DEPARTMENT OF SOCIAL POLICY AND INTERVENTION

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Dear IDREC Secretariat and Committee,

Changes in Protocol for PACCASA Project

Please find below detail of changes made in the protocol for the PACCASA (Preventing the Abuse of Children in the Context of AIDS in sub-Saharan Africa) project being implemented by Dr. Lucie Cluver (Approval Ref SSD/CUREC2/11-40). This project has been granted ethical approval by CUREC. Please find Oxford's ethical approval attached. It has also been granted ethical approval from the University of Cape Town Psychology Department Research Ethics Committee (ref 2012_05_01) and from the South African Eastern Cape Provincial Department of Social Development and Department of Education.

While there are no substantive changes compared to the original protocol, the project needed to implement some small adaptations to the research process primarily due to our close collaboration with research partners. These changes do not involve any modifications to the ethical issues stated in the original CUREC 2 form.

The changes made from the original protocol include:

1. Location:

The original protocol stated that the study would take place in either the Eastern or Western Cape, pending government approval. Our last update in November 2012 indicated that we were going to divide the study into 2 locations: 1) a rural study with children aged 9-17 in the Eastern Cape, and 2) an urban study with children aged 3-8 in the Western Cape.

All further changes apply only to the Eastern Cape branch within the larger study.

2. Age of child participants:

Original plan: The original age of child participants was 3 to 17 years.

Current plan: The Eastern Cape branch will work only with families with children aged 10-17, rather than aged 3-17 as initially proposed. We divided the groups by age due to different developmental challenges and appropriateness of interventions.

3. Changes in implementation of study:

(a) Phase 1:

Original plan: Phase 1 was going to consist of a qualitative study with individual interviews and focus groups (n=8 semi-structured focus group sessions) to examine issues of cultural adaptation of intervention components, participant recruitment/retention, intervention structure, outcome measurements, and any relevant challenges that might occur.

Current plan: Phase 1 also included a pre-post pre-pilot test of the draft intervention programme, in collaboration with two NGOs in the Eastern Cape site: Clowns Without Borders South Africa, and Keiskamma Foundation. This pre-post pre-pilot (n=30 dyads) provided data that was used to further develop and improve the programme.

(b) Phase 2:

Original plan: Phase 2 involved a small-scale pilot randomised controlled trial of the adapted intervention (n= 60 dyads)

Current plan: In the Eastern Cape site, phase 2 consisted of a pre-post pilot study of the adapted intervention (n=117 dyads). We chose this study design because we needed a further stage of development and to gain some data by which to power our randomised trial.

(c) Phase 3:

Original plan: Phase 3 was initially going to be a Cluster Randomised Controlled Trial with 30 sites (n=1200 child-parent dyads). The evaluation was going to use a cluster randomised controlled trial design with wait-list control families. Follow-up was set up at 6 months post intervention.

Current plan: The cluster randomisation for the trial in the Eastern Cape will be done in 40 sites. Study size has been reduced to n=600 dyads due to funding. Due to funding instead of a wait-list control design, families in the control group will receive a one-day family intervention on hygiene. If funding is secured, follow-up will be conducted at 12 months post intervention.

5. Differentiation of primary and secondary outcomes:

Original plan: Primary research questions were the effectiveness of the intervention in: abuse outcomes i) reducing reported physical, emotional and sexual abuse and intentional neglect of children; ii) improvements in positive parenting and parental praise; ii) improvement in supervision of children; HIV-related outcomes iv) improved 'succession planning' for custody of children facing caregiver bereavement v) increased planned disclosure of HIVstatus to children; child development outcomes vi) improved child mental health and educational attendance. The research will also test hypothesised linking factors to secondary outcomes of vii) improved social support for caregivers and viii) improved caregiver mental health, ix) intervention attendance rates x) caregiver and adolescent quality of program participation and xi) facilitator fidelity to the programme.

Current plan: All the aims remain, but with the addition of reducing violence exposure for adolescents in the community. Succession planning and increased disclosure of HIV-status are no longer primary outcomes as specific HIV goals were too sensitive to discuss

in mixed groups. We will also be measuring educational outcomes and financial stress and coping of the families.

6. Changes in Assessment of Primary and Secondary Outcomes

(a) Assessment of Primary and Secondary Outcomes

We will be using the following scales to assess outcomes:

Demographics and socioeconomic characteristics

1. Basic Necessities Scale (Wright, 2008) (household poverty)
2. South African National Food Consumption Survey (1999) (Labadarios et al., 2007) (food insecurity)
3. South African Census (2001) (Statistics South Africa, 2001) (employment, household dwelling, educational attainment)
4. Household Income and Labour Dynamics survey (Siahpush, Spittal, & Singh, 2007) (financial stress)
5. Household map (Cluver, Gardner, & Operario, 2007) (household structure)

Caregiver exposure to family violence

6. Conflict Tactics Scale (Straus, Hamby, Boney-McCoy, & Sugarman, 1996)
7. International Child Abuse Screening Tool – Retrospective Version (Dunnea et al., 2009)

Child AIDS-related orphanhood, caregiver HIV-status and/or AIDS sickness

8. Verbal Autopsy Questionnaire (Lopman et al., 2006)

Adolescent physical and mental health

9. Census Questions on Disability Endorsed by the Washington Group (Miller, Mont, Maitland, Altman, & Madans, 2010)
10. Child Depression Inventory (CDI) short form (Kovacs, 1992)
11. Mini International Psychiatric Interview for Children and Adolescents Suicidality and self-harm subscale (Sheehan et al., 2010)

Caregiver mental health

12. Centre for Epidemiologic Studies Depression Scale (CES-D) (Radloff, 1977) (caregiver depression)
13. Parental Stress Scale (PSS) (Berry & Jones, 1995) (parenting distress)

Substance abuse

14. 10. WHO Alcohol, Smoking, and Substance Screening Tool (Humeniuk et al., 2008) (caregivers)

15. WHO for the Global School-based Health Survey (GSHS) (Centers for Disease Control and Prevention, 2009) (adolescents)

Child abuse

16. 12. ISPCAN Child Abuse Screening Tool Children's Version (ICAST-C) (52 items) (Zolotor et al., 2009) (adapted for trials)
17. ISPCAN Child Abuse Screening Tool—Parent version (ICAST-P) (Runyan, 2009) (adapted for trials)
18. Child abuse attitudes – brief survey based on ICAST-P and ICAST-C items.

Exposure to community violence

19. Researcher-designed scale, based on piloting and issues relevant to the target community

Government grants

20. Self-report of government grants received (caregivers)

Child behavior problems

21. CBCL-Youth Self-Report Form (Achenbach & Rescorla, 2001) (caregiver and adolescent self-report)

Sex risk behavior

22. National survey of HIV and risk behavior amongst young South Africans (Reproductive Health Research Unit & Lovelife, 2005)
23. South African Demographic and Health Survey (2003) (Department of Health and Medical Research Council, 2007)

Parenting behavior

24. Alabama Parenting Questionnaire (APQ) (Frick, 1991) (caregiver and adolescent self-report)

Social Support:

25. Medical Outcome Study (MOS) Social Support Survey (Sherbourne & Stewart, 1991) (perceived social support)

Stigma

26. Stigma-by-association Scale (Mason, 2008).

Caregiver-adolescent communication

27. Parent Communication Subscale (Mccarty & Doyle, 2001).

Caregiver-adolescent communication on planning for risk avoidance

1. Researcher-designed scale, based piloting and issues relevant to the target community

(b) Adolescent educational outcomes

2. Academic Motivation Scale (Ruchkin et al., 2004) (academic motivation and enjoyment of school) (adolescent self-report)
3. Young Lives (Boyden & Dercon, 2008) (school regular attendance and school assistance) (adolescent self-report)
4. General Household Survey (Cluver, Gardner, et al., 2009) (school progress) (adolescent self-report)
5. Emotionally Supportive Climate scale (UNCIEF, 2009) (teacher academic support) (adolescent self-report)
6. Social and Health Assessment Peer Victimization Scale (Ruchkin, Vermeiren, & Schwab-Stone, 2004) (affiliation with peers who achieve academically) (adolescent self-report)
7. EPSSE School Learning Environment (Sylva, Melhuish, Sammons, Siraj, & Taggart, 2014) (home learning environment) (home observational data)
8. South African standardised Annual National Assessment Learner Report (Department of Basic Education, 2013) (academic achievement and school progress) (school administrative data)
9. School records (school enrolment and academic achievement) (school administrative data)
10. Student Survey Physical and Emotional Safety scale (UNCIEF, 2009) (school safety) (school principal self-report)
11. UNICEF School Observation Survey (UNICEF, 2009) (school infrastructure) (observational data)
12. Classroom Observation Safe and Welcoming Classroom Environment Scale (UNICEF, 2009) (classroom learning environment) (teacher self-report)
13. Work Pressure Scale validated in South Africa (Laugksch, Aldridge, & Fraser, 2007) (teaching practices and characteristics) (teacher self-report)

(c) **Predictors of participation**
5-item section about the attitudes to program participation (parent and teen self-report) (adapted from Thornton et al. 2010)

(d) Assessment of process evaluation and implementation fidelity

Original plan: Assessment on programme fidelity and acceptability will be conducted by video documentation, participant feedback forms, and focus group sessions.

Current plan: In-line with the original proposal, we plan to collect data on the implementation of the programme. Due to low literacy of the target population, we have decided to substitute written participant feedback forms with participant interviews and focus groups.

Based on the pilot study findings and further literature review, we have expanded our toolkit of measures to include the following:
- Family attendance registers will be completed by program facilitators

- Project Research Assistants will visit several randomly selected sessions in each group to record their observations on participant engagement and facilitator adherence to the programme
- Research Assistants will video-record a number of sessions they attend to check the inter-rater reliability of their observations
- Reports will be collected on standard forms used for home visits conducted as part of the programme

Furthermore, a key requirement within this trial is to develop an effective, easy-to-use process evaluation tools that can be used by NGOs and government bodies assessing the effectiveness of adolescent parenting programmes in LMIC community settings. Additionally, there is a need to identify contextual factors (such as poverty, gender roles, migration) that may affect both parenting and the acceptability and impact of a parenting programme. The qualitative assessments within the trial will aim to include:

- Systematic ethnographic observations of the programme in rural, urban and peri-urban settings.
- In-depth interviews and focus groups with adult participants, including high-risk groups of older women, caregivers affected by HIV/AIDS and lone parents.
- In-depth interviews and focus groups with adolescent participants and other adolescents living in the family home.
- In-depth interviews and focus groups with fathers and paternal figures belonging to participant families to determine both the potential for including fathers/male caregivers in parenting programmes and the impact of visiting parents or grandparents.
- In-depth interviews and focus groups with programme staff from local community-based organisations, to assess experiences of training, supervision and facilitation.
- In-depth interviews with programme coordinators
- Observation and semi-structured interviews with key actors involved in government policy, funding dissemination and delivery of services through NPOs.(See protocol for Elite Interviews attached)

7. Changes in Recruitment

Original plan: Participants were going to be identified by partner community-based NGOs operating in South African and in collaboration with the South Africa Department of Social Development. Participants were going to be approached by community health workers and social workers who work with our partner NGOs in their community. Families will also be able to self-identify through schools, clinics and community meetings

Current plan: Families will not be able to self-identify from clinics and community meetings anymore. Based in our previous experience working with vulnerable families during Phase 1 and 2, we decided not to recruit from clinics and community meetings to avoid creating potential stigma to participants and ensure the recruitment of high-risk families. Hence, only recruitment through referrals from schools and the local and provincial Department of Social Development (social workers working in their communities) as well as Chieftains (where families have approached the Chieftain asking for help with their conflict in the home) will be conducted.

8. Participants:

Original plan: Inclusion criteria for children included:

1) Orphan (single or double) or vulnerable (caring for sick-cargiver)
2) Age 8-16 at initial assessment
3) Lives in the house at least 4 nights per week
4) Must have an adult primary caregiver who lives in the household, who provides consent, and who participates in the study
5) Provides assent to participate in the full study including intervention and assessments.

Current plan: In the Eastern Cape site the inclusion criteria for children will include:

1) Age 10-17 at initial assessment
2) Lives in the dwelling at least 4 nights per week
3) Must have an adult primary caregiver who lives in the household, who provides consent, and who participates in the study
4) Provides assent to participate in the full study including intervention and completing baseline, immediate post-test, and 12-month follow-up assessments.

9. Financial or other rewards to participants:

Original plan: No financial rewards will be made for participation; although a nutritious lunch will be provided during data collection and intervention workshops, and all participants will receive a certificate on concluding the study.

Current plan: Adolescents participants will also receive a school pack with school stationary.

10. Collaboration with research partners

The project is now working more closely with Provincial and District Departments of Social Development, Provincial and District Departments of Education, NGOs such as Clowns Without Borders South Africa and the National Association of Child and Youth Care Workers, and UNICEF South Africa. Community and government partnerships have strengthened.

11. Collaboration with implementation partners:

Original plan: The programme was going to be implemented and tested in South Africa by three NGO partners, all of which provide community-based support for AIDS-affected families: The National Association of Child Care Workers (a national NGO), Clowns Without Borders South Africa (a smaller NGO with sub-Saharan African reach through South Africa, Swaziland and LeSotho) and either Petals Daycare (a small community NGO in Matatiele, Eastern Cape) or Ikamva Labantu (a community NGO based in Cape Town).

Current plan: The programme will be implemented by Clowns Without Borders South Africa, local lay staff and social workers seconded to the programme.

11. Researchers involved in this project:

The following researchers from the Department of Social Policy and Intervention joined the research project: two associate researchers (Dr. Franziska Meinck and Dr. Jenny Doubt) and four doctoral student researchers (Yulia Shenderovich, Rocio Herrero Romero, Janina Steinert and Vira Ameli). They will not need training to participate in the project.

12. Collection of information from a third party:

The study will also evaluate the impact of the parenting program on the educational outcomes of adolescents in low income contexts (secondary outcome of the program). The research team will visit schools to collect data on the educational outcomes of participants. School administrative data will be collected on academic achievement and school enrolment. School principals and teachers will briefly be interviewed about school characteristics (school resources and infrastructures). Caregivers and adolescents will need to provide consent/assent for the research team to access adolescents' school records. School visits will be undertaken in collaboration with our research partners in South Africa (i.e. the Department of Basic Education). No access to school will be conducted without the authorisation of school principals and local departmental officers. No individual personal data will be collected from schools other than school results. The same ethical procedures established in the research study will applied regarding anonymity, confidentiality and data protection. No financial rewards will be made for participation.

14. Funding bodies:

Phase 3 of the study is supported by the European Research Council (ERC) under the European Union's Seventh Framework Programme (FP7/2007-2013)/ ERC grant agreement n°313421, UNICEF Innocenti Office of Research, UNICEF South Africa and the John Fell Fund.

Please find a summary of scales, data collection protocols, elite interviews protocol, and the RCT research protocol draft. If there are any further questions, please do not hesitate to ask.

Thank you,

Lucie Cluver

Professor Lucie Cluver
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