



HIS-UK January 2020 Newsletter

Achievements

- REC has reviewed and approved our non-substantial amendment.
- NIHR have approved our application for excess treatment cost funding.
- We have received our first order of condoms and lubricants from myONE, Pasante, EXS, and Durex. All other study materials, such as audio-recorders and tablet computers, have also been received.
- The first TSC and DMC meeting was held via teleconference on 30th January. Thank you to all those who attended and for a very productive meeting. It was agreed that the next TSC and DMC meetings will be held in around 9 months time (date t.b.c).
- PAG members have been confirmed. The first meeting will be organised in due course.
- The third TMG meeting has been confirmed for Thursday 9th July.
- BSMS CTU in collaboration with the research team have prepared the site initiation visit (SIV) documents and presentation.
- The online intervention (*eHIS*), website, and study site staff online tutorials have been finalised.
- Nicole discussed HIS-UK at the Wessex CRN Sexual Health Group teleconference. This was the CRN's first regional sexual health research teleconference. Attendees included research active clinicians from Solent, Bournemouth and Dorset County Hospital.

What are we working towards?

- Finalising the third pilot site (BSMS CTU are negotiating).

- In the process of confirming dates for the first site initiation visits (we are aiming to commence in February).
- Preparing and sending the site packs (such as study site staff information, participant documents, and condom kits).



HIS-UK February 2020 Newsletter

Achievements

- Our first set of condom kits are ready for delivery to Solent NHS Trust
- We welcome Styliana and Megan, our second year Psychology undergraduate voluntary research assistants who will be supporting HIS-UK throughout semester 2
- Rowena, Nicole, Ye, Styliana and Megan attended the first site initiation visit (SIV) at Royal South Hants Hospital, Southampton. Clinic attendees included Jo Turpitt (Senior Research Nurse, Southampton), Lindsey Cooke (Research Nurse, Portsmouth), Jane Whitehead (Clinical Trials Assistant, Southampton), and Natalie Parker (Clinical Trials Assistant, Portsmouth). Thank you to all attendees -we look forward to commencing the study at Solent NHS Trust!

What are we working towards?

- In the process of finalising further SIVs. We are due to visit Brighton and Sussex NHS Trust on Thursday 12th March
- Continuing conversations with Barts NHS Trust as a pilot recruitment site
- Continuing to pack up intervention materials, including condom kits and further documentation (see below!)



1 - Only a small number of the condoms and lubricants delivered. We don't have a lot of space in our office!



2 - Boxes ready for the first clinic delivery



HIS-UK March 2020 Newsletter

Achievements

- The first condom kits were delivered to Solent NHS Trust.
- On the 13th March the Solent Team received the 'green light' from Brighton and Sussex Clinical Trials Unit (BSCTU) to begin recruitment. Congratulations to Solent for being the first site to open for recruitment.
- Rowena, Nicole, and Ye attended the site initiation visit (SIV) for Brighton and Sussex NHS Trust on the 12th March. The clinical team also received the condom kits and necessary documentation during this visit. We look forward to being able to give the green light to Brighton to commence recruitment.
- Solent successfully recruited our first participant to the study.
- TDL Pathology agreed to support the study with the supply of postal chlamydia screening kits at matched NHS costings.

What are we working towards?

- Due to Covid-19, the HIS-UK have informed both the Sponsor and NIHR that study recruitment will temporarily halt along with the set-up of new sites. This is classed as a non-substantial amendment in line with the HRA guidance. Site activation and set-up completion (and recruitment) at Brighton will therefore be paused until further notice.
- The project itself, however, has not been halted and other areas of work are still continuing. Over the coming weeks we shall be working on a series of amendments to the study protocol in light of feedback received from our SIVs and on writing up the protocol for publication.

Participant numbers

- Participants recruited to the study: 1
- Participants withdrawn/lost to follow-up: 0
- Participants completed T6: 0



HIS-UK April 2020 Newsletter

Achievements

- Public health England have announced that they will be funding the recruitment site excess treatment costs
- The research team submitted a fourth amendment to the Sponsor ethics committee which has now been approved. This amendment included an updated PIS, consent form, and protocol to take into account feedback from our site initiation visits

What are we working towards?

- The research team are currently preparing a protocol publication to be submitted to JMIR
- The substantial amendment will now be sent to the Health Research Authority for their approval



HIS-UK September/October 2020 Newsletter

Impact of Covid-19

- Our first participant was recruited on the 17th March in Southampton. However, due to the Covid pandemic, study recruitment and the set-up of further sites was halted (non-substantial amendment) on the 27th March. This was due to the clinical research team needing to divert time to Covid, the non-clinical team being unable to follow-up participants, the study being non-urgent, and a potential increased risk to patient safety as prospective participants are required to attend clinic for baseline screening.
- Rowena and Nicole were furloughed from the 18th May to the 1st September to conserve budget as requested by the Funder.
- Study documents have now been amended to account for Covid, in particular adapting the study to enable the study to be conducted online if required.
- The research team are planning to recommence study recruitment in early 2021.

Achievements

- The research team held a series of committee meetings (TSC, DMEC, and TMG) to discuss the next steps for the study post-Covid. Thank you to all those who attended and provided valuable guidance and feedback.
- The HIS-UK team have now submitted a post-Covid substantial amendment to the Sponsor and Funder. This amendment has been approved.
- The submission included amendments to the protocol, participant information sheet (PIS) in clinic recruitment, and consent form. Changes to the protocol include a new trial flowchart to account for online self-referral and a Covid risk assessment in line with NIHR relevant

framework. We have also included additional elements to the study in light of Covid, including an online expression of interest form for prospective participants and an abridged PIS (if eligible, participants will be notified when a clinic space becomes available) via the management software platform Qualtrics; an online self-registration PIS; and video consultation for the proHIS condition.

- We welcome two new PPI members; Ollie Miles and Iain Gillespie. Both Ollie and Iain provided feedback on our participant facing documents prior to our amendment submission.
- The research team attended the Wessex CRN sexual health research teleconference on the 28th October to discuss HIS-UK. Discussion included plans to restart recruitment in early 2021 subject to the approval of the new protocol that will allow for online registration and video consultation. Nancy (research nurse) and James Colton (senior research practitioner) at Dorset Healthcare University NHS Foundation Trust and Felicity Young (consultant nurse) at Isle of Wight NHS Trust confirmed they would be interested in participating. Felicity highlighted that sexual health services on the Isle of Wight will now be provided by Solent NHS Trust. Wessex CRN will help promote and support HIS-UK in finding new sites. The next sexual health meeting will be held in January 2021.

What are we working towards?

- The research team are finalising the protocol journal paper to be submitted to JMIR research protocols. Thank you to the TMG for providing feedback on the first draft.
- The team will now submit our amendment to the HRA research ethics committee. We hope this will be approved by December 2020.
- The HIS-UK study is being updated on Lifeguide to facilitate the study amendments.
- We are working on visual basic code within Excel to enable multiple individuals (namely the research team and voluntary research assistants) to input information simultaneously on a single user form. This database will help the research team track participant progress within the study i.e. completion of monthly questionnaires, condom ordering, and ensuring screening data has been captured at T0, T6, and T12.
- The HIS-UK website will be amended to facilitate potential participants to submit an expression of interest to participate.



HIS-UK November/December 2020 Newsletter

Achievements

- We have now gained approval from the Sponsor, REC (Oxford B), and HRA for our substantial amendment. The submission included amendments to the protocol, participant information sheet (PIS) in clinic recruitment, and consent form.
- Our next HIS-UK TMG videoconference is scheduled for Tuesday 12th January 2021. Thank you to everyone who confirmed their availability.
- We are excited that we are now in talks with three potential new sites who have all shown interest in joining the study. These include: University Hospitals Birmingham NHS Foundation Trust, Oxford Health NHS Foundation Trust, and Central London Community Healthcare NHS Trust. It is expected that Jonathan Ross (Professor of Sexual Health and HIV) and Alice Manley (Sexual Health and HIV Research Manager) from Birmingham, as well as Hannah Longford (Senior Health Advisor in Sexual Health) from Oxford will be joining us on the TMG call in January.
- We are also excited to announce that Isle of Wight has now become part of Solent NHS Trust and will be included as a recruitment clinic for the study. Solent will most likely initially restart recruitment using the clinic on the island early in 2021.
- Ollie Miles has been appointed Chair of our PPI group and is also now a member of our TMG.

What are we working towards?

- The team originally planned to restart the study in January, however in light of the continued disruption caused by Covid to clinic sites and the upcoming holiday period, the chances of this start date is low. We now expect to begin recruit in February/March 2021. In

the meantime, we will continue to prepare for site set up, including site initiation visits (subject to research and development approval and site expected start dates).

- We are preparing a non-substantial amendment to be submitted after the TMG meeting in January.
- Nicole has been busy developing Lifeguide and Qualtrics (a survey software provider) to account for prospective participants who wish to express an interest in the study online, as well as ensuring the Chlamydia screening data transfer and self registrant participant follow-up consultations with site staff processes are working as efficiently as possible. Rowena has been acting as mock participants by testing out the intervention and email notifications.
- Rowena has been working on the study website (his-uk.net). This will be the central hub for participants to express interest in the study, login to the study intervention, and for staff to recruit participants, transfer screening results, and perform follow-up consultations.