


 SPHERE NEWSLETTER

 FIRST PARTICIPANTS  
RECRUITED

Royal Sussex County Hospital, Brighton recruited the first SPHERE participant on 4th September.

Total recruitment so far is 3 to the RCT and 4 to the Observational Cohort.

A huge thank you to the SPHERE team at The Lawson Unit, Brighton for their hard work, it is a great start for our recruitment.



## Hints and tips for maximising recruitment

*It isn't until we start recruiting that we know what really happens! We have received some really helpful feedback from The Lawson Unit in Brighton, so here are some updates and clarifications*

- Exclusion criteria.** There are two exclusion criteria, as discussed at the SIVs: the first one is about excluding anyone with serious mental health issues, and we would like to emphasise that this would be really serious mental health issues such as acute severe psychosis. This would be an unusual event and we expect very few PWH seen in routine clinic would meet this criteria. In summary, we want as many people with HIV as possible to have the chance to experience the intervention if they have need (i.e. PO-11  $\geq 16$ ). This is important going forward, as if the trial shows the intervention works, we need to know that we have included the breadth of people with HIV in the UK.

**So, there is no need to exclude people with mild/moderate depression or longstanding stable mental health issues. If you have any questions, or wish to discuss specific cases, please contact Professor Alison Rodger ([alison.rodger@nhs.net](mailto:alison.rodger@nhs.net)).**

The second exclusion criteria is for PWH who are **in the first 12 weeks of a new psychotherapeutic intervention that involves talking to a counsellor**. Such people could be approached later when they have finished psychotherapy or more than 12 weeks after starting.
- Baseline questionnaire completion.** Some participants requested to take the baseline questionnaire away to fill in later. However, this is not possible in this study. Participants should be consented, complete the questionnaire, and then be randomised or registered.

**We recommend** that completion of the questionnaire is discussed as part of the PIS/Consent interview and **before consent:**

  - ◇ Show participants the questionnaire and explain that the data that will be collected will be incredibly important to inform best care for people with HIV in the future
  - ◇ Explain that the baseline questionnaire needs to be completed in clinic so that they can be registered/randomised into the study.
  - ◇ They will receive £20 voucher when they hand back completed questionnaire
  - ◇ They will receive link to complete **follow up questionnaires** online—they do not need to attend clinic

Inclusion criteria include 'willing and able to take part in the study' Therefore, if participants are unable/unwilling to complete the questionnaire as part of baseline procedures, then they must be excluded.

## Site update

We have made a good start, but we need all sites on board as soon as possible to reach minimum pilot target of 57 RCT participants by the end of November.

**Please be ready to start recruiting as soon as greenlight is issued.**

### *What is needed before Greenlight is issued?*

- ✓CVs and GCPs for all staff on the delegation log. CVs must be signed and dated and GCPs current to Trust requirements.
- ✓Completed Delegation Log
- ✓Database training
- ✓Site Initiation Visit
- ✓mNCA signed by Trust, PI and University of Birmingham
- ✓Confirmation of Capacity and Capability

Please send any outstanding documents to SPHERE trial office, and maintain contact with your R&D to expedite mNCA approval and CCC.

### Associate PI Scheme

#### **Another first for The Lawson Unit, Brighton!**

Zoe, one of the Health and Wellbeing Coaches at Royal Sussex, was the first to register on the SPHERE Associate PI Scheme. Good luck with the programme, Zoe.

A reminder from the scheme:

*Please make sure you register prospectively if you wish to take part.*

For more information and to register, search for 'NIHR Associate PI scheme'.

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