



HIS-UK April Newsletter

What have we achieved so far?

- University Ethics has been submitted
- Members of our research team have registered to attend the BASHH annual conference this summer in Birmingham
- Our Clinical Trials Unit have recruited a Trials Manager, Ye To Ming, who will be starting at the beginning of July
- Site costings are under review by Public Health England
- Professor Rick Crosby, the original developer of HIS at the Kinsey Institute, visited us from the University of Kentucky.

What are we doing now?

- Next month we will be submitting the NHS IRAS form (we are required to obtain University Ethics approval before submitting to IRAS)
- We are currently in the process of organising a Trial Management Committee Meeting (to which all Co-Applicants are invited) for mid-July
- Identification and invitations are to be sent to our Project Advisory Group, Trial Steering Committee and Data Monitoring and Ethics Committee members
- Further development of the website

HIS-UK May Newsletter

What have we achieved so far?

- Ross Nation kindly provided feedback from a PPI perspective on the new website and study PIS.
- We submitted our application to University Ethics and Research Governance. Our study has received sponsorship approval subject to minor amendments.
- Rowena has further developed the study website.
- Nicole, Rowena and Nicky Perry attended the Imperial NHS monthly Research Committee Meeting to discuss the study.
- Wessex CRN have validated the soECAT.
- An application has been submitted to Public Health England to cover the study excess treatment costs.
- Sarah Williams, Associate Director for Research and Improvement, has kindly agreed for Solent NHS Trust to be our lead Research and Development site.

What are we doing now?

- Preparing our application to submit to IRAS.
- We are in contact with EXS and Durex to act as suppliers for the study condom kits.
- Nicole is developing the online intervention on the web based software platform Lifeguide.
- Cynthia will be presenting the HIS-UK study at the BASHH Scientific Meeting at the Royal Society of Medicine in London on 7th June.
- Rowena and Nicole will be attending the BASHH annual conference in Birmingham at the end of June.
- Our first Trial Management Meeting will be held on July 16th at University of Westminster (11-2pm).



HIS-UK June and July Newsletter

What have we achieved so far?

- We welcome Ye To to the team as the HIS-UK Trials Manager.
- Registered for ISRCTN approval.
- Sent TSC and DMC committee member names to be approved by NIHR.
- The TMC meeting took place at the University of Westminster on 16th July. Many thanks to all those that attended.
- Cynthia presented the HIS-UK study at the BASHH Scientific Meeting, Royal Society of Medicine London, on 7th June.
- Rowena attended the BASHH Annual Conference from 30th June - 2nd July in Birmingham.
- We made a Public Health England Application for payment of Excess treatment/intervention costs (ETCs) for research. We should hear the outcome of this within the next two months.
- Our application to Durex for the supply of free condoms and lubricants is currently under review by their internal support board.
- We are still in consultation with EXS as to what supplies they are able to provide free and at discount.

What are we doing now?

- Finalising the IRAS application.
- Waiting on confirmation regarding the assigned NHS research ethics committee.
- Waiting to hear from Public Health England as to whether our application for excess treatments costs has been approved.

- Actively looking for Wave 2 and 3 sites.
- Nicole is finalising the first draft of eHIS to then be sent for testing.



HIS-UK August Newsletter

What have we achieved so far?

- *We have submitted our IRAS application and have booked the Research Ethics Committee (REC) for 8th October in Oxford (South Central Oxford B).*
 - *The next TMC Meeting will be held on Tuesday 10th December at the University of Westminster from 11-2pm. A calendar invitation has been sent.*
 - *Jake Bayley has kindly discussed the trial with teams at Barts and Kings College Hospitals who are both keen to get involved. Thank you Jake!*
 - *We have gained further feedback from our PPI representatives on the eHIS intervention.*
 - *Cynthia, Nicole, and Rowena met with Louise Jackson on the 21st August in Oxford to discuss incorporating health economic based questions into our questionnaire.*
 - *Rowena and Cynthia submitted a progress report to NETSCC.*
 - *Rowena and Cynthia submitted TSC and DMC potential members to NIHR.*
 - *EXS and Pasante have agreed to provide us with discounted supplies of condoms and lubricants.*
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What are we doing now?

- *We are awaiting the outcome of our excess treatment cost (ETC) application to PHE. This fund is currently subject to budget availability and therefore at present the contribution paid by PHE cannot be confirmed until early 2020.*
 - *Waiting to hear from Durex as to whether they will provide us with discounted supplies.*
 - *Preparing for our REC review in October.*
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HIS-UK September Newsletter

Achievements this month

- *The study has been deemed eligible for NIHR Clinical Research Network support.*
 - *myONE condoms have agreed to provide 4500 condoms (two different types) for free.*
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What are we working towards?

- *Preparing for the REC review in October. Rowena, Cynthia, and Nicole will be attending.*
 - *Updating the study information leaflets (as part of the condom and lube kit) and 'business cards' for participants.*
 - *Still awaiting to hear from Durex re. the possibility for discounted condoms and lube. It is required that our protocol be reviewed by a number of committees, including a scientific committee, before a decision is made.*
 - *Still awaiting the outcome of our excess treatment cost (ETC) application to PHE.*
 - *NIHR approved all of our committee nominations, however our intended TSC Chair has declined our invitation. We are therefore in the process of securing a new Chair.*
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HIS-UK October & November Newsletter

Achievements

- NHS Ethical Approval: Cynthia, Nicole, and Rowena attended the REC meeting in Oxford on the 8th October. This meeting went well and only minor revisions were requested. Our re-submission has now been accepted by REC. Due to these revisions, we have also amended our application to the Sponsor Ethics Committee.
- The study is now registered with the ISRCTN.
- Durex scientific review committee reviewed our study and have agreed to provide our requested products free of charge. These include 3 types x 36,700 individually foiled condoms and 2 types x 49,000 lubricants.
- PHE are willing to try and accelerate an initial excess treatment cost payment so that we can begin recruitment for our pilot in January.
- We have received prints of our study advertisements (leaflet, flyer, posters and contact cards) – thank you to all those who provided feedback.
- Cynthia and Rowena attended Hampshire County Council offices in Winchester to discuss the study with Gina Birkett (part of the family information and services hub – teenage pregnancy) and Alice Mooney (Service Manager at No Limits Youth Service – specific interest in sexual health).
- TSC and DMC members have been confirmed.
- We have developed a Lifeguide training resource that guides clinic staff through a mock participant recruitment and screening.
- Imperial have unfortunately withdrawn their participation in the study as a pilot site due to workload constraints.

- Final decisions of the condom and lube brands/types for use in the kit have been made.

What are we working towards?

- Awaiting delivery of the Durex and MyOne condoms.
- Additional condoms and lubes for the kit are currently on order (LTC Healthcare and Pasante).
- The supply of condoms from Durex has resulted in a small change to the Patient Information Sheet (Durex wish to be informed of any adverse events relating to the use of their products). This has resulted in us having to submit an amendment to Ethics, and we are currently awaiting approval.
- Preparing for our site initiation visits.
- We are aiming for the study to commence recruitment in January 2020.
- Intervention randomisation testing will be completed by the end Nov.



HIS-UK December Newsletter

Achievements

- The second Trial Management meeting of the Year took place on the 10th December at the University of Westminster, Regent Street, London. It was great to see so many of you there and to meet new faces!
- On the 13th December, Cindy was interviewed about HIS-UK by the NIHR communication team. During the visit to Southampton, the team were shown the condom kits, intervention, and study website. This is part of a series of interviews that NIHR plan on promoting on their social media channels in the New Year.
- The Sponsor Ethics application amendment has been approved. We have now submitted to REC as a non-substantial amendment.
- The contract with Durex has been finalised. The first shipment (3 types of condom) should arrive in the third week of January.
- Invitations to prospective Project Advisory Committee members have been sent and we have already received letters of acceptance.
- We have received our first order from myONE totalling 4000 condoms to cover the pilot phase.
- We have ordered our first supply of condoms and lubes from LTC Healthcare (EXS and Skyns) and Pasante.

What are we working towards?

- We are aiming to start recruitment in January 2020.
- Preparing for our site initiation visits in January.
- Organising the first Trial Steering Committee meeting.

- Considering possible Wave 2 and 3 sites. It is encouraging that we have already received CRN interest from 10 sites.