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Field testing safe, reusable menstrual health products in Nepal

Submission date 12/01/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 26/01/2026	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 11/02/2026	**Condition category** Other	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

This study is a comprehensive field test of safe, reusable menstrual health products with material developed by the Cardiff University (CU) team in areas where access to clean water is limited, to validate the effectiveness of our technology in the field. This work package will work out whether it is possible to conduct a large-scale study where women are allocated at random (i. e. by chance) to SunPad coated liners or liners without the SunPad coating. Following completion of this WP, there will be an understanding of how the reusable menstrual product works within Kaski District, Nepal, what some of the challenges of implementation of such products within this community are, and how best to conduct a larger study across different areas of Nepal.

Who can participate?

Adults females currently using washable menstrual health pads.

What does the study involve?

Participants will be randomly allocated to receive a standard reusable menstrual kit (containing liners without SunPad coating) and to receive a SunPad reusable menstrual kit (containing liners with SunPad coating). All participants will be followed up for six months and at the end of the study and all liners will be collected. Feedback will be obtained on their experiences and thoughts. The liners will be analysed in the laboratory to determine whether there may be important differences in the quantity and types of bugs (microorganisms) between those who use SunPad coated liners and those that use standard liners. All participants will be provided with replacement liners at the end of the study.

What are the possible benefits and risks of participating?

Benefits and risks not provided at time of registration.

Where is the study run from?

Cardiff University, UK.

When is the study starting and how long is it expected to run for?

January 2026 to September 2026

Who is funding the study?
Gates Family Foundation, USA.

Who is the main contact?
Rebecca Milton, MiltonRL1@cardiff.ac.uk

Contact information

Type(s)
Principal investigator, Public, Scientific

Contact name
Ms Rebecca Milton

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Additional identifiers

Study information

Scientific Title
Field testing safe, reusable menstrual health products in Nepal

Acronym
SUNPAD

Study objectives
To understand prototype field performance within the target setting, the challenges of implementation of such products within target communities and how to conduct a large-scale study of the implementation of these products across communities in Nepal.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 21/11/2025, School of Medicine Research Ethics Committee at Cardiff University (School of Medicine UHW Main Building Heath Park, Cardiff, CF14 4XN, United Kingdom; -; Medic_REC@cardiff.ac.uk), ref: 23/94

2. approved 07/01/2026, Nepal Health Research Council (Ramshah Path, Kathmandu, Nepal P.O. Box 7626, Kathmandu, P.O.Box 7626, Nepal; +977-1-5327460; nhrc@nhrc.gov.np), ref: 517 - 2025

Primary study design

Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Health services research

Study type(s)

Health condition(s) or problem(s) studied
Menstrual Health

Interventions
The intervention, SunPad reusable menstrual pads, will be evaluated through a comprehensive field test of safe, reusable menstrual health products with material developed by the Cardiff University (CU) team in areas where access to clean water is limited, to validate the effectiveness of the technology in the field. The SunPad product will be a reusable menstrual pad made with material developed by the CU team. The reusable product will be comprised of a similar fabric to what is currently used in existing Days for Girls-type menstrual care kits (cotton flannel), which will be treated with the PAC coating developed by the CU team. Prior to enrolment, there is confirmation that the product meets ISO10993 requirements, which demonstrates that the pads have passed cytotoxicity (ISO10993-5), vaginal irritancy (ISO10993-23), and sensitisation (ISO10993-10) tests. This aligns with the Technical Specifications of Reusable Menstrual Pad issued jointly by UNFPA/UNICEF/UNHCR. The intervention product is a cotton liner impregnated with non-toxic metal/metal oxide Photo Active Catalysts (PACs) capable of reducing organic load and microbial pathogens using daylight.

Participants will be randomly divided into one of two groups. One group will receive a menstrual care kit, which includes a storage bag, 16 liners, three shields (pad holders), a plastic zip lock dry bag, soap, user instructions and a daily diary. The other group will receive the same menstrual care kit but with uncoated liners. Assuming an average menstrual period of five days, each product may go through up to 20 wear-wash-dry cycles. Instructions will involve a combination of written and pictographic information, with an emphasis on drying the product in direct daylight.

A parallel groups individually randomised controlled pilot trial will be conducted, with participants randomly allocated (1:1) to receive either SunPad or uncoated reusable menstrual pads. Participants will be followed up for six months. Allocation concealment will be maintained through a centralised randomisation process developed in CU, using sequentially numbered anonymised “Pack IDs” without revealing the allocation to those recruiting, participating or analysing data. This process also maintains blinding.

The intervention will be delivered by fully trained field researchers who have been working on SunPad and for Global Action Nepal for some time. They have both received training from the CU team on this work package and have access to training resources and direct contact with the team at CU as and when required. The mode of delivery will be face-to-face, with participants meeting the researchers on an individual basis for recruitment.

Both research sites, rural and urban, are the location of women's groups, so are known by the participants as this is where they would have been when they learnt about the research opportunity. The researchers will travel to these sites at pre-arranged time points to recruit and distribute the intervention product. The intervention will be delivered once, at the beginning of this work package, and participants will use the intervention and standard products for six months during the study follow-up period.

A total of 70 participants will be recruited. As this is a pilot study, the team will not be testing any hypotheses and will instead focus the analysis on estimation. For outcomes where the estimate is a proportion, it will be possible to calculate a 95% confidence interval around the estimate to within +/- 12.2%. Global Action Nepal (GAN) field researchers will recruit 70 participants from the Kaski district of Nepal, with 35 from a rural area (ward 5) and 35 from an urban location (ward 16). Participants must meet the eligibility criteria and provide informed consent prior to enrolment. Randomisation will be based on randomly permuted blocks, stratified by ward. Menstrual kits will be identical in appearance and labelled centrally with sequential "Pack IDs", maintaining blinding and allocation concealment. Blinding will additionally be maintained by standardising washing and drying instructions across arms and ensuring that both SunPad and uncoated liners have no discernible features.

The study outcomes will:
• Determine levels of satisfaction of the SunPad product among its users, compared to the control product
• Obtain feedback on product quality and use, as well as offer the opportunity to provide recommendations
• Determine microbial bioburden of the SunPad product compared to the control product and establish antibiotic susceptibility profiles (Tribhuvan University)
• Estimate the proportion of PAC retained on the SunPad product (CU; shipped after sterilisation and decellularization protocols that do not interfere with PAC physicochemical integrity)
• Determine de-staining and de-odourising of SunPad, compared to the control product
• Microbiological, PAC retention, de-staining, and de-odourising data will be compared against self-reported number of uses and other process measures, collected via the questionnaire at final follow-up.

Used SunPad liners and standard reusable liners will be collected by the research team in GAN and sent to the Central Department of Microbiology, Tribhuvan University, Kathmandu for analysis. The following analyses will be conducted on liners from each participant:
• Enumeration of bacteria and fungi
• Identification of bacteria and fungi via numerous techniques including staining, growth on selective media and biochemical reaction tests
• Antibiotic susceptibility of selected bacteria
• Total DNA extraction and 16S rRNA sequencing from selected bacteria
• Specific antibiotic resistance genes and virulence genes will be quantified by polymerase chain reaction (PCR)
• Metagenomic analysis of recovered microorganisms for community analysis
• Total protein quantification

• Haematin quantification Microbial analysis
• TVC of pooled samples
Participants will be followed up on monthly for six months and all liners will be collected at the end of participant involvement.

Furthermore, we will also begin exploring the feasibility and acceptability of study measurement processes. We will also collect data on:
• Product use (e.g. how often it was used; how often it was changed for another product; how easy products were to use etc.)
• Product cleaning and drying (e.g. how it was cleaned and dried; timing of cleaning and drying, storage of product, how this differs from normal use of previously used products)
• Menstrual bleeding (including frequency, flow and duration)
• Usual product cost (i.e., what is affordable? Does the fact that the product is free influence participants' choice or view on the product?)
• Satisfaction of the product (look, ease of use) as assessed by survey data
• User feedback on product quality and use
• User feedback on the guidance and instructions
• User feedback on staining
• User feedback on odour
• Any concerns or conditions they may have experienced.
These data will be collected via a questionnaire administered face-to-face or over the telephone by a member of the GAN research team.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
SunPad

Primary outcome(s)
1. Enumeration of bacteria and fungi: Total bacterial load from each liner following 6 months of use measured using the growth of extracted material on agar and presented as colony-forming units (CFU)/cm2 at one time point

2. Identification of bacteria and fungi isolated from each pad after 6 months of use measured using Gram staining (Gram positive/Gram negative), growth on selective agar (positive/negative outcome) and a variety of biochemical reaction tests (positive or negative reaction) at one time point

3. Antibiotic susceptibility of selected bacteria, defined by the European Committee on Antimicrobial Susceptibility Testing (EUCAST) measured using the European Committee on Antimicrobial Susceptibility Testing (EUCAST) protocol at one time point

4. Taxonomic identification (genus, species of bacteria) and alpha (diversity within a sample) and beta diversity (diversity between samples) measured using Total DNA extraction and 16S rRNA sequencing at one time point

5. Quantification of antibiotic resistance genes and virulence genes measured using polymerase chain reaction (PCR) at one time point

6. Gene and taxon abundance profiles of the microbes present in the community (eg isolated from each pad) measured using Metagenomic analysis of recovered microorganisms at one time point

7. Total protein burden on each pad will be determined after 6 months of use measured using the BCA protein quantification method and measured as mg/ml at one time point

8. Haematin quantification in the menstrual blood on each pad at 6 months measured using the alkaline haematin method and expressed as g/dL of haemoglobin at one time point

9. Microbial analysis: The total viable count (all bacteria and fungi) of pooled samples measured using growth on agar and expressed as (CFU)/cm2 at one time point

10. The feasibility and acceptability of study measurement processes: Product use (e.g. how often it was used; how often it was changed for another product; how easy products were to use etc.), product cleaning and drying (e.g. how it was cleaned and dry; timing of cleaning and drying, storage of product, how this differs from normal use of previously used products), menstrual bleeding (including frequency, flow and duration), usual product cost (i.e., what is affordable? Does the fact that the product is free influence participant's choice or view on the product?), satisfaction of the product (look, ease of use) as assessed by survey data, user feedback on product quality and use, user feedback on the guidance and instructions, user feedback on staining, user feedback on odour, and any concerns or conditions they may have experienced measured using a questionnaire administered face-to-face or over the telephone by a member of the GAN research team at one time point

Key secondary outcome(s))

Completion date
30/09/2026

Eligibility

Key inclusion criteria
1. Currently using washable menstrual health pads
2. Able to provide informed consent
3. Agree to follow recommended instructions regarding cleaning and drying processes for the pads
4. Willing to provide information regarding experience and satisfaction using the pads throughout the study
5. Has access to a mobile phone
6. Willing to return the pads for laboratory analysis
7. Menstruators 18 years old or over

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Had a baby less than six weeks ago
2. Pregnant
3. Breastfeeding
4. Under 18 years old
5. Unable to engage in study processes (e.g., unwilling to dry the pads outside, uncovered (in natural daylight))
6. Identified as known or suspected to be experiencing urinary/reproductive infection at time of study initiation
6.1. A need to urinate more often than usual
6.2. Pain or discomfort when urinating
6.3. Sudden urges to urinate
6.4. Feeling as though the bladder is unable to be emptied fully
6.5. Lower abdominal pain:
6.6. Urine that is cloudy, foul-smelling or contains blood
6.7. Abnormal discharge
6.8. Lower back pain (kidney) coupled with other symptoms
7. known to be experiencing menorrhagia (abnormally prolonged/heavy menstrual bleeding)

Date of first enrolment
01/01/2026

Date of final enrolment
28/02/2026

Locations

Countries of recruitment
Nepal

Sponsor information

Organisation
Cardiff University

ROR

https://ror.org/03kk7td41

Funder(s)

Funder type

Funder Name
Gates Family Foundation

Alternative Name(s)
Gates Foundation, FUNDACIÓN DE LA FAMILIA GATES, Fundación Gates, GFF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.5	23/10/2025	15/01/2026	No	Yes
Protocol file	version 1.1	11/11/2025	15/01/2026	No	No