ISRCTN31852047 https://doi.org/10.1186/ISRCTN31852047

Randomised feasibility trial of an onward HIV disclosure intervention

Submission date
08/01/2019

Recruitment status
No longer recruiting

Registration date
21/01/2019

Overall study status
Completed

Last Edited
18/03/2024

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Current plain English summary as of 21/02/2022:
Background and study aims
There are large numbers of young people with HIV globally, many with HIV acquired around the time of birth or through breastfeeding (perinatally acquired HIV [PAH]). Young people with PAH face challenges in adhering to antiretroviral therapy (ART), managing onward HIV transmission risk, and maintaining wellbeing. Onward HIV disclosure (sharing one's HIV status with others) may facilitate positive outcomes in the above areas. Sharing of one's HIV status with sexual partners may decrease HIV transmission risk through more consistent condom use, or the use of pre and post-exposure prophylaxis (preventative treatment), if virally non-suppressed. Onward disclosure may also facilitate ART adherence and improve wellbeing. Despite the public health and individual benefits of onward disclosure, there are low rates of onward disclosure in young people with PAH. No interventions have been developed to support this population to make decisions about sharing their status, and there is a lack of onward disclosure guidance for this population or for professionals working with them. This study aims to develop and test the feasibility of a behavioural intervention to increase onward disclosure levels and support onward disclosure decision-making in perinatally infected 18-29-year-olds in the UK and Uganda.

Who can participate?
Perinatally infected 18-29-year-olds in the UK and Uganda

What does the study involve?
The study involves developing a programme (an intervention) for 18-29-year-olds who have grown up with HIV in the UK and Uganda, to help with decision-making about sharing an HIV-positive status with others (onward HIV disclosure). In particular, the researchers want to know whether people will take part in the study, stay in the study until the end, and whether the programme is acceptable. Participants are randomly allocated to receive the intervention or standard care. The intervention consists of four sessions (90 minutes per session) delivered in a mixed group/individual format (3 group and 1 individual session). Intervention sessions will be online via zoom in the UK. Face to face interviews with ten participants in Uganda and interviews over the phone with ten participants in the UK will also be conducted.

What are the possible benefits and risks of participating?
Being part of this study may help participants to think about sharing their status. By being part of this study, participants are helping to develop new ways to help support other young people with HIV to make decisions about whether and how to share their status. The researchers do not think there are risks with taking part. It may be difficult, however, to talk about some aspects of living with HIV if participants are assigned to the intervention group.

Where is the study run from?
1. St. Mary's Hospital (UK)
2. King's College Hospital (UK)
3. Guy's Hospital (UK)
4. St George's Hospital (UK)
5. Heartlands Hospital (UK)
6. Joint Clinical Research Centre (Uganda)
7. North Manchester Healthcare NHS Trust (UK)

When is the study starting and how long is it expected to run for?
June 2019 to September 2022

Who is funding the study?
ViiV Healthcare

Who is the main contact?
Dr Michael Evangeli
michael.evangeli@rhul.ac.uk

_____
Previous plain English summary:
Background and study aims
There are large numbers of young people with HIV globally, many with HIV acquired around the time of birth or through breastfeeding (perinatally acquired HIV [PAH]). Young people with PAH face challenges in adhering to antiretroviral therapy (ART), managing onward HIV transmission risk, and maintaining wellbeing. Onward HIV disclosure (sharing one's HIV status with others) may facilitate positive outcomes in the above areas. Sharing of one's HIV status with sexual partners may decrease HIV transmission risk through more consistent condom use, or the use of pre and post-exposure prophylaxis (preventative treatment), if virally non-suppressed. Onward disclosure may also facilitate ART adherence and improve wellbeing. Despite the public health and individual benefits of onward disclosure, there are low rates of onward disclosure in young people with PAH. No interventions have been developed to support this population to make decisions about sharing their status, and there is a lack of onward disclosure guidance for this population or for professionals working with them. This study aims to develop and test the feasibility of a behavioural intervention to increase onward disclosure levels and support onward disclosure decision-making in perinatally infected 18-25 year olds in the UK and Uganda.

Who can participate?
Perinatally infected 18-25 year olds in the UK and Uganda

What does the study involve?
The study involves developing a programme (an intervention) for 18-25 year olds who have grown up with HIV in the UK and Uganda, to help with decision-making about sharing an HIV-positive status with others (onward HIV disclosure). In particular, the researchers want to know whether people will take part in the study, stay in the study until the end, and whether the

programme is acceptable. Participants are randomly allocated to receive the intervention or standard care. The intervention consists of four sessions (90 minutes per session) delivered in a mixed group/individual format (3 group and 1 individual session). Face to face interviews with ten participants in the UK and ten participants in Uganda are also conducted.

What are the possible benefits and risks of participating?
Being part of this study may help participants to think about sharing their status. By being part of this study, participants are helping to develop new ways to help support other young people with HIV to make decisions about whether and how to share their status. The researchers do not think there are risks with taking part. It may be difficult, however, to talk about some aspects of living with HIV if participants are assigned to the intervention group.

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1. St. Mary's Hospital (UK)
2. King's College Hospital (UK)
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6. Joint Clinical Research Centre (Uganda)

When is the study starting and how long is it expected to run for?
June 2019 to August 2022

Who is funding the study?
ViiV Healthcare

Who is the main contact?
Dr Michael Evangeli
michael.evangeli@rhul.ac.uk

Study website
http://pc.rhul.ac.uk/sites/headsup

Contact information

Type(s)
Scientific

Contact name
Dr Michael Evangeli

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michael.evangeli@rhul.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CPMS 39850

Study information

Scientific Title
Randomised feasibility trial of an onward HIV disclosure intervention for 18-29-year-olds living with perinatally acquired HIV

Acronym
HEADS-UP (HIV Empowering Adults Decisions to Share - UK/Uganda Project)

Study objectives
1. The intervention will be feasible, in relation to recruitment, retention and acceptability.
2. Participants in the intervention group will have a higher rate of onward HIV disclosure in the previous 6 months at follow-up than participants in the SOC group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/01/2019, London - Brent Research Ethics Committee (80 London Road, Skipton House, London, SE1 6LH, UK; +44 (0)2071048129; nrescommittee.london-brent@nhs.net), REC ref: 18/LO/1810

Study design
Randomized; Interventional; Design type: Treatment, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)

Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
HIV infection

Interventions
Current intervention as of 21/02/2022:
The trialists plan a 30 month project to:
1. Develop the planned intervention for each context (Phase 1) with 50 participants (20 young people with PAH; 20 partners, friends and family of young people with PAH; 10 professionals working with young people with PAH).
2. Conduct a randomised feasibility parallel group trial of the intervention alongside a standard of care condition (Phase 2 - main study). The use of standard of care as the comparison condition reflects the fact that onward disclosure is likely to be discussed in an unstructured way in standard practice (Kazdin, 2015). The primary outcome relates to the feasibility of the intervention, in particular recruitment, retention and acceptability (Bowen et al., 2009). The main secondary outcome is the level of onward disclosure. A sample size of 64 per condition (intervention or standard of care) (128 participants in total: 85 in Uganda, 43 in the UK) with data at both the baseline and follow-up time points, across UK and Ugandan sites will be recruited, consistent with existing guidance (Craig et al., 2008). The median retention rate in comparable disclosure interventions reported in the Kennedy et al systematic review was 68% (Kennedy et al., 2015). Therefore we will aim to recruit additional participants at baseline to allow for attrition (approximately 30 per country).
3. Conduct face-to-face interviews with ten participants in Uganda and telephone interviews with ten participants in the UK (Phase 2 - sub-study).

Study settings
1. UK – the trialists will recruit participants mainly from Imperial Healthcare NHS Trust in St. Mary' s Hospital, London's 900 Clinic, a service for HIV+ young people (16+ years) with a caseload of approximately 120 individuals with PAH within the 18-29 years age range. They will recruit from a further three NHS clinics (Guy's Hospital, London; King's College Hospital, London, and Heartlands Hospital, Birmingham).
2. Uganda – the trialists will recruit participants from the Joint Clinical Research Centre, Lubowa, Kampala. The JCRC is a not-for-profit organization that provides HIV care to approximately 300 young people with PAH ≥18 years.

Phase 1 – Intervention Development and Adaptation
This phase will involve: assessing barriers and facilitators to onward disclosure; developing a theory of onward disclosure relevant to the study contexts using an intervention development framework (Michie, van Stralen, & West, 2011), developing intervention and recruitment strategies; carrying out formative assessment of intervention components for feasibility, understanding and acceptability; manualising the intervention; developing semi-structured interview guides; developing and adapting measures of primary and secondary outcomes and other variables (e.g., ART adherence self-efficacy); developing a fidelity measure for the intervention; developing a measure to describe standard of care; and training therapists. The following methods will be used: individual assessments, focus groups and surveys.

Phase 2 Main study – Feasibility trial

Design

This phase will use a pilot randomised feasibility parallel group design. Participants will be randomised to either the intervention or standard of care. Assessments will be carried out at three timepoints – pre-intervention/baseline (for both conditions), post-intervention (at the end of the final session, only for the intervention condition), and six month follow-up (six months from baseline, both conditions).

Intervention condition

The intervention condition will consist of four sessions (90 minutes per session) delivered in a mixed group/individual format (3 group and 1 individual session for all participants in the intervention condition); professionally-led; mixed gender; face-to-face in Uganda and online via zoom in the UK; with peer mentor involvement and follow-up emotional, informational and problem-solving support (in the 6 months from baseline to the follow-up data point) from a peer worker for both young people in the intervention condition and people whom they have disclosed to. This will involve the use of both phone and online/social media options (Henwood et al., 2016). In total, participants in the intervention condition will be asked to attend for seven main study visits (consent, enrollment, baseline assessment/intervention session 1 (group session), intervention session 2 (group session), intervention session 3 (group session), intervention session 4 (individual session)/post assessment, and 6 month follow-up assessment). During the enrolment session, a study id will be provided, personal information will recorded, and randomisation will take place. During assessment sessions, questionnaires will be administered (see below).

Standard of Care condition

The nature of psychosocial support provided (in particular relating to onward HIV disclosure) and the age of transition from paediatric care during the study period at all sites will be recorded. Both the main UK site and the Uganda site have a dedicated clinic for young people who have previously been in paediatric care, with peer support and professional psychosocial support available. In these clinics, young people can discuss HIV disclosure with their multidisciplinary team, attend with their partner, and have access to a range of other services (e. g., HIV testing and condom provision). Standard of care in both countries, however, is for there to be no routine or structured psychosocial intervention to facilitate HIV disclosure or disclosure decision-making, and it has been reported that discussions between professionals and young people with HIV about more affectively-laden sexual health issues (e.g., discussing disclosure within intimate relationships) is infrequent (Fair, Albright, & Houpt, 2016). In total, participants in the standard of care condition will be asked to attend for three study visits (consent, enrollment /baseline assessment, 6 month follow-up assessment). During the enrolment session, a study id will be provided, personal information will recorded, and randomisation will take place. During assessment sessions, questionnaires will be administered (see below).

Phase 2 Sub-study - Process Evaluation

Face to face one-off interviews with ten participants in Uganda and telephone one-off interviews with ten participants in the UK will be conducted post-intervention (immediately after the final intervention session, and at the six-month follow-up) by the study coordinators to aid in the assessment of feasibility and to clarify potential causal mechanisms of the intervention. Individuals will be sampled purposively from both conditions (interventions and standard of care) to ensure that a range of participant characteristics are represented. They will be contacted by phone after the baseline assessment if they have been selected for the sub-study (if they have consented to take part in this aspect of the research).

Previous intervention:
The trialists plan a 30 month project to:
1. Develop the planned intervention for each context (Phase 1) with 50 participants (20 young people with PAH; 20 partners, friends and family of young people with PAH; 10 professionals working with young people with PAH).
2. Conduct a randomised feasibility parallel group trial of the intervention alongside a standard of care condition (Phase 2 - main study). The use of standard of care as the comparison condition reflects the fact that onward disclosure is likely to be discussed in an unstructured way in standard practice (Kazdin, 2015). The primary outcome relates to the feasibility of the intervention, in particular recruitment, retention and acceptability (Bowen et al., 2009). The main secondary outcome is the level of onward disclosure. A sample size of 64 per condition (intervention or standard of care) (128 participants in total: 32 in each condition in each country) with data at both the baseline and follow-up time points, across UK and Ugandan sites will be recruited, consistent with existing guidance (Craig et al., 2008). The median retention rate in comparable disclosure interventions reported in the Kennedy et al systematic review was 68% (Kennedy et al., 2015). Therefore we will aim to recruit additional participants at baseline to allow for attrition (approximately 30 per country).
3. Conduct face to face interviews with ten participants in the UK and ten participants in Uganda post-intervention (Phase 2 - sub-study).

Study settings
1. UK – the trialists will recruit participants mainly from Imperial Healthcare NHS Trust in St. Mary' s Hospital, London's 900 Clinic, a service for HIV+ young people (16+ years) with a caseload of approximately 120 individuals with PAH within the 18-25 years age range. They will recruit from a further three NHS clinics (Guy's Hospital, London; King's College Hospital, London, and Heartlands Hospital, Birmingham).
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Design
This phase will use a pilot randomised feasibility parallel group design. Participants will be randomised to either the intervention or standard of care. Assessments will be carried out at three timepoints – pre-intervention/baseline (for both conditions), post-intervention (at the end of the final session, only for the intervention condition), and six month follow-up (six months from baseline, both conditions).

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The intervention condition will consist of four sessions (90 minutes per session) delivered in a

mixed group/individual format (3 group and 1 individual session for all participants in the intervention condition); professionally-led; mixed gender; face-to-face; with peer mentor involvement and follow-up emotional, informational and problem-solving support (in the 6 months from baseline to the follow-up data point) from a peer worker for both young people in the intervention condition and people whom they have disclosed to. This will involve the use of both phone and online/social media options (Henwood et al., 2016). In total, participants in the intervention condition will be asked to attend for seven main study visits (consent, enrollment, baseline assessment/intervention session 1 (group session), intervention session 2 (group session), intervention session 3 (group session), intervention session 4 (individual session)/post assessment, and 6 month follow-up assessment). During the enrolment session, a study id will be provided, personal information will recorded, and randomisation will take place. During assessment sessions, questionnaires will be administered (see below). We will try to combine study visits with routine clinic appointments where possible.

Standard of Care condition
The nature of psychosocial support provided (in particular relating to onward HIV disclosure) and the age of transition from paediatric care during the study period at all sites will be recorded. Both the main UK site and the Uganda site have a dedicated clinic for young people who have previously been in paediatric care, with peer support and professional psychosocial support available. In these clinics, young people can discuss HIV disclosure with their multidisciplinary team, attend with their partner, and have access to a range of other services (e. g., HIV testing and condom provision). Standard of care in both countries, however, is for there to be no routine or structured psychosocial intervention to facilitate HIV disclosure or disclosure decision-making, and it has been reported that discussions between professionals and young people with HIV about more affectively-laden sexual health issues (e.g., discussing disclosure within intimate relationships) is infrequent (Fair, Albright, & Houpt, 2016). In total, participants in the standard of care condition will be asked to attend for three study visits (consent, enrollment /baseline assessment, 6 month follow-up assessment). During the enrolment session, a study id will be provided, personal information will recorded, and randomisation will take place. During assessment sessions, questionnaires will be administered (see below). We will try to combine study visits with routine clinic appointments where possible.

Phase 2 Sub-study - Process Evaluation
Face to face one-off interviews with ten participants in the UK and ten participants in Uganda will be conducted post-intervention (immediately after the final intervention session, and at the six month follow-up) by the study coordinators to aid in the assessment of feasibility and to clarify potential causal mechanisms of the intervention. Individuals will be sampled purposively from both conditions (interventions and standard of care) to ensure that a range of participant characteristics are represented. They will be contacted by phone after the baseline assessment if they have been selected for the sub-study (if they have consented to take part in this aspect of the research). If they agree to be interviewed, participants will be asked to attend the clinic site for this to take place. We will try to combine this visit with routine clinic appointments where possible.

Intervention Type
Behavioural

Primary outcome measure
The feasibility of the intervention will be assessed in relation to:
1. Recruitment rates calculated for each site and for each condition at baseline
2. Retention rates calculated for each site and for each condition at 6 months

3. Acceptability measured using rating scales for participants in the intervention condition (satisfaction, intention to continue to use, and perceived appropriateness of the intervention) (Bowen et al., 2009) post intervention

Secondary outcome measures
1. HIV disclosure - Self-reported HIV disclosure events assessed through recording the frequency of new disclosures (full or partial; first hand or second hand with consent) in last six months to partners, friends and family. For each disclosure, recipient and relationship characteristics, perceived satisfaction with disclosure decision, and the nature of the recipient's response will be assessed. In addition, for those individuals in a participant's social network not disclosed to, satisfaction with disclosure decisions and disclosure intention will be measured. Any social harms occurring as a result of disclosure will be recorded. The trialists will develop this measure with reference to existing relevant measures (O'Connor, 1995; Serovich, Craft, & Reed, 2012; Serovich, Craft, & Yoon, 2007; Teti et al., 2010). At the follow-up time point for those in the both conditions, they will also ask about whether any disclosure support was sought from therapists or peers during the previous six months. Measured at baseline and 6 months.
2. ART adherence behaviour assessed by the CASE adherence index (Mannheimer et al., 2006). Biological correlates of ART adherence (most recent viral load and CD4 count, if available) will be collected from participants' clinical records. Measured at baseline and 6 months.
3. Psychological wellbeing, assessed using the six-item psychological domain from the WHOQOL BREF (Skevington, Lotfy, O'Connell, & Group, 2004) at baseline, post intervention (just for intervention condition), and 6 months
4. Social support, assessed using the six-item Social Support Questionnaire Short form – SSQ6 (Sarason, Sarason, Shearin, & Pierce, 1987) at baseline, post intervention (just for intervention condition), and 6 months
5. Hope, assessed using the State Hope Scale (C. R. Snyder et al., 1996) at baseline, post intervention (just for intervention condition), and 6 months
6. The frequency and rate of unprotected sexual intercourse calculated for casual and regular partners with self-report data. Partner status will also be recorded. Measured at baseline and 6 months.

Overall study start date
01/06/2019

Completion date
30/09/2022

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 21/02/2022:
Phase 1:
1. Ten young people with PAH in the UK and ten in Uganda (recruited purposively with a range of levels of onward disclosure):
1.1. Aged 18 to 29 years inclusive
1.2. Living with PAH. PAH status will be ascertained using the following criteria if information is available: HIV diagnosis before 15 years, evidence of parental HIV+ diagnosis/maternal death consistent with HIV, no other risk factors for behavioural acquisition
1.3. Knowledge of own HIV status
1.4. Able to give informed consent
2. Friends, family and partners of young people with PAH in the UK (ten individuals in total) and

in Uganda (a further ten in total)
2.1. Friends, family or partners of people currently or recently aged 18-29 with PAH
2.2. Aged 16 years or over
2.3. Awareness of the HIV status of the young person with PAH
2.4. Able to give informed consent
3. Five professionals working with young people with PAH in the UK and five in Uganda
3.1. Current or recent involvement in the care of the people aged 18-29 with PAH

Phase 2 – Feasibility trial:
1. Aged 18 to 29 years inclusive
2. Living with PAH. PAH status will be ascertained using the following criteria: HIV diagnosis before 15 years, evidence of parental HIV+ diagnosis/maternal death consistent with HIV, no other risk factors for behavioural acquisition
3. Receiving HIV care at study sites
4. Knowledge of own HIV status
5. Able to give informed consent

Previous participant inclusion criteria as of 08/04/2020:
Phase 1:
1. Ten young people with PAH in the UK and ten in Uganda (recruited purposively with a range of levels of onward disclosure):
1.1. Aged 18 to 29 years inclusive
1.2. Living with PAH. PAH status will be ascertained using the following criteria if information is available: HIV diagnosis before 15 years, evidence of parental HIV+ diagnosis/maternal death consistent with HIV, no other risk factors for behavioural acquisition
1.3. Knowledge of own HIV status
1.4. Able to give informed consent
2. Friends, family and partners of young people with PAH in the UK (ten individuals in total) and in Uganda (a further ten in total)
2.1. Friends, family or partners of people currently or recently aged 18-29 with PAH
2.2. Aged 16 years or over
2.3. Awareness of the HIV status of the young person with PAH
2.4. Able to give informed consent
3. Five professionals working with young people with PAH in the UK and five in Uganda
3.1. Current or recent involvement in the care of the people aged 18-25 with PAH

Phase 2 – Feasibility trial:
1. Aged 18 to 25 years inclusive
2. Living with PAH. PAH status will be ascertained using the following criteria: HIV diagnosis before 15 years, evidence of parental HIV+ diagnosis/maternal death consistent with HIV, no other risk factors for behavioural acquisition
3. Receiving HIV care at study sites
4. Knowledge of own HIV status
5. Able to give informed consent

Previous participant inclusion criteria:
Phase 1:
1. Ten young people with PAH in the UK and ten in Uganda (recruited purposively with a range of levels of onward disclosure):
1.1. Aged 18 to 25 years inclusive
1.2. Living with PAH. PAH status will be ascertained using the following criteria if information is available: HIV diagnosis before 15 years, evidence of parental HIV+ diagnosis/maternal death

consistent with HIV, no other risk factors for behavioural acquisition
1.3. Knowledge of own HIV status
1.4. Able to give informed consent

2. Friends, family and partners of young people with PAH in the UK (ten individuals in total) and in Uganda (a further ten in total)
2.1. Friends, family or partners of people currently or recently aged 18-25 with PAH
2.2. Awareness of the HIV status of the young person with PAH
2.3. Able to give informed consent

3. Five professionals working with young people with PAH in the UK and five in Uganda
3.1. Current or recent involvement in the care of the people aged 18-25 with PAH

Phase 2 – Feasibility trial:
1. Aged 18 to 25 years inclusive
2. Living with PAH. PAH status will be ascertained using the following criteria: HIV diagnosis before 15 years, evidence of parental HIV+ diagnosis/maternal death consistent with HIV, no other risk factors for behavioural acquisition
3. Receiving HIV care at study sites
4. Knowledge of own HIV status
5. Able to give informed consent

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Upper age limit
29 Years

Sex
Both

Target number of participants
Phase 1: 50 participants; Phase 2: 128 participants (85 Uganda, 43 UK)

Total final enrolment
192

Key exclusion criteria
Current participant exclusion criteria as of 21/02/2022:
Phase 1:
1. Young people with PAH:
1.1. Current serious mental health problems. Professional opinion will be sought regarding the assessment of any mental health difficulties that might render young people unsuitable for the study
1.2. Moderate to severe learning disability/executive functioning difficulties. Individuals with

clinically documented moderate to severe cognitive difficulties will be excluded
1.3. Current serious physical health problems with life expectancy < 12 months, according to professional opinion
1.4. Inability to understand or communicate in English (UK) or either English or Luganda (Uganda) according to professional opinion
1.5. Current participation in other psychosocial intervention/support research
2. Friends, family and partners of young people with PAH:
2.1. Inability to understand or communicate in English (UK) or either English or Luganda (Uganda)

Phase 2 – Feasibility trial:
1. Current serious mental health problems. Clinician opinion will be sought regarding the assessment of any mental health difficulties that might render young people unsuitable for the study
2. Moderate to severe learning disability/executive functioning difficulties. Individuals with clinically documented moderate to severe cognitive difficulties will be excluded
3. Current serious physical health problems with life expectancy < 12 months, according to clinician opinion
4. Inability to understand or communicate in English (UK) or either English or Luganda (Uganda) according to clinician opinion
5. Current participation in other psychosocial intervention/support research
6. Provided feedback about the intervention draft in phase 1 of the study
7. Participation in phase 2 of another individual within the household

Previous participant exclusion criteria as of 08/04/2020:
Phase 1:
1. Young people with PAH:
1.1. Current serious mental health problems. Professional opinion will be sought regarding the assessment of any mental health difficulties that might render young people unsuitable for the study
1.2. Moderate to severe learning disability/executive functioning difficulties. Individuals with clinically documented moderate to severe cognitive difficulties will be excluded
1.3. Current serious physical health problems with life expectancy < 12 months, according to professional opinion
1.4. Inability to understand or communicate in English (UK) or either English or Luganda (Uganda) according to professional opinion
1.5. Current participation in other psychosocial intervention/support research
2. Friends, family and partners of young people with PAH:
2.1. Inability to understand or communicate in English (UK) or either English or Luganda (Uganda)

Phase 2 – Feasibility trial:
1. Current serious mental health problems. Clinician opinion will be sought regarding the assessment of any mental health difficulties that might render young people unsuitable for the study
2. Moderate to severe learning disability/executive functioning difficulties. Individuals with clinically documented moderate to severe cognitive difficulties will be excluded
3. Current serious physical health problems with life expectancy < 12 months, according to clinician opinion
4. Inability to understand or communicate in English (UK) or either English or Luganda (Uganda) according to clinician opinion
5. Current participation in other psychosocial intervention/support research
6. Participation in phase 1 of this study
7. Participation in phase 2 of another individual within the household

Previous participant exclusion criteria:
Phase 1:
1. Young people with PAH:
1.1. Current serious mental health problems. Professional opinion will be sought regarding the assessment of any mental health difficulties that might render young people unsuitable for the study
1.2. Moderate to severe learning disability/executive functioning difficulties. Individuals with clinically documented moderate to severe cognitive difficulties will be excluded
1.3. Current serious physical health problems with life expectancy < 12 months, according to professional opinion
1.4. Inability to understand or communicate in English (UK) or either English or Luganda (Uganda) according to professional opinion

2. Friends, family and partners of young people with PAH:
2.1. Inability to understand or communicate in English (UK) or either English or Luganda (Uganda)

Phase 2 – Feasibility trial:
1. Current serious mental health problems. Clinician opinion will be sought regarding the assessment of any mental health difficulties that might render young people unsuitable for the study
2. Moderate to severe learning disability/executive functioning difficulties. Individuals with clinically documented moderate to severe cognitive difficulties will be excluded
3. Current serious physical health problems with life expectancy < 12 months, according to clinician opinion
4. Inability to understand or communicate in English (UK) or either English or Luganda (Uganda) according to clinician opinion

Date of first enrolment
01/07/2019

Date of final enrolment
28/02/2022

Locations

Countries of recruitment
England

Uganda

United Kingdom

Study participating centre
St Mary's Hospital
Praed Street
London
United Kingdom
W2 1NY

Study participating centre
King's College Hospital
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
Guy's Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Study participating centre
Heartlands Hospital
Bordesley Green East
Birmingham
United Kingdom
B9 5ST

Study participating centre
Joint Clinical Research Centre
Lubuwa
Uganda
-

Study participating centre
St George's Hospital
Blackshaw Road
Tooting
London
United Kingdom
SW17 0QT

Study participating centre
Children’s HIV Association (CHIVA)
Orchard Street Business Centre
13 Orchard Street

Bristol
United Kingdom
BS1 5EH

Study participating centre
North Manchester Healthcare NHS Trust
North Manchester General Hospital
Delaunays Road
Crumpsall
Manchester
United Kingdom
M8 5RB

Sponsor information

Organisation
Royal Holloway College and Bedford New College

Sponsor details
c/o Alicen Nickson
RHUL, Director of Research and Enterprise
Egham
England
United Kingdom
TW20 0EX
+44 (0)1784414691
alicen.nickson@rhul.ac.uk

Sponsor type
University/education

ROR
https://ror.org/04g2vpn86

Funder(s)

Funder type
Industry

Funder Name
ViiV Healthcare

Alternative Name(s)
ViiV Healthcare Limited

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The trialists aim to publish the study protocol in a peer review journal.

Intention to publish date
31/07/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository. Anonymised electronic data from the study will be transferred to a data repository (e.g., Figshare or RHUL Research Data Archive) at the end of the study. This will be freely accessible under Creative Commons CC BY licence and will be retained for 10 years.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		24/09/2020	12/04/2021	Yes	No
HRA research summary			28/06/2023	No	No
Basic results		29/07/2023	01/08/2023	No	No
Results article		15/03/2024	18/03/2024	Yes	No