of CM present with a number of complex needs, including: substance abuse, mental health problems, health difficulties, educational deficits, unemployment, child disabilities, and so forth. The components outlined above may not be able to deal effectively with these issues. Consequently, caseworkers will collaborate with families in order to help them engage with relevant community-based agencies to address such issues. The additional supports may include, but are not restricted to, outreach activities, resilience and social skills training, housing and financial advice, referral to a substance abuse clinic, therapeutic services for family members, and so forth. Families will also be encouraged to utilize informal supports. The type and frequency of services and supports received by families will be documented as part of the costs and process evaluations conducted within the context of this study.

Services as usual. Standard services will be provided by the child welfare and protective system in Ireland and may vary by site and family need. Families in the comparison condition will be assigned a caseworker who will arrange referrals to appropriate services as required, e.g. referral to substance abuse clinic or adult mental health centre. The type and amount of services received by families in the control condition will be documented by the research team. Families in the control group will be offered the ChARM programme at T2, i.e. at six-month follow up.

Sample size

Due to major restructuring of services and staff within the Tusla Child and Family Agency in 2014–2016, our key collaborating site had to withdraw from the research. Thus, our sample size will be smaller (n = 50) than that advised by our sample size calculation that indicated that, factoring in 30 per cent attrition, we would need to recruit 150 families to detect a 0.8 effect size on our primary outcome measures. Given the reduced sample size, the results of this RCT should be interpreted with some caution.

Measures

Table 1 and Table 2 outline the measures used within the RCT, process evaluation and costs analyses.

RCT

The trial has two primary outcomes:

- Parent-reported incidences of child maltreatment, assessed with The Conflict Tactics Scales Parent-Child – Short Form Amended (CTSPC – SFA) (Straus *et al.*, 1998). The CTSPC-SFA measures incidences of psychological aggression, neglect and non-violent discipline, and threats of corporal punishment. The parent will complete the CTSPC-SF for a chosen index child and sibling.

- Child behaviour and wellbeing, assessed using both the parent- and child-report versions of the Strengths and Difficulties Questionnaire (SDQ) (Goodman, 1997). The SDQ assesses child conduct problems, hyperactivity, emotional symptoms, peer problems, and pro-social behaviour among 3–17 year olds. Parents will complete the SDQ for a chosen index child. The child-report version of the SDQ is appropriate for administration to children seven years and above; therefore, it is will be administered to a subsample of children within this study, i.e. children aged 7–10 years (Di Riso *et al.*, 2010).

Table 1. Measures within the RCT. A list of psychometric and observational measures will be administered as part of the impact evaluation to assess outcomes for families.

Measure	Participant	Objective
Impact evaluation		
Conflict Tactics Scale Parent-Child – Short Form	Parent	Parent-reported incidences of child maltreatment
Strengths and Difficulties Questionnaire adult version	Parent	Parent report of child behaviour and wellbeing: conduct, peer & emotional problems, hyperactivity
Strengths and Difficulties Questionnaire child version	Child 7–10 years	Child report of own behaviour and wellbeing: conduct, peer & emotional problems, hyperactivity
Brief Child Abuse Potential Inventory	Parent	Risk factors for child abuse, e.g. parental distress, rigidity, problems with child, self, family and others
Parenting Stress Index	Parent	Parenting stress and parent-child relationship
HOME SF 3–5/6–10 years	Parent and child	Observation of parent-child interaction in the home
Depression, Anxiety and Stress scale	Parent	Parental depression, anxiety and stress
CAGE	Parent	Screener for alcoholism of parent and partner
Drug Abuse Screening Test	Parent	Drug use of parent and partner
Record of incidence of child maltreatment	Collaborating site	Social work record of incidence of child maltreatment in previous six months
Record of out-of-home placement	Collaborating site	Social work record of incidence of out-of-home placement in previous six months
Profile Questionnaire	Parent	Demographic information on families

Secondary outcomes are:

- Risk factors for child abuse (Brief Child Abuse Potential Inventory [BCAPI]: parent report; Ondersma *et al.*, 2005);
- Parenting stress and parent-child interaction (Parenting Stress Index – Short Form [PSI-SF]: parent report; Abidin, 1995);
- Observation of parent-child relationship in the home environment (Home Observation for Measurement of the Environment Short Form [HOME-SF]; Caldwell & Bradley, 2001);
- Parental depression and anxiety (Depression, Anxiety and Stress Scale – Short Form [DASS-SF]: parent report; Lovibond & Lovibond, 1995);
- Parental alcohol and drug use (CAGE and the Drug Abuse Screening Test - 10 [DAST-10]: parent reports; Ewing, 1984; Skinner, 1982); and
- Child welfare reports of CM and out-of-home placements, assessed by records within the collaborating sites.

Demographic and background information on families and children will be collected by means of a Profile Questionnaire. Details on socioeconomic status (SES), and risk of CM, will be collated from questions on, for example, parental age, health, marital status, education and employment, living circumstances, child health, and so forth. Data for all outcomes will be collected at baseline, 6- and 12-month follow ups by a researcher who will meet with the participant in the family home, or, if preferred, in a local family/health care centre.

Process evaluation. The process evaluation will utilize a range of qualitative and quantitative measures to assess programme fidelity and implementation, recruitment of sites and families, participant engagement and experiences, and the feasibility of implementing the programme within child and family services in Ireland not involved in the trial (Table 2). Fidelity and implementation will be assessed with: weekly session checklists of all key components; practitioner capacity to engage parents (Work Alliance Inventory short form; Hatcher & Gillaspy, 2006) ; site and practitioner capacity to implement the programme with integrity (adapted version of the IY Agency Administration Implementation Effectiveness Questionnaire; Webster-Stratton, 2014); and in-depth semi-structured interviews with practitioners and managers following programme delivery. Records of meetings, training, certification and receipt of supervision will also be documented.

Parental engagement and experiences will be assessed using: attendance records; parental feedback on key intervention components (e.g. the Incredible Years Parent Satisfaction

Table 2. Measures within the process evaluation and economic analyses. The process evaluation will utilize a range of qualitative and quantitative measures to assess programme fidelity and implementation, recruitment of sites and families, participant engagement and experiences, and the feasibility of implementing the programme within child and family services in Ireland not involved in the RCT. Several measures will also be applied in order to conduct a costs analyses of ChARM.

Measure	Participant	Objective
Process evaluation		
Session checklists	Practitioners	Fidelity of program content
Work Alliance Inventory	Practitioners	Practitioner-parent relationships
IY Agency Implementation Effectiveness Questionnaire	Practitioners & managers	Site and practitioner capacity to implement the program with integrity
In-depth semi-structured interviews	Practitioner & managers	Assess experiences of developing, coordinating and implementing program
Records of meetings	Research team	Assess experiences of recruiting sites, developing and implementing program
Attendance records	Practitioners	Records of parental attendance to program
PLSP feedback form	Parent	Parental feedback on Positive Life Skills Program
Home visits feedback form	Parent	Parental feedback on home visits
IY parent satisfaction questionnaire	Parent	Parental feedback on Incredible Years parenting program
Working Alliance Inventory	Parent	Parent-practitioner relationship
Semi-structured interview for parents (including attritors)	Parent	Assess experiences of participating in the program
Draw and Tell interview	Child 7–10 years	Experiences of child wellbeing and family
Cantril's ladder	Child 7–10 years	Life satisfaction on 1–10 scale of ladder
My family and me	Child 7–10 years	Emotional closeness of family relationships
Semi structured interview/focus group	Child and Family services	Assess feasibility of implementing the ChARM program within current systems of care in Ireland
Economic analyses		
Costs diaries for program inputs	Practitioners & managers	Estimate the cost per family of delivering the program
Service Utilisation Questionnaire	Parent	Document health, educational and social services used by families in previous six months

Questionnaire); the Work Alliance Inventory short form that measures a participant's experience of the practitioner (Hatcher & Gillaspy, 2006); and an in-depth semi-structured interview with a purposive sample of participating parents (n = 15; selected based on site and demographic characteristics, including those who dropped out from the intervention). Brief interviews will also be conducted with children aged 7–10 years at baseline and 6-month follow up in order to assess the impact of the programme on their perceptions of family relationships and their own wellbeing. The child measures include: the Draw and Tell technique (Merriman & Guerin, 2007), Cantril's My Life Ladder (Cantril, 1965) and My Family and Me (Hill *et al.*, 1996).

We will also conduct interviews/focus groups with a range of child and family services nationally (n = 30 organisations) in order to investigate the feasibility of implementing the ChARM programme within current systems of care in Ireland. This is important in light of the difficulties experienced in retaining collaborating sites as part of the RCT.

Interviews will be conducted in the participants' home/place of work or a local health care centre. Participants can elect whether to participate in an individual interview or a focus group. Written informed consent will be requested. Interviews will be audio-recorded (with participants' consent) and will last no more than one hour with parents and service providers, and no more than 30 minutes with children. The parent of the child will be approached to seek their consent for their child to participate in the study and we will also seek the child's written and verbal assent. To reduce participant burden, interviews with parents and children will be conducted at a different time from the administration of the measures for the impact evaluation.

Costs analyses. In order to estimate the costs per family of delivering the ChARM programme, comprehensive cost diaries will be completed by sites (practitioners and managers) during and following the implementation process. Costs will be collected on: costs of training and supervision, staff time and materials involved in preparation, recruitment of families, intervention delivery, managerial overheads, referrals, and so forth. Parents (n = 50) will also complete a Services Utilization Questionnaire (SUQ) at baseline and 6-month follow up in order to record all health, educational and social services used by the family in the previous six months. The SUQ is based on an adaptation of the Client Service Receipt Interview (Beecham & Knapp, 1992).

Data analysis

RCT. Changes in continuous primary and secondary outcomes at baseline and at six-month follow-up will be compared for the intervention and control groups using ANCOVA, controlling for intervention status, site, baseline score and any other baseline differences identified. Mean difference effect sizes, 95% confidence intervals (CIs), and p values will be reported for continuous outcomes. Changes at 12-month follow up will be conducted using ANOVA. Changes between study arms in categorical variables (i.e. data records of incidences of CM and out-of-home placements) at baseline and six-month follow up will be analysed using the Chi Square test of independence, reporting relative risk, 95% CIs and p values. Descriptive statistical summaries (e.g. means, standard deviations, frequencies) will be presented for primary and secondary outcome measures at each time point. All data for primary and secondary outcomes will be analysed using an intention-to-treat analysis, using multiple imputation (MI) to compensate for missing data at different assessment points. Imputation assumptions for MI will be reported and justified, and imputed data analysed as part of a sensitivity analysis. Parallel per protocol analyses will also be conducted for outcomes. Attrition analyses will be conducted at each time point to assess for differences between those who dropped out from the programme me and those who stayed. This will be based on an examination of key baseline variables (e.g. intervention arm, participant SES and wellbeing, child gender) and qualitative data outlining reasons for attrition.

Multiple regression techniques will be used to explore moderators of intervention effects. Moderators will include: severity of risk and CM at baseline (measured using below and above clinical cut-off scores on the BCAPI, CTSPC, as well as frequency of CM incidences within substantiated reports); age and SES of parents and children (measured using a composite risk factor score derived from demographic data on the Profile Questionnaire); gender of child; parental mental health and problem substance use (using above or below clinical scores on the DASS, CAGE and DAST); site; number of components (comparison of 'core intervention' with 'core intervention plus additional supports'), and programme fidelity (e.g. participant engagement, and site readiness to implement programme). Statistical analyses will be conducted using SPSS and Stata. We are aware of the possibility of low statistical power given that our numbers are lower than desired. Hence these analyses are more exploratory in nature.

Process evaluation. Quantitative assessments of programme fidelity and participant engagement/satisfaction will be assessed using descriptive statistics and using correlational and regression techniques, where necessary. Interview data will be fully transcribed and coded using the qualitative analysis software package MaxQDA (MaxQDA, 2016). Key themes and subthemes will be identified using framework analysis, a method suitable for applied policy research that has specific questions, a limited period, a pre-designed sample and a priori issues (Ritchie & Lewis, 2003). Analysis of themes will be informed by the MRC framework, and will identify programme and implementation processes, contextual factors, mechanisms of impact, and intended outcomes (Moore *et al.*, 2014). Framework analysis uses five steps to identify themes: familiarization; identifying a thematic framework; indexing; charting; and mapping and interpretation (Ritchie & Lewis, 2003).

For the child measures, drawings will be analysed using Visual Content Analysis (VCA), which is a technique for systematically describing written, spoken or visual communication (Bell, 2001). Analysis of the drawings will involve coding for common themes/categories, such as who is present in the picture (peers, family, friends, or pets); the setting (such as watching TV or playing outside); use of colour; and facial expressions (e.g. happy or sad). Data from the VCA will be supported by data from the audio-recordings used in each child interview in order to thematically analyse the child's perception of their life and family relationships.

Economic evaluation. A societal perspective (public sector perspective and individual costs incurred by participants in attending the intervention) will be taken in the economic analysis. The CEA will be calculated through a three-step process. Firstly, the costs diaries will estimate the cost per family of delivering the programme. Unit costs of health and social care services used by families (e.g. GP, nursing, hospital visits) will be obtained from official government documentation, official government pay scales, the Casemix/HIPE unit of the Health Service Executive and any other relevant sources and/or agencies. Thirdly, a CEA will calculate an incremental cost-effectiveness ratio (ICER) to give the cost of obtaining a one-unit decrease on the two primary outcome measures (CTSPC-SF and SDQ) when comparing the ChARM programme to usual services at six-month follow up.

The ICER will use a 1000 replication bootstrap to provide a 95% CI accompanied by appropriate sensitivity analyses. Such sensitivity analyses may include how the ICER may vary according to the severity of the presenting problem at baseline or, for example, excluding non-recurrent costs (e.g. training, materials). The ICER accommodates sampling (or stochastic) uncertainty and varying levels of willingness to pay for reductions in the primary outcomes of interest.

A CBA will also be conducted to investigate the downstream impact of the intervention on later costs, such as generating savings in relation to reduction in child welfare services, foster and residential placements, health and mental health service utilization, crime, education and unemployment. To

conduct the CBA, the results of the CEA will be combined with estimates of the effects of CM on key outcomes in adult life. The effects of CM on adult outcomes can be assessed using secondary data sources and a monetary value will be assigned to the associated gains/losses of programme me delivery. The CBA will calculate an 'internal rate of return' to assess the desirability of investment in the programme. The 'internal rate of return' refers to the discount rate at which the value of the stream of future benefits exactly equals the initial cost of the programme, yielding a net present value equal to zero.

Discussion

The prevention of child maltreatment (CM) is a public health priority given its negative impact on long-term personal, social, and economic outcomes. Although a range of interventions have been developed to prevent child abuse and neglect, even the most promising fail to engage families most at risk, or are targeted only at very young children (0–3 years). This study will evaluate the ChARM wraparound-inspired intervention, which incorporates evidence-based programmes and community-based supports in order to address the multiple and complex needs of vulnerable families whose children are aged 3–11 years. Furthermore, key process and implementation mechanisms of the programme will be investigated. The study is the first evaluation of a wraparound-inspired programme designed to prevent child abuse and neglect. Therefore, the findings will provide unique and valuable insights into the development and implementation of programmes designed to prevent child abuse and neglect.

Trial status

The study is in the process of collecting data.

Compliance with ethical standards

Ethical approval: All procedures performed in studies involving human participants will be in accordance with the ethical standards of Maynooth University's Social Research Ethics Committee (Reference number SRESC-2015-005, approved 16.02.2015) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards (World Medical Association Declaration of Helsinki, 2013).

Informed consent: Informed consent will be obtained from all individual participants in the study. Children over seven years will be asked to give their verbal and written assent where parental written informed consent has first been obtained.

Confidentiality and data protection: All data will be anonymized and will not be identifiable. Data will be encrypted and uploaded to a secure, central site to which only members of the research team will have access.

Study withdrawal: All participants will be informed that they may withdraw from the study, and/or withdraw their data, at any point without affecting their access to services.

Child welfare: If a researcher becomes concerned about the safety of a child, Children First guidelines will be followed so as to protect the welfare of the child (Department of Children and Youth Affairs, 2011).

Data availability

No data is associated with this article.

Competing interests

No competing interests were disclosed.

Grant information

The study is funded by the Health Research Board in Ireland under its new 'Collaborative Applied Research Grants in Population Health and Health Service Research 2012' awarded to Professor Sinead McGilloway as the Principal Investigator (CARG/2012/17).

The HRB had no role in the design of the study and will not have any role during its execution analyses, interpretation of the data, or decision to submit results.

Acknowledgements

Many thanks to our partners for their continuing help and support with this research, in particular Cherry Orchard Social Work, Archways and Kildare/West Wicklow Social Work.

ENRICH Research Team: Mairead Furlong, Sinead McGilloway, Ann Stokes, Grainne Hickey, Yvonne Leckey (Department of Psychology, John Hume Building, National University of Ireland Maynooth, Maynooth, Co. Kildare, Ireland); Tracey Bywater (University of York, York, UK); Ciaran O'Neill, Chris Cardwell, Michael Donnelly (Queens University Belfast, Belfast, Northern Ireland); Brian Taylor (Ulster University, Derry, Northern Ireland).

Supplementary material

Supplementary Figure 1: The Hardiker model (Hardiker *et al.*, 1991). A planning framework widely used in child welfare and protection whereby a child's level of risk is judged according to levels of risk 1–4. Among inclusion criteria for participants in this study is whereby a child's level of risk is between levels 2–3.

Click here to access the data.

Supplementary Figure 2: Medical Research Council (MRC) framework for process evaluations (Moore *et al.*, 2014). This figure outlines the key functions of process evaluation and relations among them. MRC guidance provides a framework for conduction and reporting this process evaluation study.

Click here to access the data.

References

Abidin RR: **Parenting Stress Index.** 3rd ed. Odessa, FL: Psychological Assessment Resources. 1995.
Reference Source

Afifi TO, MacMillan HL: **Resilience following child maltreatment: a review of protective factors.** *Can J Psychiatry.* 2011; **56**(5): 266–72.
PubMed Abstract | Publisher Full Text

Akmatov MK: **Child abuse in 28 developing and transitional countries--results from the Multiple Indicator Cluster Surveys.** *Int J Epidemiol.* 2011; **40**(1): 219–27.
PubMed Abstract | Publisher Full Text

Axford N, Lehtonen M, Kaoukji D, *et al.*: **Engaging parents in parenting programs: lessons from research and practice.** *Child Youth Serv Rev.* 2012; **34**(10): 2061–71.
Publisher Full Text

Beecham J, Knapp M: **Costing psychiatric interventions.** In Thornicroft G, Brewin CC, Wing JK, (Eds.), *Measuring mental health needs.* London: Gaskell. 1992: 163–183.
Reference Source

Bell P: **Content analysis of visual images.** In Leeuwen TV, Jewitt C (Eds.), *Handbook of visual analysis.* London: SAGE. 2001; 10–34.
Publisher Full Text

Bernstein A, Chorpita BF, Rosenblatt A, *et al.*: **Fit of evidence-based treatment components to youths served by wraparound process: a relevance mapping analysis.** *J Clin Child Adolesc Psychol.* 2015; **44**(1): 44–57.
PubMed Abstract | Publisher Full Text

Better Outcomes Brighter Futures: **The national policy framework for children and young people 2014–2020.** Accessed 13 February 2017. 2014.
Reference Source

Browne DT, Puente-Duran S, Shlonsky A, *et al.*: **A randomized trial of wraparound facilitation versus usual child protection services.** *Res Social Work Prac.* 2014; **26**(2): 168–179.
Publisher Full Text

Bruns EJ, Suter JC, Leverentz-Brady K: **Is it wraparound yet? Setting quality standards for implementation of the wraparound process.** *J Behav Health Serv Res.* 2008; **35**(3): 240–52.
PubMed Abstract | Publisher Full Text

Bruns EJ, Walker JS, Bernstein A: **Family voice with informed choice: coordinating wraparound with research-based treatment for children and adolescents.** *J Clin Child Adolesc Psychol.* 2014; **43**(2): 256–69.
PubMed Abstract | Publisher Full Text | Free Full Text

Burns BJ, Schoenwald SK, Burchard JD, *et al.*: **Comprehensive community-based interventions for youth with severe emotional disorders: multisystemic therapy and the wraparound process.** *J Child Fam Stud.* 2000; **9**(3): 283–314.
Publisher Full Text

Caldwell BM, Bradley RH: **HOME inventory and administration manual.** 3rd ed. Arkansas: University of Arkansas for Medical Sciences and University of Arkansas at Little Rock. 2001.
Reference Source

Cantril H: **The pattern of human concerns.** New Brunswick, NJ: Rutgers University Press. 1965.
Reference Source

Cassidy A, Devaney C, McGregor C: **Early implementation of Meitheal and the Child and Family support networks: lessons from the field.** National University of Ireland, Galway: UNESCO Child and Family Research Centre. 2016.
Reference Source

Chan AW, Tetzlaff JM, Gøtzsche PC, *et al.*: **SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials.** *BMJ.* 2013; **346**: e7586.
PubMed Abstract | Publisher Full Text | Free Full Text

Chen M, Chan KL: **Effects of Parenting Programs on Child Maltreatment Prevention: A Meta-Analysis.** *Trauma Violence Abus.* 2016; **17**(1): 88–104.
PubMed Abstract | Publisher Full Text

Children and Young People Now Jobs. Accessed 10 February 2017, 2017.
Reference Source

Corso PS, Lutzker JR: **The need for economic analysis in research on child maltreatment.** *Child Abuse Negl.* 2006; **30**(7): 727–38.
PubMed Abstract | Publisher Full Text

Department of Children and Youth: **The children first: national guidance for the protection and welfare of children.** Dublin, Ireland: Government Publications. 2011.
Reference Source

Di Riso D, Salcuni S, Chessa D, *et al.*: **The Strengths and Difficulties Questionnaire (SDQ). Early evidence of its reliability and validity in a community sample of Italian children.** *Pers Individ Dif.* 2010; **49**(6): 520–75.
Publisher Full Text

Ewing JA: **Detecting alcoholism. The CAGE questionnaire.** *JAMA.* 1984; **252**(14): 1905–07.
PubMed Abstract | Publisher Full Text

Furlong M, McGilloway S: **Barriers and facilitators to implementing evidence-based parenting programs in disadvantaged settings: A qualitative study.** *J Child Fam Stud.* 2015; **24**(6):1809–1818.
Publisher Full Text

Furlong M, McGilloway S, Bywater T, *et al.*: **Behavioural and cognitive-behavioural group-based parenting programmes for early-onset conduct problems in children aged 3 to 12 years.** *Cochrane Database Syst Rev.* 2012; (2): CD008225.
PubMed Abstract | Publisher Full Text

Gilbert R, Widom CS, Browne K, *et al.*: **Burden and consequences of child maltreatment in high-income countries.** *Lancet.* 2009; **373**(9657): 68–81.
PubMed Abstract | Publisher Full Text

Gomby D: **Home Visitation in 2005: Outcomes for Children and Parents.** Invest in Kids Working Paper No. 7. Washington, DC: Committee for Economic Development. 2005.
Reference Source

Goodman R: **The Strengths and Difficulties Questionnaire: a research note.** *J Child Psychol Psychiatry.* 1997; **38**(5): 581–86.
PubMed Abstract | Publisher Full Text

Haase T, Pratschke J, Gleeson J: **The 2011 All-Island HP deprivation index.** Dublin, Ireland: Pobal. 2014.
Reference Source

Hardiker P, Exton K, Barker M: **The social policy contexts of prevention in child care.** *Br J Soc Work.* 1991; **21**(4): 341–59.
Publisher Full Text

Hatcher RL, Gillaspy JA: **Development and validation of a revised short version of the working alliance inventory.** *Psychother Res.* 2006; **16**(1): 12–25.
Publisher Full Text

Hill M, Laybourn A, Borland M: **Engaging with primary-aged children about their emotions and well-being: methodological considerations.** *Children and Society.* 1996; **10**(2): 129–44.
Publisher Full Text

Hurlburt MS, Nguyen K, Reid J, *et al.*: **Efficacy of the Incredible Years group parent program with families in Head Start who self-reported a history of child maltreatment.** *Child Abuse Negl.* 2013; **37**(8): 531–543.
PubMed Abstract | Publisher Full Text

Lees DG, Fergusson DM, Frampton CM, *et al.*: **A pilot study to evaluate the efficacy of adding a structured home visiting intervention to improve outcomes for high-risk families attending the Incredible Years Parent Programme: study protocol for a randomised controlled trial.** *Trials.* 2014; **15**: 66.
PubMed Abstract | Publisher Full Text | Free Full Text

Letarte MJ, Normandeau S, Allard J: **Effectiveness of a parent training program "Incredible Years" in a child protection service.** *Child Abuse Negl.* 2010; **34**(4): 253–61.
PubMed Abstract | Publisher Full Text

Leventhal JM: **Getting prevention right: maintaining the status quo is not an option.** *Child Abuse and Neglect.* 2005; **29**(3): 209–13.
PubMed Abstract | Publisher Full Text

Lovibond PF, Lovibond SH: **The structure of negative emotional states: comparison of the Depression Anxiety Stress Scales (DASS) with the Beck Depression and Anxiety Inventories.** *Behav Res Ther.* 1995; **33**(3): 35–43.
PubMed Abstract | Publisher Full Text

Lundahl BW, Nimer J, Parsons B: **Preventing child abuse: a meta-analysis of parent training programs.** *Res Social Work Prac.* 2006; **16**(3): 251–62.
Publisher Full Text

Macdonald G, Bennett C, Higgins JP, *et al.*: **Home visiting for socially disadvantaged mothers.** *Cochrane Database Syst Rev.* 2010.
Publisher Full Text

MacKenzie MJ, Kotch JB, Lee LC: **Toward a cumulative ecological risk model for the etiology of child maltreatment.** *Child Youth Serv Rev.* 2011; **33**(9): 1638–1647.
PubMed Abstract | Publisher Full Text | Free Full Text

MacMillan HL, Wathen CN: **Research brief: interventions to prevent child maltreatment.** Accessed 10 February 2017. 2014.
Reference Source

MAXQDA: **Software for qualitative data analysis.** Berlin: VERBI Software. 2016.

McGilloway S, Mhaille GN, Bywater T, *et al.*: **A parenting intervention for childhood behavioral problems: a randomized controlled trial in disadvantaged community-based settings.** *J Consult Clin Psychol.* 2012; **80**(1): 116–127.
PubMed Abstract | Publisher Full Text

Merriman B, Guerin S: **Exploring the aspirations of Kolkatan (Calcuttan) street children living on and off the streets using drawings.** *Int J Psychol Therp.* 2007; **7**: 269–83.
Reference Source

Mikton C, Butchart A: **Child maltreatment prevention: a systematic review of reviews.** *Bull World Health Organ.* 2009; **87**(5): 353–61.
PubMed Abstract | Publisher Full Text | Free Full Text

Moher D, Hopewell S, Schulz KF, *et al.*: **CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials.** *BMJ.* 2010; **340**: c869.
PubMed Abstract | Publisher Full Text | Free Full Text

Moore GF, Audrey S, Barker M, *et al.*: **Process evaluation of complex interventions.** UK Medical Research Council (MRC) guidance. 2014. Accessed 10 February 2017. 2014.
Reference Source

Munro E: **The Munro review of child protection: final report, a child-centred system.** London: TheStationery Office. 2011.
Reference Source

National Wraparound Initiative: Regional Research Institute, School of Social Work, Portland StateUniversity. Accessed 10 February 2017. 2017.
Reference Source

Ondersma SJ, Chaffin MJ, Mullins SM, *et al.*: **A brief form of the child abuse potential inventory: development and validation.** *J Clin Child Adolesc Psychol.* 2005; **34**(2): 301–11.
PubMed Abstract | **Publisher Full Text**

Ritchie J, Lewis J: **Qualitative research practice: a guide for social science students and researchers.** London: Sage. 2003.
Reference Source

Schneider-Muñoz AJ, Renteria RA, Gelwicks J, *et al.*: **Reducing risk: families in wraparound intervention.** *Families in Society: The Journal of Contemporary Social Services.* 2015; **96**(2): 91–98.
Publisher Full Text

Sethi D, Bellis M, Hughes K, *et al.*: **European report on preventing child maltreatment.** Copenhagen: WHO Regional Office for Europe. 2013.
Reference Source

Selph SS, Bougatsos C, Blazina I, *et al.*: **Behavioral interventions and counseling to prevent child abuse and neglect: a systematic review to update the US Preventive services task force recommendation.** *Ann Intern Med.* 2013; **158**(3): 179–90.
PubMed Abstract | **Publisher Full Text**

Skinner HA: **The drug abuse screening test.** *Addict Behav.* 1982; **7**(4): 363–71.
PubMed Abstract | **Publisher Full Text**

Stith SM, Liu T, Davies LC, *et al.*: **Risk factors in child maltreatment: a meta-analytic review of the literature.** *Aggress Violent Beh.* 2009; **14**(1): 13–29.
Publisher Full Text

Stoltenborgh M, Bakermans-Kranenburg MJ, Alink LR, *et al.*: **The universality of childhood emotional abuse: a meta-analysis of worldwide prevalence.** *J Aggress Maltreat Trauma.* 2012; **21**(8): 870–90.
Publisher Full Text

Stoltenborgh M, Bakermans-Kranenburg MJ, van Ijzendoorn MH: **The neglect of child neglect: a meta-analytic review of the prevalence of neglect.** *Soc Psychiatry Psychiatr Epidemiol.* 2013a; **48**(3): 345–55.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

Stoltenborgh M, Bakermans-Kranenburg MJ, van Ijzendoorn MH, *et al.*: **Cultural-geographical differences in the occurrence of child physical abuse? A meta-analysis of global prevalence.** *Int J Psychol.* 2013b; **48**(2): 81–94.
PubMed Abstract | **Publisher Full Text**

Straus MA, Hamby SL, Finkelhor D, *et al.*: **Identification of child maltreatment with the Parent-Child Conflict Tactics Scales: development and psychometric data for a national sample of American parents.** *Child Abuse Negl.* 1998; **22**(4): 249–70.
PubMed Abstract | **Publisher Full Text**

Suter JC, Bruns EJ: **Narrative review of wraparound outcome studies.** In Bruns E, Walker J (Eds.), *The resource guide to wraparound.* Portland, OR: National Wraparound Initiative, Research and Training Center for Family Support and Children's Mental Health, Portland State University. Accessed 24 January 2017. 2008.
Reference Source

Suter JC, Bruns EJ: **Effectiveness of the wraparound process for children with emotional and behavioral disorders: a meta-analysis.** *Clin Child Fam Psychol Rev.* 2009; **12**(4): 336–51.
PubMed Abstract | **Publisher Full Text**

Tusla: **Thresholds for referral to Tusla social work services.** Dublin, Ireland: Child and Family Agency. 2014.

Tusla: **Meitheal toolkit – a Tusla-led national practice model.** Accessed 8 February 2017. 2015.
Reference Source

Tusla: **Tusla Quarterly National Performance Activity Report Q1 2015.** Accessed 9 February 2017. 2015.
Reference Source

Tusla, Child and Family Agency. Accessed 10 February 2017. 2017.
Reference Source

U.S. Department of Health and Human Services, Administration on Children, Youth and Families: **Child maltreatment.** Washington DC: U.S. Government Printing Office. Accessed 30 January 2017. 2013.
Reference Source

Walter UM, Petr CG: **Best practices in wraparound: a multidimensional view of the evidence.** *Soc Work.* 2011; **56**(1): 73–80.
PubMed Abstract | **Publisher Full Text**

Webster-Stratton C: **The Incredible Years (IY) Agency Administration Implementation Effectiveness: Parent Programme.** Accessed 20 January 2017. 2014.
Reference Source

Webster-Stratton C, Hancock L: **Parent training: content, methods and processes.** In Shafer E, (Ed.), *Handbook of parent training.* 2nd ed. New York: Wiley and Sons. 1998.

Webster-Stratton C, Reid M: **Adapting The Incredible Years, an evidence-based parenting programme, for families involved in the child welfare system.** *J Child Serv.* 2010; **5**(1): 25–42.
Publisher Full Text

Williams J, Nixon E, Smyth E, *et al.*: **Cherishing all the children equally? Children in Ireland 100 years on from the Easter Rising.** Cork: Oak Tree Press. 2016.
Reference Source

Winters NC, Metz WP: **The wraparound approach in systems of care.** *Psychiatr Clin North Am.* 2009; **32**(1): 135–51.
PubMed Abstract | **Publisher Full Text**

World Medical Association: **World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects.** *JAMA.* 2013; **310**(20): 2191–4.
PubMed Abstract | **Publisher Full Text**

Open Peer Review

Current Peer Review Status: ? ✓

Version 1

Reviewer Report 23 July 2018

https://doi.org/10.21956/hrbopenres.13872.r26304

✓ **Nuala Connolly**
[1] Barnardos Ireland, Dublin, Ireland
[2] EU-CoE Youth Partnership Pool of European Youth Researchers, Dublin, Ireland

Abstract:
The abstract introduces the ChARM model, study type and sample size. The abstract also describes the outcomes and provides a rationale for the study. The study is multifaceted and ambitious. The stage of the study is not entirely clear; it is described as “being conducted”, while assessments “will take place”. While this could be clarified, overall the abstract is clear and well-written.

Introduction:
The introduction is detailed and covers considerable ground on CM and associated risk and protective factors.

The wraparound approach, and rationale for an approach inspired by wraparound principles that incorporates evidence based programmes is well-presented and concise.

Evidence on home-based supports and parent training is subsequently introduced.

The case presented focuses on why parenting programmes alone/ home-visiting programmes alone are insufficient in improving risk factors and reducing incidences of CM.

The authors have not acknowledged that parenting programmes can be home-based. For example, the evidence provided on parenting programme attrition speaks to centre-based group parenting programmes. Likewise, the next paragraph begins with the assertion that “home-based interventions have more capacity than parenting programmes”.

Meitheal is an important inclusion, but should be described as a national practice model, rather than a national policy initiative.

Page 5, Para 3 & 4 have some typographical errors, with the word ‘me’ inadvertently inserted a few times.

The objectives are ambitious – particularly given the statistical power of the sample size. The hypotheses will be difficult to prove, particularly where they depend upon a subsample (secondary hypotheses). This is acknowledged by the authors.

Method:
The methodology provides a detailed description of the RCT. Inclusion and exclusion criteria are covered, in addition to eligibility of programme providers.

The procedure is robust and described in detail, including randomisation, blinding and contamination. It is clear the authors have paid particular attention to this aspect of the methodology.

The recruitment timeline is a little unclear stating that the aim is to recruit 50 families between 2015 and 2017. What stage is the study currently at?

While the main limitation (sample size) is addressed under said heading, it would be helpful to have a limitations section.

Ethics:
The number of assessment scales used is considerable, particularly in the context of vulnerable parents. This could be better addressed in the paper. While ethical compliance is described, aspects relating to the potential risk to parents are not addressed. Will the parents have the option of having a project worker present during the administration of the measures/ interviews? Who will gate-keep access to the parents? What support will be provided during and following data collection? Additional discussion would benefit the paper.

Overall:
Overall, this is an interesting, timely and informative article on a study that aims to evidence a particular type of wraparound approach. With some edits, it will make a valuable and important addition to the literature.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Yes

Competing Interests: The lead author was commissioned by an affiliated organisation through a competitive tendering process to undertake a small-scale service evaluation in 2017, and is therefore known to the reviewer in a once-off professional capacity.

Reviewer Expertise: Child and family research, youth research, parenting support, research methods

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Author Response 11 Sep 2018

Ann Stokes, National University of Ireland Maynooth, Maynooth, Co. Kildare, Ireland

The abstract introduces the ChARM model, study type and sample size. The abstract also describes the outcomes and provides a rationale for the study. The study is multifaceted and ambitious. The stage of the study is not entirely clear; it is described as “being conducted”, while assessments “will take place”. While this could be clarified, overall the abstract is clear and well-written.

The description of this study is in the future tense because this is a protocol and indeed, at the time of writing, the study is still ongoing. Thus, the aim of this article is to outline the study methods and activities involved therein. We have now added a sentence in the abstract to make this more clear (lines 5-6, p.1).

Introduction:
The introduction is detailed and covers considerable ground on CM and associated risk and protective factors.

The wraparound approach, and rationale for an approach inspired by wraparound principles that incorporates evidence based programmes is well-presented and concise.

Evidence on home-based supports and parent training is subsequently introduced.

The case presented focuses on why parenting programmes alone/ home-visiting programmes alone are insufficient in improving risk factors and reducing incidences of CM.

The authors have not acknowledged that parenting programmes can be home-based. For example, the evidence provided on parenting programme attrition speaks to centre-based group parenting programmes. Likewise, the next paragraph begins with the assertion that “home-based interventions have more capacity than parenting programmes”.

We understand that some parent programmes are delivered in the home. Home-based interventions in the context of this study, refer to supports provided in the home via individual home visits designed to supplement the group-based parenting intervention that forms part of the ChARM model. We have now clarified this point and amended the original sentence on p.4, para 1.

Meitheal is an important inclusion, but should be described as a national practice model, rather than a national policy initiative.

This has been revised as suggested on p.5, para 3.

Page 5, Para 3 & 4 have some typographical errors, with the word ‘me’ inadvertently inserted a few times.

These typos have been corrected as highlighted (removal of ‘me’) (p5., para 4; p.6, paras

3, 4,).

The objectives are ambitious – particularly given the statistical power of the sample size. The hypotheses will be difficult to prove, particularly where they depend upon a subsample (secondary hypotheses). This is acknowledged by the authors.

Method:
The methodology provides a detailed description of the RCT. Inclusion and exclusion criteria are covered, in addition to eligibility of programme providers.

The procedure is robust and described in detail, including randomisation, blinding and contamination. It is clear the authors have paid particular attention to this aspect of the methodology.

The recruitment timeline is a little unclear stating that the aim is to recruit 50 families between 2015 and 2017. What stage is the study currently at?

As indicated earlier, the description of the study is written in the future tense as this is a protocol; therefore, we do not feel it is appropriate to comment on the current stage of the project. However, we have amended the 'trial status' section at the end of the paper (indicating that at this stage, data collection has just been completed).

While the main limitation (sample size) is addressed under said heading, it would be helpful to have a limitations section.

The research team have followed the SPIRIT reporting guidelines in preparing this article, as recommended by HRB Open Access and in so doing, the paper does not stipulate a specific limitations section. However, we have now included some brief information on limitations of the study on p.15, para 2.

Ethics:
The number of assessment scales used is considerable, particularly in the context of vulnerable parents. This could be better addressed in the paper. While ethical compliance is described, aspects relating to the potential risk to parents are not addressed. Will the parents have the option of having a project worker present during the administration of the measures/ interviews? Who will gate-keep access to the parents? What support will be provided during and following data collection? Additional discussion would benefit the paper.

The research team have followed the guidelines of HRB Open Access in preparing this article and in so doing, the paper follows the SPIRIT reporting guidelines in terms of ethical (amongst other) requirements. However, we have now expanded the section entitled 'ethical standards' on pp.15-16 to try to address these important points. We have also added another section entitled 'other ethical issues' on p.16.

Competing Interests: No competing interests were disclosed.

Reviewer Report 22 May 2018

https://doi.org/10.21956/hrbopenres.13872.r26184

?

Marie-Josée Letarte
Department of Psychoeducation, University of Sherbrooke, Sherbrooke, QC, Canada
Isabelle-Ann Leclair Mallette
Department of Psychoeducation, University of Sherbrooke, Sherbrooke, Canada
Caroline Temcheff
School of Psychology, McGill University, Montreal, QC, Canada

This study presents a protocol for a program evaluation using a RCT. The program studied here aims to prevent child maltreatment through the coordination of evidence-based programs. This paper is interesting for several reasons:

1. The social pertinence of the program is obvious. The authors demonstrate how important it is to prevent child maltreatment before it occurs. We know that intervention is less effective when offered once maltreatment is present in the family. The authors also demonstrate that empirically-supported programs are useful, but none can prevent child maltreatment on its own since vulnerable families are so hard to reach.

2. A good description of the RCT design is provided. Everything seems to be planned for a proper RCT protocol, with several controls regarding the randomization and blinding. The description is clear and precise.

3. The number of aspects considered in the evaluation is vast. Indeed, the authors are planning to evaluate primary and secondary outcomes, the therapeutic processes, and the cost-benefit ratio. The acceptability and feasibility of the program outside the involved sites is also noteworthy. Though ambitious, these considerations are valuable since it is a new and pertinent initiative and the authors seem to be confident that they will be able to disseminate the program throughout Ireland once it is evaluated, through another national initiative.

4. It is to the credit of those involved in the Irish CPS to look for real solutions to child abuse and neglect and to rely on empirically-supported programs in order to do so

We believe that the project merits indexing despite some limitations. However, a few aspects could be improved. These suggestions are detailed below.

Abstract
The abstract presents the different sections of the article. To avoid any confusion, authors should state in the first or second sentence that this paper presents the protocol for a study currently being carried out or will be carried out in the near future (i.e., results not available yet). It is also slightly unclear whether the study has begun at this stage or not. For example, in the abstract it is stated that the study “is being conducted” whereas in the methods it is stated “ The ChARM programme will be delivered…”

Again, to avoid confusion, the last sentence should be rephrased at the future tense: "the findings will offer ..."

Introduction
The introduction is a plea for the prevention of child abuse and neglect. The goal of the program is relevant, as this problem is of major concern for most societies.

The authors make a good demonstration that intervention is less effective when offered once maltreatment is present in the family and that prevention programs should be developed. However, it is not that clear from the methods that they propose a prevention program since targeted families are involved in child protection for child maltreatment (some only at-risk for maltreatment, but some will have documented maltreatment already). The authors also demonstrate that empirically supported programs are useful, but none can prevent child maltreatment on its own since vulnerable families are so hard to reach. Another argument for such a program could be that child maltreatment is explained by multi-systemic factors.

Even though we are not questioning the fact that child maltreatment has important consequences on the victims' development, the study cited to support this link is about child maltreatment prevention in general (Sethi et al., 2013). Perhaps studies examining consequences of child maltreatment (primary or meta-analysis) would be more appropriate to support this link.

The authors present the incidence of maltreatment and more specifically of its different forms. In order to do so, they report rates found in meta-analyses of self-reported incidences. Afterward, they provide data for substantiated abuse. It seems to be a good idea to report both since they do not provide exactly the same information. However, when it comes to presenting the rates of the different forms of maltreatment, a little nuancing would be appropriate. In fact, even if it is true that, according to the self-reported rates, neglect is less frequent than physical abuse, this seems to be an under-representation that may be related to the type of measure used.

Again, in relation to incidence, it is not clear why the authors introduce rates from different countries. When it is written that "prevalence rates of CM are even higher in low and middle-income countries…", it is unclear why this is relevant to the current study. Does the critique about the unreliable detection and surveillance in most countries apply to Ireland? The pertinence of this discussion is questionable and it is unclear how it reflects the Irish situation.

The authors mention some protective factors of CM: knowledge of parenting, nurturing parenting skills, parental resilience, social network, etc. These are not protective factors, as protective factors must have made the demonstration they can interrupt or interact with risk factors. These may be viewed as favorable factors or positive factors that MAY prevent CM and promote child well-being.

The most important problem with the introduction is that it does not introduce ChARM, but focuses on the WA model of care. We understand that this model is central as it demonstrates the value of an approach that consist of coordinating services around the family. It would be good to discuss strengths and limitations of this model and the need to incorporate empirically-supported programs in WA care. The authors also introduce Meitheal, another program, also inspired by WA. However, there are very few allusions to ChARM, which leads to some confusion. It seems important to discuss the WA model, however I think the authors need to place the focus more on ChARM and to demonstrate the value of this program. Perhaps the progress of the WA implementation in Ireland and Meitheal could be discussed in the discussion ?

Objectives
Though the objectives are totally relevant, we do have a concern about a specific hypothesis: (1) the

ChARM program will reduce parent-reported incidences of child maltreatment. This comment will be detailed in the method, but the administrative data is considered as a secondary outcome, which is not consistent with the introduction.

Methods
Since we are now in 2018, and the recruitment was planned for 2015-2017, would it be possible to have an update and the authors to state the exact number of participants they recruited? The authors could then perform post hoc computations of statistical power.

There is slight inconsistency in the targeted age of the children. Sometimes it is written 3-10 and sometimes it is 3-11. Please verify.

In this section, it is said that the ChARM program prevents child maltreatment “within intact families”. We were not sure if the term “intact family” refers to families in which both biological parents are living together or family in which the child is not in out-of-home placement.

The objectives of the study are relevant, clear and precise. However, the first hypothesis is not clear. Why should the parent-reported incidences of child maltreatment decrease? Is it that parents will report having less maltreating behavior after the program?

The introduction convinced us that the program to be evaluated is a prevention program of maltreatment, implemented in the community with families that are at risk to commit child maltreatment. We were surprised to see that participants were actually followed by child welfare, including some that had already committed child maltreatment. This apparent inconsistency may be due to differences between child protective services in Ireland compared to our system in Quebec (if it is the case, a brief description of CPS in Ireland could help). Or maybe ChARM is not a prevention program but an intervention one.

Can you explain on what basis the child welfare professionals refer a parent at risk of abuse or neglect?

The first and third exclusion criteria seem to be redundant with inclusion criteria.

The eligibility criteria for program providers to be part of the study is not precise enough. What do you mean by “considerable experience”? In what capacity are they working within CPS? How much experience is required in order to deliver the components? It could be interesting to quantify this experience in months/years.

***The most important problem with this protocol is the number of participants to the study. 50 (25+25) over two years, seem to be very few, especially after the authors mention that this is a prevalent problem. If probing practices are implemented in order to reach and engage families, how do you explain such a small n? An analysis of the statistical power is essential. Indeed, we have to know if the number of participants available in your study and the number of outcomes to consider make it possible to reach your goals. It would be disappointing for everyone that you come to the conclusion that you can not state on the effectiveness of ChARM since your negative results are due to insufficient statistical power.

This will probably not be enough to test moderations. You state that 150 families would be necessary in order to detect a 0,8 effect size, which is quite big for this population and this context. Are you willing to accept that with 50, you wouldn’t detect a 0.8 effect size? I read that the authors are aware of this problem. But we think they really need to find solutions.

Since the protocol is so complete, we are interested to know more about the way contamination will be measured and controlled statistically if needed.

Since the age of the children show a wide range, what program is used from IY? The preschool or the school age basic program?

We would like to know more about the name and number of "subscales" for each measure used. Could you also give some information on the psychometric value of the selected tools? I also notice that these are several measures for very few participants. What correction are you planning to use to compensate, knowing that Bonferroni is relatively conservative... In addition, I invite the researchers to question the potential impact of the number of measures on the recruitment of participants. Indeed, the number of questionnaires provided in the protocol could have an impact on the possibility of generalizing the results to all the very vulnerable parents who would have refused to participate in the research.

The WAI is used to measure the capacity to engage parents. This is known to be a measure of working alliance. There is at least two versions of this questionnaire: parent and therapist. Why not use the parent version? Furthermore, when is it going to be completed? Some researchers have shown that the validity of this measure and its capacity to detect relevant working alliance is at its best around the third meeting. We invite the authors to have a discussion about this question of timing.

We wonder why you presented maltreatment report by parents as a primary outcome, and CPS report of maltreatment as a secondary outcome. We believe that because the parents are followed in CPS, which is a pretty coercive context, they could be tempted to give answers to their advantage which can cause a social desirability bias to this outcome. That is why we also suggest the use the official CPS report of maltreatment in combination to the parent-reported maltreatment as primary outcomes.

It is a very interesting idea to have interviews with those who abandon the program. I wonder how they will be recruited. If they do not agree to go through the program, it is not very likely that they will accept the go further with the research process. In addition, those who could accept would have specific characteristics to be considered.

We are also very satisfied that the fidelity of implementation of the program that is described in this study. However, we question the validity of using it as a moderator, because to be eligible as a moderator, a variable should respect criteria of temporal precedence and independence with the program (Kraemer, Kiernan, Essex & Kupfer, 2008).

Thus, many good ideas, but perhaps not the statistical power to accomplish all this!

Discussion
Very short. More information regarding the anticipated limitations of the study would be helpful.

Ethics Standards
We appreciated the section about how the authors are planning on complying with ethical standards. This section, like all others, is precise and detailed. It shows the authors' concern to follow best practices in program evaluation with vulnerable clientele.

General
There are some language errors or typos. In the second paragraph, it is written that "In Ireland, over 40,000 referrals of child welfare and abuse cases." I suppose authors mean abuse and neglect cases?...

On p.5, paragraph starting with “This study involves the evaluation of…” and in the next one starting with “The objectives of the study…”, there are many typo problems. Many little “me” are inserted, and I cannot explain why. See the whole text for other problems of this kind.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Partly

Are sufficient details of the methods provided to allow replication by others?
Partly

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Program evaluation, especially parenting programs – implementation and efficacy evaluation. But I am not a expert of economic analysis.

We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however we have significant reservations, as outlined above.

Author Response 11 Sep 2018

Ann Stokes, National University of Ireland Maynooth, Maynooth, Co. Kildare, Ireland

Abstract
The abstract presents the different sections of the article. To avoid any confusion, authors should state in the first or second sentence that this paper presents the protocol for a study currently being carried out or will be carried out in the near future (i.e., results not available yet). It is also slightly unclear whether the study has begun at this stage or not. For example, in the abstract it is stated that the study “is being conducted” whereas in the methods it is stated “ The ChARM programme will be delivered…”

Again, to avoid confusion, the last sentence should be rephrased at the future tense: "the findings will offer ..."

The description of this study is in the future tense because this is a protocol and indeed, at the time of writing, the study is still ongoing. Thus, the aim of this article is to outline the study methods and activities involved therein. We have now added a sentence in the abstract to make this more clear (p.1, lines 5-6). The text has also been changed to the future tense throughout (i.e. ‘will be conducted’ ‘will offer’ etc.).

Introduction
The introduction is a plea for the prevention of child abuse and neglect. The goal of the program is

relevant, as this problem is of major concern for most societies.

The authors make a good demonstration that intervention is less effective when offered once maltreatment is present in the family and that prevention programs should be developed. However, it is not that clear from the methods that they propose a prevention program since targeted families are involved in child protection for child maltreatment (some only at-risk for maltreatment, but some will have documented maltreatment already). The authors also demonstrate that empirically supported programs are useful, but none can prevent child maltreatment on its own since vulnerable families are so hard to reach. Another argument for such a program could be that child maltreatment is explained by multi-systemic factors.

ChARM is designed to be both an early intervention and prevention programme and for purposes of this study, targeted families will be those deemed to be at risk of child maltreatment as well as those who are currently in contact with social workers due to ongoing child protection concerns. We have now attempted to clarify this point by revising p.3, para 2 accordingly. We have also acknowledged that child maltreatment may be explained by multi-systemic factors (p.2, para 4, line 1).

Even though we are not questioning the fact that child maltreatment has important consequences on the victims' development, the study cited to support this link is about child maltreatment prevention in general (Sethi et al., 2013). Perhaps studies examining consequences of child maltreatment (primary or meta-analysis) would be more appropriate to support this link.

We have amended the text in the Introduction (p.1, final para) to include other studies that have examined the consequences of child maltreatment.

The authors present the incidence of maltreatment and more specifically of its different forms. In order to do so, they report rates found in meta-analyses of self-reported incidences. Afterward, they provide data for substantiated abuse. It seems to be a good idea to report both since they do not provide exactly the same information. However, when it comes to presenting the rates of the different forms of maltreatment, a little nuancing would be appropriate. In fact, even if it is true that, according to the self-reported rates, neglect is less frequent than physical abuse, this seems to be an under-representation that may be related to the type of measure used.

We are in agreement with this comment. Therefore, we have added a sentence to the end of para 1 on p.2 to refer to methodological variations across studies.

Again, in relation to incidence, it is not clear why the authors introduce rates from different countries. When it is written that "prevalence rates of CM are even higher in low and middle-income countries…", it is unclear why this is relevant to the current study. Does the critique about the unreliable detection and surveillance in most countries apply to Ireland? The pertinence of this discussion is questionable and it is unclear how it reflects the Irish situation.

Yes, Ireland too has unreliable detection and surveillance systems – we have now indicated this in the first sentence of para 2, p.2.

The authors mention some protective factors of CM: knowledge of parenting, nurturing parenting skills, parental resilience, social network, etc. These are not protective factors, as protective factors must have made the demonstration they can interrupt or interact with risk factors. These may be

viewed as favorable factors or positive factors that MAY prevent CM and promote child well-being.

In light of this comment, we have re-written this section in order to eliminate any confusion over the terms used. For example, we have provided a definition of 'protective factors' plus further information on p.2, para 4, and p.3, para 1.

The most important problem with the introduction is that it does not introduce ChARM, but focuses on the WA model of care. We understand that this model is central as it demonstrates the value of an approach that consist of coordinating services around the family. It would be good to discuss strengths and limitations of this model and the need to incorporate empirically-supported programs in WA care. The authors also introduce Meitheal, another program, also inspired by WA. However, there are very few allusions to ChARM, which leads to some confusion. It seems important to discuss the WA model, however I think the authors need to place the focus more on ChARM and to demonstrate the value of this program. Perhaps the progress of the WA implementation in Ireland and Meitheal could be discussed in the discussion?

We appreciate the above point and we have addressed it by re-locating a paragraph which was originally later in the introduction to earlier (see p. 3, para 2) where the ChARM model is now explicitly mentioned and described. We have also linked the WA model of care which is introduced in the subsequent para, to the ChARM model (see p.3, para 3, opening sentence), whilst also making more explicit references to ChARM at various junctures thereafter (e.g. p.5,; p.6, para 2). We do believe that the discussion of Meitheal is important here as it provides important background /context for the development of the ChARM model. We have now added subheadings for clarity. Please note also that we have followed the HRB Open guidelines when drafting this article; these require that the detailed description of the intervention be provided within the Method section of the paper.

Objectives
Though the objectives are totally relevant, we do have a concern about a specific hypothesis: (1) the ChARM program will reduce parent-reported incidences of child maltreatment. This comment will be detailed in the method, but the administrative data is considered as a secondary outcome, which is not consistent with the introduction.

We have responded to this comment in sections below.

Methods
Since we are now in 2018, and the recruitment was planned for 2015-2017, would it be possible to have an update and the authors to state the exact number of participants they recruited? The authors could then perform post hoc computations of statistical power.

We appreciate why the reviewers would like an update on the study, but given that this is a protocol, we do not believe that it would be appropriate to provide an update on the study within the body of the manuscript. Data collection has just been completed and we have indicated this under the heading 'trial status' on p.15.

There is slight inconsistency in the targeted age of the children. Sometimes it is written 3-10 and sometimes it is 3-11. Please verify.

We apologise for this oversight – this has been amended to the correct age band throughout (3-11 years old) highlighted sections on pp.1, 3, 6, 7, 15, 31 and 32).

In this section, it is said that the ChARM program prevents child maltreatment “within intact families”. We were not sure if the term “intact family” refers to families in which both biological parents are living together or family in which the child is not in out-of-home placement.

The ChARM intervention is evaluating a wraparound-inspired approach to the prevention of child maltreatment with families of children still living in the home. Therefore, we have amended the text accordingly (p.1, para 1; p.3, paras 2 and 4).

The objectives of the study are relevant, clear and precise. However, the first hypothesis is not clear. Why should the parent-reported incidences of child maltreatment decrease? Is it that parents will report having less maltreating behavior after the program?

Yes, we believe that, if the programme is found to be effective, it should help to reduce maltreating behaviour in parents, although we are also aware that this is a difficult outcome to measure due to the need to rely solely on parent report.

The introduction convinced us that the program to be evaluated is a prevention program of maltreatment, implemented in the community with families that are at risk to commit child maltreatment. We were surprised to see that participants were actually followed by child welfare, including some that had already committed child maltreatment. This apparent inconsistency may be due to differences between child protective services in Ireland compared to our system in Quebec (if it is the case, a brief description of CPS in Ireland could help). Or maybe ChARM is not a prevention program but an intervention one.

ChARM has been designed as an early intervention and prevention programme for children still living within the home. This means that whilst it is a prevention programme first and foremost, it may also be used as a form of early intervention for ‘at risk’ families in which there are early signs of child maltreatment ,but where these are not sufficiently severe to warrant placement (as yet) in state care (please see second inclusion criterion on p. 7). As described on p.7 (para 1), social care professionals in Ireland use the Hardiker model to determine the level of risk in the families with whom they work (see Figure 2). From anecdotal evidence, we know that these professionals are reluctant to remove children from their families unless absolutely necessary.

A brief description of Child Protective Services in Ireland is now provided, as requested, on p.5, para 1 (with a new sub-heading also added).

The first and third exclusion criteria seem to be redundant with inclusion criteria.

We understand why this might be perceived as such, but we felt it was necessary to include exclusion criteria points 1 and 3 for purposes of total clarity.

The eligibility criteria for program providers to be part of the study is not precise enough. What do you mean by “considerable experience”? In what capacity are they working within CPS? How much experience is required in order to deliver the components? It could be interesting to quantify

this experience in months/years.

We have revised and added the additional text on the eligibility criteria for program providers on p.7 (penultimate para).

***The most important problem with this protocol is the number of participants to the study. 50 (25+25) over two years, seem to be very few, especially after the authors mention that this is a prevalent problem. If probing practices are implemented in order to reach and engage families, how do you explain such a small n? An analysis of the statistical power is essential. Indeed, we have to know if the number of participants available in your study and the number of outcomes to consider make it possible to reach your goals. It would be disappointing for everyone that you come to the conclusion that you cannot state on the effectiveness of ChARM since your negative results are due to insufficient statistical power.

This will probably not be enough to test moderations. You state that 150 families would be necessary in order to detect a 0,8 effect size, which is quite big for this population and this context. Are you willing to accept that with 50, you wouldn't detect a 0.8 effect size? I read that the authors are aware of this problem. But we think they really need to find solutions.

Yes this is a problem in many 'real world' trials of this nature. We have encountered many difficulties and challenges beyond our control in the design and development of this study. Most notably, a major restructuring of services and staff within the Tusla Child and Family Agency (with whom we are working) took place at the same time as the study was being designed and we met with subsequent difficulties in securing collaborating sites. This hugely affected our projected recruitment and proposed sample size, with the result that the sample is much smaller than originally anticipated (or calculated). This small sample size also reflects the challenges inherent more generally in recruiting families with high needs to research programmes (Horowitz et al. 2002). Furthermore, we realise that 150 families is, by any standards, very large and it is debatable as to whether or not we would have achieved that number, had everything gone according to plan in terms of our collaborating sites and projected recruitment.

Having said that, we are reluctant to abandon the trial at this point and it has become a more exploratory piece. At a minimum, we will obtain very useful information on these vulnerable families in terms of their profile and outcomes over time. Furthermore, we have an embedded process evaluation which, we believe will yield very interesting results on the implementation of these kinds of programmes, barriers/challenges to implementation and how they might be improved.

Since the protocol is so complete, we are interested to know more about the way contamination will be measured and controlled statistically if needed.

We are unsure if the reviewers are referring to contamination of the research team to treatment condition (i.e. unblinding) or contamination of the control group (i.e. where the control group receive some or all of the intervention). Regarding the former, issues relating to potential unmasking are described in the randomisation and blinding section (p.9). Potential contamination of the control group is also addressed on p.9, para 2 ('Contamination' Section). As noted in the manuscript, to reduce the threat of contamination, practitioners delivering the intervention will not be involved in delivering

usual services to control group participants. After intervention delivery, we will also ask practitioners to report whether any contamination of the control group occurred. Relevant statistical controls are also described (see p.9).

In addition, the Service Utilisation Questionnaire will provide information on if/and how contamination has occurred by eliciting information on the various 'in-house' and other services used/accessed by parents since the date of entry into the study.

Since the age of the children show a wide range, what program is used from IY? The preschool or the school age basic program?

The Incredible Years school age Basic Programme will be used. This is delivered in two-hour, weekly group sessions over 14 weeks.

We would like to know more about the name and number of "subscales" for each measure used. Could you also give some information on the psychometric value of the selected tools? I also notice that these are several measures for very few participants. What correction are you planning to use to compensate, knowing that Bonferroni is relatively conservative... In addition, I invite the researchers to question the potential impact of the number of measures on the recruitment of participants. Indeed, the number of questionnaires provided in the protocol could have an impact on the possibility of generalizing the results to all the very vulnerable parents who would have refused to participate in the research.

Furthers details on the scales and subscales for each measure that will be used in this study are now provided in the supplementary material (p.25). We have also added a new para on p.11 (para 2) to address this point.

We acknowledge that the number of measures which participants are required to complete may be time-consuming and there is the potential that this may deter vulnerable parents to refuse to participate in the research. However, we have used multiple test batteries in our previous (and current) work with vulnerable parents and children and this has not affected our recruitment (or retention) rates which have remained strong. We are acutely aware of the issue of participant burden and we have endeavoured to address this in detail as part of our ethical approaches and procedures as outlined in the ethics application pertaining to this study (which was approved by the Maynoooth University Social Research Ethics Sub-Committee. For instance, care will be taken to minimise participant burden where possible and it is estimated that individual data collection sessions will take approximately 40-60 minutes, although this is likely to vary across participants depending on their level of literacy. Breaks will also be provided as and when required and an additional visit made at a later date if necessary, in order to complete data collection. It has been our experience that families (both vulnerable and otherwise) enjoy meeting with a researcher and that, at times, there may also be therapeutic benefits for the families concerned (McGilloway et al. 2012).

We appreciate the potential statistical challenges of using multiple outcome measures, but we are also aware that this is not straightforward and also quite a controversial issue. Firstly, we have selected only two primary outcomes against which we will test our main hypotheses. Secondly, with regard to the other findings, we will follow the guidelines suggested by Feise (2002). Thus, we will evaluate the quality of study and the amplitude

(effect size) of all findings before interpreting their statistical significance whilst also referring to other studies in the literature. In addition, we will regard the findings as tentative until they are corroborated. According to Feise, "a single study is most often not conclusive, no matter how statistically significant its findings". This is particularly so here in view of the exploratory nature of the study.

The WAI is used to measure the capacity to engage parents. This is known to be a measure of working alliance. There is at least two versions of this questionnaire: parent and therapist. Why not use the parent version? Furthermore, when is it going to be completed? Some researchers have shown that the validity of this measure and its capacity to detect relevant working alliance is at its best around the third meeting. We invite the authors to have a discussion about this question of timing.

We will be administering both versions of the WAI in the process evaluation of ChARM – the practitioner and parent versions – in order to assess practitioner –parent relationships. Table 2 (p.31) has been amended accordingly in order to avoid any confusion. We appreciate the point in relation to the optimal validity of the measure at the third meeting; in this case, the WAI will be completed upon completion of the IY programme at which stage, both the parents and practitioners will have established and built up a relationship, having been in contact for 18 weeks in total (4 weeks PLSP, 14 IYPP). This should allow us to detect a meaningful working alliance.

We wonder why you presented maltreatment report by parents as a primary outcome, and CPS report of maltreatment as a secondary outcome. We believe that because the parents are followed in CPS, which is a pretty coercive context, they could be tempted to give answers to their advantage which can cause a social desirability bias to this outcome. That is why we also suggest the use the official CPS report of maltreatment in combination to the parent-reported maltreatment as primary outcomes.

Ideally, we would have preferred to have used CPS reports of maltreatment as our primary outcome and indeed, we explored this in our initial discussions with the service providers. However, we understand that this information is not routinely recorded in Ireland, nor is it always accurate. There were attendant concerns around confidentiality/accessibility by the research team. For this reason, we selected parent-reported incidences of child maltreatment (assessed using he Conflict Tactics Scales Parent-Child – Short Form Amended (CTSPC – SFA) (Straus et al. 1998), as our primary outcome alongside child behaviour and wellbeing as the second primary outcome (assessed using both the parent- and child-report versions of the Strengths and Difficulties Questionnaire (SDQ) (Goodman 1997)).

However, we are aware that there is likely to be some degree of socially desirable responding by parents on the former and indeed, this has also been reported in other research (Hurlburt et al 2013). Therefore, we hope to address this, at least indirectly, through interviews with the practitioners who are working with the families and who have access to their records. At a minimum, we hope to be able to ascertain the existence of any out-of-home placements that may have occurred during the study (as a secondary outcome).

It is a very interesting idea to have interviews with those who abandon the program. I wonder how

they will be recruited. If they do not agree to go through the program, it is not very likely that they will accept the go further with the research process. In addition, those who could accept would have specific characteristics to be considered.

We acknowledge that parents who have dropped out of the programme may refuse to subsequently speak to a researcher, but we have used this approach successfully in our previous research (e.g. Furlong and McGilloway, 2014). All parents will be asked to provide their written informed consent to agree to be contacted by the research team irrespective of whether or not they complete the ChARM programme. We also provide a small shopping voucher as a 'thank you' to all participants for taking part in interviews/assessments. With regard to the characteristics of 'leavers' who are willing to be involved in research, in our previous work, we recruited 'drop-out' parents purposively using a range of criteria , such as age, marital status, age of the child, location etc. This enabled us to recruit a heterogeneous sub-sample and to sidestep, for the most part, the issue of response bias.

We are also very satisfied that the fidelity of implementation of the program that is described in this study. However, we question the validity of using it as a moderator, because to be eligible as a moderator, a variable should respect criteria of temporal precedence and independence with the program (Kraemer, Kiernan, Essex & Kupfer, 2008).

We understand that it is desirable for moderator variables to be uncorrelated with both the predictor and criterion variables, but here, we believe that the 'site readiness' aspect of programme fidelity is an important situational factor/element of the environment or context in which the model will be delivered; thus, it are may legitimately influence the direction and strength of the intervention effect. However, participant engagement (dosage) ought not to have been included here as a moderator, because it is a mediator, hence the confusion. Therefore, we have amended accordingly the relevant section of on p.13, para 3. In addition, we should point out that moderator effects will only be explored if they meet the criteria outlined by Kraemer et al. (2002) and will be carefully chosen given the limited sample size.

Thus, many good ideas, but perhaps not the statistical power to accomplish all this!

We share the reviewers' concerns in relation to the small sample size and a number of other challenges, but we believe that this research is worth pursuing and we will, of course, take care to acknowledge the exploratory nature of the study and its limitations at the time of reporting the findings.

Discussion
Very short. More information regarding the anticipated limitations of the study would be helpful.

As outlined earlier, the research team have followed the guidelines of HRB Open Access in preparing this article and in so doing, the paper adheres to the SPIRIT reporting guidelines which do not stipulate a specific limitations section. However, we have now included some brief information on limitations of the study on p.15, para 2.

Ethics Standards

We appreciated the section about how the authors are planning on complying with ethical standards. This section, like all others, is precise and detailed. It shows the authors' concern to follow best practices in program evaluation with vulnerable clientele.

General
There are some language errors or typos. In the second paragraph, it is written that "In Ireland, over 40,000 referrals of child welfare and abuse cases." I suppose the authors mean abuse and neglect cases?...

No, this is not a typo. We are referring to <u>both</u> child welfare concerns and abuse cases here because, in Ireland, data are collected on both together.

On p.5, paragraph starting with "This study involves the evaluation of…" and in the next one starting with "The objectives of the study…", there are many typo problems. Many little "me" are inserted, and I cannot explain why. See the whole text for other problems of this kind.

All of these typos have now been corrected (e.g. on p.6 as highlighted and throughout paper (removal of 'me') (p5., para 4; p.6, paras 3, 4,).

Competing Interests: No competing interests were disclosed.