



2. Summer 2024

# SPHERE NEWSLETTER

**Welcome to the SPHERE newsletter!**

**We are so close to opening...**

**THANK YOU for all the hard work so far.**



◆ SPHERE received REC Favourable Opinion on 8 July 2024

◆ Five Site Initiation Visits have been completed, Thanks to all those at:

- Chelsea and Westminster Hospital, London
- Royal Sussex County Hospital, Brighton
- King's College Hospital, London
- Southmead Hospital, Bristol
- Royal Hallamshire Hospital, Sheffield.



We look forward to visiting the **Hathersage Centre, Manchester** and **Bart's Health NHS Trust** in the next couple of weeks.

UPDATES

## SPHERE Database training



We have sent dates for SPHERE database training to all sites that have completed SIVs.

The training is not site specific, so you don't need to co-ordinate availability. Just respond directly to the SPHERE trial office ([sphere@trials.bham.ac.uk](mailto:sphere@trials.bham.ac.uk))

**Database training commences 8 August 2024.**

**Sessions are available: 8, 9, 12, 13 August (am and pm) and 14 and 16 August am.**

**Training must be completed before log-in details are provided.  
Please book your training ASAP :)**

**We are anticipating that the first sites will get greenlight during the week commencing 19th August 2024**

***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
- ✓Localisation details for ICF and PIS—Trust header, study team contact details and local PALS
- ✓Database training
- ✓Site Initiation Visit

***Please ensure these are sent to the SPHERE trial office***

mNCA must be signed by Trust and University of Birmingham. This is usually dealt with by Trust R&D, but CI and main contact(s) at site will be copied in any correspondence.

## Process Evaluation sub study

SPHERE includes a Process Evaluation sub study (see Protocol for details). This is being carried out by researchers at University College London. Here is a brief summary.

- The sub study applies to RCT participants randomised to the intervention and site staff involved with SPHERE
- The Informed Consent Form for RCT includes an **optional** clause, which is consent to be **contacted about the sub study** by a member of the UCL team. If a participant ticks this box, then please complete Contact Details form (online). Details will be passed to UCL team
- Process Evaluation PIS is provided and site staff can give this to participant, so they can read about the sub study
- Discussion about the study and full informed consent will be carried out by UCL researchers
- You or other members of the SPHERE study team at your site may be contacted to see if you would be happy to participate in the study (up to 1 hour interview with UCL researcher)

## Associate PI Scheme

SPHERE is now registered for the Associate PI Scheme. You will be able to register to be an Associate PI from 15 August 2024.

Please see details on NIHR website:

<https://www.nihr.ac.uk/health-and-care-professionals/training/applying-to-be-an-associate-principal-investigator.htm>

### SPHERE Trial Office Contact Details

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