Trials

STUDY PROTOCOL

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"SPHERE" multi-component novel psychosocial intervention for people with HIV: study protocol for a randomised controlled trial

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Abstract

Background Antiretroviral therapy (ART) has transformed HIV into a manageable health condition with normal life expectancy. However, people with HIV continue to have poorer mental health compared to background populations, which may be linked to stigma, lack of social support, or socioeconomic challenges. Personalised care aims to improve the outcomes of people with long-term health conditions and the National Health Service (NHS) Long Term Plan looks to implement this (including access to health coaching and social prescribing). The SPHERE trial aims to assess whether a health and well-being coaching and social prescribing intervention improves patient-reported health and well-being among people living with HIV who have psychosocial needs.

Methods SPHERE will be conducted across seven HIV outpatient clinics in England and is a pragmatic, two-arm, parallel group randomised controlled trial (RCT) embedding a routine assessment of psychosocial needs in HIV care. Eligibility criteria are people living with HIV aged 18 or older, available for the duration of study follow-up and scoring 16 or more on an assessment of psychosocial need: "Positive-Outcomes-11" (PO-11), covering physical, psychological, social and socioeconomic aspects of health and well-being. The RCT requires 568 participants who will be individually randomised in a 1:1 ratio to either a health and well-being coaching and social prescribing intervention or usual care. The intervention consists of up to eight coaching sessions that will be delivered by health professionals (e.g. HIV nurses) who have received specialist training to become health and well-being coaches. The trial will also include an internal pilot phase, process evaluation (to evaluate intervention feasibility, acceptability and mechanisms of action), economic evaluation (to assess the cost-effectiveness of the intervention and impact on NHS resource use) and parallel observational study (to assess subsequent development of psychosocial needs among those not initially eligible for the trial). The primary outcome is defined as achieving a reduction in PO-11 score of at least 40% from baseline to 6 months post-randomisation. Secondary outcomes include symptoms of depression and anxiety, social support, self-stigma, coping self-efficacy, resilience, lifestyle factors and health-related quality of life.

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Discussion The SPHERE trial will evaluate the effectiveness and cost-effectiveness of implementing psychosocial health and well-being coaching in a secondary HIV care setting. If effective, this model of personalised care could be transferable to other long-term health conditions.

Trial registration International Standard Randomised Controlled Trials Number (ISRCTN) Registry: ISRCTN47187932 [registered 12 July 2024].

Keywords Economic evaluation, England, Health coaching, HIV, Mental health, Process evaluation, Psychosocial intervention, Randomised controlled trial, Social prescribing, Stigma, Wellbeing

Background

HIV is a treatable long-term health condition, with a normal life expectancy among people on suppressive antiretroviral therapy (ART) with high blood T cell CD4 counts [1]. Around 100,000 people (100,063) were receiving HIV care in 2023 across England, Wales and Scotland [2]. Despite remarkable advancements in the prognosis of HIV over the past three decades, improvements in the mental health of people with HIV are less apparent, with the burden of mental health conditions among people with HIV being greater than the general population [3–5]. For example, the prevalence of anxiety and depression among people living with HIV in the UK is about twice as high as the background population [5, 6]. Wider socioeconomic factors also impact people living with HIV in the UK including poverty, unemployment, lack of social support and intimate partner violence [7–9]. Smoking, alcohol and drug use may also influence the physical and mental health of people with HIV [10–12]. People with HIV often experience intersecting vulnerabilities including societal stigma, structural inequalities and co-morbidities which impact mental health and well-being [3].

Mental health and HIV appear to have a bi-directional relationship; poor mental health may increase risk of acquiring HIV and HIV may result in poor mental health [3, 13]. A HIV diagnosis may result in anxiety and fears for the future and may also affect interpersonal relationships, impacting mental health and well-being. A further negative impact on health and well-being for people with HIV are experiences of socioeconomic disadvantage and lack of social support, factors that have extremely strong associations with poor mental health and reduced quality of life [5, 6]. In addition, people with HIV experience different forms of stigma including perceived, internalised and intersectional, with stigma found to be associated with depressive symptoms, social exclusion and lower levels of social support [14, 15]. People with HIV may also experience enacted stigma, discrimination or marginalisation due to factors including sexual orientation, gender and ethnicity [14–18].

National guidelines [19] for virologically suppressed people living with HIV (approximately 86,178 of 88,116 people [20]) recommend six monthly HIV viral load checks and annual follow-up with specialist HIV services. However, the majority access HIV specialist services more frequently than that, with a mean of 6.4 clinic appointments every year in virologically suppressed people attending one London HIV clinic between 2010 and 2017 [21]. This may be partly due to the high levels of trust people with HIV have in HIV services and difficulties accessing primary care services. Primary care satisfaction and trust may also be lower due to concerns including perceived stigma, issues around confidentiality and a perceived lack of HIV expertise [22, 23]. There is increasing awareness that to reduce use of secondary care to recommended guideline levels [19] by people with stable and controlled HIV, wider psychosocial needs must be addressed. The current usual model of HIV care does not address needs such as stigma, social support or socioeconomic disadvantage.

The National Health Service (NHS) Long Term Plan aims to implement personalised care across England to improve the outcomes for people with long-term health conditions such as HIV [24]. This would shift healthcare towards a model of a "shared responsibility for health" [25]. There are six key components of the NHS Comprehensive model of Personalised Care: (1) shared decision making; (2) supported self-management; (3) personalised care and support planning; (4) social prescribing; (5) patient choice; (6) personal health budgets, "social prescribing and community-based support" and "supported self-management" [24, 26]. Health coaching is a key component of supported self-management, focusing on empowering people to play a more active role in their health by developing knowledge, skills and confidence and by engaging in goal setting to reach solutions [27, 28]. A health coach may also link individuals to existing sources of support or voluntary sector organisations (social prescribing) such as smoking cessation services and mental health support [29]. However, evidence on the effectiveness of health coaching interventions remains mixed with higher-quality evaluations needed and there are few studies evaluating the effectiveness of health coaching in people living with HIV [30, 31].

Rationale

We propose an alternative model of care for people living with HIV, developed and evaluated through the "A person-centered Needs Informed model for Care for people with HIV" (NICHE) research programme. NICHE aims to improve the mental health and well-being of people living with HIV through a health and well-being coaching with social prescribing intervention delivered within specialist HIV services. The intervention aims to address and alleviate needs related to mental health problems, lack of social support, socioeconomic disadvantage and stigma. The health and well-being coaching will be delivered by HIV healthcare professionals who have undergone specialist training in coaching and social prescribing. This intervention will be evaluated in the randomised controlled trial (RCT) "Psycho-*S*ocial Intervention for *P*eople with *H*IV – *E*vidence from a *R*andomised *E*valuation (SPHERE)" trial. HIV clinic populations will be screened to identify those individuals with psychosocial need. Consenting individuals will be randomised to either a one-to-one health and well-being coaching with social prescribing intervention or usual care. Our definition of psychosocial needs is broad and includes mental and physical health and well-being and social support. A psychosocial intervention addressing such needs could also have positive impacts on the delivery of HIV care in the UK as it may be cost-effective or cost-neutral for NHS services.

The trial research questions are:

(1) Does a health and well-being coaching and social prescribing intervention lead to an improvement in health and well-being among people with HIV who have psychosocial needs?
(2) How does the intervention achieve its outcomes?
(3) Is the intervention cost-effective?

Trial objectives

Primary objective

To assess whether a psychosocial health and well-being coaching with social prescribing intervention improves participant-reported health and well-being for people with HIV who have physical, psychological, social or socioeconomic needs.

Secondary objectives

(1) To assess the impact and mechanisms of action of the intervention on depressive symptoms, anxiety symptoms, health-related quality of life, stigma, social support, coping self-efficacy, resilience, lifestyle factors and NHS resource use.
(2) To assess the cost effectiveness of the intervention.
(3) To assess the acceptability of, uptake of, and long-term engagement with the intervention.

Internal RCT pilot objectives

(1) To assess the feasibility of identifying eligible patients.
(2) To assess the acceptability of randomisation to receive the intervention or not.
(3) To determine if the pilot phase should continue to a full trial.

Observational cohort objectives

(1) To investigate the feasibility of clinic-wide assessment of psychosocial needs.
(2) To assess the changes in psychosocial needs in people living with HIV in those who do not initially meet the screening criteria for trial entry.
(3) To identify factors associated with subsequent development of psychosocial needs.

Trial methods

Our protocol adheres to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) [32] checklist (see Additional File 1).

Study design

SPHERE is a national, pragmatic, multi-centre, individually randomised, two-arm, parallel group, superiority RCT that will use a routine assessment of psychosocial need in HIV care to identify those eligible for a health and well-being coaching and social prescribing intervention. The intervention will be delivered by HIV healthcare professionals who have received accredited training in coaching and social prescribing. Participants will be 1:1 randomised to receive the intervention or usual care. The trial will include an internal pilot phase (with stop/go criteria), process evaluation and economic evaluation (within-trial cost-effectiveness analysis), as well as a parallel observational cohort study among those not eligible for the intervention.

A shortened version of the Positive Outcomes tool [33] ("Positive Outcomes-11") will be used to assess eligibility. This consists of eleven questions (each with response options 0 to 4, coded such that higher score indicates poorer health and well-being) covering physical health and well-being (pain; stomach or bowel problems; memory or concentration problems; sleep problems; ability to carry out usual activities), emotional/mental health and

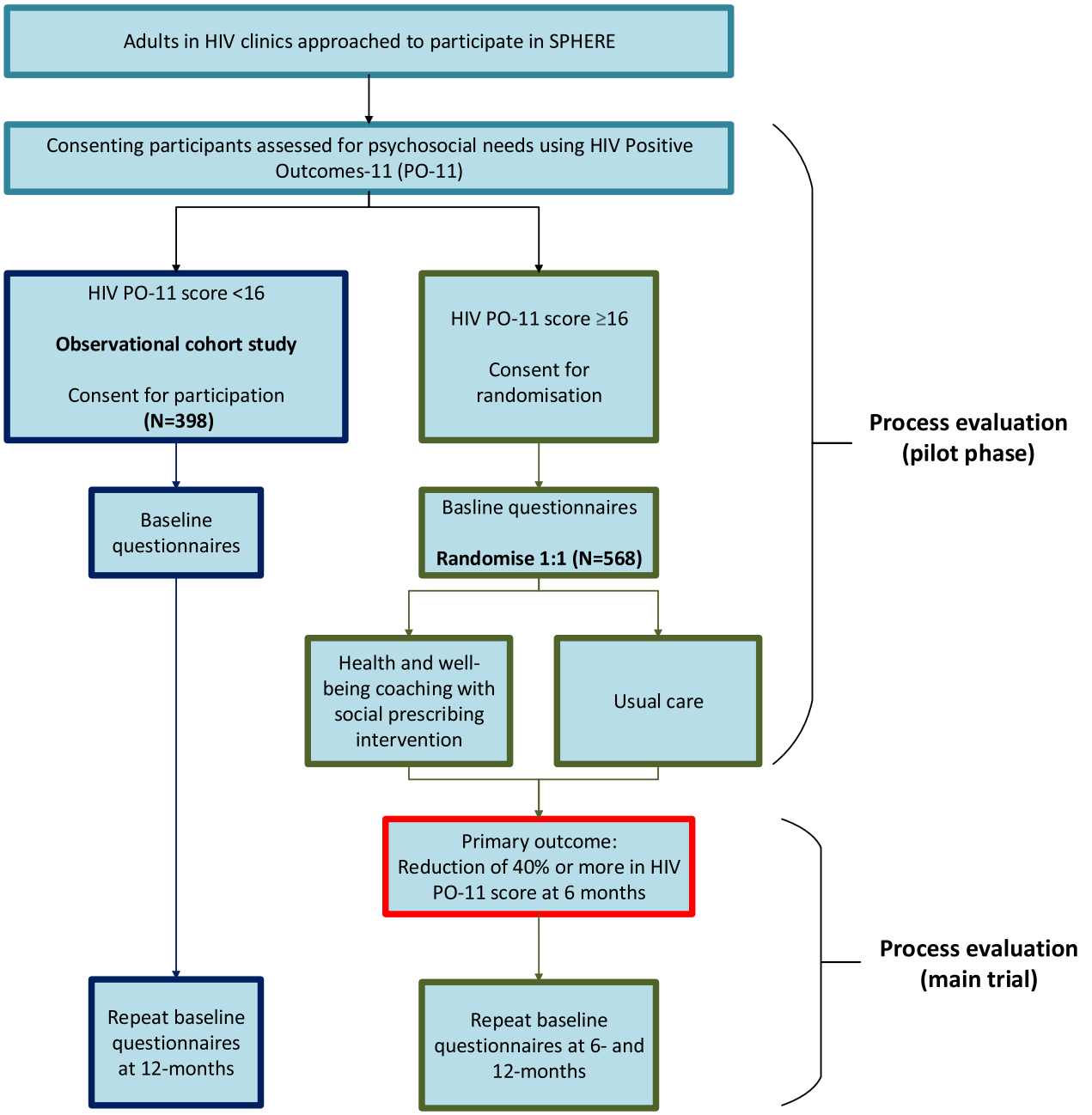

Fig. 1 SPHERE trial schema. Green boxes indicate RCT arm; dark blue indicates observational cohort

well-being (feeling anxious or worried; feeling depressed or in low mood; feeling good about yourself; feeling at peace), and social/socioeconomic well-being (having enough support from people around you; being worried about money), in the past 4 weeks. Those scoring above a threshold (16 or more out of a possible maximum score of 44) are eligible to be considered for randomisation.

People with HIV who are eligible and consent to participate will be randomised at the level of the individual in a 1:1 ratio to either a health and well-being coaching with social prescribing intervention or usual care (Fig. 1). Participants will be followed-up for 12 months, with the primary outcome assessed at 6 months.

The intervention was informed by a mixed-methods programme of original research, namely a systematic review [31], qualitative research (focus group discussions and key informant interviews) [34], a national survey or people living with HIV [7] and a discrete choice

experiment [35]. The programme theory was developed in Theory of Change workshops with 39 stakeholders including people with HIV, doctors, nurses, psychologists, third sector representatives (e.g. health coaching and social prescribing practitioners), commissioners and academics (manuscript in development).

There is a paucity of longitudinal data on changing symptoms and needs among people with HIV. Therefore, those who are not eligible for the trial (i.e. those with a PO-11 score < 16) will be invited to join a longitudinal observational study that will run in parallel with the RCT. This will investigate changes in well-being in this population to inform frequency of routine psychosocial assessment, with a view to implementing it as part of a new model of care for people living with HIV.

Primary and secondary outcomes

The primary outcome is health and well-being at month 6, measured using a binary outcome in which success is defined as a reduction of 40% or more in the Positive Outcomes-11 (PO-11) score [33] from baseline to month 6. PO-11 is comprised of 11 questions on health and well-being, each with a 5-point Likert scale response (scored 0 to 4). The total score ranges from 0 to 44 with a higher score indicating poorer health and well-being. Initial feasibility work for SPHERE has shown PO-11 to be a statistically valid tool that is effective in identifying people with poor mental health and well-being [33].

Secondary outcomes (all measured post-randomisation)

Clinical

(1) Health and well-being at month 12, measured using a binary variable in which success if defined as a 40% or greater reduction from baseline in the PO-11 score [33].
(2) Health and well-being at month 6 and month 12, measured using the PO-11 total score as a continuous measure (range 0 to 44). [33].
(3) Health and well-being at month 6 and month 12 measured using the PO-20 total score as a continuous measure (range 0 to 80). PO-20 is a longer form of the Positive Outcomes questionnaire [36] from which the PO-11 was derived [33]. It is comprised of 20 questions covering health and well-being and concerns in the past 4 weeks, each question with a 5-point Likert scale response (0 to 4, with a higher score indicating poorer health and well-being).
(4) Depressive symptoms at month 6 and month 12 measured using the total score of the Patient Health Questionnaire (PHQ-9) [37]. PHQ-9 is comprised of nine questions covering depression symptoms in the past 2 weeks each with a 4-point Likert scale response (0 = not at all to 3 = nearly every day). The total score ranges from 0 to 27 with a higher score indicating higher depression severity.
(5) Depressive symptoms at month 6 and month 12 as a binary measure, defined as PHQ-9 total score ≥ 10.
(6) Anxiety symptoms at month 6 and month 12 measured using the total score of the General Anxiety Disorder-7 questionnaire (GAD-7) [38]. GAD-7 is comprised of seven questions covering anxiety symptoms in the past 2 weeks, each with a 4-point Likert scale response (0 = not all to 3 = nearly every day). The total score ranges from 0 to 21 with a higher score indicating higher anxiety severity.
(7) Anxiety symptoms at month 6 and month 12 as a binary measure, defined as GAD-7 total score ≥ 10
(8) Plasma HIV viral load (VL) suppression as a binary measure, defined as all VL measures ≤ 40 copies/mL from baseline to month 12.
(9) Self-stigma at month 6 and month 12, measured using three questions from the relevant section of the Positive Voices questionnaire [39] that concern being ashamed about HIV status; having poor self-esteem because of HIV status; finding it difficult to tell people about HIV status. Each question has a 4-point Likert scale response (strongly disagree to strongly agree). Each question will be considered separately, with strong agreement or agreement classified as positive for self-stigma. Experienced and anticipated stigma because of HIV (from family, friends, in healthcare settings) in the last three months, measured at month 6 and month 12, using five questions from the relevant section of the Positive Voices questionnaire; each question will be considered separately
(10) Social support at month 6 and month 12, measured using the mean score from a modified version of the Duke-UNC Functional Social Support Questionnaire (FSSQ) [40]. The modified FFSQ is comprised of six questions about aspects of social support received, each with a 5-point Likert response (1 = much less than I would like to 5 = as much as I would like). An individual's mean score across the six questions will be used, and will range from 1 to 5 with a higher score indicating greater perceived social support.
(11) Resilience at month 6 and month 12, measured using the total score of the Resilience Scale

(RS14) [41]. RS14 is comprised of 14 statements, each with a 7-point Likert scale response (1 = strongly disagree to 7 = strongly agree). The total score ranges from 14 to 98. A higher score indicates greater levels of resilience.

(12) Current cigarette smoking status at month 6 and month 12 as a binary measure (current smoker or not).

(13) Alcohol use at month 6 and month 12 measured using the total score of the Alcohol Use Disorders Identification Test Consumption (AUDIT-C) [42]. AUDIT-C consists of three questions on frequency of drinking, typical amount consumed and frequency of heavy drinking with a standard scoring system [42]. The total score ranges from 0 to 12 (0 = no alcohol use) with a higher score indicating higher alcohol intake. Alcohol use at month 6 and month 12 will also be evaluated as a binary measure with a total AUDIT-C score of 5 or above indicating drinking that is potentially or currently harmful to health.

(14) Recreational drug use including any use of recreational drugs, polydrug use (use of ≥ 3 drugs) and chemsex (use of one or more specific recreational drugs before or during sex) in the past 3 months, will be categorised and reported at month 6 and month 12. These are measured using the relevant sections of the Positive Voices questionnaire [39].

(15) Physical activity at month 6 and month 12 measured using the second question of the General Practice Physical Activity Questionnaire (GPPAQ) [43]. which covers five activity domains. Standard scoring methods will be used to score activities into four levels: inactive, moderately inactive, moderately active and active [43]. Walking pace will be measured using the third question of the GPPAQ which is categorised as slow pace, steady average pace, brisk pace, and fast pace [43].

(16) Coping self-efficacy at month 6 and month 12, measured using (i) the total score from the 13 items of the shortened version of the Coping Self-Efficacy Scale (CSES) [44] and (ii) the total score from 16 items of the CSES (the shortened version plus 3 additional items) [44]. Each CSES item has an 11-point Likert scale response (0 = cannot do at all to 10 = certain can do). Measures (i) and (ii) above range from 0 to 130 and 0 to 160 respectively, with a higher score indicating a higher level of coping self-efficacy.

Cost effectiveness

(17) Health-related quality of life measured at 6 and 12 months captured using the generic EuroQol five dimension five level (EQ-5D-5L) score [45], which facilitates the calculation of quality adjusted life-years (QALYs) for both the within-trial and model extrapolated analysis.

(18) Health care, social care and welfare utilisation (self-reported) measured at 6 and 12 months captured using a modified Client Services Receipt Inventory [46] designed specifically for this study to complement the intervention costing that will be conducted within the trial period.

Eligibility criteria

To be eligible to participate in either the RCT or observational cohort study, participants must be:

- Adults living with HIV (aged 18 +)
- Attending a specialist HIV clinic in England
- Able to provide informed consent to participate, willing and able to participate
- Available for the duration of follow-up in the study.
- Sufficient level of English to take part.

Participants will not be eligible for the RCT if they:

- Have an active serious mental health condition (including psychosis, bipolar disorder, or active suicidality) determined by the staff member obtaining consent in consultation with the site Principal Investigator
- Are within the first 12 weeks of receiving a new psychotherapy intervention.

Potential participants will complete an eligibility screening survey [the HIV Positive Outcomes (PO-11) [33] either online or on paper. To be randomised to the RCT, participants must have a PO-11 score ≥ 16, indicating poorer psychosocial health and well-being. If they score < 16, they will be invited to enrol in the observational arm of the study. Screening logs will be used to calculate response rates including eligibility, numbers excluded and reasons for exclusion.

Setting and recruitment

The study will take place across seven HIV outpatient clinics in England: London (three clinics), Brighton, Bristol, Manchester and Sheffield. A full list of participating clinics can be found on the trial registration

website [47]. We determined that a secondary-care intervention based in HIV services would have the greatest potential for success. People with HIV tend to have greater engagement and trust in secondary care than primary care and rate HIV services highly [7, 23]; this may be particularly relevant for more marginalised groups. Training HIV healthcare professionals to deliver the coaching intervention ensures the intervention will be delivered by people with knowledge and experience in HIV clinical care and may help to reduce participant concerns related to stigma and discrimination. Furthermore, the current commissioning model for funding HIV care is solely given to HIV services. Commissioning refers to how needs are assessed, priorities are set and subsequently services are planned, procured and monitored; for example, NHS England service specification outlines that HIV services should ensure that "outcomes, well-being and quality of life are maximised" [48, 49]. Therefore, it also makes commissioning sense to build the model within HIV services rather than primary care.

Potentially eligible participants will be invited to participate in SPHERE by members of their clinical care team, which will include research team members, during their routine HIV clinic visits at trial sites, or by telephone, text message or email. Study information will be available on the trial website (www.niche.ac) and posters will also be on display in clinical areas of participating sites. Taking part is voluntary and will not impact on usual care.

Enrolment and consent

Participants attending for routine HIV clinic appointments will be approached in clinic by members of the clinic's research team and asked to complete the PO-11 as a screening tool for health and well-being. Potential participants will self-complete the online PO-11 questionnaires via a link on tablets. Completing the self-screening assessment will imply consent to the screening questionnaire. A PO-11 score will be calculated automatically on the tablet and research staff will be notified when an individual has completed the questionnaire and of their score. No data will be stored or transferred if the potential participant decides not to enrol in the study.

If an individual scores 16 or more on the PO-11, they will be notified that they may be eligible for a trial of a well-being intervention. Staff will provide the eligible individual with the participant information sheet (PIS) for the RCT. If the individual agrees to participate and meets criteria on the eligibility checklist, informed consent will be obtained, including optional consent to be contacted for interviews for the process evaluation (see below). If the PO-11 score is less than 16, the individual will be notified that they are eligible for the observational study. A member of staff will explain this to them and provide them with the cohort study PIS and obtain informed consent (e-consent; a paper version will also be available).

Co-enrolment on other studies will be considered on a case-by-case basis by the trial office and Chief Investigator. Participants will not be able to take part in any other social prescribing, health and well-being coaching or similar interventions.

Consent for additional information

We will also invite participants to take part in the process evaluation sub-study at the point of recruitment to SPHERE. A qualitative researcher will subsequently send further information about the sub-study and will consent the participant prior to interview.

Participants will also be requested for optional consent to link patient data from NHS routine clinical datasets; for example, primary care (including Clinical Practice Research Datalink) and secondary care (Hospital Episode Statistics) data. The purpose for this long-term data linkage is to assess health service usage without the need for further contact.

Participant timeline

The same baseline questionnaire will be completed by observational cohort and RCT participants with randomisation for the trial taking place after questionnaires are completed. Participant completed questionnaires will be repeated at 6 and 12 months (RCT) and 12 months only (observational cohort). An assessment schedule can be found in Table 1.

Randomisation, allocation concealment and blinding

Following the PO-11 assessment for eligibility, participants will provide informed consent and complete the baseline questionnaire. Once this is completed, they can then be randomised into the trial. Randomisation will be at the level of the individual in a 1:1 ratio via a secure, online system at the trial co-ordinating centre (Birmingham Clinical Trials Unit – BCTU) to ensure allocation concealment. A minimisation algorithm will be used to make sure there is a balance in intervention allocation based on the levels of needs as indicated by the PO-11 score (using strata: 16–19; 20–25; $\geq$ 26) and study centre. Once randomised, all participants will be issued with a unique trial number. Blinding is not possible due to the nature of the intervention.

Intervention

Experienced (NHS band 6 or above) HIV healthcare professionals (HIV specialist Nurses, Health Advisors, HIV Pharmacist and HIV Social Worker) have been

Table 1 Assessment schedule

Form	Timepoint			
	Screening/baseline	**Intervention (RCT only)**	**Follow up**	
	0 months	**0–3 months** ***Up to 8 sessions***	**6 months** ***(RCT only)***	**12 months**
Eligibility checklist	✓			
Screening PO-11	✓			
Randomisation/registration form	✓			
Participant completed questionnaire	✓		✓	✓
Clinical form	✓		✓	✓
Health coach diary		✓ *(per session)*		
Serious adverse events	**To be monitored throughout**			
Change of trial participation status	**As required**			

trained as health and well-being coaches (HWCs) to deliver the SPHERE intervention across seven clinical sites. The intervention has been co-developed with people with lived experience of HIV and experts in the fields of psychology, coaching and social prescribing including practitioners with extensive experience of delivering counselling and coaching to people living with HIV. The intervention was designed to include a focus on needs identified in the national Positive Voices survey [7]. Further details of the training are given below.

Staff will book the participants randomised to the intervention for the initial health and well-being coaching session while in clinic. The HWCs delivering the intervention will conduct up to eight sessions with participants over a 3-month period, including a preliminary in-depth assessment that will last 1–2 h. The initial sessions at least will be face-to-face; however, the format of delivery (face-to-face, by phone or online) will be agreed between the HWC and participant after the first face-to-face session. Sites that have more than one HWC trained to deliver the intervention will aim for participants to see the same HWC throughout the intervention. The HWCs delivering the intervention will ensure participants are in a safe and confidential environment if taking part by telephone or video call.

Sessions will focus on establishing a relationship alliance between the HWC and participant, identifying priorities in the physical, mental or social health and well-being of the participant, and setting goals to address health and well-being needs. HWCs may support onward referral to local social prescribing initiatives, as required. For example, coaching may focus on:

- Offering support to increase self-efficacy, motivation and commitment to identify and make changes to lifestyle and improve health
- Facilitating support with socioeconomic issues
- Reducing social isolation and stigma
- Improving mental health and emotional well-being
- Improving health literacy.

Intervention providers' training and support

All HWCs delivering the intervention have received an accredited and bespoke training programme delivered by a not-for-profit organisation (Living Well CIC) that provides a range of mental health and well-being services, with over two decades of experience in the HIV sector. Training was delivered to 14 HIV health care professionals in early 2024 over 12 weeks by a behavioural psychologist. The training programme involved 4 days of face-to-face group training, 8 weeks of skills practice and 2 days of follow-up online group training. The training programme addresses a framework of 52 competencies that underpin health and well-being coaching and is accredited (Level 2 Qualification). All trainees completed pre- and post- "standardised patient" training assessments [50] to provide an impact evaluation of the course and to identify areas of development or support. Standardised patient assessments involved people with HIV being specially trained to act as coaching participants for the practice and assessments of the HWCs undertaking the training.

Social prescribing training was delivered by the London Regional Social Prescribing Unit in conjunction with the health and well-being coaching training. Training provided insight into the role and skills of a social prescribing link worker, the referral pathway and current

social prescribing initiatives at a national level. The Unit also developed a social prescribing directory for each SPHERE site which outlines local community resources. These resources will be kept updated through the intervention HWCs and social prescribing trainers collaborating with local authority social prescribing link workers, Third Sector organisations and primary care local clinical networks.

HWCs will be supervised and supported for the duration of the trial by a professional behavioural psychologist who co-led the health and well-being coaching training, at mandatory, small group (up to 4 people) monthly supervisions. Additionally, HWCs will receive oversight from the Social Prescribing training team at monthly online drop-in sessions.

Control

The control group will receive usual care, as recommended in the British HIV Association Standards of Care for People Living with HIV which would typically include outpatient HIV clinic visits every 6 months and a minimum of one assessment for physical, psychological and social needs [51].

Follow-up

A £20 remuneration voucher is offered to participants for completing the baseline questionnaire and every full questionnaire after (i.e. 12 months for cohort participants; 6 and 12 months for RCT participants) to acknowledge their time and contributions. Participants will be able to claim travel expenses of up to £10/visit as part of intervention visits (health and well-being coaching sessions).

Changes to trial participation may include no longer receiving the trial intervention but willing to be followed up according to the schedule of assessments; not willing to attend trial-related follow-up; withdrawing consent for long-term follow up; and not willing to take part in further data collection. Details of changes to trial participation will be clearly documented in source documents.

Participants in either arm who exhibit serious mental health symptoms or suicidal ideation will be engaged with established clinical care pathways by the HWC. Participants will be free to withdraw from the study at any time, without giving a reason.

Participant completed questionnaire

The data captured at baseline will be the same for both the RCT and observational cohort, and is detailed in Table 2.

The same data will be provided by RCT participants at 6 and 12 months, and by cohort participants at 12 months only. Questionnaires will be completed online or by paper, if preferred. It is estimated that surveys will take between 20 and 30 min to complete.

Researcher completed forms

Data recorded by researchers at baseline for the RCT and observational study is specified in Table 2. The same data will be collected at 6 and 12 months (RCT) and 12 months only (observational study).

- In addition, for the RCT only in the intervention group (at each coaching session): health coach diary which will record issues of concern discussed during coaching sessions, referrals to support services made, record of attendance at referrals, documents if next session booked (or reason if next session not booked)
- Change of status (as required)

Sample size

Nine hundred and sixty six adults living with HIV will be enrolled (568 for the RCT, 398 for the observational cohort).

The sample size for the RCT was based on an estimation that between 25 and 35% of participants in the control arm will achieve the primary outcome: at least a 40% reduction from baseline in PO-11 score at 6 months. Data on change in symptom score from one occasion to another among people with an initially high score, based on an annual repeated assessment of the PHQ-9 in the Attitudes to, and Understanding of, Risk of Acquisition of HIV cohort study of HIV-negative MSM (AURAH2) [52] was used to inform the 40% reduction endpoint and the 25–35% range for the estimated proportion achieving this in the control group. It was judged that to justify implementing a new model of care, a difference of 15% in the primary outcome between intervention and control arms (25% versus 40%, or 35% versus 50%) would be the minimum clinically important difference. This difference equates to an odds ratio of between 1.86 and 2, equivalent to a standardised effect size of approximately 0.35, which is between a small and a medium effect according to Cohen's criteria [53]. To detect a difference of 15% between arms if assuming success proportions of 35% and 50% in the control group and intervention group respectively (the most conservative scenario in terms of sample size) requires 454 participants overall, assuming 90% power and a 5% type I error rate. Allowing for 20% attrition, the overall sample size required for the RCT is 568 participants.

This total sample size could be achieved with six study sites recruiting over 9 months, with each site seeing

Table 2 Summary of measures collected at each timepoint. Adapted from SPIRIT checklist [32]

Visit/Outcome	Assessments	Schedule				
		Screening	Baseline	From month 1	6 months	12 months
Eligibility check		✓	✓			
Valid informed consent		✓	✓			
Participant-completed questionnaire measures						
Demographic/social factors	Gender; date of birth; ethnicity; country of birth; time resident in UK; employment; housing; household composition; poverty; education; religion; sexuality; partnership status		✓			
Relevant medical history	Year of HIV diagnosis; year of ART initiation; adherence to ART; other diagnosed co-morbidities; mental health diagnoses and treatment		✓		✓	✓
Health and well-being	HIV Positive Outcomes-11 (PO-11) [33]	✓	✓		✓	✓
Health and well-being	HIV Positive Outcomes-20 (PO-20) [36]		✓		✓	✓
Depressive symptoms	Patient Health Questionnaire (PHQ-9) [37]		✓		✓	✓
Anxiety symptoms	General Anxiety Disorder-7 Questionnaire (GAD-7) [38]		✓		✓	✓
Stigma	Stigma from friends, family and healthcare. Three questions on self-stigma as detailed in "Primary and secondary outcomes" Section.		✓		✓	✓
Social support	Modified version of the Duke-UNC Functional Social Support Questionnaire (FSSQ) [40]		✓		✓	✓
Resilience	Resilience Scale (RS-14) [41]		✓		✓	✓
Smoking status	Cigarette smoking status		✓		✓	✓
Alcohol use	Alcohol Use Disorders Identification Test Consumption (AUDIT-C) [42]		✓		✓	✓
Recreational drug use in past 3 months	Questions of recreational drug use and chemsex [2] as detailed in "Primary and secondary outcomes" Section.		✓		✓	✓
Sexual history	Recent sexually transmitted infections; number of recent sexual partners		✓		✓	✓
Physical activity	Questions two and three of the General Practice Physical Activity Questionnaire (GPPAQ) [43]		✓		✓	✓
Self-efficacy	Coping Self-Efficacy Scale Short Form [44] plus three additional questions		✓		✓	✓
Health-related quality of life	EuroQol EQ-5D-5L [45]		✓		✓	✓
Health care, social care and welfare utilisation	Modified Client Services Receipt Inventory [46]		✓		✓	✓
Other measures						
Service use	Self-reported		✓		✓	✓
Intervention acceptability					✓	
Health coach diary	Issues of concern discussed; referrals to support services made; record of attendance at referrals; documents if next session booked (or reason if next sessions not booked)			✓	✓	
Serious adverse events				✓	✓	✓
Randomisation/registration			✓			
If randomised: start intervention				✓		
If registered: follow-up assessments						✓

Table 2 (continued)

Visit/Outcome	Assessments	Schedule				
		Screening	Baseline	From month 1	6 months	12 months
Researcher completed clinical forms						
Viral load/CD4 count	Including most recent (if follow-up)		✓		✓	✓
Blood pressure	Including most recent (if follow-up)		✓		✓	✓
Height and weight			✓		✓	✓
Date first attended clinic			✓			

over 2500 patients in clinic in this time. Using our previous experience of recruiting to observational studies [54], and assuming a lower participation acceptance rate, a researcher could approach over half of these 2500 patients, of which we assumed 40% would agree to participate in the first stage and complete the initial PO-11 screening questionnaire ($n=500$). Our initial work suggested that approximately 35% of the screened population will be eligible for the RCT (i.e. their PO-11 score will be ≥ 16). We assumed that a high percentage (90%) of those undertaking screening would agree to participate as participants have already consented at the first stage. This would result in 158 participants per site which meets our requirements.

For the observational study, the primary endpoint is the proportion of participants with poor psychosocial health/well-being at 12 months, defined as PO-11 ≥ 16, among those who did not meet the criteria for the RCT at baseline. Data from the AURAH2 [55, 56] suggested that up to a third of participants may fulfil this criterion at the 12-month timepoint. We wish to estimate this percentage to within 10% accuracy (i.e. 95% confidence interval total width of 10%)). Assuming 33% of participants in the observational cohort have PO-11 ≥ 16 at 12 months, using the exact binomial method we would require 358 individuals. Accounting for 10% loss to follow up, we will recruit 398 participants. Loss-to-follow-up is assumed lower than in the RCT, as the study only requires completion of a questionnaire, at month 12 which can be done in tandem with a routine clinic appointment.

Patient and public involvement (PPI)

We have an established PPI Advisory Group which continues to inform all aspects of the trial and the pre-trial formative work. The group consists of people with HIV from the community, charity and voluntary sector; some members are both PPI (i.e. people living with HIV) and professional representatives. The group was formed in 2022 in response to an expression-of-interest call that was publicised through community-based organisations (UK Community Advisory Board (UK-CAB), the Terrence Higgins Trust and Changing Perceptions) and the NICHE website (www.niche.ac). Meetings are held virtually every quarter with budgeted time to support group activities and the opportunity to join the group remains open. The PPI group have provided input into the intervention design, supporting the HWCs training package, and the review and development of study materials (e.g. for language and accessibility). The group continues to be involved as the trial progresses.

As part of the formative work for the trial, we conducted a series of focus group discussions with people living with HIV and key informant interviews with clinical and non-clinical HIV workers to inform the design of the intervention [34]. Additionally, we held two Theory of Change workshops in September 2023, to shape the intervention parameters and map the key components of the intervention to be trialled in the RCT. A significant proportion of attendees (over a third) at the workshops were people with lived experience; specifically, eight members of the PPI Advisory Group had key roles at the workshops including co-facilitating group activities. Other attendees included NHS commissioners, academics, health psychologists, clinicians (e.g. nurses and consultants) and charity and Third Sector staff. The workshops ensured the intervention was relevant, inclusive and reflective of the needs of the target population for the study.

To support the development of the HWCs training package, in January 2024, six members of the PPI Advisory Group underwent a 3-hour training session to become "standardised patients" to provide pre- and post-training assessments for the trainee HWCs. Involving people living with HIV ensured that real-world experiences (e.g. HIV-related stigma) were integrated into the training assessments. Individual online sessions were then organised between trainee coaches and a standardised patient within 2 weeks prior to the training (pre-course assessment) as well as within 2 weeks of the training course being completed (post-assessment).

Data collection, management and confidentiality

Participants will be able to select their preferred method for data collection which may include a link by text message or email, or completing the assessment online in clinic, or completing a paper questionnaire either in person at the clinic or later to be returned by post to the site.

Data will be managed using the SPHERE database stored on secure servers controlled by the University of Birmingham. Participants will give explicit consent for the transfer and storage of their personal data on the trial database which will also be used to centrally monitor the consent process. Entries from any paper questionnaires and forms will be transcribed to the online database. The SPHERE Data Management Plan (available on request) will outline data entry processes and other procedures to facilitate accuracy and data completeness.

Source data will be accessible and maintained to allow for accurate reconstruction of trial and clinical management of participants. This will include participant questionnaires, clinical forms (baseline, 6 months and 12 months), recruitment and withdrawal records. Archiving will be authorised by the trial coordinating centre on behalf of the Sponsor (University of Birmingham) following the submission of an end of trial report. The trial master file will be stored at BCTU for at least 3 years after the end of the trial with data stored securely and confidentially for at least 10 years in long-term offsite data archiving facilities.

Any personal and sensitive data collected will be held confidentially and stored in accordance with the Data Protection Act 2018 (and subsequent amendments). Personal data collected includes full name and date of birth, contact details and sensitive personal data may include medical history and demographic data. A unique SPHERE identification number will be used to identify participants and will be used for any correspondence with the trial office. If a participant requests a link to access follow-up questionnaires to be sent by text message, their phone number will be shared with a UK-based General Data Protection Regulation compliant third-party SMS platform where there is also a data sharing agreement with the provider. Confidentiality will be upheld at all times and the SPHERE team will not disclose participant identifiable data to any third party, unless in very specific circumstances such as specific issues or queries from regulatory authorities or for quality assurance purposes (by representatives of the SPHERE trial team and Sponsor).

We will grant access to the final dataset to the statistical team who will undertake the final analyses. Any additional requests for data access will be considered by the trial co-ordinating centre which will require a formal data sharing agreement before fully de-identified (anonymised), or participant identifiable, data can be released and transferred using a secure and encrypted method. Any requests for data access will be reviewed by the BCTU Data Sharing Committee, the Chief Investigator and, where necessary, the SPHERE Sponsor, relevant Trial Management Group members and/or independent Trial Steering Committee. Data will be available for potential data sharing approximately 6 months after the primary publication.

Data monitoring

The trial will be coordinated by the BCTU based at the University of Birmingham. The Trial Management Group will include people responsible for day-to-day trial management including the Chief Investigator, co-lead, project manager, PPI manager, trial statisticians, trial management team leader and trial manager. The group will monitor all aspects of trial conduct and progress, adherence to the trial protocol and act to safeguard trial participants and the quality of the trial.

The trial will also have a Programme Steering Committee (PSC) or Joint Oversight Committee for SPHERE, which includes independent and non-independent members, PPI and community representatives, overseeing the conduct of the NICHE programme. The PSC will meet annually or more frequently depending on the needs of the trial. The Committee will provide oversight to the trial, monitor trial progress and conduct and provide advice on scientific credibility. This will also encompass a data monitoring safety board role.

Adverse event reporting and harms

The trial is a very low-risk study. The SPHERE intervention is not considered to present a risk to participants nor is there considered to be any higher risk than the risk of usual care. As the trial is not a Clinical Trial of an Investigational Medicinal Product (CTIMP), we do not plan to use the Medical Dictionary for Regulatory Activities (MedDRA) to report harms as this was developed to facilitate sharing of regulatory information internationally for medical products. However, adverse events (AE) will be recorded and reported according to the UK Policy Framework for Health and Social Care Research, the Principles of Good Clinical Practice as set out in the UK Statutory Instrument (2004/1031; and subsequent amendments) and the requirements of the Health Research Authority.

Information on harms will be collected informally in those receiving the intervention by the HWCs through the health and well-being coaching diary. We will report any, and all, identified harms including any reported via AEs or severe AEs (SAEs) reported, where this constitutes as an SAE. We will report SAEs related to SPHERE from randomisation until the end of trial follow-up.

There will be no safety reporting for observational participants. Only SAEs will be reported to the trial office (including death, life-threatening condition, non-elective hospitalisation). In addition, all SAEs will be recorded in medical notes and reported to the Trust, according to local requirements. Any SAEs requiring non-expedited reporting to the trial office must be done within 28 days of becoming aware (for instance, hospitalisations related to HIV or other pre-existing conditions; hospital admissions lasting less than 24 h related to mental health issues). SAEs which do not require reporting to the trial office should be included in medical notes (for instance, pre-planned hospitalisations, hospital admissions lasting less than 24 h and unrelated to mental health issues). All other SAEs should be reported to the trial office in an expedited manner within 24 h of the site research team becoming aware of the event.

The Sponsor will notify the Research Ethics Committee (REC) of any serious breaches to the conditions and principles of Good Clinical Practice related to the trial conduct or protocol.

Auditing

All trial sites will be monitored according to a monitoring plan and trial risk assessment conducted by BCTU and University of Birmingham staff. Central monitoring will review informed consent and case report forms for protocol compliance, data consistency, completeness and compliance with the timing at a frequency and intensity outlined in the Data Management Plan (available on request). Automatic range checks will be conducted by the data capture system to check for data quality. Any queries relating to missing data or to clarify inconsistencies or discrepancies in the data will be sent as data clarification forms to sites on a regular basis.

Any protocol amendments such as changes to the study eligibility criteria, outcomes, analyses will gain necessary local approvals, be updated on the trial registration website and reported to investigators. Trial-related monitoring, audits, ethical review and regulatory inspections may occur at sites.

Statistical analyses

All analyses will be based on the intention to treat principle that participants are analysed in intervention group they were randomised to, irrespective of adherence to intervention or protocol deviations. Treatment effects will be adjusted for minimisation variables (strata of the PO-11 scores and study centre). No adjustment for multiple comparisons will be made.

The primary outcome will be compared between randomised groups using a log-binomial model adjusting for the minimisation variables. Treatment effects will be presented as adjusted risk ratio and risk difference for intervention versus control, with associated 95% confidence intervals and p-values. Statistical significance of the estimated treatment group parameter will be set at 5%.

Binary secondary outcomes measured at 6 and 12 months will be analysed using the same methods. Continuous secondary outcomes measured at 6 and 12 months will be analysed using linear regression models with adjustments for minimisation variables and baseline measures where relevant. Treatment effects will be presented as adjusted mean differences for intervention versus control, with associated 95% confidence intervals and p-values. Ordinal secondary outcomes measured at 6 and 12 months will be analysed using ordinal logistic regression models with adjustment for minimisation variables. Treatment effects will be presented as adjusted odds ratios for intervention versus control with associated 95% confidence intervals and p-values.

The observational cohort will be used to assess the proportion, with 95% confidence interval, who score ≥ 16 on the PO-11 at 12-months. The association of demographic, socioeconomic, HIV and health-related factors with this outcome will be explored.

Further details on all analyses will be provided in the Statistical Analysis Plan (SAP) (Additional File 2).

Pilot phase

We will run an internal pilot phase for the first 6 months of recruitment to determine whether the trial should continue based on a 10% recruitment target of the total planned sample size of randomised participants ($n = 57/568$). A traffic light system (stop/go criteria) will be used to determine study progression (Table 3).

Insights from the process evaluation will also be used to inform any changes to how the trial is being conducted (see below).

Subgroup analyses

Subgroup analyses will use the minimisation variable PO-11 based on the stratification of psychosocial needs at baseline (score 16–19; 20–25; ≥ 26) and the primary outcome only. We will present tests for statistical heterogeneity between subgroups along with the effect estimates and 95% confidence intervals. These results will only be used to generate hypotheses.

Handling missing data

Every attempt will be made to collect full follow-up data on all study participants to minimise missing data. Participants with missing primary outcome data will be excluded from the analysis in the first instance. This presents a risk of bias, and a sensitivity analysis will be

Table 3 Internal pilot recruitment target ($n=57$) after 6 months of recruitment

	Red[a]	Amber[b]	Green[c]
Number recruited to RCT at end of pilot phase as a percentage target of recruitment ($n=57$)	< 28	28–56	> 56
% of target recruitment	< 50%	50–90%	> 90%
Number of sites open to recruitment at end of pilot phase	< 4	4–5	> 6
Participants recruited per open site per month	< 1.3	1.3–2.6	> 2.6

[a] Discuss remedial action and next steps with Programme Steering Committee and funder

[b] Discuss feasibility with Programme Steering Committee and develop improvement plans

[c] Trial continues

carried out to investigate the potential impact of the risk. In brief, the PO-11 score will be imputed using important prognostic factors including intervention group; study centre; baseline PO-11 score; and adherence to intervention. This imputed score will then be used to determine whether the participant's score has reduced by greater or equal to 40% from baseline score. Further sensitivity analyses will be undertaken that will be detailed in the SAP (see Additional File 2).

Process evaluation methods

The aim of the process evaluation sub-study is to allow for a more in-depth understanding and exploration of the implementation process and context. The process evaluation will be conducted by UCL and the London School of Hygiene & Tropical Medicine in two phases.

In the pilot phase, we will address the following research question:

1. What factors promote or inhibit the implementation and impact of coaching and social prescribing for people living with HIV in SPHERE?

   The primary objective of this phase is to identify any elements that need modification to improve recruitment, training or operationalisation as well as the performance of implementation practices across clinic sites.

   In the definitive phase of the trial, we will also address the research question:
2. How do interactions between intervention mechanisms and their operational contexts shape outcomes for practitioners and people living with HIV?
   The primary objective of this phase is to identify interactions between SPHERE trial participants and processes, and the operational contexts (NHS and Third Sector) that shape both their lived experiences of participation in the trial and trial outcomes.

Theoretical framework and study design

The RE-AIM Framework [57] and Normalization Process Theory [58, 59] will be used to explore the reach, efficacy, adoption, implementation and maintenance of the intervention within and across participating sites. We will use a mixed-methods approach including:

(1) *Qualitative semi-structured interviews* with people living with HIV receiving the intervention and HWCs delivering the intervention. Interviews will explore views and experiences of the intervention and the different factors that influence the implementation, outcomes and effectiveness of the intervention.

In the pilot phase, we will recruit from the first three clinics to obtain NHS research and development approvals and will conduct approximately 20 interviews (clinic staff: $n=6$; trial participants: $n=14$) between weeks 4 and 16. This will form part of a high-intensity process evaluation.

In the main trial, we will conduct approximately 60 interviews with participants and staff. We will purposively sample trial participants to ensure diversity of age, ethnicity, sexual orientation, gender and time since diagnosis. Interviews will take approximately 60 min. We will also conduct up to 40 repeat semi-structured interviews with staff (NHS and Third Sector) and participants across all sites to examine trial dynamics and how perceptions, experiences and relationships change over time. Interviews will take between 45 and 50 min and will be conducted from week 20 to the end of the trial. This will form part of a low-intensity process evaluation.

(2) *Quantitative data* recording programme reach, uptake of referrals and acceptability metrics. This will include data collected through baseline case report forms (e.g. baseline questionnaires and any other data collected), health coaching diaries com-

pleted by the health coaches (which includes free text fields) and 6- and 12-month questionnaires.

Recruitment and consent Trial participants will be asked about their interest in participating in the process evaluation sub-study at the point of recruitment to the trial and will be given a PIS with further information. HWC delivering the intervention will be approached in person or by email by members of the qualitative research team and emailed a PIS. Consent to the sub-study will be taken by the qualitative researcher prior to interview either written (if in person) or audio-recorded (if remote). Interviews will be conducted in person or online according to participants' preferences. We will offer a £30 remuneration to trial participants interviewed as part of the process evaluation sub-study.

Proposed data analysis The interview topic guide will be mapped to wider Normalization Process Theory constructs [60] and the RE-AIM framework [57] for outcomes evaluation in public health interventions. We will analyse data using a combination of framework or qualitative content analysis [61], and abductive approaches to the interpretation of qualitative data [62]. We will consider factors that shape trial outcomes using methods proposed by Miles and Huberman [63] and develop associated robust explanatory models of the causal mechanisms that lead to these outcomes [64].

Data management Process evaluation data will be managed by University College London (UCL) and securely stored on the UCL Data SafeHaven. Transcripts will be generated by a Data Protection Act compliant UCL-approved professional transcription service whereby a signed confidentiality agreement exists. Personal data of study participants will be kept separate from interview data which will also be pseudonymised. Sub-study data will be archived for 20 years at the end of the study and stored digitally on a secure server with access controlled by the UCL Research Data Service. Qualitative data, including audio-recordings and transcripts from interviews from the process evaluation, will not be available to external researchers to maintain the anonymity of participants.

Health economic evaluation methods

The health economic evaluation aims to assess the cost-effectiveness of the intervention and the impact of the intervention on NHS resource use and will be conducted in two phases: (1) within-trial analysis and (2) model-based economic evaluation.

Stage 1: Within-trial analysis

This will relate to the first 12 months of data capture and will include:

- Total number of coaching sessions attended
- Format of coaching sessions (face-to-face/virtual)
- Length of session
- Total number of scheduled visits to the HIV clinic (intervention and usual care arms)
- Additional health care resources use recorded using a modified Client Services Receipt Inventory [46] (intervention and usual care arms)

All health care resource used will be costed using standard reference sources including unit cost data from the Health and Social Care Unit Cost database [65], National Schedule of NHS Costs [66] and Schedule of Events Cost Attribution Template [67].

It is anticipated that the costs of certain categories within the intervention will change (increase and decrease); therefore, costs will be disaggregated by cost category before providing a total cost. For example, the intervention could increase engagement with social prescribing and alcohol prevention programmes but may also reduce both scheduled and non-scheduled contacts with secondary care services. We will use generalised linear modelling to analyse categories of cost to handle potential skewness (we anticipate using a gamma distribution family with log link). Aggregated non-significant difference in total costs will only be presented if there is evidence of significant cost-offsets attributable to the intervention. Otherwise, the cost of the intervention will be assumed to represent the best estimate of the true intervention cost.

Data from the EQ-5D-5L at baseline, 6 months and 12 months will be mapped to utility index scores from the 3-level version of the score as recommended by the UK National Institute for Health and Care Excellence [68]. We will analyse data using a generalised linear model on dis-utility (1 − EQ-5D-DL utility score) to allow for potential skewness together with clustering to allow for repeated measures from the same individual and obtain robust standard errors. The average EQ-5D-5L utility score predicted will be interpreted as a quality-adjusted life year (QALY) as the time frame of the analysis is one whole year.

An analysis of the cost-effectiveness of the coaching intervention will be performed by combining the statistical equations for healthcare resource cost and 1-year EQ-5D-5L (or QALY). Cost and QALYs will be plotted on the cost-effectiveness plane with uncertainty represented by bootstrapping with cost-effectiveness acceptability curves used to summarise data [69, 70].

Stage 2: Model-based economic evaluation

This will involve extrapolating the within-trial analysis if significant differences in key variables are detected at stage 1. We will extrapolate beyond the trial timeframe to explore the long-term cost effectiveness of the intervention, including potential impacts on improvements to HIV management or general health (e.g. reduction in health-harming behaviours).

Where the within-trial analysis shows improvements in HR-QOL (EQ-5D-5L at 12 months), we will also develop a simple model to examine the implications for long-term cost-effectiveness. We will include a waning parameter to explore the importance of the duration of treatment effect for the cost-effectiveness result.

Where the within-trial analysis shows health improvements at 12 months associated with the intervention, we will conduct lifetime extrapolation modelling virological suppression, smoking status, dangerous alcohol consumption and drug use. The parameters of the lifetime model would be assigned distributions to reflect uncertainty, and probabilistic modelling would be used to demonstrate the uncertainty in overall cost-effectiveness [71]. A separate Health Economics Analysis Plan provides further details of analyses.

Discussion

The SPHERE trial will test whether a psychosocial coaching and social prescribing intervention based in secondary care improves self-reported health and well-being for people with HIV who have physical, psychological, social or socioeconomic needs. This is timely given the NHS model of personalised care being implemented across England with an aim to improve support and outcomes for people with long-term conditions and make the NHS more sustainable. The evidence base for a personalised care approach still lags behind policy implementation in the UK and significant methodological limitations exist with the sparse research to date [30]. This work will contribute to filling the evidence gap for more robust, higher-quality research [59].

A strength of the trial is continuous stakeholder involvement which will enable the timely application of findings. SPHERE has been co-developed with people living with HIV. Our PPI advisory group were integral to the design of the intervention through Theory of Change workshops, the intervention training through the co-production of training assessments and the co-development of the participant-facing material in the trial. Ensuring that PPI are involved across the management of the trial with representatives on the Trial Steering Committee as well as the Trial Management Group has facilitated their feedback into all aspects of the trial design and implementation.

SPHERE also has two sub-studies embedded within the work which will strengthen its implementation. First, the process evaluation will allow the trial team to reflect and adapt the trial as it begins to recruit participants and identify challenges and provide potential solutions to these, as the trial progresses. Critical evaluation of localised implementation processes affords a more detailed understanding of how the intervention may be applied, and translates, across different settings [58, 59]. Secondly, the economic evaluation will present an opportunity to explore the cost-saving implications, if any, for the NHS and sustainability of the intervention in the long term. The intervention is designed to address needs identified by previous research among people living with HIV in the UK [39]; however, we acknowledge that there is not yet scope to develop the intervention to provide support in additional languages within this programme of research.

Learnings from the trial have the potential to be applied in other health areas. Although the specific components of a psychosocial needs assessment and intervention may vary in different settings, the principles may be transferable to other chronic and potentially stigmatising medical conditions treated primarily in specialist or hospital settings. Future work may consider the potential adaptation and application of the intervention to other patient populations with chronic diseases attending secondary care services (for example, chronic respiratory or renal disease, diabetes, etc.).

Dissemination plans

A multi-dimensional approach will be developed to deliver key information for people with HIV, programme participants, service providers, policymakers, health care commissioners and the research community. We will work with the UCL communications team and representatives from key community organisations, such as the UK-CAB which is a peer-led HIV treatment advocates network, as well as news outlets such as HIV i-Base. This will ensure maximum reach for the dissemination and impact. Our PPI group will draft a communications strategy, liaising with the National Institute for Health and Care Research (NIHR) PPI Centre for additional guidance.

A study report will be published following study completion. The results of the trial will be published in peer-reviewed journals and presented at national and international conferences. Manuscripts will be submitted to the Trial Management Group for review prior to publication. All participating sites will be sent results and will share these with participants recruited there who will be invited to discuss the findings with the local research team. We will regularly update our study website (www.

niche.ac) with study outputs and information on PPI activities.

Authorship for future trial publications will be determined based on each author's contribution to the work, in line with ICJME criteria, and we do not plan to use any professional writers.

Trial status

This protocol is aligned with NHS Health Research Authority protocol version 3.0 (dated 28 June 2024), approved on 9 July 2024. Recruitment to the trial started on 19 August 2024 with an anticipated date for completed recruitment by 1 August 2025. Trial website: https://www.birmingham.ac.uk/research/bctu/trials/pd/sphere and research programme website: www.niche.ac.

Abbreviations

AE	Adverse event
ART	Antiretroviral therapy
ASTRA	Antiretrovirals, Sexual Transmission Risk and Attitudes study
AUDIT-C	Alcohol Use Disorders Identification Test-Consumption
AURAH2	Attitudes to, and Understanding of Risk of Acquisition of HIV over time study
BCTU	Birmingham Clinical Trials Unit
CSES	Coping Self-Efficacy Scale
FSSQ	Duke-UNC Functional Social Support Questionnaire
GAD-7	Generalised Anxiety Disorder-7 Questionnaire
GPPAQ	General Practice Physical Activity Questionnaire
HR-QOL	Health-Related Quality of Life
HWC	Health and Well-being Coach
ISRCTN	International Standard Randomised Controlled Trials Number
NHS	National Health Service
NICHE	A person-centered Needs Informed model of Care for people with HIV
NIHR	National Institute for Health and Care Research
PHQ-9	Patient Health Questionnaire-9
PIS	Participant Information Sheet
PO-11	HIV Positive Outcomes-11 questionnaire
PO-20	HIV Positive Outcomes-20 questionnaire
PPI	Patient and Public Involvement
PSC	Programme Steering Committee
QALY	Quality-Adjusted Life Year
RCT	Randomised controlled trial
REC	Research Ethics Committee
RS-14	Resilience Scale
SAE	Serious adverse event
SAP	Statistical Analysis Plan
SPHERE	Psycho-Social Intervention for People with HIV – Evidence from a Randomised Evaluation
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials checklist
UCL	University College London
UK-CAB	UK Community Advisory Board
VL	Viral load

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-025-08904-9.

Additional file 1.

Additional file 2.

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Authors' contributions

Conceptualization: AR (study CI), FL. Funding acquisition: AR, FL, AP, CS, CM, FB, RO, ML, LS, RH, MB, AS, VA, RW, NI. Methodology: AR, FL, CS, CM, FB, AB, RO, RH, AS, JS, VC, RW. Investigation (process evaluation-ongoing): CM, FB, VP, AR, JS. Investigation (health economic evaluation-ongoing): AB. Trial management and Supervision: SL, NI, SLoi, SD, DA, GS, EN, MB, VA, CR, CH, MJ, RW. VP wrote the first draft of the manuscript. AR, FL, JS, CM, FB, RW, CS, AB, RO, VC, AP, LS, RH, ML revised the paper critically. All authors read and approved the final manuscript.

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Data availability

Not applicable.

Declarations

Ethics approval and consent to participate

The trial will be conducted in accordance with the UK Policy Framework for Health and Social Care Research and applicable UK Acts of Parliament and Statutory Instruments (and relevant subsequent amendments), and the principles of Good Clinical Practice as set out in the UK Statutory Instrument (2004/1031 and subsequent amendments).
Ethical approval has been received from London – Fulham Research Ethics Committee (ref: 24/LO/0449). All participants will provide informed consent throughout the trial by completing an online form (e-consent) or by paper. The Principal Investigator at each trial site is required to obtain necessary local approvals before any participants are enrolled to SPHERE.

Consent for publication

Not applicable. The manuscript does not contain individual personal data from patients.

Competing interests

The authors declare that they have no competing interests.

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