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The SunPad Study

PARTICIPANT INFORMATION SHEET – PILOT STUDY

Version 1.5 dated: 23/10/2025

We would like to invite you to take part in The SunPad Study, a research study which is led by Cardiff University (United Kingdom), in collaboration with Global Action Nepal (GAN) and Tribhuvan University, Nepal. This Participant Information Sheet tells you the why the research is being done and what will happen if you take part.

If you have any questions or would like to discuss taking part please speak to the researcher, email: sunpad@gmail.com or phone ********. Joining the study is entirely up to you.

Study overview: Our team has developed washable menstrual pads which kill bacteria and other microorganisms when dried in natural daylight. We are developing these menstrual pads to reduce the risk of urinary and reproductive tract infections. In this study, we want to find out whether the pads work effectively outside of a laboratory environment, when used by women living in Nepal. We are looking to recruit 70 participants into a randomised controlled trial. Thirty-five of the participants will be allocated to receive SunPad and 35 will be allocated to receive a standard menstrual product. These products are identical in appearance, and product care, and you will not know which trial arm you have been allocated to. Over the following six months researchers will collect monthly data from you and on completion of the six months the researchers will collect your used liners and send them to the laboratory for analysis. The aim is to see whether SunPad is more effective at killing bacteria and other microorganisms than its uncoated counterpart.

How do the pads work? Are they safe? The pads are coated with a thin layer of minerals ("titanium dioxide"), which react with water and oxygen when exposed to **daylight**. This reaction kills microorganisms and may also reduce stains and odours. Titanium dioxide is used in many products, including tampons, toothpaste, medicines and foods. As the coating requires light to work, the reaction does not happen when the pads are being worn. Prior to this study, the pads were tested to an international safety standard (ISO10993-5, ISO10993-23, and ISO10993-10) and confirmed as non-toxic, non-irritating and safe to use.

What will taking part involve? You will be allocated at random to use either SunPad or a standard reusable pad for six months (with a 50/50 chance of allocation to either SunPad or standard reusable pad). During these six months you will be asked to follow the washing and drying instructions provided, you will document your experiences using a daily diary (throughout your menstrual cycles only) and each month you will have a follow-up appointment with a researcher who will input your experiences into a database. At the end of the six months, you will return the pads for laboratory analysis. At the end of your involvement, you will received new standard menstrual liners to replace those you have donated.

Study setting: Kaski District, Nepal. (Reevan (ward no.5) and Batulechaur (ward no. 16)).

Study duration: The study has been funded since 1st January 2024 and the funding ends on 30th September 2026. It is anticipated that recruitment for this work package will start in at the end of 2025 / beginning of 2026, participants will be involved for six months.

Participants: We are looking for 70 people who currently use washable menstrual pads to participate in this study.

Inclusion criteria:

- currently using washable menstrual health pads
- able to provide informed consent
- agree to follow recommended instructions regarding cleaning and drying processes for the pads
- willing to provide information regarding experience and satisfaction using the pads throughout the study
- has access to a mobile phone

- willing to return the pads for laboratory analysis
- menstruators 18 years old or over

Exclusion criteria:

- had a baby less than six weeks ago
- pregnant
- breastfeeding
- under 18 years old
- unable to engage in study processes (e.g., unwilling to dry the pads outside, uncovered (in natural daylight))
- identified as known or suspected to be experiencing urinary/reproductive infection at time of study initiation
    - A need to urinate more often than usual
    - Pain or discomfort when urinating
    - Sudden urges to urinate
    - Feeling as though the bladder is unable to be emptied fully
    - Lower abdominal pain:
    - Urine that is cloudy, foul-smelling or contains blood
    - Abnormal discharge
    - Lower back pain (kidney) coupled with other symptoms
- known to be experiencing menorrhagia (abnormally prolonged/heavy menstrual bleeding).

Note: in the case of suspected urinary/reproductive tract infection, prospective participants will be provided with information on where to seek confirmatory diagnosis and treatment (e.g., nearest community health post).

Consent process: If you would like to take part in this pilot study you will need to provide informed consent. This will be collected by the researcher from GAN. You can refuse to participate in the study at any time without giving a reason and this will not impact your current or future care. Paper-based consent forms will be securely stored at GAN and one copy will be given to you.

Study process: On expressing an interest in participating in this research study you will meet a researcher from GAN, who will go through the study with you, confirm eligibility and obtain informed consent. Then the researcher will go through a questionnaire with you gathering information on you,

and information about your experience of using washable menstrual pads. Once complete you will be provided with a randomly allocated pack which will contain three pad holders (shields), 16 absorbent fabric liners, a storage bag, and guidance on how to wash, dry and care for the menstrual product, ziplock bags and soap. You will also be given diaries to keep daily records of your menstruation, number of pads used, the weather and any issues you encountered. These diaries can be used as a reminder to help complete the follow up questionnaires which will be administered by a researcher over the telephone or face to face at the end of each cycle.

Participants will be followed up for six months. At the end of the study, you will bring your pads back to an agreed collection point in a discreet bag so they can be sent to the laboratory to be analysed for microbial and protein contamination by the research team. There will be an additional questionnaire which will capture your experiences of using the pads and overall feedback. You will be given new standard menstrual liners as a thank you for returning your used liners.

Benefits of taking part: Your input will contribute to improved menstrual pad development which aims to improve menstrual hygiene and health. You will be given eight new liners as a thank you for returning your used pads.

Risks of taking part: Potential risk or direct harm is extremely unlikely. It may be uncomfortable to talk about some of the more personal issues surrounding menstrual product use. If at any time you are experiencing emotional distress during the study, you can stop. SunPad has passed irritation, sensitisation and toxicity testing and has been piloted in-person in the UK, however if you experience any irritation during use, please stop using the product and get in touch with your study contact.

Withdrawal: If you wish to withdraw from the study, you can at any time without providing a reason and this will not impact the service or care you currently receive. Please note if you decide to withdraw, and request that your data collected to date is not used in analysis that this will only be possible within the data collection timeframe. It may not be possible after this time point, and any data collected up to this point may be continued to be used as per the consent process. Please note that a withdrawal form will need to be completed.

Study results: Will be published in high calibre journals, available on institutional/University websites, and presented at meetings. All data will be reported in an aggregate form which will not identify any individual participant.

Data Privacy / Confidentiality Statement: Records identifying you will be kept confidential and will not be made publicly available. If the results of the study are published, your identity will remain confidential. Any sensitive information (data containing personal information) will not be transferred outside of GAN and will be securely stored in accordance with company policies and procedures. Anonymised data collected will be shared with Cardiff University and may be used in other research in the future. Any quotes and data used in publications will not be identifiable.

Samples from used menstrual liners be analysed anonymously for bacteria and protein content at Tribhuvan University. The data and the samples from this analysis will be shared with Cardiff University. Samples shared with Cardiff University undergo a cleaning process and will not contain any human cells.

Who has reviewed this study?: This study has been reviewed and given favourable opinion by Research Ethics Committee at the School of Medicine Research Ethics Committee at Cardiff University (reference: 23/94) on 21st November 2025 and Ethical Review Board of Nepal Health Research Council, Ramshahpath, Kathmandu (Ref. ……..).

Further information: If you require any further information or have any concerns, please email the study manager (sunpad@cardiff.ac.uk) or if you would prefer, please contact the Chief Investigator Dr Jennifer Edwards (EdwardsJK@cardiff.ac.uk)

If you have a concern this study, you should ask to speak to the researchers (sunpad@gmail.com or phone ***). Dr. Megha Raj Banjara and Dr. Dev Raj Joshi at Central Department of Microbiology, Tribhuvan University, Kathmandu, Nepal (Phone: 01 4331869) or Global Action Nepal, Lalitpur (Phone:……..). If you remain unhappy and wish to complain formally, you can do this by contacting the research team at Cardiff University: sunpad@cardiff.ac.uk or the lead organisation representative at Cardiff University: resgov@cardiff.ac.uk

Insurance: Cardiff University, United Kingdom maintains insurance to meet the potential legal liability of the lead organisation for harm to participants arising from the management of the research.

Funding: Cardiff University has received funding to conduct this research from the Bill & Melinda Gates Foundation, the grant number is: INV-048434.

Thank you for reading this information.