





1. Spring 2024

SPHERE NEWSLETTER



Psycho-social Intervention for People with HV—Evidence from a Randomised Evaluation

NICHE Progamme (University College London)

NICHE Programme Lead: Professor Alison Rodger Co Lead: Dr Fiona Lampe NICHE Programme Manager: Dr Janey Sewell

SPHERE

Trial Management: Birmingham Clinical Trials Unit Chief Investigator: Professor Alison Rodger Trial Team Lead: Shrushma Loi Trial Manager: Suzanne Lockyer Senior Data Manager: Serena Dhir

DESIGN

A national, pragmatic, multi-centre, 2-arm, parallel group, randomised controlled trial (RCT) with an internal pilot phase, process evaluation and economic evaluation, and a parallel observational cohort study.

AIM To assess if a psychosocial health coaching intervention improves health and wellbeing in people living with HIV.

SAMPLE SIZE 568 participants for RCT 398 participants for observational cohort

STUDY DURATION Study to open to recruitment in June 2024 15 months recruitment 12 month follow up

TRIAL SPONSOR University of Birmingham

FUNDER NIHR Programme Grant for Applied Research (reference202038) Grant is for the NICHE Programme

Welcome to the SPHERE study team!

SPHERE was developed in response to concerns from the community that for many people with HIV, poorer mental health, lack of support and experiences of stigma remained a real problem which stops some people with HIV living a fulfilling life. We aim to see if there is a benefit to providing a more person-centred approach to care using an intervention based on health coaching and social prescribing and whether this improves overall wellbeing. We are very grateful to everyone for your enthusiasm and support with the study and we look forward very much to working with you on this.

> Professor Alison Rodger SPHERE Chief Investigator

As well as managing the NICHE programme, Janey is also training as a SPHERE Health and Wellbeing Coach, and shares her experience of training:

We are just over half way through our Health & Wellbeing Coaching and Social prescribing training for the SPHERE trial. It was fantastic to meet the nurses, health advisors, pharmacist and social worker from all the sites and see the huge amount of experience and skills that the group has to share. We had a really interesting, motivating and inspiring four days of face-to-face training in Feb. I don't think I have been on a course before that has had such a huge impact on how I think and communicate and I'm really looking forward to the next stage of training and then putting it all into practice once the trial opens

We know you will share Janey's enthusiasm to put your training into practice.

Here are the revised timelines for trial set up

Mid April



Draft protocol sent to sites Submit application package for REC/HRA Approval Health coaches complete their training **End April** Local Information Pack sent to all sites **May** Anticipated REC approval Ongoing communication with sites to facilitate set up Site Initiation Visits start **June** First SPHERE sites open Recruit participants

Timelines depend on response from REC/HRA, but we will keep sites updated. Please contact us for any information that can help start set-up procedures at your site.

SPHERE Trial Office Contact Details

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Trial Manager: Suzanne Lockyer | Senior Data Manager: Serena Dhir

The SHERE Trial Office will be closed for the Easter break, from Friday 29 April to Wednesday 3 April inclusive HAVE A WONDERFUL EASTER!



FUNDED BY

IIHR National Institute for Health Research

This study is funded by the National Institute for Health and Care Research (NIHR) Programme Grant for Applied Health Research (Grant Code 202038). The views expressed are those of the authors and not necessarily those of the the NIHR or the Department of Health and Social Care.