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Psycho-social intervention for people with HIV

Submission date
04/07/2024

Recruitment status
No longer recruiting

Registration date
12/07/2024

Overall study status
Ongoing

Last Edited
04/09/2025

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
HIV is now a treatable chronic condition with near-normal life expectancy, often requiring only annual specialist monitoring. However, a unique and interlinked set of adverse factors including high levels of depression, stigma and socioeconomic disadvantage impact on wellbeing and use of specialist services. A new model of care could better address these issues while being cost-saving or cost-neutral for the NHS. The NHS Long Term Plan has an increased emphasis on personalised care to improve health and wellbeing and reduce reliance on clinical services. However, evidence lags behind policy, with significant methodological shortcomings in existing studies, and no UK studies in People Living with HIV (PLWH).
This study aims to evaluate the effectiveness and cost-effectiveness of a health and wellbeing coaching intervention designed as part of the wider NICHE programme. A process evaluation sub-study will investigate factors promoting or inhibiting the uptake of the intervention.

Who can participate?
People living with HIV (PLWH) aged 18 years and over, who are attending an HIV clinic at a recruiting centre.

What does the study involve?
Participants will be randomly allocated to either health and wellbeing coaching + standard care or standard care alone. Participants will complete questionnaires at the start of the study and after 6 and 12 months. Some of the participants will be asked to complete additional study questionnaires at the start of the study and after 12 months to provide information on changes over time in the measures of health and wellbeing, and how frequently PLWH should be re-assessed for psychosocial needs. This will help to inform how clinic-wide psychosocial assessment is implemented into routine care.

What are the possible risks and benefits of taking part?
It is hoped that the intervention and the results of the trial will help improve health and wellbeing among people living with HIV. The trial intervention involves health and wellbeing coaching. There is no specific risk involved. Participants will be asked to complete questionnaires which may be time-consuming, but this can be done online.

Where is the study run from?
1. University College London (UK)

2. University of Birmingham (UK)
3. Birmingham Clinic Trials Unit (UK)

When is the study starting and how long is it expected to run for?
June 2021 to December 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Sphere trial office at BCTU, sphere@trials.bham.ac.uk

Study website
http://www.birmingham.ac.uk/sphere

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
337571

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 62794, IRAS 337571, NIHR202038

Study information

Scientific Title
Psycho-social intervention for people with HIV (SPHERE) - evidence from a randomised evaluation

Acronym
SPHERE

Study objectives
The null hypothesis is that there is no difference in change in PO-11 score where an individual will be counted as a ‘success’ if there is a reduction of 40% or more in their score from their baseline value score between the intervention groups. The alternative hypothesis is that there is a difference between the groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/07/2024, London - Fulham Research Ethics Committee (postal address: not available; +44 (0)207 104 8084; Fulham.rec@hra.nhs.uk), ref: 24/LO/0449

Study design
Randomized; Both; Design type: Process of Care, Education or Self-Management, Psychological & Behavioural, Complex Intervention, Cohort study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Interventions
The SPHERE intervention will focus on improving mental health and emotional wellbeing, reducing social isolation and stigma, facilitating support with socioeconomic issues and improving health literacy. Eight health and wellbeing coaching sessions (including the initial assessment) will be offered with the aim that they be delivered within a 3-month period.

The HWC will work collaboratively with the participant to identify ways to improve physical /mental health and ameliorate any major social stressors and prioritise the main problem areas. The intervention will use a range of cognitive–behavioural change and problem-solving techniques. Healthcare workers from NHS HIV clinical services participating in the trial will be trained to deliver the SPHERE intervention.

Participants will be randomised in a 1:1 ratio to either health and wellbeing coaching + standard care or standard care alone. Participants will complete questionnaires at baseline, 6 months and 12 months.

In addition there will be an observational cohort which will include participants who scored less than 16 on the PO-11 tool. Participants will be asked to complete the study questionnaires at baseline and 12 months. This will provide information on changes over time in the measures of health and wellbeing, and how frequently PLWH should be re-assessed for psychosocial needs. This will help to inform how clinic-wide psychosocial assessment is implemented into routine care.

Intervention Type
Behavioural

Primary outcome measure
A binary health and wellbeing measure based on the change in PO-11 score where an individual will be counted as a ‘success’ if there is a reduction of 40% or more in their score from their baseline value. This will be assessed at 6 months post-randomisation.
PO-11 is comprised of 11 questions, each with a 5-point Likert response scale scoring from 0 (best response) to 4 (worst response). The total score will be 0-44 where a higher score indicates a higher burden of symptoms and concerns.

Secondary outcome measures
Clinical:
1. Health and wellbeing measured by the above binary measure based on the PO-11 score as defined for the primary outcome, assessed at 12 months

2. Health and wellbeing measured using the Positive Outcomes (full version) score at 6 and 12 months
3. Depressive symptoms measured using the Patient Health Questionnaire (PHQ-9) at 6 and 12 months (total score and ≥10)
4. Viral load (VL) suppression (≤40 c/ml [copies/millilitre]) measured using blood test over 12 months
5. Anxiety symptoms measured using the General Anxiety Disorder-7 questionnaire (GAD-7) (score total score and ≥10) at 6 and 12 months
6. Self-stigma measured using the relevant Positive Voices questionnaire section at 6 and 12 months
7. Social support measured using a modified version of the Duke-UNC Functional Social Support Questionnaire (FSSQ) measured at 6 and 12 months
8. Resilience measured using the Resilience Scale (RS14) at 6 and 12 months
9. Smoking status self-reported on the participant-completed questionnaires (current smoker, ex-smoker, non-smoker) at 6 and 12 months
10. Alcohol use measured using the Alcohol Use Disorders Identification Test Consumption (AUDIT-C) at 6 and 12 months
11. Recreational drug use in the past 3 months measured using the relevant Positive Voices questionnaire sections at 6 and 12 months
12. Physical activity measured using the modified General Practice Physical Activity Questionnaire (GPPAQ) at 6 and 12 months
13. Self-efficacy measured using the Coping Self-Efficacy Scale (CSES) Short Form at 6 and 12 months

Cost-effectiveness:
1. Health-related quality of life measured using the EuroQol EQ-5D-5L score at 6 and 12 months
2. Health care, social care and welfare utilisation self-reported at 6 and 12 months

Observational cohort:
Participants taking part in the observational study will receive treatment as usual but will complete all baseline assessments and then be re-assessed for unmet needs at 12 months after baseline. The same outcome measures will be collected as for the RCT participants.

Overall study start date
01/06/2021

Completion date
01/12/2026

Eligibility

Key inclusion criteria
1. HIV positive and attending a specialist HIV clinic
2. Aged 18 years or over
3. Able to give valid informed consent for study participation
4. Willing and able to participate in the study and be available for the duration of follow-up

For randomisation only:
5. Scoring >=16 on the HIV Positive Outcomes-11 PROM (PO-11) tool

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 966; UK Sample Size: 966

Key exclusion criteria
For RCT only:
1. Active major mental illness (i.e. psychosis or bipolar disorder or active suicidality)
2. Within the first 12 weeks of receiving a new psychotherapy intervention

Date of first enrolment
19/08/2024

Date of final enrolment
01/08/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal London Hospital
Whitechapel Rd
London
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E1 1FR

Study participating centre
Kings College Hospital
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Study participating centre
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Sponsor information

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Sponsor type
University/education

Website
http://www.birmingham.ac.uk/index.aspx

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR202038

Results and Publications

Publication and dissemination plan
The researchers plan to publish the results of the trial in a high-impact peer-reviewed journal approximately 1 year after the end of the study

Intention to publish date
01/12/2027

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study have not been finalised and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website			12/07/2024	No	No
Study website			12/07/2024	No	No
Protocol article		02/09/2025	04/09/2025	Yes	No