Lindus Health Limited
Company Number 13298185

STAMP - PARTICIPANT INFORMATION SHEET (PIS) - UK

Study title:	Screening with Tampons: Evaluating Diagnostic Accuracy for STIs and HPV and Assessing Participant Views (STAMP)
Sponsor:	Tampon Innovations Ltd, a subsidiary of DAYE
Study conducted by:	Lindus Health
Chief Investigator:	Dr John Luke Twelves
Trial Contact Details:	STAMP@lindushealth.com

What is the purpose of this study?

The purpose of this study is to find out whether the DAYE Diagnostic Tampon (DDT) can be used to find out if you have a range of common vaginal infections (HPV, BV, chlamydia and gonorrhoea). It will also compare the DDT to using a standard vaginal swab (self-swab and a swab taken by a female clinician). The trial aims to understand how acceptable using a tampon for this type of testing is for women, what potential barriers there are to using tampons in this way, and how easy they find the tampon to use. It is hoped that by incorporating diagnostic testing into a tampon, more women could find out about infections and get appropriate treatment faster than the way things are done at the moment. The trial aims to recruit 350 women from the UK and Italy, of which 50 will have recently tested positive for HPV.

What are the infections being tested for?

Infection	Description
Human Papillomavirus (HPV)	A common virus that spreads mainly through close skin-to-skin contact, often during sexual activity. Whilst most HPV infections resolve on their own without any treatment certain strains can cause problems such as warts on the skin, genital warts and an increased risk of certain cancers like cervical cancer, throat, mouth, anus, and genital cancers. Regular medical check-ups, screenings, and vaccines can help prevent these serious health problems.
Bacterial vaginosis (BV)	A condition where the bacteria in the vagina is off balance, causing symptoms like odour and discharge. It is not a sexually transmitted infection. It can be treated with antibiotics and may be prevented by taking care of vaginal health.

Chlamydia	A common bacterial infection that spreads through sexual contact. It might not cause symptoms, but if it does, they could include discomfort while peeing or unusual discharge. It's treatable with antibiotics.
Gonorrhoea	A bacterial infection that spreads through sexual contact. It might not cause symptoms, but if it does, they could include discomfort while peeing or unusual discharge, and is treatable with antibiotics.

What is the DAYE Diagnostic Tampon (DDT)?

The DDT is a tampon made entirely from cotton and consists of an absorbent core wrapped in a protective sleeve, and sits in an applicator to aid with insertion. It looks and feels exactly like a normal, regular sized, menstrual tampon that you would use when you are on your period, but has been designed to collect samples from the vaginal canal and should not be used during your period. To do this, the cotton core is wrapped in a protective sleeve to prevent fibre loss but also ensure easy sample collection; you will not feel the protective sleeve. The DDT is a class A device with a CE mark, which is like the gold star for safety and quality in Europe. Class A means it's on the lower-risk side. In a previous study of 60 women, 90% chose the DDT in preference to a clinician taken vaginal swab.

Can I take part?

We are inviting individuals assigned female at birth, aged 25-65, who are sexually active (defined as having penetrative vaginal sex) to participate in this study. Some people invited to the study will already have been recently diagnosed with HPV (based on a recent test). A member of the trial team will check whether you are suitable for the study based on the study eligibility criteria and the data you provide.

Do I have to take part?

Participation in the study is entirely voluntary, and it is up to you to decide if you want to take part. If you do decide to take part, you will be asked to read this Participant Information Sheet (PIS) and then sign the Informed Consent Form (ICF) electronically. If you do not want to take part, and you have recently been diagnosed with HPV, your standard care for your HPV diagnosis will not be impacted. You are welcome to discuss the study, the PIS and the ICF with the trial team, and will be given every opportunity to ask questions. After consenting, you are still free to withdraw at any time, without giving a reason, and without your medical care being affected. Your GP or a study investigator also has the authority to withdraw you from the study if they feel it is appropriate.

What will happen to me if I take part?

Trial Visit/Process	Description
Informed Consent	This form explains what the study involves and the potential risks and benefits of taking part. The trial team will be available to answer any questions you may have. If you are still willing and eligible to take part, you will be asked to provide informed consent by electronically signing a consent form, a copy of which will be provided to you. A trial team member will review your signed form and confirm you are suitable based on the inclusion and exclusion criteria before you are formally enrolled in the trial.
Randomisation	After you are enrolled in the trial you will be randomly allocated to one of two groups. Half of the participants will be allocated to take the self-swab first and then the DDT, and half the participants will take the samples the other way around. This is to test whether the sample order affects how well the DDT detects the infections. Group assignments cannot be changed after randomisation.
Baseline	You will be asked for some information about yourself and your medical history. This information is important as it will be used by the trial team to confirm you can take part in the study. If relevant to you, you will be asked to provide proof of your recent HPV diagnosis. This can be provided by a screenshot of your medical record via your healthcare app or by a recent clinic test result which should be uploaded via a form provided to you online.
Clinic Visit & Sampling	You will be asked to book a clinic visit once you have provided all the baseline information. Clinic visits will (normally) be Monday-Friday during working hours. A trial kit containing the self-swab and DDT will be sent to you in the post in discreet packaging. 24 hours prior to the clinic visit you will use the DDT and perform the self-swab. You should not be on your period when you take these samples, therefore you should book your clinic visit at a time when you know you will not be on your period. At the visit you will have the clinician swab taken by a female trial nurse. You will be sent reminders via email or text of your visit date, and when to complete the DDT and self-swab in the time leading up to the visit.
Questionnaires	Two questionnaires sent to you via email during the trial to collect your views on the samples being taken. You will need access to a computer/tablet/smartphone to complete them and they should take no longer than 10 minutes each to complete.
Focus Groups	As part of the study, we will be conducting focus group discussions to gather

(Optional)	insights and experiences from participants. These are voluntary and we may invite you to participate, but you can decline involvement in these additional groups without affecting your position in the study. These discussions will happen via video conference and be recorded for analysis purposes.
Communication of Results	If you give your consent, you will be informed of the test results directly via email. The results of these tests are experimental and do not replace STI screening or any ongoing national screening programmes (e.g. the cervical screening programme) and you are advised to contact your health provider if you are concerned. If you receive any positive results you will be offered the chance to book a telephone follow-up call with a medically qualified member of the trial team who will be able to offer advice and signpost you to appropriate resources. The email will also provide guidance as to next steps for each of the infections should they show a positive result. Negative results do not rule out the possibility of infection because the tampon sampling method is still experimental. Medical advice should be sought if there are symptoms suggestive of a sexually transmitted infection. If you are concerned about any of the results or require further information you can use the following resources to find out more and access support: ● https://www.nhs.uk/live-well/sexual-health/where-can-i-get-sexual-health-advice-now/ ● https://www.jostrust.org.uk/information/hpv/what-is-hpv ● https://www.bashh.org/public/public-and-patient-information/

The total duration of your study participation should last around 2-4 weeks, depending on the timing of your clinic visit.

What samples will be taken?

You will have three different samples taken as part of this study. Everyone taking part will have the same samples taken. The DDT and self-swab will be used at home. The samples should be taken in the order specified in the instruction booklet that came with your trial kit. This order is determined by the randomisation done when you were enrolled in the trial. You must leave 1 hour between taking the samples. This is to prevent the collection of the first sample impacting on the second one. Detailed instructions on how to take these samples will be provided in the trial kit, as well as a spare swab and DDT just in case. The other sample (clinician swab) will be taken at the study clinic visit by a female trial nurse. All of the samples taken as part of the trial should cause minimal discomfort, but if you are concerned you should contact the trial team, or your doctor.

Sample	When should you take it?	How should the sample be taken?	Other information
DAYE Diagnostic Tampon (DDT)	At home, 24 hours prior to your clinic visit	You should use the DDT 24 hours prior to the clinic visit. The tampon should be inserted into the vaginal canal using the provided applicator. You should not have your period when you use the DDT. The DDT should be worn for at least 20 minutes and then be removed and immediately placed in the sterile container provided.	The DDT should be taken to the clinic visit with you and handed over to the female trial nurse at the visit.
Vaginal Self-Swab	At home, 24 hours prior to your clinic visit	You should perform the self-swab 24 hours prior to your clinic visit. You should insert the swab into your vagina and rotate it three times to collect a sample. After removal, the swab will be placed in a sterile container.	The self-swab should be taken to the clinic visit with you and handed over to the female trial nurse at the visit
Clinician Vaginal Swab	The female trial nurse will take this at the clinic visit	The swab will be collected by the female trial nurse by inserting a swab into the vaginal canal, rotating it three times, and then placing it in a sterile container.	You will be able to ask for a chaperone whilst the swab is being performed if it would make you more comfortable.

Expenses and payments

You can receive £50 as financial compensation for taking part in this research study. The payment will be made to you once all study activities have been completed, i.e. once all samples have been taken and all questionnaires have been filled in. Reasonable travel expenses will also be reimbursed up to a maximum of £50 and you should keep a record of your tickets/receipts where possible. Additional expenses may be available in cases where a participant is unable to use public transport (e.g. for medical reasons). If you participate in the focus group there will be additional compensation.

What are the possible benefits of taking part?

You will not benefit directly from taking part in this study, but the results of this trial may result in women having access to an easier, more convenient method of testing for HPV, BV and chlamydia and gonorrhoea in the future.

What are the possible disadvantages and risks of taking part?

No significant risks are anticipated, as the DDT and the other sampling methods are not expected to cause any side effects. If you do experience any untoward events or symptoms you should report these to the trial team and your Doctor. You should ensure you only wear the DDT for the time indicated in the instruction booklet, and for no longer than 4 hours to minimise the rare risk of Toxic Shock Syndrome (TSS). TSS is a rare but serious condition that can occur when certain bacteria produce harmful toxins in your body. It can be associated with tampon use, and can lead to symptoms like high fever, low blood pressure, a rash, and problems with organs like the liver and kidneys. If not treated promptly, it can be life-threatening. It's crucial to be aware of the symptoms, especially when using tampons, and seek medical help if you suspect TSS. Completing the questionnaires will take time, but these have been designed to be as short as possible and easy to access online.

What if I start to experience side effects or a medical event?

If you have a side effect or medical event from the DDT, self-swab or clinician swab please seek suitable help from your usual medical provider contact. **NOTE: Please call 999 if you are having a medical or mental health emergency.** Once you have sought appropriate medical help please could you contact the trial team to report any information you think we should be aware of via phone or email. If you become pregnant you should tell the trial team and your Doctor straight away and you will be withdrawn from the study.

Will my taking part in the study be kept confidential?

People allowed to look at your health information will be limited, to include the trial team, the sponsor and the regulatory authorities who check that the trial is being carried out to legal and ethical standards. On joining the trial you will be given a unique ID number and this will be used to label their study information and samples so your name does not appear with your samples, questionnaires or other results. Your identity will not be revealed in the results or any publications.

What if relevant new information becomes available?

Sometimes new information becomes available about the product used in a study while the trial is ongoing. If new information becomes available, we will notify you. The relevant ethical authorities will also be informed and the study may be stopped or changed if appropriate. If the information sheet changes significantly, you will be asked to read the new information sheet and sign another

consent form. You will have the opportunity to discuss these changes with the Lindus Health team and ask any questions.

What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time, without giving a reason, and this will not affect the standard of care you receive or your legal rights. If you decide to withdraw, or are no longer able to consent, we will still use all the data collected up to the time of your withdrawal. This means that all the questionnaires that you have submitted will be analysed.

What if there is a problem?

Complaints

If you have any concerns about any aspect of this study, you can contact STAMP@lindushealth.com, and any complaint, or any possible harm you might suffer, will be addressed.

Am I covered by insurance?

In the unlikely event that you become ill or are injured as a result of taking part in this study, you will be covered by insurance held by the Sponsor. Compensation will be provided for any injury caused by taking part in this study, in accordance with guidelines of the Association of the British Health Tech Industries (ABHI). We will pay compensation where the injury has resulted from:

- A product being administered as part of the trial protocol; or
- Any test or procedure you received as part of the trial.

Any payment would be without legal commitment (please enquire if you would like more information on this). The Sponsor would not be bound by these guidelines to pay compensation where:

- The injury resulted from a drug or procedure outside the study; or
- The study procedures were not followed.

In the unlikely event that something does go wrong and you are harmed during the research due to someone's negligence, then you may have grounds for legal action for compensation. In this case, you may have to pay your legal costs. If you wish to make a claim against this insurance you should talk to the Lindus Health team.

This study should not affect your health, but if you have private insurance you should check with your insurance company before agreeing to take part in the study, to ensure that your participation will not affect your medical insurance.

What will happen to the samples I give?

The sample you give as part of the study will only be used for the purposes of this research. Once the samples have been successfully analysed they will be destroyed. If you provide consent, the samples you provide as part of the trial will be processed to extract a sample of DNA or RNA. DNA, which stands for deoxyribonucleic acid, is like the instruction manual for living things. RNA is a nucleic acid similar to DNA, which plays a key role in turning DNA instructions into functional proteins. The DNA or RNA extracted will be anonymised and stored for use in future ethically approved research projects. These projects will not be designed to diagnose or provide information about specific genetic conditions for individual participants. The remaining sample will be systematically and irreversibly destroyed.

How will we use information about you?

We will use information from you, and your GP for this research project.This information will include your:

- Name and Initials
- Date of birth and/or age
- Contact details
- Medical history

This information will be used to conduct the research, or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. You will also consent to share your name and contact details with third parties. These third parties will be vendors and parties who require your details for the logistics of trial conduct (e.g. sending trial kit). This data will only be shared for the duration of the study. Once the study is finished, we will keep some of the data so we can check the results. We will write our reports in a way that prevents all participants from being identified.

What are your choices about how your information is used?

You can stop taking part in the study at any time, without giving a reason. In this case, the information collected up until that point will still be used.We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information from the following places:

- Online, at www.hra.nhs.uk/information-about-patients/
- Our leaflet available from www.hra.nhs.uk/patientdataandresearch
- By asking one of the research team
- By sending an email to: STAMP@lindushealth.com
- By ringing us on: 0808 189 3802

Other information about your data

Your data will be handled, processed, stored and destroyed in accordance with the Data Protection Act of 2018. We will keep identifiable information about you for up to 12 months after the trial has finished. This doesn't include any research documents with personal information, such as consent forms, which will be held securely for 10 years after the end of the study.Lindus Health may also retain personal data for business improvement purposes. For example, use of behavioural data to make feature improvements to the Electronic Data Capture platform.

Involvement of the General Practitioner/family doctor (GP)

Your GP will be informed about your participation in the study. Your GP will be contacted as a safety precaution, and we advise that you contact your GP if you experience any medical problems during or shortly after the study period. If you have consented, we will also notify your GP of any positive test results, but this is optional. You will be advised to contact your GP if you receive a positive result for any of the infections so that they can advise you on next steps (which may include repeat testing) and any required treatment.

What will happen to the results of the research study?

The results and findings may be published in scientific papers and presented at meetings. Your identity will not be disclosed in any of these, nor will any information that could identify you as a participant in this study. If you wish, we can notify you if an article based on the results of this study is published. We will also release a plain English summary of the trial results.

Who is organising and funding the research?

This study is sponsored and organised by Tampon Innovations Limited and conducted by Lindus Health. The Chief Investigator is Dr. John Luke Twelves.

Who has reviewed the study?

This study has received a favourable opinion from the London - Camberwell St Giles Research Ethics Committee Research Ethics Committee.

Further information and contact details

If you require further information about taking part in a clinical study, the following link can assist you. It provides information about how clinical trials are run, and what to expect if you take part in a trial: http://www.nhs.uk/conditions/Clinical-trials/Pages/Introduction.aspx

If you would like to know more about this study, or if you have any questions, you can contact the study team. Study team contact details:

- **Email**: STAMP@lindushealth.com
- **Phone:** 0808 189 3802

If you would like advice about whether you should participate in the study, you may want to contact your GP surgery or the study team. It is often useful to discuss the study with your friends and family. Thank you for reading this information sheet, and for considering taking part in the study.