# Trials

**A parenting programme to prevent abuse of adolescents in South Africa: study protocol for a randomized controlled trial.**

--Manuscript Draft--

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| Abstract:          | Background  An estimated one billion children experience child abuse each year, with highest rates in low and middle income countries. The Sinovuyo Teen programme is part of Parenting for Lifelong Health, a WHO/UNICEF initiative to develop and test violence prevention programmes for implementation in low-resource contexts. The objectives of this parenting support programme are to prevent the abuse of adolescents, improve parenting, and reduce adolescent behavior problems. This trial aims to evaluate the effectiveness of Sinovuyo Teen compared to an attention-control group of a water hygiene programme.  

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Discussion  This is the first known trial of a parenting programme to prevent abuse of adolescents in a low or middle income country. The study will also examine potential mediating pathways and moderating factors. |
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Dear Dr Coventry
Re: TRLS-D-16-00277

Thank you for the opportunity to revise and resubmit this paper for Trials. We have responded below to each Reviewer’s comment (in italics), with the added sections from the paper pasted below each response. We would like to thank the reviewer for extremely helpful and constructive comments.

We have also completed the SPIRIT checklist and included additional information where required for SPIRIT, as well as a flowchart and sample of a consent form (this is from the pilot, as the consent forms for the main trial were on tablets, but the wording is the same).

Sincerely
The Sinovuyo Teen team.

Reviewer reports:
1) This is a well written and sufficiently detailed protocol to allow replication. The area is clearly a challenging one to work in and it is important that the authors have provided additional contextual information about the logistical and practical problems encountered doing this research - it will be of great interest to those doing or planning similar work in comparable LMIC. I have only a couple of minor points that the authors should consider as part of a revision:

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Thank you for this. We have made two small additions to this contextual information. The first into the section on ‘measurement points and methods’ explains that there
have been fieldwork delays due to civil violence, and the second into the Discussion section adds a recent source of unrest: ‘taxi wars’ in which all transport is stopped due to rival public transport firms protesting and attacking any vehicle that contains more than one person. These added sections are copied below.

Measurement points:
The 3-8 month post-test has been extended due to substantial levels of civil and election-related violence in the study areas, which have necessitated closing down of fieldwork for around 50% of the time. A 15-20-month or 20-26 month post-test is planned but will depend on financial resources, especially given the unanticipated costs related to violent community protests.

Discussion:
Violent armed conflict between private taxi operators and petrol-bombing of roads have restricted transport of staff to field sites.

2) I wasn't completely clear how the exploratory outcomes section related to the section on mediators and moderators. Perhaps the authors can condense information about outcomes and analysis that relate to exploratory tests of mediation and moderation in one section. What time points will be used for this kind of analysis as I'd expect there to be a minimum of 3 data points (I assume this will be baseline, 3-8 months and 15-20 months but worth making that clear and stating if possible how these models will be constructed and tested).

Thank you for this point – we agree that we were not sufficiently clear about the distinctions, and that calling them both ‘exploratory’ leads to confusion between two quite separate foci of the study. We have thus removed the word ‘exploratory’ from the description of mediation and moderation analyses, and completely re-written these sections to clarify better what they involve. We have also, as suggested, added a section clarifying the data points and analysis methods for these planned analyses, with citations:

Potential mediating pathways that have been shown to mediate change in primary outcomes in other studies of child abuse prevention, will be explored. Given that no known RCTs have tested a parenting program for families with adolescents in a LMIC, these mediation analyses will be tentative and based on the program’s theory of change, thus including potential mediators of change in parenting and child abuse such as parenting stress, parent mental health and social support. However, based on more substantial literature on parenting as a mediator of change in youth outcome, if there are main effects on the secondary outcomes of adolescent behavior problems and mental health, we plan to examine change in positive and harsh parenting as mediators of change in adolescent outcomes.

Potential moderating factors of program effects will also be examined. Again, given the novel nature of this study, these are tentatively hypothesized. Potential moderators (see below) will include family AIDS-illness/death, measured using verbal autopsy/illness questionnaires validated for high-prevalence areas [39]; poverty measured using the National Food Consumption Survey [40] and the South African Social Attitudes Survey [41]; Caregiver experience of maltreatment as a child and current gender-based violence: ISPAN Child Abuse Screening Tool-Retrospective (15 items) [42], 5 items from the revised Conflict Tactics Scale [43] and 5 items from the 15-item sexual relationship power scale [44]. Potential moderators will also include access to social protection provisions such as grants, community gardens and soup kitchens. We prefer not to predict whether poverty, family psychosocial or illness related factors will increase or reduce program effects, since the parenting intervention literature is very mixed on the direction of these moderator effects [45, 46] We will also examine variations in program effects based on attendance and participation in the intervention, and implementer fidelity.

Potential mediation and moderation effects will be tested using structural models (either using Hayes’ PROCESS path models, or structural equation modelling depending on variable type [47]), and ideally using three data points of baseline, 3-8 months post-intervention and 15-20/20-26 months post-intervention. If the final follow-up is not possible due to financial or practical constraints, models will use change...
between the mediating/moderating variable from pre to post-intervention and be clear that analyses should be interpreted with caution.

3. It would be worth adding a methodological note and reference about the benefits of randomising clusters before the intervention started as this is best practice and it is good to see this approach being taken in a pragmatic trial.

Thank you for highlighting this. We have added a note and a citation from the Cochrane Handbook to clarify why the timing of randomization was chosen.

Following Cochrane guidelines and in order to reduce the possibility of recruitment bias [19], randomisation was performed by the study statistician (Lombard) after recruitment of clusters and before the intervention started, using a random number generator in Excel.

4. Can the authors update the trial status and inform readers how many clusters and participants were recruited and if on track/target.

This is a very helpful suggestion – we have expanded the ‘trial status’ section with details of the recruitment, implementation and attendance of the program, the immediate brief post-test and the ongoing full follow-up data collection.

**Trial status**

As of revised submission of this manuscript in June 2016, the trial is ongoing. Recruitment commenced in March 2015 and a total of 1,108 participants (554 caregiver-adolescent dyads) have been recruited and completed baseline assessments. Despite some delays due to violent protests in program areas, the intervention took place with all 14 sessions conducted in 19 village peri-urban clusters and 13 sessions conducted in one cluster, and 87% of caregivers and 85% of adolescents received >90% of the sessions through groups or home visits. A brief immediate post-test data collection with a subset of primary outcomes was completed in December 2015, with 91% caregiver and 92% adolescent retention rate. These immediate results were primarily to determine safety and initial effectiveness for policy-makers planning the South African national scale-up. Three to eight-month follow-up data collection was due to complete in May 2016, but is currently delayed due to severe civil and political violence related to the 2016 local elections, and is now hoped to complete in August. The research team are currently estimating whether a 15-20 month follow-up or a 20-26-month follow-up is financially and practically possible, and if so this would be expected to complete by December 2017. Since submission of this manuscript, 16 countries in Southern, Eastern, Central and Northern Africa, South-East Asia and the Middle East have requested access to the program in order to adapt and take it to scale in their contexts.
A parenting programme to prevent abuse of adolescents in South Africa: study protocol for a randomized controlled trial.

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Abstract

Background

An estimated one billion children experience child abuse each year, with highest rates in low and middle income countries. The Sinovuyo Teen programme is part of Parenting for Lifelong Health, a WHO/UNICEF initiative to develop and test violence prevention programmes for implementation in low-resource contexts. The objectives of this parenting support programme are to prevent the abuse of adolescents, improve parenting, and reduce adolescent behavior problems. This trial aims to evaluate the effectiveness of Sinovuyo Teen compared to an attention-control group of a water hygiene programme.

Methods

This is a pragmatic cluster randomized controlled trial, with stratified randomization of settlements (rural and peri-urban) with 40 study clusters in the Eastern Cape of South Africa. Settlements receive either a 14-session parenting support programme or a 1-day water hygiene programme. The primary outcomes are child abuse and parenting practices, and secondary outcomes include adolescent behavior problems, mental health and social support. Concurrent process evaluation and qualitative research are conducted. Outcomes are reported by both primary caregivers and adolescents. Brief follow-up measures are collected immediately after the intervention, and full follow-up measures collected at 3-8 months post-intervention. A 15-24 month follow-up is planned, but this will depend on financial and practical feasibility given delays related to high levels of ongoing civil and political violence in research sites.

Discussion

This is the first known trial of a parenting programme to prevent abuse of adolescents in a low or middle income country. The study will also examine potential mediating pathways and moderating factors.
Trial registration

Pan-African Clinical Trials Registry PACTR201507001119966. Registered on 27/4/2015. It can be found by searching for the key word ‘Sinovuyo’ on their website or via the following link

http://www.pactr.org/ATMWeb/appmanager/atm/atmregistry?_nfpb=true&_windowLabel=BasicSearchUpdateController_1&BasicSearchUpdateController_1_actionOverride=%2Fpages%2Ftrial%2FbasicSearchUpdate%2FviewTrail&BasicSearchUpdateController_1id=1119

Key Words

Child abuse, parenting, low and middle income countries

See attached SPIRIT Checklist and Figure for details of trial flow and management.

Background

Worldwide, an estimated one billion children experience abuse each year [1], with the highest rates in low and middle-income countries (LMIC) and in particular the WHO Africa region [2]. Although prevalence data is limited, new studies suggest increases in abuse during adolescence [3], which is also a time of important social, emotional and continued neural development [4].

Despite this, systematic reviews find that the vast majority of research into child abuse prevention is in high-income countries and with younger children [5]. In LMIC, three trials have tested abuse-prevention parenting programmes, two targeted at children under 10 years old: in South Africa [6] and Liberia [7] and one for 13 year olds and under in Burundi [8]. To date, there are no known randomised trials of a parenting programme to prevent abuse of adolescents in any LMIC [9].
Existing evidence – albeit from different contexts and child age groups - demonstrates good effect sizes of group-based parenting programmes that are grounded in social learning theory, problem-solving and behaviour management skills acquisition [10]. And indeed, a recent systematic review showed high transportability of parenting programmes to address problem behaviour amongst younger children across high-income countries and contexts [11].

However, three major limitations exist to transportability to LMIC. Firstly, many existing evidence-based programmes charge fees for training and manuals, making costs prohibitive for low-resource agencies and governments [12]. Other programmes require qualified health professionals for implementation, who are not available in the highest-need areas. Finally, many have technological components (e.g. videos, web-based modalities) that are as yet inaccessible in areas with poor electricity and internet access.

In response, an international collaboration was started in 2012, to develop and rigorously test a suite of child abuse prevention programmes for different age groups. ‘Parenting for Lifelong Health’ (PLH) includes the World Health Organization, UNICEF and academics from the global South and North, with donor partners, LMIC governments and PEPFAR-USAID. PLH programmes are developed with participatory input from families in LMIC, for implementation by lay community workers, and have minimal equipment requirements. If shown effective in randomised trials, programmes will be freely available under licensing prohibiting any commercial or profit interests.

The adolescent programme, called ‘Sinovuyo (‘we have joy’) Teen’, has undergone incubation development and testing in very low income rural and peri-urban areas of South Africa. Initial development used systematic reviews to identify effective components [10], input provided voluntarily from over fifty international academics and practitioners, and in-depth qualitative work with adolescents and caregivers [6]. Draft programme manuals were
written in partnership between a local NGO (Clowns Without Borders South Africa) and academics from the Universities of Oxford and Cape Town.

A first pilot pre-post non-controlled test with 30 adolescent-caregiver dyads showed initial reductions in abuse and adolescents behavior problems, and no evidence of harm [13]. Concurrent qualitative research identified participant requests to incorporate economic strengthening approaches into the programme, to lessen family conflict over money. After adaptation, a second pre-post non-controlled test with 115 dyads showed reductions in abuse, behavior problems, improvements in positive/involved parenting, social support and reductions in depression and caregiver (but not adolescent) substance abuse [14]. This second stage also piloted family budgeting and savings sessions, which were subsequently incorporated into the third version of the manual. The studies also found unanticipated high levels of programme dissemination within communities, particularly through church groups and community meetings.

At all stages the project has been a close partnership between NGOs, the South African Department of Social Development and UNICEF. These agencies intend to decide whether to implement the programme within a provincial and national rollout, based on the results of this trial. Furthermore, an additional seventeen countries in Sub-Saharan Africa, Central Asia, Eastern Europe and the Middle East have expressed strong interest in implementing the programme. The timing of this trial is thus critical for policy-making for child abuse prevention in LMIC.

Due to extenuating circumstances (high levels of civil and political unrest in research sites in the first six months of the trial) this protocol is submitted after recruitment of participants, and therefore falls outside the journal’s usual policies. Data collection is still underway at the time of submission.
Methods and Design.

In this pragmatic cluster randomized trial in real-world settings, 40 rural and peri-urban settlements, containing 600 caregiver-adolescent dyads, are randomized to two parallel arms.

Study Aims

To compare effectiveness of a 14-session caregiver and adolescent programme with an attention-control group, amongst high-risk adolescents aged 10-18 and their families. Primary outcomes for the trial are 1) harsh and abusive discipline and 2) parenting. Secondary outcomes include adolescent externalizing behaviour, parenting stress, mental health, social support. Exploratory outcomes include family financial coping, avoiding risk in the community, sexual harassment/abuse and educational engagement.

Inclusion criteria

Communities: Rural and peri-urban settlements within a 1-hour driving distance of King William’s Town, in the Eastern Cape province of South Africa. All areas have high rates of unemployment, poor infrastructure and high HIV/AIDS prevalence [15].

Participants: Adolescents are between 10 and 18, and either sleep in the same dwelling for at least four nights a week as their primary caregiver or have regular contact with them. Adolescents and their primary caregivers gave informed consent to participate. Recruitment followed pragmatic trial principles of closely approximating methods of inclusion in NGO or government services. Families were referred by a range of social services, schools, local chieftains and were also able to self-refer as struggling with an adolescent. All families completed a brief screening questionnaire asking if there were regular arguments in the home.

Exclusion criteria
Following pragmatic trial principles, there were no exclusion criteria for families. There were no requirements for a biological relationship between caregiver and adolescent. Communities required approval from local traditional or political leaders (chieftains and ward councillors), and were estimated to be safe enough (during daylight hours and with local support) to hold a parenting group without serious risk to participants. If a participant had such severe learning disabilities that they were unable to consent to participation, they were not included in the study for ethical reasons.

**Control sites**

Control rural and peri-urban settlements receive a 1-session hygiene programme called ‘SinoSoap’. This is implemented by an NGO Clowns Without Borders South Africa and involves drama-based skills-building on safe water conservation and handwashing for children. All participating families in control sites receive a ‘hope soap’: a bar of soap containing a small toy that is only accessible when the soap is used.

**Intervention sites**

Intervention rural and peri-urban settlements receive the 14-session parenting programme called ‘Sinovuyo Teen’. Weekly sessions take place in communities (church and community halls, schools, under trees).

**Programme and training**

The intervention programme is implemented by locally-recruited unqualified community members, and local social auxiliary workers. All programme facilitators received 1 week’s initial training and weekly supervisions from Clowns Without Borders South Africa. The training was participatory and activity-based, and training materials are being developed for free availability.
The programme is based on evidence-informed parenting principles, such as praising each other, managing anger and stress, joint problem-solving, non-violent discipline, rules and routines, keeping adolescents safe in the community, and responding to crises (see Table 1). It uses collaborative problem-solving techniques (not didactic methods) and traditional stories, role-play, modelling and stress reduction activities [16-18].

10 programme sessions are joint with caregivers and adolescents, and 4 sessions have separate components to allow sensitive discussions. Participants are encouraged to engage in ‘home practice’ in the week following each session. For participants unable to attend sessions due to illness, disability etc., ‘khaya (home) catch-ups’ are arranged to give brief session content at home or in the hospital. A simple lunch is included at the beginning of each session as many participants find concentration difficult due to hunger.

Randomisation
Stratified randomisation was used. There were 40 eligible study clusters, 32 rural and 8 peri-urban clusters, representing the two strata. Complete randomisation was done for clusters within strata in a 1:1 ratio for the intervention and control arms. Following Cochrane guidelines and in order to reduce the possibility of recruitment bias [19], randomisation was performed by the study statistician (Lombard) after recruitment of clusters and before the intervention started, using a random number generator in Excel.

Allocation concealment
Blinding of patients and programme implementers is not possible because participants know whether they are receiving a parenting or hygiene programme. However, the trial statistician carrying out randomization and analyses is blinded, and all efforts are made to keep data collection research staff blinded as to allocation for as long as possible. Due to the nature of the intervention (i.e. families displaying home practice sheets or certificates on their walls, children in villages singing programme songs from either Sinovuyo Teen or SinoSoap)
blinding is not always maintainable. To alleviate this, audio-CASI (audio computer-assisted self-interview) methods are used, and training of data collectors included consistent administration and awareness of biases.

Measurement points and methods

Primary caregivers and adolescents complete measures independently and in private using a tablet with data collector support at pre-test and 3-8 months post-intervention. Tablet-based questionnaires were designed to be engaging, with embedded activities and pictures, and modified scale responses using colours etc., for participants with low literacy. All questionnaires and audio-CASI sections were pre-piloted with local adolescents and caregivers. Open source software was used, and all questionnaires will be made freely available for other researchers.

Due to the high mobility of adolescents at the beginning of the new school year in January and the national government plans to scale the programme nationally in 2016, an additional brief immediate post-test data collection point was added, with a subset of outcome measures, in order to assess safety for this unanticipated scale-up. The 3-8 month post-test has been extended due to substantial levels of civil and election-related violence in the study areas, which have necessitated closing down of fieldwork for around 50% of the time. A 15-20-month or 20-26 month post-test is planned but will depend on financial resources, especially given the unanticipated costs related to violent community protests.

To increase participant retention in the study, we will continue to hold community meetings, and to work with chieftains and local councillors in all sites prior to returning for data collection. Only data on reasons for non-participation will be collected from participants who choose not to continue in the study.
Measures

All measures were translated into Xhosa and back-translated. Interviews take place in homes and community settings, using tablet-based questionnaires with audio-assisted interviews for stigmatized measures (child abuse, HIV/AIDS etc.). The research team are recruited locally but do not conduct data collection in their home areas, and are trained for a month on research ethics and in working with vulnerable children and families. All questionnaire are available at www.youngcarers.org.za

Primary outcomes

Abusive parenting (physical abuse, emotional abuse, neglect) is measured using an adapted version of the International Society for Prevention of Child Abuse and Neglect Child Abuse Screening Tool (ICAST-Child, 18 items; and ICAST-Parent, 22 items) [20, 21] for use in intervention studies. Positive and involved parenting (16 items), monitoring and inconsistent discipline (16 items) and Corporal punishment (5 items) are measured using the Alabama Parenting Questionnaire (parent and child versions) [22].

Secondary outcomes

Adolescent behaviour problems uses the Child Behavior Checklist [23] rule-breaking and aggressive behaviour subscales (35 items). Parenting stress is measured using the Parental Stress Scale [24] (18 items). Caregiver depression (caregiver report only) is measured using the Centre for Epidemiologic Studies Depression Scale [25] (20-items). Adolescent depression (adolescent report only) uses the short-form Child Depression Inventory (CDI) (10 items) [26]. Adolescent suicidality is measured with the Mini International Neuropsychiatric Interview for Children and Adolescents [27]. Social support (for caregivers and adolescents) is measured using the MOS Social Support Survey [28].

Exploratory outcomes
Family financial coping uses items assessing shortages in monthly budgets for purchasing meat, electricity etc., and level of emotional stress experienced as a result, plus items on capacity to respond to emergencies, and borrowing and savings behaviours [29-31] Planning for avoiding risk in the community is measured using the adapted Parent Teen Sexual Risk Communication Scale III (4 items) [32], and 5 items from the Parent Communication Scale [33]. Exposure is measured using items from the National Survey of HIV and Sexual Behaviour amongst Young South Africans [12,13], sexual abuse items from the ICAST, and exposure to community violence using three items based on risks identified in the Victimization/Witnessing of Community Violence subscales of the Social And Health Assessment (SAHA) [34, 35]. Education is measured using 4 adapted items of the SAHA academic motivation scale [36], with school attendance, grade repetition, and school records of the South African standardised Annual National Assessment Learner Report if this is conducted as intended in 2016 [37]. Attitudes towards gender norms in relationships uses 4 items from the Gender Equitable Men scale [38].

Process evaluation assessments

Process evaluation assessments include implementer records of home visits, programme attendance rates, as well as independent observations of participant engagement and implementer fidelity and adherence during sessions. In addition, focus groups with implementers, participants, and data collectors explored these topics qualitatively. In the pre-test questionnaire, participants self-assessed their motivation to improve their relationship with their adolescent/caregiver, intentions to participate in both intervention and control arm programmes, and estimated difficulties and utility of attendance.

Qualitative assessment

Linked qualitative data collection aims to understand how policy, service delivery, social and economic factors may impact the effectiveness and scalability of the intervention. This focuses on a) recommendations of local staff delivering the programme, b) family
experiences of the parenting programme in the wider context of their lives and c) policy and programming-level considerations for scaling a parenting programme in South Africa. The qualitative research study is conducted in partnership with UNICEF’s Office of Research – Innocenti. Ongoing qualitative methods throughout the pilot and randomised trial stages (in English and Xhosa) include record analysis, semi-structured interviews with local and international NGOs, government partners and implementing partners; elite interviews with South African policy-makers at the local, provincial and national level; focus group and individual interviews with beneficiaries and implementers, including interactive activities and participatory visual methodologies and programme workshop observation.

**Mediating and moderating pathways**

Potential mediating pathways that have been shown to mediate change in primary outcomes in other studies of child abuse prevention, will be explored. Given that no known RCTs have tested a parenting program for families with adolescents in a LMIC, these mediation analyses will be tentative and based on the program’s theory of change, thus including potential mediators of change in parenting and child abuse such as parenting stress, parent mental health and social support. However, based on more substantial literature on parenting as a mediator of change in youth outcome, if there are main effects on the secondary outcomes of adolescent behavior problems and mental health, we plan to examine change in positive and harsh parenting as mediators of change in adolescent outcomes.

Potential moderating factors of program effects will also be examined. Again, given the novel nature of this study, these are tentatively hypothesised. Potential moderators (see below) will include *family AIDS-illness/death*, measured using verbal autopsy/illness questionnaires validated for high-prevalence areas [39]; *poverty* measured using the National Food Consumption Survey [40] and the South African Social Attitudes Survey [41]; *Caregiver experience of maltreatment as a child and current gender-based violence*: ISPCAN Child Abuse Screening Tool-Retrospective (15 items) [42], 5 items from the revised Conflict
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Potential mediation and moderation effects will be tested using structural models (either using Hayes’ PROCESS path models, or structural equation modelling depending on variable type [47]), and ideally using three data points of baseline, 3-8 months post-intervention and 15-20/26 months post-intervention. If the final follow-up is not possible due to financial or practical constraints, models will use change between the mediating/moderating variable from pre to post-intervention and be clear that analyses should be interpreted with caution.

**Socio-demographic covariates**

Socio-demographic covariates include age, gender, disability level, urban/rural location, household structure, caregiver-child relationship, household employment, and HIV/AIDS-related stigma.

**Statistical analysis plan**

*Sample size calculation* was conducted by YS using the ICAST child abuse measure as the basis as it is the main outcome of policy interest. We estimated the range of ICCs up to 0.08 based on pilot testing in the study area. We note that there are a large number of zero values in reporting of child abuse in any pragmatic sample. Using Optimal Design software [48], 40 clusters with 12 families per cluster were required for a minimum detectable effect size of 0.36 for desired power of .80 with a significance level of 5% with a two-tailed test. To account for attrition of up to 20% within each cluster, the target sample size was set at 600.
families (40 clusters with 15 families per cluster). Our estimate of expected effect size was based on the effect sizes for maltreatment and parenting outcomes in a recent review of parenting programs for child maltreatment prevention [49]. This showed an average program effect of 0.2, but the present study was limited by financial constraints, so will need to reach an effect of 0.36 to find significance.

**Types of analysis**

A baseline table reflecting the demographic profile of the households, caregivers and adolescents by arm will be compiled. Statistical analyses will be by intention to treat, with additional per-protocol analysis. For the analysis of the primary outcomes the suitability of using linear regression models will be checked. For primary outcomes that can be analysed with this approach a hierarchical linear mixed effects model will be used to evaluate the intervention effect with the cluster and participant (caregiver or adolescent) as the nested random effects. To account for dropouts in the intention to treat analysis the baseline measurement will be part of the repeated outcomes and estimation of the intervention effects will be via maximum likelihood. The significance of the intervention effect will be based on the significance of the arm by time interaction effect. The models will include the stratification as a fixed effect. The impact of the missing data on the estimated intervention effect will be checked by imputing missing outcome data (10 imputations) using complete baseline and follow-up data and running the same models. For primary outcome that does not meet the criteria for an individual level analysis, an analysis at the cluster level will be used using a standard linear regression model or a non-parametric quantile regression model. These models will allow for the comparison of arms, adjusted for the stratification and baseline cluster value. A similar sensitivity analysis will be done for the cluster level analysis based on the imputed data. The primary and secondary outcome will be analysed separately for caregivers and adolescents and a joint outcome model will be done as an exploratory analysis for the understanding of dependence of outcomes within a dyad. The impact of adherence (number of session attended) to the intervention will be assessed using the same
models but restricted to the intervention arm.

**Ethical procedures**

Ethical protocols were approved by the Faculty of Humanities Ethics Review Committee, University of Cape Town (PSY2014-001) and the Social Sciences & Humanities Inter-divisional Research Ethics Committee, University of Oxford (SSD/CUREC2/11-40), the European Research Council (ERC-2012-StG 313421-PACCASA) and South African provincial Departments of Social Development and Basic Education. Written voluntary informed consent is obtained from all participants and consent procedures are read aloud for those with limited literacy. Families do not receive monetary incentives, but receive ‘thank-you packs’ with a certificate of participation, a snack, stationery for school and toiletries at pre-test. At post-test, families receive a small food parcel. Confidentiality is maintained, except if participants are at risk of significant harm or request assistance. If participants report severe abuse, rape, recent suicide attempts or other significant harm, immediate referrals are made to child protection, health and HIV/AIDS services, with follow-up support.

**Stopping procedures**

An independent trial steering committee has been established. Two pilot studies showed no evidence of harm [13]. If there are any indications of negative effects, as noted in process observations or participant reports, the PI and partner NGOs will be alerted, and preventative action taken.

**Modifications to the protocol**

Any changes to the protocol will be communicated to the relevant partners and funding bodies via e-mail. The current protocol at Pan African ClinicalTrials Registry will be updated online.

**Coordinating centre**
The coordinating centre at Oxford University consists of research and academic staff. It provides administrative and scientific and runs the fieldwork component of the research. Oxford and the South African site jointly run safety responses to political violence, through WhatsApp messaging for instant communication of unsafe areas and evacuation of staff when needed.

Steering committee
The steering committee is composed of an independent, international group of academics with experience in running randomised trials of parenting interventions in low- and middle-income countries, child protection and child abuse prevention specialists. It provides scientific support and data monitoring where needed. Trial conduct is reviewed with this committee 6-monthly.

Data management
Only a small number of the research team have access to personal identifiers in order to match caregiver and child interviews. Using a password-protected internet network, tablet devices transmit participant responses to a password-protected server where the data are automatically captured. Questionnaires sent to the server cannot be altered. Data collected on tablets cannot be accessed unless key coded when uploaded to a central network server, which is hosted by the University of Oxford. Thus, data are protected from both server failure and confidentiality breaches. Non-electronic data are stored in a locked filing cabinet. In reporting the findings of this study, names will be omitted and only general locations in which the study took place will be reported. Data will be made available at Data Archive UK or a similar open-access archive. Non-anonymised data will be kept for a period of up to five years in locked cabinets.

Capacity-building and resource sharing
The trial aims to build capacity in low-resource contexts. This includes recruitment and intensive training of unqualified local staff, with provision of financial support for educational needs and recruitment and training of local community members in programme implementation. All study materials (qualitative and quantitative) will be freely available via the UNICEF and WHO websites. Doctoral and pre-doctoral students from LMIC are included in the study team.

Dissemination

Community-level: Findings will be disseminated to all local communities, local leaders, NGOs and government departments through presentations, and a core research team will remain in the field site for 6 months in order to do this. Policy/academic-level: Ongoing dissemination is being carried out at academic and professional conferences and to international NGOs, LMIC governments and policy makers with regards to the development and testing of the intervention.

Discussion

This study has potentially substantive scientific, policy and programming value. It is the first known randomised trial of a programme to prevent abuse of adolescents in a low or middle income country. It uses a pragmatic cluster randomised controlled trial design, in order to provide maximum relevance to programming in low-resource settings. It is located in an area and with a population experiencing multiple concurrent challenges – and as a result of this, a number of key practical issues have emerged in beginning this trial. The study site has experienced increasing civil unrest, including violent riots related to service access, political rallies, xenophobic violence, and protests against corruption. These have caused staff safety concerns, and disruptions to both data collection and intervention programming. Extended periods without electricity, drought and flooding have caused operational delays. Violent crime (hijacking of project vehicles etc.) has been rare but has required restructuring of
research processes to increase staff security. Violent armed conflict between private taxi operators and petrol-bombing of roads have restricted transport of staff to field sites. Despite these challenges, the value of a pragmatic trial design is clear: increased external validity to assist decisions by policy-makers. The strong interest shown by multiple countries and agencies in this programme highlights the perceived need for effective interventions to combat abuse amongst adolescents, and the importance of rigorous research evidence in this area.

**Trial status**

As of revised submission of this manuscript in June 2016, the trial is ongoing. Recruitment commenced in March 2015 and a total of 1,108 participants (554 caregiver-adolescent dyads) have been recruited and completed baseline assessments. Despite some delays due to violent protests in program areas, the intervention took place with all 14 sessions conducted in 19 village/peri-urban clusters and 13 sessions conducted in one cluster, and 87% of caregivers and 85% of adolescents received >90% of the sessions through groups or home visits. A brief immediate post-test data collection with a subset of primary outcomes was completed in December 2015, with 91% caregiver and 92% adolescent retention rate. These immediate results were primarily to determine safety and initial effectiveness for policy-makers planning the South African national scale-up. Three to eight-month follow-up data collection was due to complete in May 2016, but is currently delayed due to severe civil and political violence related to the 2016 local elections, and is now hoped to complete in August. The research team are currently estimating whether a 15-20 month follow-up or a 20-26-month follow-up is financially and practically possible, and if so this would be expected to complete by December 2017. Since submission of this manuscript, 16 countries in Southern, Eastern, Central and Northern Africa, South-East Asia and the Middle East have requested access to the program in order to adapt and take it to scale in their contexts.
Abbreviations

**audio-CASI**: audio computer-assisted self-interview  
**CDI**: Child Depression Inventory

**ICAST**: IPSCAN Child Abuse Screening Tools  
**ICC**: Intra-cluster Correlation Coefficient

**ISPCAN**: International Society for the Prevention of Child Abuse and Neglect  
**LMIC**: lower middle income country  
**MOS**: Medical Outcomes Study  
**NGO**: non-governmental organisation  
**PEPFAR**: President’s Emergency Plan for AIDS Relief  
**PI**: principal investigator  
**PLH**: parenting for lifelong health  
**SAHA**: Social and Health Assessment

**UNICEF**: United Nations Children’s Emergency Fund  
**WHO**: World Health Organization

**USAID**: US Agency for International Development

Declarations

Acknowledgements

The team wishes to acknowledge resources made available from the Adolescent Well-being Research Programme, funded primarily by DFID, the ESRC Impact Acceleration Account at the University of Oxford, the Eastern Cape Provincial Department of Social Development, and the South African National Arts Council. In the broader PLH suite, we are grateful to our many donor partners. Please see http://www.who.int/violence_injury_prevention/violence/child/plh/en/ for further details of both the full suite of programmes and our donor partners. The authors would also like to thank those who contributed to the study: Lorraine Sherr, Tshiamo Petersen, Sibongile Tsoanyane, Christopher Mikton and Lulu Ncobo.

Funding

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Availability of data and material

Sinovuyo Teen manuals and programme materials will be made freely available online, and UNICEF has sponsored free printed versions. All research materials (i.e. questionnaires, study process materials, qualitative toolkit) will be made freely available on UNICEF and WHO websites. Study data will be made available on open access websites such as the South African Data Archive and the European Clinical Trials database.

Competing interests

JD, LC, JL, CLW and ST were involved in the design of the Sinovuyo Teen programme. No profit or financial gain will be made from this programme.

Authors’ contributions

LC conceived of the study and drafted the manuscript for publication. FM participated in the design of the study and drafted an extensive study protocol. YS participated in the design of the study, drafted an extensive study protocol and performed sample size calculations. CW provided overall guidance in RCT design and contributed to the development of the protocol. RHR participated in the design of the study and drafted an extensive study protocol. AR participated in the design of the study, drafted an extensive study protocol and trialled methods in the planning stages. CL participated in the design of the study and planned the statistical analyses. JS and DB participated in design and trial of measures and helped draft the protocol. RC, CW, NS and PM participated in design and adaptation of the trial through trial methods and community liaison in the planning stages. JL participated in the design of this study and provided feedback during protocol development. FG provided overall guidance in RCT design. JD and HL participated in the design of the qualitative study. MN and SDS developed innovative methods for use of audio-CASI with non-literate populations. ML
participated in the design of the study and provided feedback on the manuscript. All authors read and approved the final manuscript.
References


Table 1

<table>
<thead>
<tr>
<th>Session</th>
<th>Content</th>
<th>Mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Introducing the programme &amp; defining participant goals</td>
<td>Joint</td>
</tr>
<tr>
<td>2</td>
<td>Building a positive relationship through spending time together</td>
<td>Joint</td>
</tr>
<tr>
<td>3</td>
<td>Praising each other</td>
<td>Joint</td>
</tr>
<tr>
<td>4</td>
<td>Talking about emotions</td>
<td>Separate</td>
</tr>
<tr>
<td>5</td>
<td>What do we do when we’re angry?</td>
<td>Separate</td>
</tr>
<tr>
<td>6</td>
<td>Problem solving: Putting out the fire</td>
<td>Joint</td>
</tr>
<tr>
<td>7</td>
<td>Motivation to save and making a budget with our money</td>
<td>Joint</td>
</tr>
<tr>
<td></td>
<td>topics</td>
<td>method</td>
</tr>
<tr>
<td>---</td>
<td>--------------------------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>8</td>
<td>Dealing with problems without conflict I</td>
<td>Separate</td>
</tr>
<tr>
<td>9</td>
<td>Dealing with problems without conflict II</td>
<td>Separate</td>
</tr>
<tr>
<td>10</td>
<td>Establishing rules and routines</td>
<td>Joint</td>
</tr>
<tr>
<td>11</td>
<td>Ways to save money &amp; making a family saving plan</td>
<td>Joint</td>
</tr>
<tr>
<td>12</td>
<td>Keeping safe in the community</td>
<td>Joint</td>
</tr>
<tr>
<td>13</td>
<td>Responding to crisis</td>
<td>Joint</td>
</tr>
<tr>
<td>14</td>
<td>Widening Circles of Support</td>
<td>Joint</td>
</tr>
</tbody>
</table>
Recruitment & Baseline surveys
Conducted by trial site staff: screen potential participant dyads by inclusion and exclusion criteria, obtain informed consent, baseline surveys completed on tablets using ODK software

Random allocation of clusters

Intervention Group (n=20)
Intervention phase: 14 sessions of the Sinovuyo Teen Parenting Programme
Conducted by Clowns without Borders: facilitator training and supervision of facilitation

Process evaluation
Conducted by trial site staff: observation of all sessions and checklists for adherence to manual

Control Group (n=20)
1 session SinoSoap Intervention, drama-based skills-building on safe water conservation and handwashing
Conducted by Clowns Without Borders

Brief immediate post-test
Conducted by trial site staff: abbreviated questionnaire of primary outcomes completed on tablets
occurs between 2 weeks and 8 weeks post-intervention

Qualitative research
Conducted by trial site staff: focus group discussions, workshops and qualitative interviews with participants

3-8 month follow-up survey
Conducted by trial site staff: post-test survey questionnaire completed on tablets

Qualitative research
Conducted by trial site staff: semi-structured interviews with targeted participants

15-20 month or 20-26 month follow-up
Conducted by trial site staff: post-test survey questionnaires completed on tablets
Click here to access/download

**Supplementary Material**

Sinovuyo Teen Parenting Programme Evaluation Consent Form.docx