# A prospective cohort study evaluating a psychosocial programme for adolescents living with HIV and their caregivers in Botswana

**Protocol Version 4.8 – May 2020**

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**Revision Chronology**

**Date 9.4.18 Version 2**

Changes made as follows:

- Change of local PI from Frank Mwangemi to Lesego Busang.
- Allowing recruitment of caregivers to be through young people not participating in the study.
- Minor changes to study procedure.

**Date 31.8.18 Version 2.1**

Changes made as follows:

- Replacing co-investigators Judith Shongwe and Christopher Bastalelwang with Barney Morake and Samuel Tope Ajayi.
- Allowing caregiver to be a caregiver of any Sentebale young person.
- Change of ART adherence belief measures.
- Not eliciting information about pregnancy.
- Adding background information to be collected from caregivers.
- Adding information on responsibilities of project staff.

**Date 21.9.18 Version 3**

Changes made as follows:

- Updates to background section.
- Change to inclusion criteria, to allow attendance at Sentebale clubs within last three months (instead of one month).
- Change to the HIV communication measure.
- Change to the sampling procedure to allow recruitment of young people new or recently referred to Sentebale.
- Information on co-investigator, Barney Morake, added.

**Date 6.12.18 Version 4**

Changes made as follows:

- Clarification of inclusion criterion than young people should have attended Sentebale clubs with attendance at no more than three clubs.
- Exclusion criteria - Giving an example of a different club/organisation providing a similar function to Sentebale (e.g., Baylor); clarifying that if participant plans to leave the area served by Sentebale clubs they will be excluded.

- Extending the eligible period for VLs from six to twelve months.
- Removing the assessment of intervening events over the study period.
- Stating that a new HIV knowledge measure would be developed.
- Changing the HIV stigma measure.
- Clarifying the cognitive interviewing procedure.
- Minor changes to various aspects of the study procedure.

**Date 23.12.18 Version 4.1**

Changes made as follows:

- Clarification of clinical data to be obtained.

**Date 8.1.19 Version 4.2**

Changes made as follows:

- Inclusion of collection of viral load data throughout the study period.

**Date 4.3.19 Version 4.3**

Changes made as follows:

- Replacing co-investigator Anabelle McGregor with Tsitsi Chawatama and Alice Lycett Green.
- Changes to the data analysis section to examine a number of potential moderators of changes in outcome variables.
- Changes to the dissemination section

**Date 6.6.19 Version 4.4**

Changes made as follows:

- Replacing co-investigator Samuel Tope Ajayi with Moemedi Keatanse

**Date: 22.12.19 Version 4.5**

Changes made as follows:

- Reducing the size of the follow-up sample by 24% due to budget restrictions.
- Changing VL to a secondary outcome as baseline VL suppression was 90%. The original power calculation for the VL co-primary outcome assumed a baseline VL suppression rate of 80%. Therefore, focusing on QoL/psychopathology as the only primary outcome. The reduced sample size at follow up is appropriately powered to detect changes in QoL/psychopathology.
- Clarifying that follow-up recruitment should occur within one month of the twelve-month target (after baseline recruitment).

- Changes to the sub-study procedure to make this process more straightforward.
- Removal of one advisory group meeting.
- Additional details added to the data analysis section to clarify analysis of Qol/psychopathology outcome (assessing differences in scores on the Pediatric Symptom Checklist between baseline and follow-up).

**Date 26.2.20 Version 4.6**

Changes made as follows:

- Amendment to sub-study sampling. In particular, specifying:
    - stratified random sampling for young people (resulting in a sample of two male 10-14 year olds, two female 10-14 year olds, three male 15-19 year olds and three female 15-19 year olds)
    - stratified random sampling for caregivers (resulting in a sample of two males and eight females).
- Clarification of the follow-up prompting process. Reminders and prompts will be provided before the second study visit and attempts will be made to arrange the location and time of this visit.

**Date 1.4.20 Version 4.7**

Changes made as follows:

- Changes to specify phone interviews

**Date 28.5.20 Version 4.8**

Changes made as follows:

- Adding specificity to list of previous protocol changes
- Reduction of target young person sample size due to suspension of face to face recruitment due to COVID-19 from 175 to a range from 146 to 175
- Reduction of target caregiver sample size due to suspension of face to face recruitment due to COVID-19.
- Change of Lesego Busang's job title

**Project summary**

Adolescents/young adults with perinatally acquired HIV (PAH) face a number of antiretroviral (ART) adherence and well-being challenges. Two psychosocial interventions that have been developed to address a range of needs of this population (and their caregivers) are residential interventions (camps) and support groups (clubs). There has

been little quantitative evaluation of the effects of attending camps for young people and clubs (for children or caregivers), globally. This study aims to investigate whether a package of psychosocial support (camps and clubs) offered to young people living with HIV and their caregivers in Botswana by the Sentebale organisation, is associated with improvements in psychological, behavioural and clinical outcomes from first attendance to one year follow-up. In addition, the study will explore how the psychosocial programme is experienced by young people and their caregivers, and what the perceived impact is. The project as a whole will take place over three years. There will be an initial six month preparatory phase that will include the adaptation of self-report measures for the study context. Subsequently, two studies will be undertaken. The main study will involve a single group within-participants prospective cohort design with two time points (baseline and one year follow-up) with young people and caregivers. The sub-study will involve a qualitative cross sectional design involving semi-structured interviews with young people and caregivers. Young people will be eligible to participate if they are aged 10 to 19 years at the time of study enrolment, are living with HIV and aware of HIV-positive status, have recently started attending the Sentebale programme, and are able to give informed assent/consent. We will aim to retain up to 175 young people (of 253 recruited). We will also aim to retain up to 178 caregivers (of 263 recruited). The sample size for the sub-study will consist of ten young people and ten caregivers.

**Background and rationale**

There are approximately two million young people between 10 and 19 years, living with HIV (UNAIDS, 2013). Many of this population have been living with HIV since birth. Adolescents/young adults with perinatally acquired HIV (PAH) face a number of antiretroviral (ART) adherence and well-being challenges. They often have long histories of ART use with suboptimal regimens (Sohn & Hazra, 2013) and rates of viral suppression are variable, often associated with poor ART adherence (Kim, Gerver, Fidler, & Ward, 2014). Challenges to positive well-being in young people with PAH include some experiencing multiple caretaking transitions, loss due to parental illness or death, and other stressors associated with living with a chronic and stigmatised illness (e.g., hospitalisations, missed school and social opportunities, HIV disclosure challenges and pain). There is evidence of lower levels of wellbeing in young people living with PAH compared to their HIV unaffected peers (Mellins & Malee, 2013).

Offering psychosocial interventions for young people living with HIV has the potential for enhancing well-being, HIV adjustment, ART adherence, self-esteem and increasing HIV knowledge and HIV disclosure. There are a small number of quantitative studies evaluating interventions to enhance antiretroviral adherence in young people with HIV (Shaw & Amico, 2016) but few robust quantitative evaluations of psychosocial interventions to enhance well-being in this population (King, De Silva, Stein, & Patel, 2009). There are no interventions on enhancing onward HIV disclosure in adolescents living with HIV (Evangeli & Foster, 2014).

Two psychosocial interventions that have been developed to address a range of needs of this population (and their caregivers) are residential interventions and support groups. Regarding *residential interventions,* there is quantitative evidence in other chronic conditions of increased youth self-esteem after attendance (Odar, Canter, & Roberts, 2013). There is also some qualitative literature on evaluating residential interventions (support camps) for young people living with HIV in the US (Gillard & Allsop, 2016; Gillard, Witt, & Watts, 2011; Pearson, Johnson, Simpson, & Gallagher, 1997). Interviews with Camp attendees have revealed that this intervention can elicit a sense of belonging, enjoyment, escape, personal growth, being oneself, and caring connections, as well as increasing HIV knowledge, attitudes and skills. A recent quantitative evaluation of a residential intervention in the UK showed evidence for increases in HIV knowledge and pro-

HIV disclosure attitudes and cognitions that were maintained at six month follow-up (Visser, Kershaw, Makin, & Forsyth, 2008).

There is also some global evidence of positive benefits of *support groups* for children living with HIV, who report that groups provide a sense of belonging, normality, confidence and safety; supportive relationships; and a place to learn about treatment adherence and living healthily (Brothers, Harper, Fernandez, Hosek, & Adolescent Trials Network for, 2014; Funck-Brentano et al., 2005; Midtbo, Shirima, Skovdal, & Daniel, 2012; Mupambireyi, Bernays, Bwakura-Dangarembizi, & Cowan, 2014; Muskat, Salter, Shindler, Porter, & Bitnum, 2016). There has been little quantitative evaluation of the effects of attending support groups (for children or caregivers), although one pilot study using non-random allocation, showed some evidence of decreased worry about illness, less negative perception about treatment and greater rates of viral suppression in adolescents living with HIV (Funck-Brentano et al., 2005).

Sentebale is an organisation that has been providing residential interventions (camps) to adolescents living with HIV, and follow up support groups (clubs) for these adolescents and their caregivers, amongst other psychosocial interventions, in Lesotho for a number of years. Sentebale is now offering a similar package of psychosocial services to young people and caregivers in Botswana, partnering with Serious Fun Children's Network. The aims of Sentebale are to provide support that will enable young people to living healthy and hopeful lives, increase confidence, improve educational and occupational functioning, increase care and support, enhance HIV communication, increase caregiver support, reduce onward transmission, and increase remembering to take medication. We will evaluate the above psychosocial programme, given the need to investigate the psychosocial, behavioural and clinical outcomes of this type of intervention in high HIV prevalence contexts. Botswana has an estimated HIV prevalence of 6.6% in 15-19 year olds, and an estimated adult prevalence rate of 18.5%, and despite high levels of ART adherence, psychological difficulties in this population are common (Gupta et al., 2010).

## Aims and objectives

This three year study aims to answer the following questions in a population of adolescents living with HIV and their caregivers:

1. Is the package of support offered by Sentebale (camps for young people, clubs for young people and caregivers) associated with improvements in psychological, behavioural and clinical outcomes from first attendance to one year follow-up?
2. How is the package of support experienced by young people and their caregivers, and what is the perceived impact for young people and their caregivers?

## Study Design

1. Main study - single group within-participants prospective cohort design with two time points (baseline and one year follow-up) with 146 to 175 young people and up to 178 caregivers retained in the study (Study Aim 1).
2. Sub-study – qualitative cross sectional design involving semi-structured interviews with 10 young people and 10 caregivers (Study Aim 2).

## Inclusion and exclusion criteria

<u>Young people (for main study and sub-study)</u>

*Inclusion criteria*

- Aged 10 to 19 years at the time of study enrolment
- Living with HIV and aware of HIV-positive status
- Able to give informed consent if 18 or 19 years
- Able to give informed assent if 10-17 years
- Presence of a caregiver to give caregiver consent if 10-17 years
- Attending Sentebale clubs with attendance at no more than three clubs

*Exclusion criteria*

- Previous camp attendance
- Any attendance at a different club/organisation providing a similar function (e.g., Baylor)
- Planning to leave areas served by Sentebale clubs within the next year

Caregivers (for main study and sub-study)

*Inclusion criteria*

- Primary caregiver for a young person attending Sentebale
- Able to give informed consent
- Attending Sentebale clubs with first attendance within previous three months

*Exclusion criteria*

- Any attendance at a different club/organisation providing a similar function
- Planning to leave areas served by Sentebale clubs within the next year

**Methodology**

Setting

The research will take place in Botswana in the regions where Sentebale are operating.

Intervention

The intervention offered by Sentebale will consist of residential interventions (camps) for the young people, and community based support (clubs) for the young people and the caregivers.

Measures for the main study

Self-report measures will be used for baseline and follow up assessments. These will either be delivered face to face, over the phone, or through audio-computerised self-interview (ACASI) to increase measurement validity (Zimmerman, Morisky, Harrison, & Mark, 2014). Assistance to participants to complete measures will be offered, given potential literacy and receptive language difficulties. The measures will take approximately 60 minutes to complete on each of two occasions.

*Outcome variables (young people)*

The following psychological and behavioural variables (either outcomes or potential mediators of outcome) will be assessed at baseline and follow-up:

Primary Outcome

- *Quality of life/well-being*

The 17 item Pediatric Symptom Checklist (PSY-Y-17) will be used. This self-report measure of psychosocial health has been translated into Setswana and has shown good psychometric properties in HIV positive Batswana children aged 8 to 16 years (E. Lowenthal et al., 2011).

Secondary Outcomes

- *HIV knowledge*

A new measure will be developed to assess general HIV knowledge, transmission, medication and reproduction information. Items will include those sourced and adapted from other measures (e.g., Aaro et al. 2011; Carey and Schroder 2002) and from a measure developed and used in a recent evaluation of a residential intervention for adolescents living with HIV in the UK (Visser et al., 2008). The questions and response options will be adapted for use in Botswana and the relevance of items to the intervention offered by Sentebale will be assessed.

- *HIV adjustment*

The 18 item Illness Cognition Questionnaire will be used (Evers et al., 2001). This measure has been used with young adults living with HIV (Andrinopoulos et al., 2011) and adolescents living with cystic fibrosis (Casier et al., 2011). The measure has three subscales (acceptance, helplessness and perceived benefits) and will be translated and adapted for the Botswana context.

- *ART adherence*

The antiretroviral medication attitudes scale (Viswanathan, Anderson, & Thomas, 2005) and the 12 item HIV medication self-efficacy scale (Erlen, Cha, Kim, Caruthers, & Sereika, 2010) will be used. These measures have been adapted for use with Batswana adolescents (E. D. Lowenthal et al., 2014) to produce a 9 item medication attitudes scale and a 12 item medication self-efficacy scale.

Adherence behaviour will be assessed by the CASE adherence index (Mannheimer et al., 2006). This index contains three questions relating to difficulty in taking ART medication on time, frequency of missed doses and time since most recent missed dose. It has been argued to reduce social desirability bias compared to asking about three day self-report adherence, and is more closely related to HIV outcomes than the latter method (Mannheimer et al., 2006). The questions and response options will be adapted for use in Botswana.

- *HIV onward disclosure*

The 18 item Adolescent HIV Disclosure Cognitions and Affect Scale (Evangeli, 2017) will be used to assess attitudes towards sharing one's status, normative disclosure beliefs, disclosure affect and disclosure self-efficacy. An additional item assessed the young person's intention to share their status with others over the next year will be added. Items will be adapted for use in Botswana.

HIV disclosure events will be assessed at baseline and follow-up through recording the frequency of new disclosures in last year (first hand or second hand) and the proportion in one's social network disclosed to (Serovich, Craft, & Reed, 2012; Serovich, Craft, & Yoon, 2007).

- *HIV communication*

The seven-item Adolescent HIV Communication Beliefs Questionnaire (Mundell et al., 2011) will be used to assess thoughts and feelings about communicating about HIV with people whom were already aware of the young person's HIV status (outside of one's health care team, e.g., friends and family). This measure and an additional item assessing intention to communicate about HIV will be adapted for use in Botswana. The frequency of HIV communication will also be measured.

- *Self-esteem*

The 10 item Rosenberg global self-esteem measure will be used (Rosenberg, 1965). This scale has shown good internal consistency in adolescents living with HIV in other parts of sub-Saharan Africa (Enejoh et al., 2016; Nostlinger, Bakeera-Kitaka, Buyze, Loos, & Buve, 2015). The measure will be adapted for use in Botswana.

- *HIV stigma*

The 10 item Stigma Scale – Revised (Wright, Naar-King, Lam, Templin, & Frey, 2007) will be used. This scale has been adapted for use with Batswana adolescents (E. D. Lowenthal et al., 2014).

- *Social support*

The 11 item Child and Adolescent Social Support Scale (Malecki & Demaray, 2002) will be used. This scale has been adapted for use with Batswana adolescents (E. D. Lowenthal et al., 2014).

- *Hope*

The 5 item Botswana Adolescent Beliefs about the Future Scale will be used. This was developed for use with Batswana adolescents (E. D. Lowenthal et al., 2014).

- *Viral suppression*

Most recent viral load in the twelve months before the baseline assessment, viral loads from baseline to 12 month follow-up, and most recent viral load in the twelve months after the follow-up, will be collected from participants' clinical records.

<u>Background/contextual information</u>

Some information will be only be collected at the baseline data point: date of birth, clinic, sex, age at paediatric HIV disclosure, education/occupation, parental bereavement, relationship status, medication regimen, duration on treatment, previous psychosocial interventions, housing situation and substance use. The latter will be measured with the Alcohol, Smoking and Substance Involvement Screening Test (Humeniuk et al., 2008). This scale has been adapted for use with Batswana adolescents (E. D. Lowenthal et al., 2014). In addition to recording individual disclosure events (above), participants will be asked about lifetime disclosure frequency (Serovich et al., 2012; Serovich et al., 2007; Teti et al., 2010). Some information will be collected at both the baseline and follow-up data points: information on regimen, attendance at clinic, pill counts, viral load, CD4 count, height and weight. Days missed from school will be assessed (Anabwani, Karugaba, & Gabaitiri, 2016).

*Outcome variables (caregivers)*

- *HIV knowledge*

A new measure will be developed to assess general HIV knowledge, transmission, medication and reproduction information. Items will include those sourced and adapted from other measures (e.g., Aaro et al. 2011; Carey and Schroder 2002). The questions and response options will be adapted for use in Botswana and the relevance of items to the intervention offered by Sentebale will be assessed.

- *ART adherence*

The 15 item antiretroviral medication attitudes scale (Viswanathan et al., 2005) will be used. The measure will be adapted for use with Batswana caregivers.

- *HIV stigma*

. The 12-item Personal Stigma Scale will be used (Visser et al., 2008). This scale has been used with Setswana speakers in South Africa. The measure will be adapted for use with Batswana caregivers.

Background/contextual information (caregivers)

The following information will be collected at the baseline data point: sex, relationship to young person, occupation, family income, HIV status of carer and viral load if HIV positive.

Sample size for main study

The sample size required to detect an improvement in quality of life/wellbeing in young people (as measured by the Pediatric Symptom Checklist) is 146, which is consistent with the pre to post change in quality of life reported in a recent evaluation of a residential intervention for young people with HIV (Visser et al., 2008). This sample will provide 80% statistical power to determine a statistically significant difference at the $p<0.05$ level, assuming a mean difference of 0.96 and standard deviation for the difference of 4.64 based on actual data from the pre and post time points from the CHIVA youth camp evaluation (data on file). We will aim to retain a larger sample size of young people (n=175) so as to be able to detect smaller effects and to allow for greater than 10% attrition.

Sub-study

Face to face or phone semi-structured interviews with young people and caregivers will be conducted by the researcher. Semi-structured interview guides will cover the following

areas: relationships with other young people and staff; perceived knowledge; attitudes and skills relating to areas covered in the programme; perceived impact of intervention; acceptability, appropriateness and satisfaction with the intervention; expectations before the intervention; and transition readiness. Each interview will take between 30 and 60 minutes.

The sample size for the sub-study will consist of ten young people and ten caregivers.

**Procedure for development and preparation of measurement tools (0-6 months)**

We will aim to produce linguistically and culturally validated measures where none exist. The following procedure will be used:

1. Translating existing questionnaires/items and response options. The aim of this stage will be for conceptual translation in collaboration with a health professional to produce simple, clear and concise items and response options appropriate for the target group.
2. Back translation in collaboration with a different health professional.
3. Review of translated items by an expert panel (including the original translator). This panel will go through the translations, comparing original measures, translations and background measures and will suggesting new items if these are required.
4. Cognitive interviewing (Willis, 2006). Six young people (across the target age range) and three caregivers, including Setswana-speakers, will be recruited to take part in this stage after providing informed consent. The research coordinator will assess participants' comprehension of questions and response options in Setswana; their ability to retrieve relevant information from memory; their ability to judge how to respond, and their ability to use the response options provided. Concurrent verbal probing will be used. Questions will asked and answered by participants. Probe question will then be used to assess the above areas.
5. Amendment of measures. There may be amendments to measures based on the cognitive interviewing stage. These will be discussed and agreed by the research team.
6. Preparing measures for the main study. The research coordinator will prepare materials for administration in a number of formats – interview; paper and pencil and computerised format.

**Procedure for main and sub-study (6-27 months)**

*Sampling*

For the main study, systematic sampling will be used, with all young people recently or newly referred to the programme over an estimated six month period eligible (until at least 253 young people taking antiretroviral medication have been recruited). Recruitment for caregivers will be through these young people (see below). When 253 young people have been recruited, subsequent recruitment of caregivers will be carried out linked to young people who are new to the programme but are not recruited to the study (until at least 253 caregivers have been recruited).

*Screening and provision of study information*

Young people who are due to start attending/have recently started attending the Sentebale programme will be screened for their potential eligibility, in relation to inclusion and exclusion criteria, by Sentebale staff. A record of young people who are not eligible will be kept by ACHAP staff in a site study log to ensure that these individuals are not screened or approached in the future. If young people are potentially eligible, and are 18 or 19 years, they will be informed about the study by Sentebale staff at their first/next club attendance (verbally and with a participant information sheet in either English or Setswana). If they are potentially eligible and are between 10 and 17 years, their caregiver will be informed about the study at the club that the young person attends (verbally and with a participant information sheet in either English or Setswana) by Sentebale staff. If potential young people participants express an interest in taking part in the study, Sentebale staff will ask their permission to be contacted by ACHAP. If this permission is granted, Senteable staff will inform the study coordinator, who will ask an ACHAP field worker to arrange to meet with the potential young person participant to discuss study consent. If potential young people participants are not interested in taking part, this will be communicated to the study coordinator who will record this in the site study log and the central study register.

Sentebale staff will also inform the study coordinator that a caregiver is potentially eligible for the study (based on the young person starting the Sentebale programme) and willing to be contacted by ACHAP. The study coordinator will ask an ACHAP field worker to arrange to meet with the caregiver to discuss study consent. If potential caregiver participants are

not interested in taking part, this will be communicated to the study coordinator who will record this in the site study log and the central study register.

*Consent/assent*

Young people and caregivers will be asked to offer their consent/assent (and caregivers asked to consent on the young person's behalf if the young person is between 10 and 17 years) for both the main study and the sub-study at the same time, despite the fact that only a proportion of those taking part in the main study will be asked to take part in the sub-study. Consent will be sought for access to study data and to both health clinic and Sentebale programme data. Assent/consent will also be sought for the participant to be contacted before their follow-up assessment as a reminder and after this assessment if they have not attended.

If caregivers of those young people aged 10-17 years consent for the young person to take part, the young person will be approached by an ACHAP field worker, given information about the study and asked whether they would like to offer their assent. If young people are willing to provide assent/consent, this will be taken by an ACHAP field worker. Any refusals from the young person or their caregivers (for those 10-17 years) will be documented by the ACHAP field worker and this information will be provided to the study coordinator to record in the site study log and the central study register. This will help to determine the study response rate.

The caregiver will be provided information relating to their own involvement in the study (verbally and with a participant information sheet in either English or Setswana) by an ACHAP field worker. Written consent will then be sought by the ACHAP field worker. Refusals to participate will be recorded by the ACHAP field worker and this information will be provided to the study coordinator to record in the site study log and the central study register. Details of who has consented to participate (young people and caregivers) will be also passed to the study coordinator by the ACHAP field worker to record in the central study register. Caregiver participation is not necessary for young person participation. Young person participation is not necessary for caregiver involvement.

*Study enrolment and baseline assessment (first study visit)*

The first study visit involves enrolment (provision of a study ID and recording of personal information) and the baseline assessment. An ACHAP field worker will either contact the participant (young people and caregivers) after consenting to arrange the first study visit, arrange this visit at the end of the consent process, or carry out enrolment and the baseline assessment immediately after the consent process.

This visit could take place at Sentebale club sites or at the participant's home. At the first study visit, the participant will be enrolled into the study and given a study id. Personal information will be recorded in the participant's personal study register (name, date of birth contact details etc) and non-identifiable information will be recorded in the central study register (study id, date of enrolment etc). The baseline assessment will then be administered by the ACHAP field worker, who will also collect clinic information from the participant's personal clinic card. This information will be reported in the participant's personal study register. Travel expenses will be paid to participants if any have been incurred and a receipt will be kept.

*Between the first and second study visit*

A number of activities will take place between the first and second study visit:

- After the first visit, the study coordinator or an ACHAP field worker will obtain any relevant clinic data for the participant (young person) that was not available from their personal clinic card (e.g., viral load, CD4 count, pill count, clinic attendance, regimen, duration on treatment, weight and height) from Sentebale, who will obtain this information from the District Health Team clinic. This will be recorded in the participant's personal study register.
- The study coordinator or an ACHAP field worker will also inform Sentebale that the participant has been enrolled and will ask Sentebale to record club and camp attendance for that participant over the next year.
- Reminders and prompts will be provided by the study coordinator or Sentebale worker on one or two occasions before the second study visit or phone assessment is due (by phone/SMS) and attempts will be made to arrange the location and time of this visit or phone assessment.

*Follow-up assessment (second study visit or phone assessment)*

This will occur one year after the baseline assessment (plus or minus one month). An ACHAP field worker will administer the follow-up measures. Participants will be reimbursed for their time in the study and for any travel expenses incurred. Receipts will be kept and these will be sent to the study coordinator.

*After the follow-up assessment*

A number of activities will take place after the follow up assessment (by the study coordinator or an ACHAP field worker).

- Attempts to track participants if they have not attended their second study visit or participated in the phone assessment (by phone/SMS/in person) so that the phone assessment can take place
- Obtaining programme data from Sentebale (attendance over the course of the year).
- Obtaining clinic data from Sentebale, who will obtain this information from the District Health Teams (e.g., viral load from baseline to follow-up, most recent viral load after follow-up, CD4 counts, pill counts, clinic attendance, regimen, weight and height from baseline to most recent viral load after follow-up).

**Procedure for sub-study**

*Sampling and consent.*

For the sub-study, a random sample of young people (stratified by age and sex) and caregivers (stratified by sex) will be identified once recruitment for the main study has been completed. Randomisation within strata will be carried out by the study coordinator using a random number generator. For young people, two male 10-14 year olds, two female 10-14 year olds, three male 15-19 year olds, and three female 15-19 year olds will be selected. For caregivers, two males and eight females will be selected. Consent will be sought for the main study and the sub-study at the same time (see above).

*Between the first and second main study visit*

Sampling will take place for the sub-study.

*Second study visit*

An ACHAP field worker will approach those individuals identified in the sub-study at this study visit or phone assessment, having already contacted them during the prompting for the main study. Reasons for refusal will be recorded and will be provided to the study coordinator to record in the central study register. Participants who do not want to be interviewed at all, or not during this study visit or phone assessment, or who do not attend, will be replaced by a different participant. For young people, this person will be selected randomly within the same combination of strata (i.e., age and sex), if this site has not been visited/the site phone assessments have not taken place. For caregivers, this person will be selected randomly within the same strata (i.e., sex), if this site has not been visited/the site phone assessments have not taken place. If the site has been visited/the phone assessments have taken place or the person has already been selected, stratified random sampling will take place again until a participant is chosen from a site yet to be visited/yet to have had their phone assessments and a new person has been selected. Participants will be reimbursed for their involvement in the sub-study.

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## Timetable of activities and assessments: Young people

| | Consent | Enrolment and Baseline | 0-12 months | 12 months | After 12 months |
|---|---|---|---|---|---|
| Consent | X | | | | |
| Details passed to study coordinator | X | | | | |
| Baseline appointment scheduled | X | | | | |
| Identification of caregiver | X | | | | |
| Enrolment (study id provided/personal information) | | X | | | |
| HIV knowledge | | X | | X | |
| HIV adjustment | | X | | X | |
| ART adherence | | X | | X | |
| HIV disclosure | | X | | X | |
| HIV communication | | X | | X | |
| Quality of life/well-being | | X | | X | |
| Self-esteem | | X | | X | |
| HIV stigma | | X | | X | |
| Social support | | X | | X | |
| Hope | | X | | X | |
| Demographic/contextual data | | X | | X | |
| 12 months visit scheduled | | X | | | |
| Travel expenses | | X | | | |
| Collection of baseline clinic data | | X | X | | |
| | | | | | |
| Attendance recording | | | X | | |
| 12 month visit reminder | | | X | | |
| | | | | | |
| Collection of programme/clinic data from baseline to 12 months and clinic data after 12 months | | | | X | X |
| Travel expenses and renumeration for study | | | | X | |
| Participant tracking if non-attendance | | | | | X |
| Sub-study interview | | | | | X |
| Travel expenses and renumeration for sub-study | | | | | X |

## Timetable of activities and assessments: Caregivers

| | Consent | Enrolment and Baseline | 0-12 months | 12 months | After 12 months |
|---|---|---|---|---|---|
| Consent | X | | | | |
| Details passed to study coordinator | X | | | | |
| Baseline appointment scheduled | X | | | | |
| Enrolment (study id provided/personal information) | | X | | | |
| HIV knowledge | | X | | X | |
| ART adherence | | X | | X | |
| HIV stigma | | X | | X | |
| Demographic/contextual data | | X | | X | |
| 12 month visit scheduled | | X | | | |
| Travel expenses | | X | | | |
| Attendance recording | | | X | | |
| 12 month visit reminder | | | X | | |
| | | | | | |
| Collection of programme data | | | | | X |
| Travel expenses and renumeration | | | | X | |
| Participant tracking if non-attendance | | | | | X |
| Sub-study interview | | | | | X |
| Travel expenses and renumeration for sub-study | | | | | X |

## Safety and risk considerations

Adverse event (AE) and pregnancy information will not be actively solicited from participants over the duration of time in the study. However, any serious adverse events (e.g., deaths or non-fatal AEs that: are life threatening, result in hospitalisation; are considered disabling or incapacitating; or are clinically significant/require intervention) or pregnancies that are spontaneously volunteered by participants or identified from review of Medical Records/Questionnaires, during protocoled activities, will be reported by ACHAP field workers or Sentebale staff to the study coordinator. There is the potential that adverse

events could be related to the study itself (e.g., distress associated with completing measures or as a consequence of interviews). Participants will be given the opportunity to meet with/call the study coordinator or their health team to offer support.

Participants will not automatically be withdrawn from the study if an adverse event or pregnancy occurs. The appropriateness of study withdrawal will be considered on a case by case basis. If an issue of significant risk to the participant or others is revealed to a member of the research team in the context of study participation, this information will be shared with the clinical team. Limits to confidentiality will be clearly stated in participant information sheets.

**Reporting Pregnancies to the Antiretroviral Pregnancy Registry (APR)**: All pregnancies identified by the above means will be reported by the study coordinator to the APR prospectively, and before the pregnancy outcome, using APR forms. More information including copies of applicable case report forms (CRFs) and fax numbers are available at www.apregistry.com.

**Reporting SAEs and Pregnancies to ViiV Healthcare:** All SAEs, pregnancies or pregnancy complications identified by the above means that are considered to be causally related to ViiV Healthcare products by the clinical team, will be reported by the study coordinator to ViiV Healthcare within 24 hours of causal assessments being made using either a GSK SAE CRF or an APR CRF.

**Data management**

Data collection

Data will be collected by the study coordinator or ACHAP field workers in a number of forms and from a variety of sources:

- Personally identifiable information (young people and caregivers) - for example, names and initials, date of birth, national id, signed consent forms, contact details, study id.

- Study records (young people and caregivers) – for example, record of study visits, date of enrolment, record of who has been approached, consented/refused.
- Self-report quantitative data (young people and caregivers) – for example, responses to questionnaires. These will be identified only by study id. This will allow anonymised linkage of data (between baseline and follow up, and between this and both programme and clinic data) for each individual.
- Quantitative clinic data (young people) – for example, most recent viral load. This will be linked to study and programme data through study id's, date of birth and initials.
- Qualitative interview data (young people and caregivers) – for example, audio files (MP3 or WAV files) and verbatim transcripts (word files). The verbatim transcripts will be anonymised and will only be identified by study id.
- Quantitative programme data (young people and caregivers) – for example club and camp attendance. This will be linked to study and clinic data through study id's, date of birth and initials.

Documentation and metadata

We will provide clear data description, annotation, contextual information and documentation alongside study data. For example, each SPSS data file will have an accompanying text file that will describe the dataset, variables etc.

Ethical and legal compliance

We will seek participant consent for data preservation and sharing. Data will be anonymised. The study will be reviewed by ethics committees in the UK and Botswana. RHUL will own the data. We will use identifiers to allow data linkage and data withdrawal if consent is withdrawn. Participants will be free to withdraw from the study at any point without giving a reason. This will not affect their involvement in the programme.

Storage and back-up

- Personally identifiable information will be kept electronically and in hard copy form. The hard copies will be kept separately from all other study data, at the partner organisation, in a locked filing cabinet.
- Study records will be kept in a study register/electronic folder. This will only contain study id's and will be kept electronically and in hard copy form. The hard copies will be kept separately from personally identifiable data, at the partner organisation.

- Self-report data. This will only contain study id's and will be kept electronically and in hard copy form. The hard copies will be kept separately from personally identifiable data, at the partner organisation.
- Clinic data. This will only be kept in electronic form.
- Qualitative data. This will only be kept in electronic form.
- Programme data. This will only contain study id's and will be kept electronically and in hard copy form. The hard copies, with data collected by Sentebale staff, will be kept separately from personally identifiable data, at the partner organisation.

Data entry from hard copies into electronic databases will be undertaken by the study coordinator, using Microsoft Access, Microsoft Excel and IBM SPSS programmes. Quality assurance of data entry will be checked by the Botswana local PI. Anonymised data will be stored on the UK Principal Investigator's RHUL Dropbox Business account and will be backed up in an encrypted form on Dropbox servers. Sensitive data on portable electronic devices, local computers and hard drives will be encrypted. Access to data will only be provided to the research team through shared project team folders on Dropbox. We will use a consistent system of file naming, version control and organisation of folder structure. Data will be stored in password protected databases.

Selection and preservation

Electronic and hard copy data will be retained for a minimum of 10 years, consistent with RHUL policy.

Data sharing

Anonymised electronic data from the study will be transferred to a data repository (eg.,Figshare or RHUL Research Data Archive) at the end of the study. This will be freely accessible but will not include transcripts or audiofiles. This data will be retained for a minimum of 10 years, consistent with RHUL policy.

Responsibilities and resources

The UK PI will be responsible for overseeing the data management plan. RHUL IT and Research Support Team will provide assistance.

**Data analysis**

The distribution of missing data will be assessed with Little's Missing Completely at Random Test (Little, 1988) before using Expectation Maximisation to impute missing data if the proportion of missing data is small.

For multi-item measures developed or adapted for this study, Principal Components Analysis (PCA) will first be carried out using both orthogonal (varimax) and oblique (oblimin) rotations. Scree plots will be examined to determine the number of factors to extract and analyses will be re-run specifying the number of factors. Items will be dropped from the scale if factor loadings are low or if they load on more than one factor. If any items are dropped, PCA will be re-run. Cronbach's alpha or KR-20 will calculated for the final total scale and its subscales, and item-total correlations will be examined. The relationship between the measure and other variables will be assessed using independent t tests and Pearson's correlations, with bootstrapped confidence intervals where parametric assumptions are not met. Two tailed tests will be used.

In the main study, descriptive analysis will be conducted on frequencies, percentages, central tendency and variability of data. Chi squared and Fisher's exact tests will be used to explore relationships between categorical variables; correlations will be used for continuous variables. Changes in variables between baseline and follow-up will be assessed using McNemar's test, paired sample t tests and multilevel modelling after test assumptions have been assessed.

Independent t tests (where parametric assumptions were met) and chi-squared tests will be used to compare baseline characteristics of those retained in the study to those lost to follow up to examine whether there are any systematic differences between these groups. We will interpret our findings from the main study in light of this 'lost to follow up' analysis. We will aim to obtain follow-up data from all participants enrolled in the study regardless of the extent of involvement in intervention activities.

For the primary outcome variable, we will first use paired sample t tests (if parametric assumptions are met), to assess for differences in scores on the Pediatric Symptom Checklist between baseline and follow-up. We will then use either linear regression or hierarchical linear modelling (given the nested nature of the data) to examine the effect of variables such as sex, age (10-14 versus 15-19 years), changes in regimen, the extent of involvement in intervention activities, whether the caregiver attends Sentebale, region, number of attendees per club/group, relationship of caregiver to young person, caregiver occupation, caregiver employment, caregiver HIV status, caregiver viral load, housing, and

number of days from BL assessment to follow-up assessment. One tailed tests will be used to test study hypotheses relating to the Pediatric Symptom Checklist with significance at the 0.05 level.

For the viral suppression outcome, we will first use McNenar's test to assess evidence of change in the rate of viral suppression from baseline to follow-up. We will then use multilevel logistic regression modelling to examine the effect of variables such as sex, age (10-14 versus 15-19 years), changes in regimen, the extent of involvement in intervention activities, whether the caregiver attends Sentebale, region, number of attendees per club/group, relationship of caregiver to young person, caregiver occupation, caregiver employment, caregiver HIV status, caregiver viral load, housing, and the timing of the viral load measurement. One tailed tests will be used to test study hypotheses relating to viral load suppression with significance at the 0.05 level.

The sub-study will involve thematic analysis (Braun & Clarke, 2006). Interviews will be transcribed and initial codes will be generated from the written data. Themes will be developed and reviewed from the initial codes. These themes will then be defined and named.

**Ethical issues**

Written assent/consent will be sought from attendees and caregivers. Participants will have access to a referral to their usual health care provider or support from Sentebale if significant levels of distress are reported by participants during the study. Participants will continue to have to the programme, whether they choose to remain in the study or to withdraw. Participants will be reimbursed for travel and time taken to complete follow-up assessments. Ethics proposals will be submitted to institutional review boards at the Botswana Ministry of Health and Royal Holloway University of London.

**Dissemination**

We will disseminate information about the study in a number of different formats for a range of stakeholders:

- We will develop a website to provide information about the study during the first phase of the study. This website will include the study protocol, and measures. We will upload associated publications, presentations and project news.

- We will engage with the media through the dedicated press offices in the co-applicants' and funder's institutions, who have experience at attracting media and providing press-releases. The research team will ensure that press releases are accurate, timely and co-ordinated across the partners to maximize impact. Press releases will not be issued unless RHUL, Sentebale, ACHAP and ViiV Healthcare are in agreement.
- We will produce a full report at the end of the study for ViiV Healthcare, Sentebale, and other stakeholders. A final draft version of the report will be provided by RHUL to ViiV Healthcare, Sentebale and ACHAP for review.
- We will provide information about the study (progress, findings, outputs and recommendations) through our links with local, national and global organisations. The information that is provided to such organisations will be agreed upon between the study partners (RHUL, Sentebale and ACHAP).
- We will provide a short summary of our findings in lay language in an information sheet (for participants and other stakeholders). The content of these information sheets will be agreed between study partners.
- The following peer review articles will be drafted (and presented at conferences). The final draft versions of all conference and journal submissions will be forwarded by RHUL to Sentebale, ACHAP and ViiV Healthcare for review:
    - A main quantitative outcome evaluation article for the primary (PSC) outcome.
    - A quantitative outcome evaluation article for psychological secondary outcomes.
    - A quantitative outcome evaluation for the viral load secondary outcome.
    - A qualitative process evaluation article (based on follow-up interviews/sub-study).
    - An article outlining the development of study measures.

**Advisory group**

An advisory group will be formed during the initial phase to consult with on the progress of the study. The group will involve key stakeholders, including young people living with PAH, family members and caregivers of young people living with PAH, health care workers, health academics, health professionals, representatives from Botswana MoH and civil society groups. We will aim to recruit individuals with a spread of knowledge and expertise. The group will be convened, chaired and organised by the local PI, Lesego Busang, who will provide the group with information about the study on an ongoing basis, and will seek

advice on various aspects of the project (e.g., recruitment, retention and dissemination). The meetings will be minuted and will take place on three  occasions over the life of the study – prior to main study recruitment, , at the latter stages of recruitment, and at the end of the study. The local PI will liaise with the research team about the issues to be brought to the meetings and matters arising from the meetings.

**Personnel and costs**

- Study coordinator/co-applicant (Ivor Williams) – Preparing materials, carrying out piloting, supervising field workers, monitoring programme activities, data management and analysis and writing up.
- UK PI (Michael Evangeli) – evaluation planning, developing measures, co- supervising study coordinator, and taking a lead on analysis and writing up.
- Botswana local PI (Lesego Busang) – evaluation planning, developing measures, forming and carrying out advisory group meetings, co-supervising study coordinator, analysis and write up, taking up a lead role in carrying out piloting and administering measures.
- Co-applicant (Samuel Tope Ajayi) – evaluation planning, co-supervision and all qualitative analysis and final report writing.
- Co-applicant (Tsitsi Chawatama) – evaluation planning.
- Co-applicant (Alice Lycett Green) – evaluation planning.
- Co-applicant (Barney Morake) – assisting study coordinator with obtaining data, including monitoring of programme activities.
- Co-applicant (One Nkitseng) – analysis and writing up.
- Statistician – to advise on data analysis.
- Data enterer – to input data
- Field workers (interviewers and field supervisors) – to enrol participants and to conduct baseline and follow-up interviews for study one and interviews for the sub-study.
- Participant reimbursement for transport and time – for attending follow-up assessment sessions.
- Staff travel expenses: to travel to sites (vehicles and fuel) and per diems. In addition, three UK-Botswana PI visits.
- Additional expenses: steering group meeting expenses; recruitment costs; printing costs.
- Overheads

**Research Team**

- Michael Evangeli is a Reader and Clinical Psychologist with extensive research and clinical HIV experience in the UK and South Africa. He has published widely on

psychosocial aspects of HIV in the UK and Africa. In addition to his doctoral clinical training, he has a Public Health in Developing Countries MSc from LSHTM, is the PI of a ViiV Healthcare UK funded study evaluating a residential intervention for young people living with HIV, and has been a co-applicant on a multi-centre UK MRC-funded behavioural sexual health intervention.

- Lesego Busang is the Director of Programmes, responsible for ACHAP's programmes and Research, Monitoring and Evaluation. He has over 20 years of technical experience in the monitoring, evaluation, reporting, research, statistics and leadership, informing policy and strategy development, with over 10 years at senior management level. He has considerable experience in the fields of TB and HIV across a range of African countries.
- Ivor Williams has over 20 years of experience in health programming, socio-economics and research. His work cuts across the commercial private sector that includes community based research and private sector consulting for government, the United Nations, EU supported projects and non-governmental organisations. Williams commenced his career in 1993 that led to the development of Botswana's first social marketing programme (BSMP). The BSMP under his guidance gave birth to several long standing preventative health programmes which resulted in the creation of health commodities and services specifically designed to resonate with the Botswana market. These products and services include Voluntary Counselling and Testing services, the promotion of Prevention of Mother to Child Transmission programmes, and generic HIV prevention programmes for youth. He has both consulting and programme work experience from Namibia, Malawi, Mozambique, Uganda, Tanzania, Kenya, Zimbabwe and Zambia where he spent five consecutive years as a private consultant. Williams now heads ACHAPs newly founded Consultancy Unit (TACU). He will take up a lead role in carrying out piloting and administering measures as the senior co-applicant.
- Moemedi Keakantse holds a Bachelor of Arts Degree in Psychology and International Studies from Monash University. He is currently reading for a Masters in Politics & International Relations at the University of Botswana. Mr. Keakantse has been heavily involved in studies conducted by ACHAP since he joined in July 2016 and has already demonstrated great affinity for field work. He served as a Field Supervisor in the Mapping of Counsellor Support Supervision Study (2016) and as a Field Coordinator in the Mapping of Select Key Populations in Botswana Study (2017). In 2018, he also led

fieldwork for two studies – Brand Perception Survey and the Mapping of Civil Society Organisations in Botswana. In the current study he is in charge of data collector recruitment, training, district engagement and all field logistics.

- One Nkitseng is an experienced and qualified professional with a BA degree in Health Sciences and Social Services-Psychological counselling (specialization); and a BA Hon in Psychology as well as 15 years' field work. Having coordinated a number of HIV/AIDS projects as well as training in management of HIV/AIDS projects brings with it wealth of experience in issues of management, coordination of organizations and monitoring and evaluation of projects. She has worked for BOCAIP as a Centre Coordinator/Manager, Monitoring and evaluation consultant for BNAPS project for Wazha Touch a Life Centre, worked for HRDC as a Campus Health Coordinator for University of Botswana, and a District Coordinator for FHI 360.
- Tsitsi Chawatama is a Consultant Paediatrician at Chelsea & Westminster NHS Trust with specialist interests in paediatric Infectious diseases, medical education and Global Health. She has a MSc in International Child Health (University College London) and holds Postgraduate Diplomas in Tropical Medicine & Hygiene (DTMH) and Paediatric Infectious Diseases from the London School and the University of Oxford. She is a Fellow of the Royal College of Paediatrics & Child Health (RCPCH) and member of the Children's HIV Association UK. Tsitsi spent many of her formative years living in Zimbabwe and worked in Ethiopia as a RCPCH Fellow on a UNICEF funded initiative developing an education programme, whilst contributing to the improvement of neonatal and paediatric services including HIV care. She is a trustee of Sentebale and has consultancy & research interests in health systems strengthening, safeguarding and evidence-based care.
- Alice Lycett Green has led Sentebale's Marketing and Communications function since 2011, and designed the charity's Let Youth Lead Advocacy programme in 2016 aimed at encouraging youth in southern Africa to know and manage their HIV status. Alice has led on a range of high-profile fundraising events and campaigns including the Concert with Coldplay at Kensington Palace, World AIDS Day, 'Feel No Shame' campaign, the global advocacy session at The International AIDS Conference in Durban titled, "Ending AIDS with the Voices of Youth" with The Duke of Sussex, Sir Elton John and a panel of youth advocates, and latterly a youth-led roundtable at the London School of Hygiene and Tropical Medicine attended by global HIV leaders ensuring young people affected

by HIV/AIDS play an integral part in shaping new research and policies to strengthen HIV prevention, testing and treatment in sub-Saharan Africa.

- Barnabus Morake was recently appointed at Sentebale Botswana. He is experienced in monitoring and evaluation, and previously managed and coordinated data management of child health programmes on immunization and surveillance at the Botswana Ministry of Health and Wellness. Barnabus holds a Masters degree in International Public Health and a Bachelors degree in Nursing Science.

## Timetable

| | Time in months | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0-3 | 3-6 | 6-9 | 9-12 | 12-15 | 15-18 | 18-21 | 21-24 | 24-27 | 27-30 | 30-33 | 33-36 |
| Form advisory committee and hold meetings | ■ | | | | | ■ | | | | | | ■ |
| Training of interviewers for measure development and sub-study | ■ | | | | | | | | | | | |
| Develop, adapt, pilot and prepare measures and interview guides | ■ | ■ | | | | | | | | | | |
| Developing personal study register, central study register and demographic forms, and site study logs | ■ | ■ | | | | | | | | | | |
| Setting up study database | ■ | ■ | | | | | | | | | | |
| Agree how programme activities recorded | | ■ | | | | | | | | | | |
| Preparation activities with centres | | ■ | | | | | | | | | | |
| Consent, enrolment and baseline assessments | | | ■ | ■ | ■ | | | | | | | |
| Obtain baseline clinic data | | | ■ | ■ | ■ | | | | | | | |
| Monitor programme activities, adverse events and pregnancies | | | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | | |
| Inputting, screening and summarising baseline data | | | | ■ | ■ | ■ | | | | | | |
| Sampling for sub-study | | | | | | ■ | | | | | | |
| Reminders for follow-up assessments and participant tracking | | | | | | ■ | ■ | ■ | | | | |
| Follow up assessments | | | | | | | ■ | ■ | ■ | | | |
| Carry out interviews | | | | | | | ■ | ■ | ■ | | | |
| Obtain clinic and programme data | | | | | | | ■ | ■ | ■ | ■ | ■ | |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Input, screen and summarise follow-up data** | | | | | | | | | | | | |
| | **Time in months** | | | | | | | | | | | |
| | **0-3** | **3-6** | **6-9** | **9-12** | **12-15** | **15-18** | **18-21** | **21-24** | **24-27** | **27-30** | **30-33** | **33-36** |
| **Transcribe interviews** | | | | | | | | | | | | |
| **Qualitative and quantitative analysis** | | | | | | | | | | | | |
| **Writing up** | | | | | | | | | | | | |
| **Dissemination** | | | | | | | | | | | | |

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