



HIS-UK January 2021 Newsletter

Impact of Covid-19

- In our Nov/Dec newsletter, we anticipated recruitment to commence in February/March 2021. However, in light of new government lockdown restrictions and the continued disruption to NHS services, we now expect the most feasible restart date to be Spring 2021.

Achievements

- Our latest HIS-UK TMG meeting was held on Tuesday 12th January 2021. It was great to see so many of you there and to welcome new faces including attendees from Solent NHS Trust, University Hospitals Birmingham NHS Foundation Trust, Central London Community Healthcare NHS Trust, and Oxford University Hospitals NHS Foundation Trust.
- We now have a Twitter page to advertise the study and provide updates. This page will be made public as soon as the study is up and running again.
- The team had a positive call with Western Sussex Hospitals NHS Foundation Trust on 13th January 2021 to discuss becoming a potential study site. Trust attendees included Merle Symonds (Lead Health Advisor/Team Leader), Marian Flynn-Batham (Clinical Trials Manager), and Tan Tsawayo (Research Nurse).

What are we working towards?

- Nicole is refining the Lifeguide and Qualtrics pages to ensure participant expression of interest, participant recruitment, Chlamydia screening data transfer, and self-registrant participant follow-up consultations are as seamless as possible.
- Rowena is nearing completion of the study website, the central hub for prospective/current participants and staff to access study resources. Many thanks for our PPI representatives Ollie Miles and Iain Gillespie for their useful feedback on this site.

- We are finalising a non-substantial amendment, taking into account feedback from our latest TMG meeting.
- The team are continuing to explore further possible study sites.



HIS-UK February/ March 2021 Newsletter

Impact of Covid-19

- The team are pleased to say that Brighton and Sussex University Hospitals NHS Trust have provisionally agreed May for study commencement.
- We understand that for many Trusts a Spring restart may be difficult due to the ongoing impact of Covid-19. We continue to keep in close contact with sites to establish the most feasible restart date.

Achievements

- Our non-substantial amendment has been approved by both Sponsor and Funder. This amendment included clarification to the protocol, minor updates to the participant information sheet and terms of use documents, and an additional privacy notice for the use of Qualtrics (an online survey tool).

What are we working towards?

- Preparing our site initiation visit with Brighton with the view to start the study in May.
- Nicole and Rowena are continuing to refine and test the intervention in preparation for commencement. This includes coordinating participant engagement (both online and in-clinic), screening and ordering services, payment, and recordings.
- We are exploring further study sites for the latter recruitment waves.



HIS-UK April 2021 Newsletter

Impact of Covid-19

- We understand that for some Trusts it is difficult to offer a timeline for study commencement. We will continue to keep in contact with these sites to discuss when this may be possible.

Achievements

- We are very pleased that Dorset Healthcare University NHS Foundation Trust are in a position to commence site set-up with a provisional May re-start.
- It is also great to hear that Central London Community Healthcare NHS Trust have indicated May as a feasible re-start date.

What are we working towards?

- The HIS-UK team and Brighton and Sussex Clinical Trials Unit are preparing for site initiation visits.
- The HIS-UK team are finalising study documentation and intervention testing.



HIS-UK May 2021 Newsletter

Impact of Covid-19

- We understand that for some Trusts it still difficult to offer a definitive date for study commencement. We will continue to keep in contact with sites to discuss when this is most feasible.

Achievements

- We had our site initiation call with Brighton (University Hospitals Sussex NHS Foundation Trust) on 27th May. We are excited to start recruiting our first participants from early June!
- We are pleased to say that Oxford University Hospitals have confirmed they would like to be involved in the study.
- The team received a delivery of 1250 bags for our condom kits - our store room is now very full!

What are we working towards?

- We are now back in the office (on a part-time basis) to prepare study supplies to send out to sites. We will then await our first wave of participants!
- We are working to finalise further site initiation dates with prospective Trusts.



HIS-UK June 2021 Newsletter

Achievements

- Recruitment restarted at University Hospitals Sussex NHS Foundation Trust on 9th June, the first site to be activated in the restart.
- We had our virtual site initiation visit with Dorset Healthcare University NHS Foundation Trust on 30th June. Clinic sites will include Bournemouth and Weymouth. Thank you to all those who attended.
- Our official HIS-UK Twitter page is now live: <https://twitter.com/hisukstudy>
- Thank you to UH Sussex Research Brighton and Haywards Heath Twitter account for tweeting our study! <https://twitter.com/BSUHresearch/status/1404831325585121292>

What are we working towards?

- The team are continually working with sites to determine possible recruitment commencement dates.
- Wessex Clinical Research Unit will shortly issue a general expression of interest to assist in the recruitment of new sites.
- We are preparing condom kit bags ready to be delivered to sites and participants (when required).



HIS-UK July 2021 Newsletter

Achievements

- Brighton has recruited our first participants! These include via our in-clinic and online expression of interest routes.
- Study supplies have been received by our two clinic sites at Bournemouth and Weymouth (as part of Dorset Healthcare University NHS Foundation Trust). We are looking forward to commencing recruitment with the Dorset team.
- We have received expressions of interest from Nottingham University Health Service (serving predominately University students) and Guy's and St Thomas' NHS Foundation Trust.
- Solent NHS Trust has indicated that there is capacity to re-open to recruitment in September.

What are we working towards?

- We have been working on an online questionnaire that will help track service provision changes of sites during the study. This will be completed by sites every 3 months and will cover such areas as number of patients given access to the C-card, number of chlamydia diagnoses, and number of consultations etc.
- The team are in close contact with prospective sites to establish study timelines. We appreciate the ongoing impact that Covid-19 is having on sexual health services. It is hoped to commence with these sites soon.

Recruitment

Sites open to recruitment: 1

Total participants recruited: 3

Participants completed primary end-point: 0



HIS-UK August 2021 Newsletter

Achievements

- We are very pleased to say that Dorset Healthcare University NHS Foundation Trust has received the green light to begin recruitment! Clinics will be based in Bournemouth and Weymouth.
- Nottingham University Health Service had their virtual Site Initiation Visit (SIV) on 17th August. It was great to meet the team and we look forward to having Nottingham onboard.
- The team also have further SIV's planned for September including Central London on Community Healthcare NHS Trust (Hertfordshire clinics) and Solent NHS Trust.
- We have been invited by CRN Wessex to talk about HIS-UK and provide study updates at their second regional sexual health meeting on September 20th. The team previously discussed HIS-UK at their first regional sexual health research teleconference call back in January 2020.

What are we working towards?

- We are busy preparing for upcoming SIV's and organising study supplies ready to send to sites.
- Our next trial management meeting will be on 23rd September and a joint trial steering/data monitoring meeting will take place on 4th October.

Recruitment

Sites open to recruitment: 2

Total participants recruited: 3

Participants completed primary end-point: 0



HIS-UK September 2021 Newsletter

Achievements

- Central London Community Healthcare NHS Trust (Hertfordshire clinics consisting of Hatfield, Stevenage, and Watford) had their virtual site initiation visit (SIV). Thank you to all those who attended and we look forward to working with you all.
- Solent NHS Trust had a 'refresher' virtual SIV. Solent was the first site to be opened and recruited one participant before recruitment was paused a day later due to the pandemic. It's great that Solent will be able to re-start recruitment with us very soon.
- The team attended CRN Wessex sexual health meeting (their second regional sexual health meeting) to provide study updates on HIS-UK.
- Cambridgeshire Community Services NHS Trust have expressed an interest to join the study. The research team had an introductory call with Samantha Nunn and Dr Sinna Jebakumar from the Trust to discuss HIS-UK further.
- We had our virtual Trial Management Meeting on 23rd September. Thank you to everyone for your feedback and suggestions. We expect our next meeting to be held in March 2022.
- Thank you to Bournemouth University, University of Nottingham, and the Brighton Chlamydia Screening Programme Team who have kindly agreed to display our advertisement materials (both physical copies and digital) at University and college freshers events.
- Congratulations to Ye, our clinical trial manager at BSCTU, who will be going on maternity leave on 8th October. We wish you all the best! Ye's leave will be covered by Iga Abramowicz - we look forward to working with you Iga.



1 - Study supplies and condom kits ready to be sent to the Hertfordshire clinics.

What are we working towards?

- Preparing for Solent NHS Trust site activation.
- Our joint trial steering/data monitoring meeting will take place on 4th October.
- Further contact with University services to display our advertisement material during Freshers and other University/college events.
- Further promotion of the study on social media. Cindy has been tagging sexual health charities/services in the region of activated sites and University sports societies when tweeting about our study. Please let us know if you have any other suggestions.

Face-to-face and expression of interest recruitment routes

Young men can register for the study within clinic or self-register online via the HIS-UK website once their expression of interest (Eol) application has been accepted by the HIS-UK team. Below is a summary of site's preferred recruitment route.

- **BRIGHTON (Active site):** Face-to-face and Eol.
- **DORSET (Active site):** Face-to-face and Eol.
- **NOTTINGHAM (Active site):** Face-to-face and Eol.
- **CENTRAL LONDON:** Face-to-face and Eol
- **SOLENT:** Face-to-face.
- **CAMBRIDGE:** Eol. Cambridge has suggested the possibility of their team organising a central hub to deliver the intervention. Prospective participants from surrounding clinics would then be directed to this hub.

Recruitment

Sites open to recruitment: 3

Expressions of interest made online: 13

Participants recruited to study: 9

Participants completed primary end-point: 0



HIS-UK October 2021 Newsletter

Achievements

- Our joint Trial Steering and Data Monitoring meeting took place virtually earlier this month. Thank you for all those who attended and for your suggestions. The next Trial Steering and Data Monitoring meetings will be held separately around March/April 2022.
- Solent NHS Trust had their second SIV (their first being pre-pandemic) providing an update to our latest protocol. Solent will open with Southampton initially, with Portsmouth and Isle of Wight opening at a later date. We look forward to restarting with Solent at the beginning of November.
- We welcome Esthella, our undergraduate voluntary research assistant within Psychology at University of Southampton. Esthella will be helping with research tasks during this semester.

What are we working towards?

- Finalising Central London Community NHS Trust (consisting of three clinics in Hertfordshire - Hatfield, Stevenage, and Watford) as a recruitment site.
- The team had a further meeting with Cambridgeshire Community Services NHS Trust to discuss HIS-UK after expressing an interest. We hope Cambridge will be able to join us on the study shortly.

Feedback from sites

- Brighton reported that patients are more receptive to the study when asked by the nurse/doctor as part of their clinic visit, as opposed to being approached before being seen in clinic.
- The use of contact cards as advertisement material has been particularly well received by Nottingham.

Recruitment

Sites open to recruitment: 3

Screened for Eligibility: 46

Participants randomised to a trial arm: 17

Participants completed primary end-point: 0



HIS-UK November 2021 Newsletter

Achievements

- Cambridgeshire Community Services (CCS) NHS Trust have confirmed their involvement on the study (to be activated initially within the Cambridgeshire and Norfolk services). Operating entirely remotely using the online self-referral route and advertised to young men accessing the iCASH Express Test service. All participant consultations will be completed online (telephone/ face-to-face) by the CCS research team.
- After a positive call with Royal Liverpool and Broadgreen University Hospitals NHS Trust, we are pleased that they have also agreed to join the study.
- We have received interest from Lewisham and Greenwich NHS Trust, comprising two GUM/sexual health services.
- We have revised our recruitment gantt chart to reflect the study delays seen due to COVID, and shared our recovery plan with NIHR-PHR. We await their feedback.

What are we working towards?

- Finalising site set up for Solent NHS Trust, Central London Community Healthcare NHS Trust, and Cambridgeshire Community Services NHS Trust.
- We have been asked by our funders to attend a Project Monitoring Meeting in the New Year to discuss how the study is currently performing, and any predictions or plans for its successful completion.

Recruitment

Sites open to recruitment: 3

Screened for Eligibility: 65

Participants randomised to a trial arm: 25

Participants completed all baseline activities: 15

Participants completed primary end-point: 0



HIS-UK December 2021 Newsletter

Achievements

- We are pleased to say that both Central London Community Healthcare NHS Trust and Solent NHS Trust have received the green light to begin recruitment.
- We have submitted our Protocol paper to JMIR Research Protocols. Thank you to all our Co-applicants who contributed to the paper.
- The team have submitted a new application to Sponsor ethics covering the new non-clinical recruitment pathway that extends recruitment beyond NHS sexual health services. If approved, participants will be able to be recruited England wide from community non-NHS settings. We hope this will boost recruitment figures.

What are we working towards?

- Continuing communication with Liverpool University Hospitals NHS Foundation Trust and Cambridgeshire Community Services NHS Trust to finalise site set up. Site activation has unfortunately been slowed due to the latest increases in Covid-19.
- Updating Lifeguide to account for the additional non-clinical community recruitment pathway.