Implementation Science and Impact Evaluation of PfR Programme: A hybrid cRCT design

Study Protocol

NCT NUMBER:

Date 16/04/2021

Implementation Science and Impact Evaluation of PfR Programme: A hybrid cRCT design - Study Protocol

Section 1 – Administration Information

1. Title - Description

Implementation Science and Impact Evaluation of PfR Programme: A hybrid cRCT design study will use an effectiveness-implementation hybrid type 2 design to a) determine the effectiveness and cost-effectiveness of PfR, and b) determine the feasibility and impact of three different implementation strategies in terms of programme delivery. A cluster randomised controlled trial (cRCT) will examine the effectiveness, cost-effectiveness, and implementation of the Parenting for Respectability (PfR) programme on the reduction of violence against children and gender based violence in comparison to those receiving an hour lecture on parenting in the Wakiso and Amuru districts of Uganda (N = 54 clusters, 2,160 parents, 1,080 children, 1:1 allocation ratio).

2. Trial Registration

Trial will be registered ClinicalTrials.gov

3. Protocol Version

Protocol version: Draft 2021 03 15

4. Funding

This study is funded by the Oak Foundation and Evaluation Fund. Funding covers all evaluation costs including research personnel, data collection, analysis, and dissemination locally, nationally, and internationally.

5. Roles and Responsibilities

Contributors

This Study is a collaboration between the Child Health and Development Centre at Makerere University and the Social and Public Health Sciences Unit at the University of Glasgow. Implementing partners are SOS Uganda.

All authors contributed to the refinement of this study protocol and approved the manuscript.

Dr Godfrey Siu (Child Health and Development Centre, Makerere University): Lead Principal Investigator; overall design, management and coordination, training, obtaining approvals and coordinating knowledge transfer with local stakeholders and potential partners such as Ministry of Gender Labour and Social Development, UNICEF Uganda and the Ministry of Health, as well as members of the Parenting Agenda Consortium.

Version1, 16042021, "Implementation science and impact evaluation of PfR programme: A hybrid cRCT design"

Dr Jamie M. Lachman (Social and Public Health Sciences Unit; University of Glasgow): Co-Principal Investigator; study design, ethics, protocols, data collection and statistical analyses

Ms. Caroline Namutebi (Child Health and Development Centre, Makerere University): Study Coordinator; Develop SOPs, support the collaborators in planning and implementation, tracking the budget and payments, and accountabilities and maintaining study-specific supplies and stationery. Participate in development of materials, train facilitators, observe group sessions and write project reports.

Ms. Brenda Nakafeero (Child Health and Development Centre, Makerere University): Co-Investigator; Provide statistical support to the team.

Joseph Kahwa (Child Health and Development Centre, Makerere University): Trial Manager; Responsible for overall management and conduct of the trial including quantitative and qualitative data collection and management.

Richard Sekiwunga (Child Health and Development Centre, Makerere University): Research Assistant; Conduct fieldwork activities on the project, collect qualitative data with men, and draft manuscripts.

Winifred Nalukenge (Child Health and Development Centre, Makerere University): Research Assistant; Conduct fieldwork activities on the project, collect qualitative data with women and draft manuscripts.

Kenneth Katumba (Child Health and Development Centre, Makerere University): Health Economist; designing, analysing and writing up the costing component

Professor Danny Wight (Social and Public Health Sciences Unit; University of Glasgow): Co-Investigator; consultation as a mentor and advisor on study design, data collection and qualitative data analyses

Sponsor and funder

The funders had no role in the study design and will not have any role during its execution, analyses, interpretation of data, and dissemination of results.

Trials Steering Committee

A Trial Steering Committee (TSC) will be created with the following responsibilities: agreement of the final protocol, advice for lead investigators, verification of ethical procedures, randomisation, data safety and collection, analyses, and dissemination of results. They will also be responsible for making recommendations regarding continuation, termination, or modification of the project.

Section 2: Introduction

6. Background and rationale

Intimate partner violence (IPV) and violence against children (VAC) are interlinked and are major social, development and public health concerns. Globally it is estimated that approximately 30% ever-partnered

Version1, 16042021, "Implementation science and impact evaluation of PfR programme: A hybrid cRCT design"

women worldwide have experienced physical and/or sexual violence by an intimate partner at some point in their lives [1]. IPV prevalence among women in Uganda is very high. The Uganda Demographic and Health Survey 2018 found that 36% of women had ever experienced partner physical violence, while 22% had ever experienced partner sexual violence [2]. Violence against children is extremely widespread globally, with approximately half of all children – one billion aged 2-17 years – reporting having experienced violence in the past year [3]. Furthermore, one in five women and up to one in ten men have been victims of sexual violence in childhood [2]. The Uganda national VAC survey 2015 found that 59% girls and 68% boys had experienced physical violence in their childhood, and 35% girls and 17% boys had experienced sexual violence in their childhood [4]. Such violence in Uganda and most Sub-Saharan African countries is usually perpetrated by people known to children in their homes and community [4, 5]. IPV and VAC are major causes of morbidity and mortality, they undermine the social functioning of the victims and their families, and have lifetime consequences for physical, sexual, reproductive and mental health [6, 7]. The prevention of both forms of violence would contribute to many Sustainable Development Goals since they strain health systems, lower educational achievement and economic productivity, and undermine economic and social development, [6, 8, 9] and elimination of IPV is essential to Goal Five.

Many studies confirm the link between VAC and IPV, suggesting the need for an integrated approach to their prevention. A recent narrative review identified six ways in which they are interrelated [10]: they have many shared risk factors, starting in the family; social norms legitimise both and discourage children and women from seeking help; both often occur within the same household [10, 11, 12]; both can be transmitted across generations; they can have similar consequences across the lifespan, and finally, both intersect in adolescence, a time of heightened vulnerability to violence.

Factors perpetuating IPV and VAC exist at multiple socio-ecological levels. For IPV, familial level factors include having been abused as a child, having an absent or rejecting father, inter-partner conflict, and male control of wealth and decision-making. Community level factors include women's isolation and male peer groups that legitimize men's violence. At the macro level IPV is associated with cultural norms that condone violence within the family, schools and community, establish rigid gender roles and link masculinity to toughness, male honour, dominance and ownership of women, and it thrives where policy, legislation and implementation of laws is weak [11]. VAC is more likely in families that have difficulties developing stable, warm and positive relationships [6], where parents are unresponsive to their children, have harsh or inconsistent parenting styles, believe that corporal punishment is an acceptable form of discipline [13] or have a poor understanding of child development, and therefore unrealistic expectations about the child's behaviour (8).

Recognizing that IPV is perpetuated at multiple levels [11, 12], preventative interventions often focus on other psychosocial problems, e.g. poverty or alcohol abuse, as well as on inter-partner violence, although they are more effective if their main aim is to reduce IPV [13]. The shared familial risk factors for IPV and VAC, and the increasing policy interest in optimizing parenting influence, provides a great opportunity for early intervention. An increasing number of parenting programs are being implemented and tested in LMICs to reduce VAC [14], and evidence is emerging that, if delivered by trained lay workers, they can be effective in improving child outcomes [15, 16]. However, interventions directly addressing early prevention of both IPV and VAC in LMICS remain limited [17].

Version1, 16042021, "Implementation science and impact evaluation of PfR programme: A hybrid cRCT design"

Furthermore, very few parenting programs in LMICs harness cultural drivers and pre-existing motivations to change behaviour. In sub-Saharan Africa little attention has been paid to one of the most important dimensions of parenthood for both mothers and fathers: the need to maintain the family's respectability, in large part achieved through the appropriate behaviour of the children and their parents [18, 19]. This core motivation might be harnessed in the design of interventions to reduce spousal violence, modify negative parenting and encourage sensitive parenting, in order to reduce children's future risk of sexual, physical and/or emotional violence. In Uganda, we are not aware of parenting programs that deliberately recruit parental couples to complete both single and mixed sex sessions. We therefore designed a community-based parenting program, – *Parenting for Respectability (PfR)*, – to address this gap in Uganda, and contribute evidence on how a parenting program can address both IPV and VAC. Following careful formative evaluation [20] we conducted a pre-post study to establish whether there was sufficient evidence of effectiveness to warrant progression to a randomized controlled trial.

The programme has undergone formative evaluation (2014-16), 'Proof of Concept' pre-post outcome evaluation (2016-2019), and with support from Evaluation Fund, is currently being evaluated to assess implementation and scale-up modalities (April 2020-October 2021) in central Uganda. The investment in developing PfR so far has provided important lessons about the acceptability of PfR and how to refine it. Preliminary outcome evidence suggests that a rigorous evaluation of PfR is warranted. The pre-post study has found significant change across primary outcomes for both parent- and child-reports, including large effects for reduced harsh parenting (Cohen's $f^2 = 0.42$, p < .001) and dysfunctional spousal relationships (Cohen's $f^2 = 0.28$, p < .001), as well as increased positive parenting (Cohen's $f^2 = 0.48$, p < .001). The programme has been disseminated widely in Uganda (www.parenting.ug.org), and both government and NGOs have expressed interest to scale it. However, two key uncertainties remain: (i) the optimal way to scale up the intervention in a 'real-world setting', and (ii) whether the evidence of effectiveness would be confirmed through a more rigorous, experimental, evaluation. As a result, this study will combine a rigorous cluster randomised control trial (cRCT) evaluation of PfR with an implementation study using a hybrid type 2 design to examine its effectiveness and cost-effectiveness as well as answer critical contextually relevant implementation science questions. This is essential to ensure that precious resources are not wasted and that there are no harmful unintended consequences from the programme.

7. Objectives and hypotheses

Overall goal

The overall objective of this study is to conduct a cRCT evaluation of PfR to test its effectiveness and cost-effectiveness for reducing violence against children and gender based violence.

Secondary outcomes include child-reported harsh parenting and partner conflict, positive parenting, parental support for children's education, child behaviour problems, parent/child mental health problems, material provision for children (all parent- and child-report), and inequitable gendered socialization.

Combined with an embedded nonrandomised factorial experiment, we will also examine implementation realities in two different geographical settings of Uganda.

Objectives

- 1. Test the effectiveness of PfR in modifying key outcomes on parent-child relationships and relationships between partners which underlie violence against children and girls/women. The trial will be powered to detect meaningful change in four primary outcomes: parent-reported and child-reported harsh parenting and partner conflict. Secondary outcomes include positive parenting, parental support for children's education, child behaviour problems, parent/child mental health problems, material provision for children (all parent- and child-report), as well as inequitable gendered socialisation and parenting self-efficacy, including protecting children from sexual abuse (parent-report only).
- 2. Examine the cost effectiveness of PfR using incremental cost-effectiveness analyses (CEA) based both on the primary outcomes of harsh parenting and partner conflict as well as on disability-adjusted life years (DALYs);
- 3. Examine how three implementation variables rural vs peri-urban locality, previously established groups vs new groups, and professional vs non-professional facilitators affect participation, programme fidelity, and quality of delivery (measured quantitatively);
- 4. Examine the impact of implementation variables participant engagement and quality of delivery by facilitators on primary outcomes of parent- and child-report of harsh parenting and partner conflict. We will also examine associations between baseline characteristics and participant engagement to further understand potential barriers to participation and whether there are particularly vulnerable families that have greater challenges in attending the programme.
- 5. Qualitatively investigate five elements of implementation: (i) what training facilitators need (length, follow-up, who delivers training, location, etc.); (ii) what supervision facilitators need (frequency, by whom, nature of feedback, etc.); (iii) targeting of PfR at the most vulnerable families and how this can be done; (iv) disseminating PfR's messages beyond those participating in group sessions to operate at a community, as well as individual, level; (v) differences between Wakiso and Amuru Districts in facilitative and hindering contextual factors. We will explore how these affect participation, programme fidelity, quality of delivery, participant response and community-wide impact.

<u>Hypotheses</u>

Hypothesis 1: PfR will significantly reduce rates of child maltreatment at 3-months follow-up, as measured by parent and child-reports of the ICAST-Trial Scale, in comparison to a control group receiving a one-hour lecture on parenting and partner relationships.

Hypothesis 2: PfR will significantly reduce rates of partner conflict at 3-months follow-up, as measured by parent and child-reports of an adapted version of the Conflict Tactics Scale and WHO Coercion scale, in comparison to a control group receiving a one-hour lecture on parenting and partner relationships.

Hypothesis 3: PfR will have a significant effect on secondary outcomes associated to the risk violence against children and intimate partner violence at 3-months follow-up, including positive parenting,

Version1, 16042021, "Implementation science and impact evaluation of PfR programme: A hybrid cRCT design"

parental support for children's education, child behaviour problems, parent/child mental health problems, and material provision for children (all parent- and child-report), as well as inequitable gendered socialisation and parenting self-efficacy, including protecting children from sexual abuse (parent-report), in comparison to a control group receiving a one-hour lecture on parenting and partner relationships.

Hypothesis 4: PfR will be cost-effective in terms of incremental cost-effectiveness analyses (CEA) based both on the primary outcomes of harsh parenting and partner conflict as well as on disability-adjusted life years (DALYs).

Hypothesis 5: We hypothesise that the following modalities of PfR delivery on implementation outcomes and cost (i.e., attendance, competent adherence, and cost-effectiveness):

- *A)* Geographical location (urban vs peri-urban). We hypothesise that there will be no difference between urban and peri-urban delivery on implementation and cost outcomes. While families living in higher density areas may have more accessibility to other support services, rural families may be easier to recruit due to closer inter-family dynamics.
- B) Group composition (existing vs new). We hypothesise that recruitment from existing community groups (e.g., microfinance savings groups) will have higher levels of implementation and more cost-effective than newly formed groups. Higher participation rates will, in turn, result in reductions VAWC (via indirect effects).
- C) Facilitator Experience (professional vs community). We hypothesise that although professional facilitators may achieve higher levels of implementation, community facilitators may be a more cost-effective approach and may also result in better implementation due to stronger buy-in at the community level. As a result, there will be no difference between components on VAWC (via indirect effects).

8. Trial design

We will use an effectiveness-implementation hybrid type 2 design to a) determine the effectiveness and cost-effectiveness of PfR, and b) determine the feasibility and impact of three different implementation strategies in terms of programme delivery. [21] We will conduct a cluster randomised controlled trial (cRCT) in a total of 54 clusters (1:1 intervention: control; 4 groups of 10 parents per cluster, 50% male 50% female, 2,160 in total or 1,080 adult participants per arm). In addition, approximately 1,080 children 10-14 years will be assessed (N = 540 per arm). We will also assess the quality of delivery of PfR in terms of competent adherence of 108 facilitators (1 per group, 4 per cluster).

We will also examine three different factors related to programme implementation within the clusters allocated to PfR (approximately 27 clusters, 40 parents per cluster): 1) geographical location (rural vs. peri-urban), 2) group composition (existing vs. newly formed groups), and 3) facilitator experience (experience vs. novice). Efforts will be made to have equal numbers of clusters receiving each type of component by testing every combination of implementation components in eight different experimental conditions (*N* 3 clusters and 120 families per condition).

Version1, 16042021, "Implementation science and impact evaluation of PfR programme: A hybrid cRCT design"

Section 3: Methods

9. Study setting

The study will be conducted in two districts, Wakiso and Amuru, each of them contributing parental participants to both intervention and control arms. Participating clusters will either be villages or wards (i.e., groups of villages) depending on their population side and geographical proximity.

10. Eligibility criteria

Participants must have provided written, informed consent prior to the occurrence of any study procedures.

Inclusion criteria for participating parents or caregivers:

- 1. Age 18 or older;
- 2. Primary caregiver responsible for the care of a child between the ages of 10 and 14;
- 3. Agreement to participate in the PfR programme if allocated to the treatment condition;
- 4. Provision of consent to participate in the full study.

Inclusion criteria for participating children:

- 1. Age 10 to 14 years;
- 2. Live in the same household as primary caregiver who is part of PfR study;
- 3. Parent/caregiver gives consent to participate in the study;
- 4. Provision of consent to participate in the full study.

Inclusion criteria for facilitators:

- 1. Age 18 or older;
- 2. Facilitator who is involved in the delivery of the Parenting for Respectability programme;
- 3. Provision of consent to participate in the full study.

We will also conduct interviews with community development service officials and local leaders involved in the delivery of PfR. They will have the following inclusion criteria:

- 1. Age 18 or older;
- 2. Involvement in delivery of PfR, or existing leadership role in communities where PfR is delivered;
- 3. Provision of consent to participate in the full study.

11. Recruitment

This study will rely on SOS Uganda and local municipal staff to identify target clusters (i.e., villages or sub-villages) for recruitment in the study. We will first obtain community-level consent from community leaders to conduct the study. Potential parents will then be recruited from each cluster. We aim to recruit men as much as women, and will include equal numbers to receive the intervention, regardless of age.

Version1, 16042021, "Implementation science and impact evaluation of PfR programme: A hybrid cRCT design"

By deliberately recruiting fathers, the project addresses the recurrent concern about lack of male involvement. The structure of the programme begins with single sex sessions, followed by mixed sex sessions, allowing men and women discuss sensitive issues initially without worrying of the perspectives of the other gender. We will randomly select one child between the ages of 10 and 14 per household to participate in the study, though not the intervention which is only delivered to adults.

Informed consent procedures will be administered by trained and supervised research personnel both verbally and in writing to account for low-literacy rates. They will be thoroughly trained and supervised by the co-principal investigators and co-investigators on recruitment, informed consent, and assessment procedures.

12. Randomisation

Randomisation in the cRCT will be conducted at the cluster level immediately after baseline data collection. Clusters allocated to the control group will receive a two-hour lecture. We will use concealed computer-generated codes to randomly allocate the 54 clusters. An external researcher not directly involved in the study performed random allocation of clusters from a remote site. SOS will notify the participating village and ward leaders, and families of their allocation status after baseline data collection is completed in order to assure that participants are blind to allocation during the initial assessment. The allocation status of other participating clusters will be concealed from selected villages, thus reducing the potential for inter-village rivalries. Although research assistants conducting data assessments will be blind to allocation at baseline, due the nature of the interventions it will be difficult to maintain blindness at follow-up assessments.

13. Power calculations

We conducted *sensitivity* power analyses in order to calculate minimum detectable the Incidence Risk Ratios necessary to obtain a significant intervention effect in the cRCT based on both adult- and child-reported primary outcomes of harsh parenting and parental conflict. Using two-tailed Poisson regression mixed-level models, we assumed a Type I error of p < 0.05, 80% power, and a 1:1 intervention to control ratio with an estimated 12.5% dropout rate (i.e., 6 clusters), 24 clusters (960 adults and 480 children) in each allocation group, or 48 clusters in total. We also assumed an intra-cluster correlation ICC = 0.05 to account for clustering. Even though we are using an intention-to-treat design using maximum likelihood estimation to account for missing data, we increased the final estimated sample size to N = 54 clusters or 2,160 parents and 1,080 children at baseline to account for at least a 12.5% study dropout of clusters (i.e., 6 clusters). Thus, this sample size has sufficient power to detect significant intervention effects (group differences) at IRR = 0.48 for adult-report and IRR = 0.58 for child report (i.e., 30% and 33% reduction, respectively).

For the evaluation of implementation components, we conducted similar sensitivity power analyses in order to calculate the minimum detectable Cohen's D effect size to obtain a significant effect of each component level on implementation outcomes of participation rates and implementation quality. Following recommendations for component selection by Collins et al. (2016) and Watkins et al. (2016), we assumed a Type 1 error of p < 0.10, and 80% power with a sample size of 480 adults and an ICC of

Version1, 16042021, "Implementation science and impact evaluation of PfR programme: A hybrid cRCT design"

0.05. Thus, this sample size has sufficient power to detect significant component effects at Cohen's d = .26 on implementation outcomes (i.e., implementation fidelity, competent adherence, and participation).

14. Interventions

<u>Intervention group – Parenting for Respectability</u>

PfR was developed over five years following the Six Steps for Quality Intervention Development (6SQuID) model [22]. It initially underwent formative evaluation over two years (2014-2016) with six groups in three villages in Wakiso District [20]. *PfR* is a 16-session manualised programme starting with nine single sex sessions followed by seven mixed sex sessions, delivered once a week by two local facilitators who receive one week's training [23]. The programme draws on parents' pre-existing motivation to maintain respectability, largely achieved through children's good behaviour and respect for elders and builds on parents' existing skills and experience. Activities were developed specifically for PfR or adapted from other parenting programs, including *Project H*, *Stepping Stones*, *Mema kwa Jamii*, the *International Child Development Programme* and *Parenting for Lifelong Health* [24]. The programme addresses four familial processes associated with GBV and VAC: poor parental bonding and child attachment; harsh parenting; inequitable socialisation by gender and parental conflict. A particular goal is to involve fathers, whom most parenting programmes find hard to recruit, and the first nine sessions are delivered in single-sex groups. The intervention's rationale, program theory and formative evaluation are described elsewhere [25].

Control group - Lecture

Parents allocated to the control arm will receive a two-hour structured lecture called *Parenting in a Nutshell* on parenting and partner relationships. Three topics will be covered: 1) child development; 2) positive parenting; and 3) resolving partner conflicts. Facilitators delivering this lecture will have same/similar expertise with the facilitators engaged in PfR. Their training will consist of two-hour course on how to deliver the lecture.

15. Outcomes measurements

All outcomes of intervention effectiveness will be measured at baseline, 8-months post-baseline, and 12-months post-baseline. Demographic measures will only be measured at baseline. All measures will be translated into Luganda for Wakiso and Acholi for Amuru and back-translated to check the accuracy of the translation

Primary outcomes

Child maltreatment - physical and emotional abuse: ISPCAN Child Abuse Screening Tool-Trial Parent (ICAST-TP) - Parent Report

Child maltreatment will be measured using an adapted version of the <u>ISPCAN Child Abuse Screening Tool-Trial</u> scale (17 items, ICAST-Trial) [26]. The original version of the ICAST-Trial was reduced from 19 items for caregivers and 27 items for adolescents to increase study feasibility due to the scale of the study. Respondents will report on the overall frequency of maltreatment during the past month as

well as for subscales on physical abuse (10 items; e.g., "In the past 4 weeks, how often did you discipline your child by spanking, slapping or hitting with your hand") and emotional abuse (7 items; e.g., "In the past 4 weeks, how often did you say things to shame your child in front of other people?"). Each item ranges from 0 to more than 8 times and is summed to assess frequency of overall abuse as well as for each individual subscale.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Child maltreatment - physical and emotional abuse: ISPCAN Child Abuse Screening Tool-Trial Parent (ICAST-TC) - Child Report on Male Parent Figure

Child maltreatment will be measured using an adapted version of the <u>ISPCAN Child Abuse Screening Tool-Trial</u> scale (13 items, ICAST-Trial) [26]. The original version of the ICAST-Trial was reduced from 27 items for adolescents to increase study feasibility due to the scale of the study. Child respondents will report on the overall frequency of maltreatment for male caregivers during the past month as well as for subscales on physical abuse (5 items; e.g., "In the past month, how often did your male parent figure hit, beat, or spank you with a hand?") and emotional abuse (8 items; e.g., "In the past month, how often did your male parent figure in your household insult you, say mean things to you or swear at you?"). Each item ranges from 0 to more than 8 times and is summed to assess frequency of overall abuse as well as for each individual subscale.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Child maltreatment - physical and emotional abuse: ISPCAN Child Abuse Screening Tool-Trial Parent (ICAST-TC) - Child Report on Female Parent Figure

Child maltreatment will be measured using an adapted version of the <u>ISPCAN Child Abuse Screening Tool-Trial</u> scale (13 items, ICAST-Trial) [26]. The original version of the ICAST-Trial was reduced from 27 items for adolescents to increase study feasibility due to the scale of the study. Child respondents will report on the overall frequency of maltreatment for female caregivers during the past month as well as for subscales on physical abuse (5 items; e.g., "In the past month, how often did your female parent figure hit, beat, or spank you with a hand?") and emotional abuse (8 items; e.g., "In the past month, how often did your female parent figure in your household insult you, say mean things to you or swear at you?"). Each item ranges from 0 to more than 8 times and is summed to assess frequency of overall abuse as well as for each individual subscale.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Intimate partner violence - perpetration: Revised Conflict Tactics Short Form - Parent Report

Perpetration of intimate partner violence (parent-report) will be measured using adapted versions of the Revised Conflict Tactics Scale Short Form (6 items; CTS2S) [27]. We will perpetration of emotional and physical violence against an intimate partner (e.g., "How often did you insult or shout or yell or swear at

Version1, 16042021, "Implementation science and impact evaluation of PfR programme: A hybrid cRCT design"

your partner?") over the past 30 days. Each item ranges from 0 to more than 8 times and is summed for total scores of partner conflict perpetration.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Intimate partner violence - victimisation: Revised Conflict Tactics Short Form - Parent Report

Intimate partner violence victimisation (parent-report) will be measured using adapted versions of the Revised Conflict Tactics Scale Short Form (6 items; CTS2S) [27]. We will assess victimisation of physical and emotional intimate partner violence (e.g., "How often did your partner insult or shout or yell or swear at you?") over the past 30 days. Each item ranges from 0 to more than 8 times and is summed for total scores of partner conflict victimisation.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Partner conflict: Revised Conflict Tactics Short Form – Child Report

Partner conflict will be based on two items assessing dysfunctional adult relationships in the household (e.g., "Your parents/carers or any other adults in your household quarrelled or had verbal arguments with each other"). Children will report on how typically each behaviour occurs over the past 30 days based on a Likert scale ranging from 0=Never= to 3=Often. Items will be summed to create a total score.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Secondary outcomes

Child physical abuse: ISPCAN Child Abuse Screening Tool-Trial Parent (ICAST-TP) - Parent Report

Child physical abuse will be measured using an adapted version of the <u>ISPCAN Child Abuse Screening Tool-Trial</u> scale (7 items, ICAST-Trial) [26]. Respondents will report on the frequency of physical abuse during the past month (e.g., "In the past 4 weeks, how often did you discipline your child by spanking, slapping or hitting with your hand") Each item ranges from 0 to more than 8 times and is summed to assess frequency of physical abuse.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Child physical abuse: ISPCAN Child Abuse Screening Tool-Trial Parent (ICAST-TC) - Child Report on Male Parent Figure

Child physical will be measured using an adapted version of the <u>ISPCAN Child Abuse Screening Tool-Trial</u> scale (5 items, ICAST-Trial) [26]. Child respondents will report on the frequency of physical abuse by male parent figures during the past month (e.g., "In the past month, how often did your female/male parent figure hit, beat, or spank you with a hand?"). Each item ranges from 0 to more than 8 times and is summed to assess frequency of physical abuse.

Version1, 16042021, "Implementation science and impact evaluation of PfR programme: A hybrid cRCT design"

Child physical abuse: ISPCAN Child Abuse Screening Tool-Trial Parent (ICAST-TC) - Child Report on Female Parent Figure

Child physical will be measured using an adapted version of the <u>ISPCAN Child Abuse Screening Tool-Trial</u> scale (5 items, ICAST-Trial) [26]. Child respondents will report on the frequency of physical abuse by female caregivers during the past month as well as for subscales on physical abuse (e.g., "In the past month, how often did your female/male parent figure hit, beat, or spank you with a hand?"). Each item ranges from 0 to more than 8 times and is summed to assess frequency of physical abuse.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Child emotional abuse: ISPCAN Child Abuse Screening Tool-Trial Parent (ICAST-TP) - Parent Report

Child emotional abuse will be measured using an adapted version of the <u>ISPCAN Child Abuse Screening Tool-Trial</u> scale (10 items, ICAST-Trial) [26]. Respondents will report on the frequency of emotional abuse during the past month (e.g., "In the past 4 weeks, how often did you say things to shame your child in front of other people?"). Each item ranges from 0 to more than 8 times and is summed to assess frequency of emotional abuse.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Child emotional abuse: ISPCAN Child Abuse Screening Tool-Trial Parent (ICAST-TC) - Child Report on Male Parent Figure

Child emotional abuse will be measured using an adapted version of the <u>ISPCAN Child Abuse Screening Tool-Trial</u> scale (8 items, ICAST-Trial) [26]. Child respondents will report on the frequency of emotional abuse by male caregivers during the past month (e.g., "In the past month, how often did your female/male parent figure in your household insult you, say mean things to you or swear at you?"). Each item ranges from 0 to more than 8 times and is summed to assess frequency of emotional abuse.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Child emotional abuse: ISPCAN Child Abuse Screening Tool-Trial Parent (ICAST-TC) - Child Report on Female Parent Figure

Child emotional abuse will be measured using an adapted version of the <u>ISPCAN Child Abuse Screening Tool-Trial</u> scale (8 items, ICAST-Trial) [26]. Child respondents will report on the frequency of emotional abuse by female caregivers during the past month (e.g., "In the past month, how often did your female/male parent figure in your household insult you, say mean things to you or swear at you?"). Each item ranges from 0 to more than 8 times and is summed to assess frequency of emotional abuse.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Version1, 16042021, "Implementation science and impact evaluation of PfR programme: A hybrid cRCT design"

Child neglect – Parent Report

Child neglect will be measured using an adapted version of the <u>ISPCAN Child Abuse Screening Tool-Trial</u> scale (2 items, ICAST-Trial) [26]. Parents will report on the frequency of withholding basic child essentials from their children (e.g., "In the past month, how often did you withhold a meal to punish your child?"). Each item ranges from 0 to more than 8 times and is summed to assess frequency of neglect.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Child neglect – Child Report

Child neglect will be measured using an adapted version of the <u>ISPCAN Child Abuse Screening Tool-Trial</u> scale (4 items, ICAST-Trial) [26]. Child respondents will be asked about the frequency their parent figures withheld basic child essentials from their children (e.g., "In the past month, how often did your male parent figure withhold a meal to punish you?"). Each item ranges from 0 to more than 8 times and is summed to assess frequency of neglect.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Community physical and sexual violence – Child Report

Children's experience of *physical and sexual violence in the community* in the past month will be based on one item (e.g., "In the past month, how often did adults in your community such as teachers, employer religious or community leaders, neighbours and other adults kick, punch, beat or threaten you with a knife or any other weapon physically?" and "In the past month, how often did adults in your community such as neighbours, employers, teachers, religious or community leaders, do any sexual things to you?"). Responses will be based on a Likert scale ranging from 0=Never to 3=Often. If the child responds affirmatively, then they will be asked whether or not they sought help, and if not, the reason for not seeking assistance.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Child sexual abuse: ISPCAN Child Abuse Screening Tool-Trial Parent (ICAST-TC) - Child Report

Child sexual abuse will be measured using an adapted version of the <u>ISPCAN Child Abuse Screening Tool-Trial</u> scale (10 items, ICAST-Trial) [26]. Child respondents will report on whether they experience different forms of sexual abuse in the past month (e.g., "Has anyone made a video or cell phone video of you doing sexual acts?" 0 = No, 1 = Yes). The scale will be summed and then a dichotomous variable will be created based on incidence of any form of sexual abuse.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Version1, 16042021, "Implementation science and impact evaluation of PfR programme: A hybrid cRCT design"

Intimate partner coercion - perpetration: WHO Coercion Scale - Parent Report

Intimate partner coercion perpetration (parent-report) will be measured using an adapted version of the WHO questionnaire on women's health and life events (10 items; WHO-Coercion) [28]. We will assess victimisation of coercion over the past 30 days (e.g., "How often did you refuse to give your partner money for household expenses, even when you had money for other things?"). Each item ranges from 0 to more than 8 times and is summed for a total score of perpetration of coercion.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Intimate partner coercion - victimisation: WHO Coercion Scale - Parent Report

Intimate partner coercion victimisation (parent-report) will be measured using an adapted version of the WHO questionnaire on women's health and life events (10 items; WHO-Coercion) [28]. We will assess victimisation of coercion over the past 30 days (e.g., "How often did your partner refuse to give you money for household expenses, even when they had money for other things?"). Each item ranges from 0 to more than 8 times and is summed for a total score of victimisation of coercion.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Intimate partner psychological aggression - perpetration: Revised Conflict Tactics Short Form - Parent Report

Psychological aggression reetratopm (parent-report) will be measured an adapted version of the Revised Conflict Tactics Scale Short Form (2 items; CTS2S) [27]. We will assess perpetration of psychological aggression by respondents over the past 30 days (e.g., "How often did you insult or shout or yell or swear at your partner?"). Each item ranges from 0 to more than 8 times and is summed for a total scores for perpetration of psychological aggression.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Intimate partner psychological aggression - victimisation: Revised Conflict Tactics Short Form - Parent Report

Psychological aggression victimisation (parent-report) will be measured using an adapted version of the Revised Conflict Tactics Scale Short Form (2 items; CTS2S) [27]. We will assess victimisation of psychological aggression from partners over the past 30 days (e.g., "How often did your partner insult or shout or yell or swear at you?"). Each item ranges from 0 to more than 8 times and is summed for a total scores for victimisation of psychological aggression. If the respondent answers that this did not occur during the past month, two follow-up items will assess whether or not the behaviour occurred within the previous 6 months, and whether the perpetrator was the respondent's current partner.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Version1, 16042021, "Implementation science and impact evaluation of PfR programme: A hybrid cRCT design"

Intimate partner physical aggression - perpetration: Revised Conflict Tactics Short Form - Parent Report

Physical aggression perpetration (parent-report) will be measured using an adapted version of the Revised Conflict Tactics Scale Short Form (4 items; CTS2S) [27]. We will assess perpetration of psychological aggression by respondents over the past 30 days (e.g., "How many times in the past did YOU punch, kick, or beat your partner up?"). Each item ranges from 0 to more than 8 times and is summed for a total scores for perpetration of physical aggression.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Intimate partner physical aggression - victimisation: Revised Conflict Tactics Short Form - Parent Report

Physical aggression victimisation (parent-report) will be measured using an adapted version of the Revised Conflict Tactics Scale Short Form (4 items; CTS2S) [27]. We will assess perpetration of psychological aggression by respondents over the past 30 days (e.g., "How many times in the past did your partner punch, kick, or beat you up?"). Each item ranges from 0 to more than 8 times and is summed for a total scores for victimisation of physical aggression. If the respondent answers that this did not occur during the past month, two follow-up items will assess whether or not the behaviour occurred within the previous 6 months, and whether the perpetrator was the respondent's current partner.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Intimate partner sexual violence - perpetration: Revised Conflict Tactics Short Form - Parent Report

Physical aggression perpetration (parent-report) will be measured using an adapted version of the Revised Conflict Tactics Scale Short Form (2 items; CTS2S) [27]. We will assess perpetration of sexual violence by respondents over the past 30 days (e.g., "How many times did YOU force your partner to do something sexual that they did not want to?"). Each item ranges from 0 to more than 8 times and is summed for a total scores for perpetration of sexual violence.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Intimate partner sexual violence - victimisation: Revised Conflict Tactics Short Form - Parent Report

Intimate partner sexual violence victimisation (parent-report) will be measured an adapted version of the Revised Conflict Tactics Scale Short Form (2 items; CTS2S) [27]. We will assess perpetration of psychological aggression by respondents over the past 30 days (e.g., "How many times did your partner force you to do something sexual that you did not want to?"). Each item ranges from 0 to more than 8 times and is summed for a total scores for victimisation of sexual violence. If the respondent answers that this did not occur during the past month, two follow-up items will assess whether or not the behaviour occurred within the previous 6 months, and whether the perpetrator was the respondent's current partner.

Version1, 16042021, "Implementation science and impact evaluation of PfR programme: A hybrid cRCT design"

Attitudes toward punishment – Parent Report

Attitudes toward punishment will be assessed using two items based on the <u>UNICEF Multiple Indicator Cluster Survey (MICS) 5 Child Discipline module</u>[29]. Respondents will be asked whether they agree or disagree with the following statement for both girls and boys, "In order to bring up, raise up, or educate a girl/boy properly, she/he needs to be physically punished," based on a 5-point Likert scale of 0 to 4 (0=Disagree strongly; 4=Agree strongly).

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Attitudes toward punishment – Child Report

Attitudes toward punishment will be assessed using one item from the <u>UNICEF Multiple Indicator Cluster Survey (MICS) 5 Child Discipline module</u>[29]. Respondents will be asked whether they agree or disagree with the following statement, "In order to bring up, raise up, or educate a child properly, the child needs to be physically punished," based on a 5-point Likert scale of 0 to 4 (0=Disagree strongly; 4=Agree strongly).

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Partner negotiation – Parent Report

Partner negotiation will be based on four items adapted from the Revised Conflict Tactics Scale Short Form (9 items; CTS2S) [27] assessing the frequency of negotiation in adult relationships (e.g., "How many times in the past did you/your partner show respect for, or showed that you/they cared about their/your feelings about an issue they/you disagreed on?"). Each item ranges from 0 to more than 8 times and is summed for total scores of partner conflict victimisation.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Positive partner relationships – Child Report

Positive partner relationships witnessed by children will be based on one item (e.g., "In the past month, how often did your parent figures in your household say nice things to each other in your presence?"). Responses will be based on the past 30 days using a Likert scale ranging from 0=Never to 3=Often. Items will be summed to create a total score of witnessing positive intimate partner relations.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Positive parenting: Alabama Parenting Questionnaire – Adult Report

Positive parenting will be assessed using 10 items adapted from the Alabama Parenting Questionnaire (APQ-SF)[30]. We will measure frequency of parent involvement (7 items, e.g., "You get involved in activities that your child likes"). Responses will be based on the past 30 days using a Likert scale ranging from 0=Never to 3=Often. Items will be summed to create a total score of positive parenting.

Version1, 16042021, "Implementation science and impact evaluation of PfR programme: A hybrid cRCT design"

Positive parenting: Alabama Parenting Questionnaire – Child Report

Positive parenting will be assessed using 20 items adapted from the Alabama Parenting Questionnaire (APQ-SF)[30]. We will measure frequency of parent involvement for both male and female parent figures (14 items, e.g., "Your female/male parent get involved in activities that you like"). Responses will be based on the past 30 days using a Likert scale ranging from 0=Never to 3=Often. Items will be summed to create a total score of positive parenting.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Parental monitoring: Alabama Parenting Questionnaire – Parent Report

Parental monitoring will be assessed using 6 items adapted from the Alabama Parenting Questionnaire (APQ-SF, e.g., "You tell your child that you like it when they help out in the house or with chores.")[30]. An additional item has been added to assess monitoring of the use of electronic devices. Responses will be based on the past 30 days using a Likert scale ranging from 0=Never to 3=Often. Items will be summed to create a total score of parental monitoring.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Parental monitoring: Alabama Parenting Questionnaire – Child Report

Parental monitoring will be assessed using 10 items adapted from the Alabama Parenting Questionnaire (APQ-SF, e.g., "Your female/male parent figure tells you that s/he likes it when you help out in the house or with chores.")[30]. An additional item has been added to assess monitoring of the use of electronic devices. Responses will be based on the past 30 days using a Likert scale ranging from 0=Never to 3=Often. Items will be summed to create a total score of parental monitoring.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Educational aspirations – Parent Report

Educational aspirations will be measured with one item asking the parent, "How far would you like your child to go in school?" rated on a 6-point scale (0=Primary School, 1=O level, 2=A level, 3=Some College /Vocational School, 4=University degree, 5=Graduate university degree (Masters/PhD).

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Educational aspirations – Child Report

Educational aspirations will be measured one item asking the child, "How far would you like to go in school?" rated on a 5-point scale (0=Primary School, 1=O level, 2=A level, 3=Some College /Vocational School, 4=University degree, 5=Graduate university degree (Masters/PhD), 999=Refused to answer, 888=Not Applicable).

Version1, 16042021, "Implementation science and impact evaluation of PfR programme: A hybrid cRCT design"

Educational expectations – Parent Report

Educational expectations will be measured using one item asking the parent how far they think their child will actually go in school rated on the same 6-point scale (0=Primary School, 1=O level, 2=A level, 3=Some College /Vocational School, 4=University degree, 5=Graduate university degree (Masters/PhD), 999=Refused to answer, 888=Not Applicable).

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Educational expectations – Child Report

Educational expectations will be measured using one item asking the child how far they think they will actually go in school rated on the same 5-point scale (0=Primary School, 1=O level, 2=A level, 3=Some College /Vocational School, 4=University degree, 5=Graduate university degree (Masters/PhD), 999=Refused to answer, 888=Not Applicable).

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Educational re-enrolment – Parent Report

Educational re-enrolment will be assessed for children who are not currently in school by asking parents whether or not they would want them to go back to school (0=No, 1=Yes).

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Educational re-enrolment – Child Report

Educational re-enrolment will be assessed for children who are not currently in school by asking children whether or not they would want to go back to school (0=No, 1=Yes).

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Parent support of education – Parent Report

Parental support for school will be measured by asking how often the parent engages in behaviours that support learning using a 5-point Likert scale (5 items, e.g., "I let my child's schoolwork come first, before chores and responsibilities"). Higher scores reflect more parental support and value for school.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Parent support of education – Child Report

Parental support for school will be measured by asking how often the child's male and female parent figures engage in behaviours that support learning using a 5-point Likert scale (10 items, e.g., "Your

Version1, 16042021, "Implementation science and impact evaluation of PfR programme: A hybrid cRCT design"

male/female parent figure lets your schoolwork come first, before chores and responsibilities"). Higher scores reflect more parental support and value for school.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Child behaviour problems: Child and Adolescent Behaviour Inventory – Adult Report

Child behaviour problems will be measured using the Child and Adolescent Behaviour Inventory (CABI) [31]. The CABI assesses a wide range of internalising and externalising symptoms in children and adolescents and is relatively shorter than the Child Behaviour Check List (CBCL), making it a practical and reliable tool for measuring behaviour problems. Parents report on their child's behaviour during the past month (0 = Not True, 1 = Somewhat or Sometimes True, 1 = Very True). The irritability subscale (4 items, e.g., "has frequent mood changes") and the externalizing subscale (10 items, e.g., often lies or cheats) will be used to measure problem behaviours. The 14 items are summed to create a total score of child behaviour problems.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Child behaviour problems: Child and Adolescent Behaviour Inventory – Child Report

Child behaviour problems will be measured using the Child and Adolescent Behaviour Inventory (CABI) [31]. The CABI assesses a wide range of internalising and externalising symptoms in children and adolescents and is relatively shorter than the Child Behaviour Check List (CBCL), making it a practical and reliable tool for measuring behaviour problems. Parents report on their child's behaviour during the past month (0 = Not True, 1 = Somewhat or Sometimes True, 1 = Very True). The irritability subscale (4 items, e.g., "has frequent mood changes") and the externalizing subscale (10 items, e.g., often lies or cheats) will be used to measure problem behaviours. Items are summed to create a total score of child behaviour problems.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Child substance use – Child Report

Child substance use will be measured using two items based on lifetime alcohol and tobacco consumption (e.g., "Have often do you drink alcohol?"). Responses will be based on a 4-point Likert scale of 0 to 3 (0=Never; 3=Often). Items will be summed with higher scores indicating more frequent substance use.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Child prosocial behaviour – Adult Report

Version1, 16042021, "Implementation science and impact evaluation of PfR programme: A hybrid cRCT design"

Child prosocial behaviour will be assessed from items derived from the pre-post study of PfR (5 items; e.g., "Your child is considerate of other people's feelings."). Items are summed to create a total score of prosocial behaviour.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Child prosocial behaviour - Child Report

Child prosocial behaviour will be assessed from items derived from the pre-post study of PfR (5 items; e.g., "You are considerate of other people's feelings."). Items are summed to create a total score of prosocial behaviour.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Child respectful behaviour – Parent Report

Respectful behaviour by children will be assessed by asking parents one question about how often they see their children behaving well. Responses will be based on a 4-point Likert scale of 0 to 3 (0=Never; 3=Often). Items will be summed with higher scores indicating more frequent respectful behaviour.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Gender socialisation – Parent Report

Gender socialisation of children will be assessed based on asking parents whether they agree or disagree about a series of statements regarding gender roles (8 items, e.g., "Changing diapers, giving the kids a bath, and feeding the kids are the mother's responsibility instead of the father."). Responses will be based on a 5-point Likert scale of 0 to 4 (0=Disagree strongly; 4=Agree strongly). Items will be summed with higher scores indicating stronger preference for inequitable gender roles.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Gender socialisation - Child Report

Gender socialisation of children will be assessed based on asking children whether they agree or disagree about a series of statements regarding gender roles (7 items, e.g., "Changing diapers, giving the kids a bath, and feeding the kids are the mother's responsibility instead of the father."). Responses will be based on a 5-point Likert scale of 0 to 4 (0=Disagree strongly; 4=Agree strongly). Items will be summed with higher scores indicating stronger preference for inequitable gender roles.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Respectability – Parent Report

Respectability will be assessed by asking parents two questions regarding their attitudes to parental responsibilities regarding respectability (e.g., "It is important to force children to respect other people," =Disagree strongly; 4=Agree strongly) and two questions on their own behaviours modelling

Version1, 16042021, "Implementation science and impact evaluation of PfR programme: A hybrid cRCT design"

respectability towards their children (e.g., "How often do you show respect to your child," 0=Never; 3=Often). Items will be summed with higher scores indicating more emphasis on respectability by parents.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Respectability - Child Report

Respectability will be assessed by asking children eight questions regarding parental behaviour enforcing and modelling respectability (e.g., "How often does your female/male parent figure encourage you to respect other people," 0=Never; 3=Often). Items will be summed with higher scores indicating more emphasis on respectability by parents.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Parenting stress – Parent Report

Parenting stress (parent-report) will be based a reduced version of the Parenting Stress Scale (9 items; PSS) [32]. The PSS has been widely used to measure parenting stress, including in LMIC, such as Pakistan [33] and China [34]. The scale has also been used with non-parent caregivers such as grandparents [35]. Caregivers report current and negative attitudes towards their children (e.g., "I feel overwhelmed by the responsibility of being a parent") related to parenting stress based on a five-point Likert scale (0=Strongly disagree; 4=Strongly agree). Items are summed to create a total parenting stress score.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Adult depression – Parent Report

Adult depression (parent-report) will be measured using the depression subscale from the Depression, Anxiety, and Stress Scale [36]. Caregivers are asked to respond to items related to how they have felt over the past seven days (e.g., "How often in the past week, have you felt sad or down?"). Responses are coded on a 4-point Likert-like scale, ranging from 0 = Never to 3 = Often. Items are summed with total scores indicating higher levels of adult depression.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Adult experience of violence during childhood – Parent Report

Adult experience of violence during childhood will be assessed using 6 items covering a range of childhood exposure to violence, including witnessing partner conflict to experiencing corporal punishment and sexual abuse e.g., "How often were you beaten or insulted repeatedly by your parent/family members when you were growing up?"). Responses are coded on a 4-point Likert-like scale, ranging from 0 = Never to 3 = Often. Items will be analysed individually as well as summed to create a total score with higher scores indicating more frequent exposure to violence during childhood.

[Time Frame: Baseline]

Version1, 16042021, "Implementation science and impact evaluation of PfR programme: A hybrid cRCT design"

Communication about Sexual Behaviour – Parent Report

Communication about sexual behaviour by parents will be assessed by asking caregivers whether or not they have engaged in conversations with their children about puberty and sexual reproductive health (8 items, e.g., "Have you talked to your child about when to have sex?" Items will be summed to indicate number of topics discussed and also analysed qualitatively.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Communication about Sexual Behaviour – Child Report

Child report of *communication about sexual behaviour* by parents will be assessed by asking caregivers whether or not their male and female parent figures have engaged in conversations with them about puberty and sexual reproductive health (8 items, e.g., "Has your female/male parent figure ever talked to you about the risks of engaging in sexual acts?"). Items will be summed to indicate number of topics discussed and also analysed qualitatively.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Impact of COVID-19 – Parent Report

The *impact of COVID-19* will be assessed by asking parents to indicate whether they have been stressed by Covid-19, whether the child has been affected by Covid-19 and where the spouse relationship has been affected by Covid-19 agree.

[Time Frame: Baseline, 8-months post-baseline, and 12-months post-baseline]

Other pre-specified outcomes

Adult experience of violence during childhood – Parent Report

Adult experience of violence during childhood will be assessed using 6 items covering a range of childhood exposure to violence, including witnessing partner conflict to experiencing corporal punishment and sexual abuse e.g., "How often were you beaten or insulted repeatedly by your parent/family members when you were growing up?"). Responses are coded on a 4-point Likert-like scale, ranging from 0 = Never to 3 = Often. Items will be analysed individually as well as summed to create a total score with higher scores indicating more frequent exposure to violence during childhood.

[Time Frame: Baseline]

Basic childhood necessities – Parent Report

Relative poverty will be assessed using an adapted version of the *Basic Necessities Scale* (6 items). Developed by the Centre for South African Social Policy in the 'Indicators of Poverty and Social Exclusion Project,' the Basic Necessities Scale measures levels of economic deprivation by identifying basic household items that families are unable to afford [37]. These include food, toiletries, clothes,

Version1, 16042021, "Implementation science and impact evaluation of PfR programme: A hybrid cRCT design"

shoes, and school uniforms, equipment, and fees. Items are coded dichotomously for positive or negative responses and summed to create an overall score.

[Time Frame: Baseline]

Basic childhood necessities – Child Report

Relative poverty will be assessed using an adapted version of the *Basic Necessities Scale* (6 items). Developed by the Centre for South African Social Policy in the 'Indicators of Poverty and Social Exclusion Project,' the Basic Necessities Scale measures levels of economic deprivation by identifying basic household items that families are unable to afford [37]. These include food, toiletries, clothes, shoes, and school uniforms, equipment, and fees. Items are coded dichotomously for positive or negative responses and summed to create an overall score.

[Time Frame: Baseline]

Family stressors – Parent Report

Family stressors will be based on six items measuring the presence or absence of the following challenging situations in each household: adult illness, recent death or illness of a family member, substance use, child illness, child hunger, and child disabilities. Items will be summed to create total score of family-level stressful experiences

[Time Frame: Baseline]

Food insecurity – Adult Report

Food insecurity will be assessed by asking adult respondents to report on whether their household was able to provide meals at breakfast, lunch, and dinner in the past month based on a Likert scale (0 =No; 1=Yes, sometimes; 2=Yes, always).

[Time Frame: Baseline]

Food insecurity – Child Report

Food insecurity will be assessed by asking child respondents to report on whether their household was able to provide meals at breakfast, lunch, and dinner in the past month based on a Likert scale (0 =No; 1=Yes, sometimes; 2=Yes, always).

[Time Frame: Baseline]

Version1, 16042021, "Implementation science and impact evaluation of PfR programme: A hybrid cRCT design"

Basic caregiver and child demographic information – Child and Adult Report

Basic caregiver and child demographic information will be asked using items from the UNICEF Multiple Indicators Cluster Survey (MICS) Household Survey [29]. The MICS was developed to monitor the situation of children and women on a global level and is based on Demographic and Health Surveys. It has been used widely throughout low- and middle-income countries (LMIC) including Uganda. In our study, we will collect data on caregiver/child age, caregiver/child gender, caregiver religion, caregiver educational status, caregiver/child literacy and disability, number of adults and children living in the household, child's relationship to caregiver, presence of child's biological parents and other caregivers in the household, child enrolment in school, and marital status.

[Time Frame: Baseline]

Process outcomes

Data collected from the process evaluation will investigate the implementation of the PfR programme. Quantitative data will be collected to examine implementation fidelity, competent adherence, and participation. Qualitative data will also examine barriers to implementation and participation, and potential approaches to overcoming these barriers.

Recruitment rate – Assessor Report

Recruitment rate will be based on the number of families who were eligible for inclusion and provided consent to participate in the program divided by the number of target population who were exposed to recruitment activities.

[Time Frame: 8-months post-baseline]

Enrolment rate – Facilitator Report

Enrolment rate will be based on the number of families who attend either at least one session of Parenting for Respectability or the Parenting in a Nutshell lecture divided by the number of families allocated to either study arm. Separate enrolment rates will be assessed for each arm

[Time Frame: 8-months post-baseline]

Participation rate – Parenting for Respectability participants only – Facilitator Report

Participation rates for those allocated to the *PfR* programme will be mean attendance rate for programme sessions based on those families who enrolled in the programme (i.e., parents who attended at least one session). We will also assess the percentage of families who enrolled in the programme who attended 50% (e.g., 8 sessions) and 75% (e.g., 12 sessions) or more.

[Time Frame: 8-months post-baseline]

Version1, 16042021, "Implementation science and impact evaluation of PfR programme: A hybrid cRCT design"

Dropout rate – Facilitator Report

Dropout rates for enrolled participants will be defined as the percentage of participants who fail to attend at least three consecutive sessions and do not attend any sessions at a later stage.

[Time Frame: 8-months post-baseline]

Completion rate – Facilitator Report

Completion rates for participants will be determined based on the number of enrolled participants who attend a cut-off threshold of at least 62.5% of the programme (i.e., 10 sessions) [38].

[Time Frame: 8-months post-baseline]

Implementation dosage (time) – Facilitator Report

Implementation dosage will be based on the total amount of time in minutes that the program was delivered to each parent. Facilitators will report on the start and end time of each session/lecture in their weekly reports. Implementation dosage will be based on the total amount of time delivered divided by the mean attendance rate.

[Time Frame: 8-months post-baseline]

Time cost for delivery – Facilitator Report

Time cost for delivery will be collected from facilitator weekly reports and based on the time spent on training, preparation, travel to and from, and delivery of each session/lecture. The total time will be summed for each facilitator and then mean scores will be created for the sample.

[Time Frame: 8-months post-baseline]

Implementation fidelity – Facilitator Report

Implementation fidelity by programme facilitators of the PfR programme will be examined using self-report checklists by the programme facilitators. They will report on 5 items per session/lecture ranging from an impression of the quality of delivery to the proportion of the session activities they were able to deliver (0 = No time for it to 5 = all of the activities).

[Time Frame: 8-months post-baseline]

Competent adherence – Observational

Competent adherence will be assessed using the PfR Facilitator Assessment Tool (PfR-FAT) [39]. The PfR-FAT was developed by the study investigators and programme developers to assess the proficiency of programme delivery by facilitators as a prerequisite to certification. Three standard behaviour categories are based on the core process skills (25 items), includes modelling skills (6 items, e.g., "give positive, specific, and realistic instructions"), collaborative facilitation (7 items, e.g., "accept participant responses verbally by reflecting back what the participant says"), and group management and leadership

Version1, 16042021, "Implementation science and impact evaluation of PfR programme: A hybrid cRCT design"

skills (12 items, e.g., "use open-ended questions during group discussions"). Items are summed to create a total score of competent adherence.

[Time Frame: 8-months post-baseline]

Qualitative outcomes

Qualitative data will be collected using live observation of programme delivery (at least 1 observation per group, N=32); in-depth interviews with senior implementation staff (N=4), trainers of facilitators (N=2) and a sample of facilitators (N=16); focus group discussions with caregivers (N=8, 10 per FGD). In addition, data will be collected through <u>semi-structured interviews</u> with Wakiso and A District Community Development Services (N=4) who will provide supervision of the NGO implementing partner (SOS) and from a sample of local community leaders (N=8), each lasting from 60 – 90 minutes.

Interviews and focus groups will occur during the post-evaluation and examine the following themes: 1) participants observed change in parenting practices and child behaviour at home during programme; 2) acceptability and appropriateness of programme materials, delivery, and key programme components; and 3) existing barriers to participation during sessions and engagement in home practice and other activities. Interviews will also explore facilitators' challenges in implementing the programme on both a process (e.g., using a collaborative approach and/or explaining concepts such as child-led play) and logistical level (e.g., recruitment, session length, location, meals).

Cost effectiveness data collection

Programme costs will be calculated using a micro-costing approach, multiplying resource use by unit costs, divided into 1) start-up costs including costs required for coordinating recruitment, community mobilisation, and facilitator training; 2) programme delivery costs which includes staff-time, transportation, and other materials for home-based individual consultations, parent-group sessions, and supervision sessions; and 3) administrative costs to manage the implementation.

17. Blinding

The allocation status of other participating families will be concealed from participants, thus reducing the potential for contamination. Research assistants conducting data assessments and statisticians conducting analysis will be blind to allocation in order to minimise assessment bias [40, 41]. Different groups of research assistants will be employed for outcome assessments and monitoring of implementation fidelity and adherence. Any instances of compromised blinding will be immediately reported. In the case of instances of harm or severe abuse being reported by a participant at any stage of the study, the allocation status of the participant will be un-blinded. All cases of un-blinding will be reported. Because of facilitators' involvement in the programme implementation, blinding will not be possible for service providers. Similarly, of course, participants cannot be blind to their own treatment condition.

18. Data collection, retention, and management

Data collection

Data collectors who are fluent in Luganda for Wakiso and Acholi for Amuru and who have prior experience working with vulnerable families in Uganda will serve as research assistants. They will be extensively trained in ethics, informed consent, interviewing, and observational assessment techniques by the study investigators. All data collection points will have a detailed protocol and will be scripted to ensure consistency across data collectors. Research assistants will be managed by the project coordinator (Ms Namutebi) and supervised by PI Siu. Quantitative self-report assessments and qualitative interview/focus group guides will be translated into Luganda and Acholi by bilingual researchers and the translation checked by back-translation [42].

The proposed study will use an innovative, low-cost technological data collection tool using Computer-Assisted Self-Interviewing ('CASI') methods with e-tablet technology to administer consent forms and questionnaires. This method of data collection has been pilot-tested during the previous feasibility study with high acceptability to respondents. Trained data collectors will explain the CASI procedures, read out questions, and assist participants to key in responses to their handsets. CASI supports multiple languages, and so can include English, Luganda, and Acholi. If any participants are unable or uncomfortable with the use of tablets, a paper-and-pen interviewer-assisted questionnaire will also be available in English, Luganda, and Acholi.

Data on implementation fidelity will be collected live at all programme sessions. Programme adherence data will be collected using attendance registers administered by research assistants assigned to the process evaluation. Programme participants will indicate whether they completed their home activity assignments using self-report checklists.

Qualitative data will involve in-depth interviews with study participants and focus group discussions with facilitators. Purposive sampling, a type of non-probability sampling, will be used to select 15 intervention group parents to be interviewed. This sampling technique is most appropriate as it will enable the selection of key participants of interest who could share multiple perspectives on the barriers and facilitators to engaging in the PfR programme. This subset of interest will include participants who did not enrol in the programme, as well as those that had low (attended 1 to 5 sessions;) or high attendance rates (attended 12 to 8 sessions). Data will be collected by personnel who speak fluent Luganda or Acholi, using an interview schedule with an open-ended approach to solicit views and feedback from participants. Interviewers will guide the interviews and focus groups along the following steps while allowing the discussion to evolve as themes emerge. Each step will begin with an overarching question followed by more specific questioning and inquiry. Focus groups and interviews will be captured on digital recorders with written notes as a backup. All equipment will be tested onsite prior to use. Focus groups and interviews will last approximately 120 minutes and occur in a quiet room a local community centre. Data will be transcribed verbatim and will be translated into English and verbally back-translated into Luganda or Acholi to verify accuracy.

Incentives

Participants will be offered a refreshment of approximately 4,000 Ugandan shillings after each assessment. Any participant who chooses to leave the study early will also receive a certificate stating how many sessions s/he attended. To date, we have consistently found a high level of willingness among communities to participate in research studies on parenting programmes.

19. Data management

All non-electronic data including signed consent forms, transcripts from FGDs and interviews, and quantitative paper questionnaires will be stored in a locked filing cabinet at the Child Health and Development Centre at Makerere University. Digital recordings of FGDs and interviews will be copied onto an external hard drive and also kept in this locked filing cabinet. All data collected on CASI tablets will be encrypted as soon as the questionnaire is finalised (i.e., completed by interviewer) and accessible only by senior research personnel. Access to general functioning of the tablets will be password protected, and each tablet will have a GPS tracking application installed and activated. This application will allow for remote deletion of all information on the tablet in case of theft. Tablets will be stored in a locked cabinet at the Child Health and Development Centre office every week, which is under 24-hour security protection.

The study will use two methods to upload and store data at the end of each day of data collection. First, the CASI tablets will transmit encrypted data using a 256-bit encryption via wireless networks to the study's Open Data Kit server (www.opendatakit), which will be housed at a central server managed by the University of Makerere's Information Technology Services. Only senior research personnel will have access to this server (PIs, co-Is, and data management consultants). It has a robust security system with firewalls and frequent backing up of all data. Transmission will occur on a daily basis from the Child Health and Development Centre site, which will have a reliable 3G wireless network (i.e., not dependent on electric power), and the local research manager will manually upload data from tablets onto a local server on a daily basis. This local server will also be password protected and serve as a backup of the central server system. Once data is uploaded onto the local server, it will be erased on a daily basis so that no information remains on the tablet.

Data cleaning will be conducted at the end of each data collection phase. Individual datasets from the baseline and post-test evaluation will be stored separately from the final merged dataset, so that data reference points are available in the data validation process. All electronic data, including transcripts of qualitative data as well as quantitative data, will be stored on at least two servers, each of which will be accessible by a password known only to members of the research team. Thus, data will be protected from both server failure and confidentiality breaches. Video recordings will be stored on a password-protected hard drive in a locked cabinet for a minimum of 5 years with access only to authorized members of the research team. Non-electronic data (for instance, signed consent forms) will be stored in a locked filing cabinet.

Non-anonymised paper data will be kept for 5 years in a locked storage cabinet at the Child Health and Development Centre after which it will be shredded and disposed of by the lead researchers. Anonymised data will be stored using United Kingdom Data Archive standards (www.data-archive.ac.uk/create-

manage/planning-for-sharing). Anonymising data will include removal of direct identifiers (names, addresses, postcode information, telephone numbers or pictures) as well as indirect identifiers (information on location, occupation or any other information that could be linked to a public source). This will include removing or aggregating variables or reducing the precision or detailed textual meaning of a variable in the dataset. Access to this data will be controlled and require authorisation from the research team for further use.

20. Statistical methods

Intervention effectiveness

The intervention arm (PfR) will be compared against the control (lecture) for all primary and secondary outcome analyses. All analyses will be conducted with an intention-to-treat design using full expectation maximum likelihood (FEML). Baseline differences between intervention and control groups will be examined for demographic data and outcome measures using independent t-tests and Chi-square crosstab analyses. Treatment effects will be estimated for post-treatment outcomes using two-tailed Poisson regression mixed-level models for skewed outcomes and multi-level regression analyses for continuous variables, adjusting for clusters and controlling for baseline outcome levels. In order to assess the potential clinical relevance of outcomes in this pilot study, we will examine tests for significance of effect (set at the p < 0.05 level), as well as the direction and magnitude of incidence risk ratios (IRRs) [46]. While tests for significance based on p-values may determine whether there is a statistically reasonable likelihood of detecting an intervention effect, the estimation of effect sizes is generally recommended as a more appropriate approach for studies with small sample sizes [47].

Testing theory of change

Intervention research provides an opportunity to test theoretical mechanisms and causal processes related to the role of parenting programmes in reducing risk of child maltreatment [48]. As aforementioned, this study tests two hypothesized pathways of change. Firstly, improved parenting knowledge, skill and sense of competence will increase positive parenting and reduce maltreatment. Secondly, improving caregiver mental health, intimate partner violence, and child behaviour will also mediate reductions in risk of child maltreatment. Multiple linear regression analyses [49] and structural equation modelling [50] will examine these hypotheses based on the aforementioned proximal and secondary outcomes. In addition, qualitative focus groups will provide further information regarding the mechanisms involved and essential programme elements necessary for effectiveness in other settings [51].

Testing interaction effects

The study will examine impact heterogeneity and moderation effects across population subgroups, including particularly disadvantaged groups [52]. Potential differences by subgroup population include caregiver/child gender, age, relationship to child, socioeconomic status. Additional moderators to be analysed include families with parental depression and/or children with existing behaviour problems [53]. Furthermore, the impact of parenting group variation will be examined quantitatively in statistical analyses of outcome measures. Site effects and site X treatment interactions will also be considered in analyses to investigate heterogeneity of effects over sites [54].

Implementation component analyses

This study will also examine the following main outcomes of interest related to programme implementation: participation, programme fidelity, quality of delivery, and cost. We will examine the effect and interaction effects of three modalities, or component levels, related to the aforementioned implementation uncertainties: Geographical Location (peri-urban vs rural), Group Composition (existing vs new groups), and Facilitator Experience (experienced vs community facilitators). We will estimate each main effect and interaction estimate will be based on all of the experimental conditions, since each component will be included in half of the conditions. For example, the main effect of geographical location will be estimated by comparing the implementation outcomes for groups in urban areas vs those in rural areas. Linear mixed models with effect coding will be used to examine whether each component has a significant effect on implementation outcomes. We will also examine 2-way interaction effects between components.

Implementation outcome analyses

We will investigate programme implementation and participation of PfR and its association to primary outcomes. First, quantitative data will be examined to determine whether the programme was implemented to an acceptable degree of fidelity, exposure, adherence, engagement, and participant satisfaction. Secondly, although limited by sample size, multivariate regression analyses will explore potential associations between programme feasibility outcomes and change scores for child maltreatment and partner conflict outcomes. Finally, analysis of qualitative data from participant focus groups and facilitator interviews will provide more nuanced information on programme feasibility. Using a grounded theory approach similar to that used in the development phase, this study will explore cultural acceptability and appropriateness, barriers to implementation and participation, and potential approaches to overcoming these barriers.

Programme implementation – quantitative data analysis

Implementation fidelity will be analysed by examining data from the facilitator self-report checklists and the PfR Facilitator Assessment Tool [39]. First, internal consistency with means and standard deviation per group for each measurement will be reported. Next, differences between methodological approaches in overall fidelity scores will be assessed with independent t-tests. This will help determine the reliability and consistency of using self-report versus observational assessments of fidelity. Then, in order to produce a basic level of fidelity, a ratio of program implementation to program design will be created for both self-report and observational scores [55]. According to Borrelli and colleagues, a standard of 80% programme fidelity will be considered as "high treatment fidelity" [56]. In addition, this study will examine challenges in facilitating specific components or aspects of delivery quality. For instance, facilitators may have difficulty implementing a particular session activity or have difficulty practicing reflexive behaviour with participants. Combined with in-depth interviews on barriers to implementation, this may highlight the need for additional training and/or further adaptation of programme materials.

Overall programme exposure, adherence, and engagement will be assessed based on attendance registers. Mean scores and standard deviations will be reported on attendance rates, completion rates, and activity engagement. In the previous delivery of the PfR, it has been recommended that parents participate in at

least 50% or 8 sessions. As a result, a similar standard will be used to determine an acceptable overall rate of programme attendance. This study will also report percentages of parents who participate in 50%, 25%, and 10% of the programme.

Finally, we will use the Complier Average Causal Effect analyses that provides an estimate of intervention effects, taking into account implementation (i.e., compliance) and other baseline predictors of attendance [57, 58]. These include implementation fidelity (competent adherence and content delivery) and attendance rates. This data will provide useful information on whether programme fidelity and acceptability have a role in influencing programme effects. This will be particularly useful for improving the intervention protocols and training prior to further implementation and evaluation [59].

Programme implementation – qualitative data analysis

In accordance to the procedures followed in the pre-post pilot study, qualitative data analysis will explore participants' and facilitators' views and experience using a thematic analysis approach with open, axial, and selective coding [60]. Two independent raters will assess and code data from focus group and indepth interview transcripts. The study will investigate emergent themes regarding 1) participants observed change in parenting practices and partner relationships during programme; 2) acceptability and appropriateness of programme materials, delivery, and key programme components; and 3) existing barriers to participation during sessions and engagement in home practice and other activities. Interviews will also explore facilitators' challenges in implementing the programme on both a process (e.g., using a collaborative approach and/or explaining concepts such as child-led play) and logistical level (e.g., recruitment, session length, location, meals). After consensus regarding the themes is reached within the research team, the assessors will re-examine the transcripts for evidence supporting these themes. These themes will then be grouped using axial coding into larger categories and analysed according to their properties. Finally, the categories will be integrated using selective coding into a larger theoretical representation of the shared experiences and perspectives [61].

Cost effectiveness analyses

Incremental cost effectiveness analyses (CEA) will be conducted from the payer's perspective (excluding participant costs) to assess whether the benefits of each component appear to be worth the added costs. Programme costs will be calculated using a micro-costing approach, multiplying resource use by unit costs. For outcome measures, in addition to assessing changes in the overall ICAST-Trial and partner conflict scores, the change in quality-adjusted life-years (QALYs) will be studied. Incremental cost effectiveness ratios (ICERs) will be calculated as the incremental change in costs divided by the incremental change in three health outcomes: the overall maltreatment, partner conflict, and QALYs. An ICER of \$50,000 or less per QALY gained is reasonably to be considered cost-effective. Bootstrapping techniques will be used to conduct uncertainty analyses to assess variability in our findings from potential sampling bias.

21. Data monitoring

Monitoring of data will be conducted by the Trials Steering Committee (TSC). Data will be monitored after baseline and post-test data collection, as well as after the final data analyses.

Version1, 16042021, "Implementation science and impact evaluation of PfR programme: A hybrid cRCT design"

Section 4: Ethics and dissemination

22. Research ethics

Ethical approval

Ethical approval for this study will be obtained from the respective research ethics committees and/or institutional review boards from the following institutions prior to inception of the study: Makerere University School of Humanities and Social Sciences Institutional Review Board (approval number: will insert number) and the University of Glasgow College of Social Science Research Ethics Committee (approval number: will insert number).

Informed consent procedures

Trained interviewers supervised by the research team will conduct informed consent procedures at either community centres or in the family households. Information sheets will be read to participants in Luganda and Acholi to prevent illiteracy from hindering a participant's understanding about the methods and purpose of the study. All participants should be capable of giving their own consent, and we will not include any participants that are deemed incompetent. Special care will be taken to ensure that all participants are fully aware of and understand the research.

The adult informed consent process involves presenting a detailed verbal and written description of the study as it is described on the printed information and consent forms. Staff will emphasise that participation is voluntary for adults, and that participants can refuse to participate in either the intervention or research and/or can discontinue participation at any time without penalty. Interviewers will ask whether any participants have experienced any coercion to take part in the study; those that describe any pressure or coercion to participate will be excluded, and any other household members will also be excluded. Potential subjects will receive an item-by-item reading of the consent form by the study interviewer.

Participants will be informed of the procedures for ensuring their confidentiality, including: the use of unique non-personally identifying ID numbers instead of names on research materials, the video recording of sessions (and permission to refuse being recorded with no penalty to participation in either the programme, study, or 4Ps), and maintenance of electronic and non-electronic data in locked computer databases and in locked filing cabinets in locked rooms. Tracking and contact procedures for scheduling follow-up interviews will be explained. Participants will be reminded that they may receive information regarding health or social services without participating in the study. All participants will be given the contact numbers of the co-PIs to answer questions about the study or one's rights as a human subject, as well as a 24-hour site contact number. All consenting and assenting participants will be offered a copy of the informed consent form.

Participants may consent to participate only after having the information sheet been read to them and there has been an opportunity for questions. The research team will assure that they are fully informed about the study and have had the chance to ask any questions that might have arisen.

Version1, 16042021, "Implementation science and impact evaluation of PfR programme: A hybrid cRCT design"

Participants will have the opportunity to consider consent for up to a week, before interviewers return for the baseline assessments. However, when we have previously offered participants periods of 24 hours to 1 week to consider consent, the vast majority have actively requested to participate immediately. In light of this, we propose that participants are offered the choice of whether to consent or refuse immediately, or to have 1-7 days to consider whether they choose to consent.

Informed consent procedures for facilitators and other personnel will be similar to those described above for parents. A random subset of informed consent procedures will be reviewed by senior research personnel.

Confidentiality

All precautions will be taken to ensure confidentiality for all participants. Participants will be given an individual research identification number to assure that their personal names are not disclosed. Research assistants will not be able access information from the electronic tablets as soon as they have completed and finalised the questionnaires. The electronic tablets will be password protected with the capability to remotely erase all data stored on them in the event of theft. Electronic data will be stored on a secured, password-protected, and encrypted server accessible only the principal investigators. Finally, all assessment data will be anonymised prior to statistical analysis.

Other ethical issues

In addition to the potential ethical issues that are outlined above, we have identified the following ethical issues and steps to address them:

Ethical issues regarding potential participant burden

We recognise that answering long surveys can potentially be a burden to research participants as well as have an adverse effect on the accuracy of self-report data [62]. We have estimated that each visit will last approximately 45 minutes per respondent. At approximately halfway through the assessments, we will offer participants the opportunity to stretch and take a break from answering questions during which refreshments will be provided.

Computer Assisted Self-Interviewing (CASI) methods have also been shown to reduce respondent burden while improving the efficiency and accuracy of data collection. The CASI technology was shown to: have a high degree of acceptability to research assistants and participants; decrease data collection time; and be more accurate than paper questionnaires [63].

Ethical issues regarding staff

All staff will be experienced in working on community research projects in the same or similar communities to the one in our study. Nevertheless, it is important to secure the mental wellbeing of interviewers and other research staff as well as mitigate any potential harm caused by working on the study. Thus, it is one of our utmost priorities. We will ensure that all research assistants are trained in awareness and safety measures. Staff will not undertake assessments in any situation in which they feel uncomfortable or unsafe and are encouraged to travel in pairs in areas that are less safe.

Version1, 16042021, "Implementation science and impact evaluation of PfR programme: A hybrid cRCT design"

In addition, we are aware that research with vulnerable families can result in increased stress due to the disclosing of difficult personal information and the demands of meeting deliverables. We will also conduct weekly debriefing meetings with research personnel to discuss any potentially distressing events that may have occurred during data collection. Staff will also participate in one-on-one reviews at the end of each data collection wave to assess their performance and psychological needs.

23. Potential of harm

The focus of this study is to strengthen and evaluate the impact of a community-based parenting programme. We believe that the overall potential benefits of the research and intervention in reducing the risk of child maltreatment and partner conflict will outweigh potential risks of harm against participants. Nevertheless, we must consider two levels of potential harm: participation in the study and participation in the intervention.

Potential harm from the study

It is important to consider potential harm from participation in the study, no matter how small. There is a possibility that the opportunity to discuss parenting and parent-child relationships during interviews may prompt distress in the respondents [64]. All research personnel will be trained in ethical procedures and protocols concerning research with human subjects. During the consent stage, we will inform all participants that everything said will be confidential unless it becomes clear that they are at risk of significant harm or of putting anyone else at risk of harm. We will also inform participants that they do not have to answer any questions that they feel uncomfortable with and that they can stop the interview at any time without any negative consequences. In the case of participants not completing the baseline assessment, they will be excluded from the study.

Disclosure of harm

There is the possibility that participants may disclose harsh parenting practices that would reflect potential abuse or neglect of children. This study recognises that researchers have a responsibility towards children who may be at risk of abuse or neglect or any other risk of severe harm. It is to be noted that it is an ethical principle to provide help for children whom the research identifies as in need.

As a result, the following protocol is proposed to mitigate any potential harm to children or adults that might occur during the study:

- 1. If information is disclosed that suggests that any member of the household is at risk of significant harm, the researcher will discuss concerns with the respondent at the end of the interview;
- 2. If the household member at risk of harm is a child, the researcher will discuss with the parent the possibilities for referral to child welfare, health organisations, and other services;
- 3. If the harm is considered to be significant, the research staff will inform local child protection services;

Version1, 16042021, "Implementation science and impact evaluation of PfR programme: A hybrid cRCT design"

- 4. If severe abuse is disclosed in data collection, children will be immediately referred to social or medical services and the participant will be automatically excluded from the study;
- 5. If the decision is made to take action, the participant(s) will be informed and referral will be made;
- 6. All staff will also receive additional training from the research team on how to respond to these situations in alignment with the study's referral protocols;
- 7. Weekly supervision meetings with all field interviewers will allow discussion of issues that arise concerning harm to research subjects and children;
- 8. Finally, if we determine that respondents or their families have experienced significant harm as a result of participation in the research study (i.e., severe abuse, suicidality, intimate partner violence, or other potential psychological or physical injuries), we will cease further activities until these issues can be addressed adequately.

Consistent with the abovementioned protocols, the informed consent form will indicate that relevant information may have to be disclosed without respondents' consent if the participant or a household member poses a serious danger to the self or to others, or if there is evidence to suggest child abuse or neglect.

Mitigating potential harm from the intervention

We have also considered the potential risk of harm from participating in the intervention, and will be monitoring this throughout the project [65]. There may be potential psychological harm as a result of participation in the parenting programme as a result of bringing up difficult experiences in caregivers' own childhoods or confronting intimate partner violence at home. However, decades of research on parenting interventions, including many randomised trials in LMICs [66], have not shown any evidence of harm from these interventions with plenty of evidence of benefit for parents and children, and high parent satisfaction. As a result, this study will be explicitly looking at potential benefits and risks of the parenting programmes on both children and parents. Our statistical analyses plan will use two-tailed tests for differences between groups to examine potential negative and positive intervention effects. We will also monitor research subjects to assess whether participation in the intervention is placing any individuals at potential risk of harm. In addition to post-test assessments, monitoring will occur at specific time points when we are also monitoring implementation fidelity.

We do not anticipate any direct harm as a result of withdrawing from the intervention. Participation in the programme will be completely voluntary with no direct penalties for refusing to participate. Furthermore, there is no evidence of harm from termination of parenting interventions in numerous other trials, including a number of evaluations in other low-resource settings [66]. Finally, if there is any indication of significant harm from either intervention condition at post-test, we will cease implementation of the programme until harm has been adequately addressed and the programmes have been adapted accordingly.

Version1, 16042021, "Implementation science and impact evaluation of PfR programme: A hybrid cRCT design"

Self-Referral

In addition to our rigorous referral procedure described above, we will provide a self-referral document detailing available services to all participants as part of the informed consent stage as suggested. This information will include services for family and child support, substance use, gender based violence and rape, child abuse and protection, physical, mental, and sexual health, government financial support, and contact details for available helplines. Self-referral forms will also be available during subsequent assessments at the request of participants. We will also provide up-to-date information regarding self-referral services at the end of the final wave of data collection.

24. Access to data

Only the research team will have access to raw datasets. Access to cleaned, anonymised datasets will be provided to the other investigators and members of the Trials Steering Committee. Anonymised datasets will also be stored online with password protection.

25. Dissemination

Building on our previous success with dissemination of PfR, and incorporating the new insights learnt from Spring Impact, we plan to develop a comprehensive dissemination/ research uptake plan to be delivered in collaboratively with the key stakeholders: media, district community development officers, and implementing partner. The aim of the dissemination plan is to show case the achievements of the PfR programme, share the learning and impact of the programme, increase visibility of PfR and influence policy and practice. Below, is a detailed dissemination plan in the form of a matrix table which outlines the desired outcomes, outputs, target audience and justification/ description of the process. Given its importance, we devote a substantial budget (from both Oak Foundation and Evaluation Fund) to this activity.

Desired impact	Output (specific products to be developed)	Target audience (specific)	Justification and process (how going to do it)
Visibility and awareness, and build an identify for PfR as home grown evidence based parenting intervention	 High impact, catchy flyers and brochures Blogs Web site pages Tweet campaign Briefing paper, with infographics Publications/ reports Customized/ standardized presentations Clips for the PfR website Photos disseminated in reports 	Policy makers Implementing partners District officials Beneficiaries Violence prevention community (local and regional) Research community The general public Development partners Funders Parenting Agenda Consortium	 Develop high impact, catchy technically sound content interspersed with infographics and distribute in form of briefs reports, flyers or brochures that position PfR as evidence based home grown program Hire a graphic designer/IT strategist to design PfR materials, and update the Parenting for Respectability website www.parenting.ug Disseminate output online through: Blogs Web site- micro site/pages Tweet campaign
Generate national discussion on parenting for prevention of violence against children and on the importance of evaluating implementation and scale-up modalities	Briefs and/ or reports that position PfR as evidence based home grown program Talk show scripts, ideas for radio and TV Articles for media publication	Policy makers Implementing partners Violence prevention community Public Media Parenting Agenda Consortium	Harness existing cross-sector Parenting Agenda Consortium, led by CRFR. Articles for media publication Write briefs and reports that position PfR as evidence based home grown program
Communicate the results (impact) of PfR and show case project specific achievements and processes, and the evidence on what has worked and what has not	 Power point presentations Project summaries/ leaf lets and brochures Publications/ project reports Case studies and testimonies 	 Policy makers Implementing partners Violence prevention community Beneficiaries Media Parenting Agenda Consortium 	To capture specific achievements, showcase technical expertise, successes and impact, we will: Develop professionally designed research report Hold breakfast meeting/dissemination workshops Prepare documentary

	 Stories/ case studies that provide evidence of success of interventions and include the voice of the beneficiaries. Stories about the approaches and process Photography and illustration of approaches 		Work with local newspapers to draft articles Work with a social media volunteer/ student to develop and maintain a vibrant social media Dissemination workshop Webinar Attend relevant Technical Working Groups (TWG) and the Parenting Agenda for Uganda meetings to share project progress and data
Influence policy makers to advocate for evidence based programming and scaling-up of parenting interventions	 Policy briefs designed per technical area Power point presentations Workshop 	 Policy makers Technical Officers Development partners Program managers Parenting Agenda Consortium 	 Harness existing cross-sector Parenting Agenda Consortium, led by CHDC. PfR team will work with a technical expert to draft and review concise summary of issues in relation to selected sectors. Brief will be professionally written and designed Agree on sections in briefs, review technical content edit, design and layout
Promote approaches to scaling up of parenting programs demonstrated to have worked best	 Capture the change - the evidence of what has worked through the participants of the project. Stories will be set in natural setting of community- to capture social norms, what happened before intervention and what next Develop policy briefs, research briefs, and practice briefs 	 Policy makers Implementing partners Violence prevention community Parenting Agenda Consortium Funders 	 Harness existing cross-sector Parenting Agenda Consortium, led by CRFR Attend relevant Technical Working Group (TWG) meetings to share project progress and data Host at least one webinar Share reports with funders to further disseminate to their networks

Acceptance and adoption of PfR	 End of project report Field documentation Field photos Stories Academic articles Final version of manual Final version of implementation guidelines Advocacy talking points Program promotional materials (illustration materials) Teams of facilitators trained Publications 	 Implementing partners Government Parenting Agenda Violence prevention community 	Inception meetings Finalise manual Finalise implementation guidelines and make them available Avail manual and other program documents Dissemination activities by SOS Professionally designed publication focusing on the project story
Increased capacity of the PfR Team to engage with different stakeholders and carry out promotional activities for PfR and other evidence based PfR interventions	Dissemination plans, strategies and collaboratively developed with specialists Spring Impact	PfR Team	 Networking Mentored support from Spring Impact

26. Publication policy

The research investigators will adhere to the following guidelines regarding publication of findings:

Data analysis and release of results

The scientific integrity of the project requires that all data from this Study will be analysed according to the registered protocol. All presentations and publications are expected to protect the integrity of the major objectives of the study. Any data that would compromise blindness will not be presented prior to the release of mainline results. Recommendations as to the timing of presentation of such mainline results and the meetings at which they might be presented will be given by the Trials Steering Committee.

Review process

Each paper or abstract, as described below, must be submitted to study investigators for review of its appropriateness and scientific merit prior to submission. The investigators may recommend changes to the authors and will finally submit its recommendations to the Trials Steering Committee for approval.

Authorship

Authorship of papers and presentations emerging from this Study will be decided during a meeting with co-Principal Investigators and co-Investigators. Authorship will use the following guidelines recommended by the International Committee of Medical Journal Editors (www.icmje.org):

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work;
- Drafting the work or revising it critically for important intellectual content;
- Final approval of the version to be published;
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Final decisions of authorship will be recorded in meeting minutes and submitted to the study investigators.

Primary outcome papers

The primary outcome papers of this Study are papers that present outcome data regarding the effect of the PfR programme on reducing the primary outcomes of child maltreatment and partner conflict in comparison to treatment-as-usual controls at post-test. Determination of whether or not a particular analysis represents a primary outcome will be made by the Trials Steering Committee on the recommendation of the co-Principal Investigators.

Other study papers, abstracts and presentations

All studies other than those designated as "Primary Outcomes" fall within this category. This includes studies and papers examining the effect of the PfR programme on proximal and secondary outcomes in comparison to treatment-as-usual controls at post-test, as well as any quantitative, qualitative, or mixed-methods studies examining the process evaluation of the programme. All papers and abstracts must be approved by the investigators before they are submitted.

It is possible that in certain instances members of this Study research team may be asked to contribute papers to workshops, symposia, volumes, etc. The individuals to work on such requests should be appointed by the PI and co-PIs, but where time permits.

27. Protocol amendments

Any modifications to the study protocol including changes to objectives, design, recruitment, population, sample sizes, and data collection, storage, and analyses will require formal amendment to the protocol. Amendments will be agreed upon by the Trials Steering Committee and approved by the respective research ethics committees. Minor administrative changes to the protocol that do not have an effect on the way the study will be conducted will be documented and reported to the TSC and ethics committees.

28. Declaration of interests

Version1, 16042021, "Implementation science and impact evaluation of PfR programme: A hybrid cRCT design"



References

- 1. WHO, Global Status Report on Violence Prevention 2014, World Health Organisation: Geneva.
- 2. Uganda Bureau of Statistics (UBOS) and ICF, *Uganda Demographic and Health Survey 2016*. 2018: Kampala, Uganda and Rockville, Maryland, USA: UBOS and ICF.
- 3. Hillis, S., J. Mercy, et al., *Global Prevalence of Past-year Violence Against Children: A Systematic Review and Minimum Estimates.* Pediatrics, 2016. **137**(3): p. e20154079.
- 4. The Republic of Uganda, *Uganda Violence against Children Survey: Findings from a National Survey 2015*, M.o.G.L.a.S. Development, Editor. 2017, Ministry of Gender, Labour and Social Development: Kampala.
- 5. Ravi, S. and R. Ahluwalia, *What explains childhood violence? Micro correlates from VACS surveys.* Psychology, Health & Medicine, 2017. **22**(sup1): p. 17-30.
- 6. World Health Organization, *Preventing violence: Evaluating outcomes of parenting programmes*. 2013, WHO Press: Geneva.
- 7. Knaul, F.M., F. Bustreo, and R. Horton, *Countering the pandemic of gender-based violence and maltreatment of young people: The Lancet Commission.* Lancet, 2020. **395**(10218): p. 98-99.
- 8. Hillis, S.D., J.A. Mercy, and J.R. Saul, *The enduring impact of violence against children*. Psychology, Health & Medicine, 2017. **22**(4): p. 393-405.
- 9. Pereznieto, P., A. Montes, et al., *The Cost and Economic Impact of Violence Against Children*, O.D. Institute., Editor. 2014: London.
- 10. Guedes, A., S. Bott, et al., *Bridging the gaps: a global review of intersections of violence against women and violence against children*. Global health action, 2016. **9**(1): p. 31516.
- 11. Heise, L.L. and A. Kotsadam, *Cross-national and multilevel correlates of partner violence: an analysis of data from population-based surveys.* The Lancet Global Health, 2015. **3**(6): p. e332-e340.
- 12. Capaldi, D.M., N.B. Knoble, et al., *A Systematic Review of Risk Factors for Intimate Partner Violence*. Partner abuse, 2012. **3**(2): p. 231-280.
- 13. Cork, C., R. White, et al., *Randomized Controlled Trials of Interventions Addressing Intimate Partner Violence in Sub-Saharan Africa: A Systematic Review.* Trauma Violence Abuse, 2018: p. 1524838018784585.
- 14. Gardner, F., W. Knerr, et al., *Parenting for preventing risk of child maltreatment in low- and middle-income countries: Updated systematic review and meta-analysis.* forthcoming.
- 15. Singla, D.R., E. Kumbakumba, and F.E. Aboud, *Effects of a parenting intervention to address maternal psychological wellbeing and child development and growth in rural Uganda: A community-based, cluster-randomised trial.* The Lancet Global Health, 2015. **3**(8): p. e458-e469.
- 16. Shenderovich, Y., M. Eisner, et al., *Delivering a parenting program in South Africa: The impact of implementation on outcomes.* Journal of Child and Family Studies, 2019. **28**(4): p. 1005-1017.
- 17. Bacchus, L.J., M. Colombini, et al., Exploring opportunities for coordinated responses to intimate partner violence and child maltreatment in low and middle income countries: a scoping review. Psychology, Health & Medicine, 2017. 22(sup1): p. 135-165.
- 18. Siu, G.E., J. Seeley, and D. Wight, *Dividuality, masculine respectability and reputation: how masculinity affects men's uptake of HIV treatment in rural eastern Uganda*. Soc Sci Med, 2013. **89**: p. 45-52.

Version1, 16042021, "Implementation science and impact evaluation of PfR programme: A hybrid cRCT design"

- 19. Wamoyi, J. and D. Wight, 'Mum never loved me.' How structural factors influence adolescent sexual and reproductive health through parent-child connectedness: a qualitative study in rural Tanzania. African journal of AIDS research: AJAR, 2014. **13**(2): p. 169-178.
- 20. Siu, G.E., D. Wight, et al., *Men's involvement in a parenting programme to reduce child maltreatment and gender-based violence: Formative evaluation in Uganda.* The European Journal of Development Research, 2017. **29**(5): p. 1017-1037.
- 21. Curran, G.M., M. Bauer, et al., Effectiveness-implementation hybrid designs: Combining elements of clinical effectiveness and implementation research to enhance public health impact. Medical care, 2012. **50**(3): p. 217.
- Wight, D., E. Wimbush, et al., *Six steps in quality intervention development (6SQuID)*. Journal of Epidemiology and Community Health, 2016. **70**(5): p. 520-525.
- 23. Kezami Mina, Siu Godfrey, et al., *Motivations and challenges of lay facilitators delivering a parenting programme to prevent gender-based violence and violence against children in Uganda: a formative evaluation.* PloS One, forthcoming.
- 24. Ward, C.L., C. Mikton, et al., *Parenting for Lifelong Health: From South Africa to other low-and middle-income countries*. Early Childhood Matters: Responsive Parenting: A Strategy to Prevent Violence, 2014. **49**.
- 25. Wight, D., R. Sekiwunga, et al., Parenting for Respectability A Ugandan Intervention to Modify Familial Predictors of Gender Based Violence: Description and Formative Evaluation. forthcoming
- 26. Meinck, F., M.E. Boyes, et al., Adaptation and psychometric properties of the ISPCAN Child Abuse Screening Tool for use in trials (ICAST-Trial) among South African adolescents and their primary caregivers. Child Abuse and Neglect, 2018. 82: p. 45-58.
- 27. Straus, M.A. and E.M. Douglas, *A short form of the Revised Conflict Tactics Scales, and typologies for severity and mutuality.* Violence and Victims, 2004. **19**(5): p. 507-519.
- 28. Garcia-Moreno, C., H. Jansen, et al., *Prevalence of intimate partner violence: Findings from the WHO multi-country study on women's health and domestic violence.* The Lancet, 2006. **368**: p. 9543.
- 29. UNICEF, Multiple indicator cluster survey manual, 2005: Monitoring the situation of children and women. 2005, New York: UNICEF.
- 30. Elgar, F., D. Waschbusch, et al., *Development and Validation of a Short Form of the Alabama Parenting Questionnaire*. Journal of Child and Family Studies, 2007. **16**(2): p. 243-259.
- 31. Burns, G., S. Lee, et al., *Child and Adolescent Behavior Inventory—Parent Version 1.0.* 2015, Pullman: Autor.
- 32. Berry, J.O. and W.H. Jones, *The Parental Stress Scale Initial Psychometric Evidence*. Journal of Social and Personal Relationships, 1995. **12**(3): p. 463-472.
- 33. Gulamani, S.S., *Preterm birth a risk factor for postpartum depression in Pakastani women*. Open Journal of Depression, 2013. **2**(72).
- 34. Cheung, S.K., *Psychometric properties of the Chinese version of the parental stress scale.* プシコロギア, 東洋国際心理学誌, 2000. **43**(4): p. 253-261.
- 35. Gerard, J.M., L. Landry-Meyer, and J.G. Roe, *Grandparents raising grandchildren: The role of social support in coping with caregiving challenges*. International Journal of Aging and Human Development, 2006. **62**(4): p. 359-383.

Version1, 16042021, "Implementation science and impact evaluation of PfR programme: A hybrid cRCT design"

- 36. Henry, J.D. and J.R. Crawford, *The short-form version of the Depression Anxiety Stress Scales (DASS-21): Construct validity and normative data in a large non-clinical sample*. British Journal of Clinical Psychology, 2005. **44**: p. 227-239.
- 37. Wright, G., Findings from the Indicators of Poverty and Social Exclusion Project: A Profile of Poverty using the Socially Perceived Necessities Approach. Key Report 7, Department of Social Development, Republic of South Africa. 2008: Pretoria.
- 38. Webster-Stratton, C. and K.C. Herman, *Disseminating Incredible Years Series early-intervention programs: Integrating and sustaining services between school and home.* Psychology in the Schools, 2010. **47**(1): p. 36-54.
- 39. Lachman, J.M., A. Booij, et al., Parenting for Lifelong Health Facilitator Assessment Tool. 2017.
- 40. Altman, D.G., K.F. Schulz, et al., *The revised CONSORT statement for reporting randomized trials: Explanation and elaboration.* Annals of internal medicine, 2001. **134**(8): p. 663-694.
- 41. Delgado-Rodriguez, M., Loorca, J., *Bias.* Journal of Epidemiological Community Health, 2004. **58**: p. 635-641.
- 42. Brislin, R.W., *Back-translation for cross-cultural research*. Journal Cross-Cultural Psychology, 1970. **1**(3): p. 185-216.
- 43. Phillips, A.E., G.B. Gomez, et al., A systematic review and meta-analysis of quantitative interviewing tools to investigate self-reported HIV and STI associated behaviours in low- and middle-income countries. International Journal of Epidemiology, 2010. **39**(6): p. 1541-55.
- 44. Davies, M., *Using computer-assisted self-interviewing (CASI) questionnaires to facilitate consultation and participation with vulnerable young people.* Child Abuse Review, 2005. **14**(6): p. 389.
- 45. Connolly, P., *Children, assessments, and computer-assisted interviewing.* Child Abuse Review, 2005. **14**(6): p. 407.
- 46. Gardner, M.J. and D.G. Altman, *Confidence-intervals rather than P-values: Estimation rather than hypothesis-testing.* British Medical Journal, 1986. **292**(6522): p. 746-750.
- 47. Kianifard, F. and M.Z. Islam, *A guide to the design and analysis of small clinical studies*. Pharmaceutical Statistics, 2011. **10**(4): p. 363-8.
- 48. Hinshaw, S.P., *ntervention research, theoretical mechanisms, and causal processes related to externalizing behavior patterns.* Development and Psychopathology, 2002. **14**: p. 798-818.
- 49. Sobel, M.E., Direct and indirect effect in linear structural equation models, in Common problems/proper solutions: Avoiding error in quantitative research, J.S. Long, Editor. 1988, Sage: Beverly Hills. p. 46-64.
- 50. Hsu, M., Structural Equation Modeling with Amos, in SPSS, SPSS, Editor 2009, SPSS., *Structural Equation Modeling with Amos*, in *SPSS*. 2009.
- 51. Armstrong, R., et al., *Improving the reporting of public health intervention research: advancing TREND and CONSORT.* Journal of Public Health (Oxford), 2008. **30**(1): p. 103-109.
- 52. Kraemer, H.C., et al., *Mediators and moderators of treatment effects in randomized clinical trials*. Arch Gen Psychiatry, 2002. **59**(10): p. 877-83.
- 53. Gardner, F., J. Hutchings, et al., *Who benefits and how does it work? Moderators and mediators of outcome in an effectiveness trial of a parenting intervention.* Journal of Clinical Child and Adolescent Psychology, 2010. **39**(4): p. 568-580.

- 54. Kraemer, H.C. and T.N. Robinson, *Are certain multicenter randomized clinical trial structures misleading clinical and policy decisions?* Contemporary Clinical Trials, 2005. **26**(5): p. 518-29.
- 55. Moncher, F., Prinz, R., *Treatment fidelity in outcome studies*. Clinical psychology review, 1991. **11**: p. 247-266.
- 56. Borrelli, B., D. Sepinwall, et al., A new tool to assess treatment fidelity and evaluation of treatment fidelity across 10 years of health behavior research. J Consult Clin Psychol, 2005. 73(5): p. 852-60.
- 57. Dunn, G., M. Maracy, and B. Tomenson, *Estimating treatment effects from randomized clinical trials with noncompliance and loss to follow-up: The role of instrumental variable methods.* Statistical methods in medical research, 2005. **14**(4): p. 369-395.
- 58. Jo, B., E.M. Ginexi, and N.S. Ialongo, *Handling missing data in randomized experiments with noncompliance*. Prevention Science, 2010. **11**(4): p. 384-396.
- 59. Bellg, A.J., B. Borrelli, et al., Enhancing treatment fidelity in health behavior change studies: Best practices and recommendations from the NIH behavior change consortium. Health Psychology, 2004. **23**(5): p. 443-451.
- 60. Strauss, A. and J. Corbin, *Basics of Qualitative Research: Grounded Theory Procedures and Techniques*. 1990, London: Sage Publications.
- 61. Corbin, J.M. and A.L. Strauss, *Basics of qualitative research : techniques and procedures for developing grounded theory.* 3rd ed. 2008, Los Angeles, Calif.; London: Sage. xv, 379 p.
- 62. Morsbach, S.K. and R.J. Prinz, *Understanding and improving the validity of self-report of parenting*. Clinical Child and Family Psychology Review, 2006. **9**(1): p. 1-21.
- 63. Brewster-Lee, D., Lukonge, H., Kaaya, N., Kagaruki, L., Raphael, G., Miller, C., Faster Reporting, Reducing Errors, and Creating a Community Record: Improving OVC Programming with Mobile Reporting, Catholic-Relief-Services, Editor. 2010.
- 64. Alderson, P. and V. Morrow, *Ethics, social research and consulting with children and young people*. Children, Youth and Environments. 2004, London: Barnardo's.
- 65. Lorenc, T. and K. Oliver, *Adverse effects of public health interventions: A conceptual framework.* Journal of Epidemiology and Community Health, 2014. **68**: p. 288-290.
- 66. Knerr, W., F. Gardner, and L. Cluver, *Improving positive parenting skills and reducing harsh and abusive parenting in low- and middle-income countries: A systematic review.* Prevention Science, 2013. **14**(4): p. 352-363.