sunpad

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THE SUNPAD STUDY

A PROTOCOL FOR WORK PACKAGE 3.3B: FIELD TESTING SAFE, REUSABLE MENSTRUAL HEALTH PRODUCTS IN NEPAL

PROTOCOL V1.1 DATE 11/11/2025

Lead organisation	**Cardiff University**
CTR reference	**1563**
Funder:	**Bill and Melinda Gates Foundation**
Funder ref:	**INV-048434**
REC ref:	**23/94**
Q-Pulse Template Number:	**TPL/003/2**

Signature page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the relevant study regulations, GCP guidelines, and CTR's SOPs.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the lead organisation, Cardiff University's Research Governance team.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Director:	
Name	Dr David Gillespie
Signature	
Date	
Chief Investigator:	
Name	Dr Jennifer Edwards
Signature	
Date	

General Information

This protocol describes The SunPad study and provides information about the procedures for entering participants into the study. The protocol should not be used as a guide, or as an aide-memoire. Every care has been taken in drafting this protocol; however, corrections or amendments may be necessary. These will be circulated to the known Investigators in the study. Problems relating to the study should be referred, in the first instance, to CTR.

Contact Details – Chief Investigator/s, Co-Investigator/s and Study Team Members

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Study Co-ordination:

The SunPad Study work package 3 (WP3) is being coordinated by the Centre for Trials Research (CTR), Cardiff University, a Clinical Research Collaboration (UKCRC) registered trials unit. This protocol has been developed by The SunPad Study Management Group (SMG) for WP3. For **all queries** please contact The SunPad team through the main study email address sunpad@cardiff.ac.uk Any scientific queries will be directed through the Study Manager (miltonrl1@cardiff.ac.uk) to either the Chief Investigator or Co-Investigators.

Scientific and product queries:

Scientific and product queries **sunpad@cardiff.ac.uk** **All scientific queries will be directed to the most appropriate study member.**

Contents

Glossary of Abbreviations

AE	Adverse Event
AR	Adverse Reaction
CF	Consent Form
CI	Chief Investigator
CRF	Case Report Form
CTR	Centre for Trials Research
CTU	Clinical Trials Unit
CU	Cardiff University
DCF	Data Clarification Form
GAN	Global Action Nepal
GCP	Good Clinical Practice
IC	Informed consent
IEC	Independent Ethics Committee
NGO	Non-Government Organisation
PAC	Photo Active Catalysts
PID	Participant Identification
PIS	Participant Information Sheet
QA	Quality Assurance
R&D	Research and Development
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SMG	Study Management Group
SOP	Standard Operating Procedure
TMF	Trial Master File
UGO	Urogenital Infections
WP	Work Package

1 Amendment history

The following amendments and/or administrative changes have been made to this protocol since the implementation of the first approved version.

Amendment No.	Protocol version no.	Date issued	Summary of changes made since previous version
1	1.1	1.1	1. Change project timelines to extend to 30/09/2026 2. Change study design on WP3.3b from observational study to randomised controlled trial and reduce follow-up to six months from nine months, as per funder request. 3. Amend associated objectives and outcomes to meet updated 3.3b design. 4. Add exploratory analysis detail surrounding virus extraction. 5. Add soap and a third shield to the kit for WP3.3b. 6. Ethical amendment date update.

2 Synopsis

Short title	The SunPad Study WP3.3b: Field testing safe, reuseable menstrual health products in Nepal
Internal ref. no.	1563
Funder and ref.	The Bill & Melinda Gates Foundation
Study design	Parallel groups individually randomised controlled pilot trial
Study participants	• 70 experienced reusable menstrual pad users.
Planned sample size	• 70 experienced reusable menstrual pad users.
Planned number of sites	• Two sites within the Kaski District, Nepal (one rural, and one urban) (Reevan (ward no.5) and Batulechaur (ward no. 16)).
Inclusion criteria	• Currently using reusable menstrual health pads • Able to provide informed consent • Agree to follow recommended instructions regarding cleaning and drying processes for the product • Willing to provide information regarding experience and satisfaction using the product 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 product uncovered in direct daylight) • Identified as known or suspected to be experiencing urinary/reproductive infection at time of study initiation (pain with urination, cramping, abnormal discharge. Symptoms could include: i. A need to urinate more often than usual ii. Pain or discomfort when urinating iii. Sudden urges to urinate iv. Feeling as though the bladder is unable to be emptied fully

	v. Lower abdominal pain: vi. Urine that is cloudy, foul-smelling or contains blood vii. Abnormal discharge viii. Lower back pain (kidney pain) 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).
Treatment duration	N/A
Follow-up duration	• Six months
Planned study period	9 months (from first participant being recruited to final participant completing final follow-up)
Overall study objective	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.
Work package specific objectives	• To determine the bacterial load on SunPad coated liners compared to identical uncoated menstrual liners over a 6-month period. • 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.
Work package specific outcomes	• 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 (Cardiff University; 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.

3. Study summary and timeline

3.1 Gantt chart

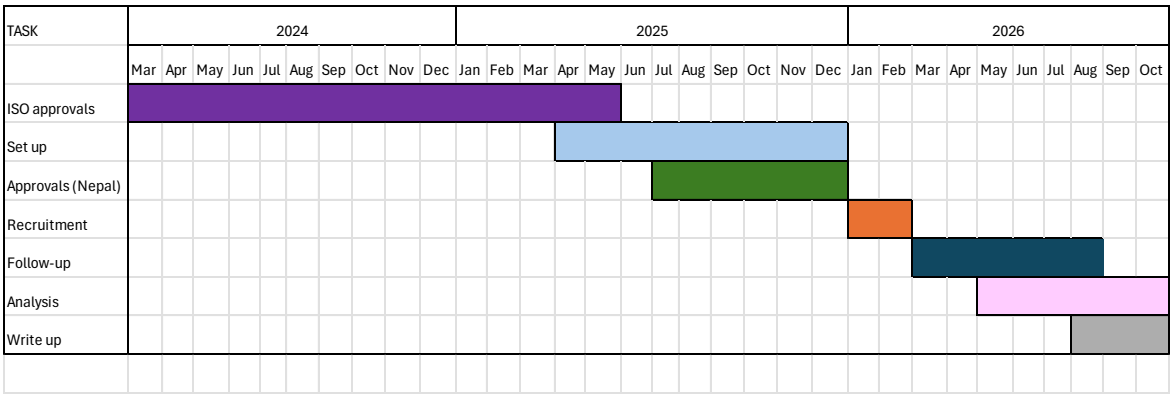

Figure 1 Gantt chart

3.2 Summary

We will conduct 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. Within this work package we 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. We aim to recruit 70 participants and randomly allocate 35 to receive a standard reusable menstrual kit (containing liners without SunPad coating) and 35 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 we will collect all liners. We will obtain feedback 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.

Following completion of this WP, we will understand 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.

4 Background and rationale

Over half a billion women and girls worldwide lack what they need for menstrual care. Use of improperly sanitised products, including pads and napkins, seriously increases the risk of urogenital infections (UGOs); as well as causing discomfort, UGOs are associated with negative health and social outcomes, including school/employment absence and miscarriage. In Nepal, up to half of female agricultural workers are estimated to be experiencing urogenital infections at any given time[1].

The aim of the initial research was to "*…produce a fabric impregnated with non-toxic metal/metal oxide Photo Active Catalysts (PACs) capable of reducing organic load and microbial pathogens using sunlight."*

Based on the progress in the initial funding stream (BMGF INV-048434) School of Chemistry Cardiff University have produced prototype fabrics that can be incorporated in the fabric of a reusable menstrual product, providing microbicidal disinfection in the absence of sanitary water and disinfectant products.

Within this phase of funding (WP3) there are three separate WPs. This protocol focuses on WP3.3b, WP3.3b: Pilot Study: Conduct a randomised controlled pilot trial to determine the bacterial load on SunPad coated liners compared to identical uncoated menstrual liners over a 6-month period. Participants will be experienced reusable users living in two locations (urban and rural) within the Kaski District, Nepal. We aim to recruit 70 participants and randomly allocate 35 to receive a standard reusable menstrual kit and 35 to receive a SunPad reusable menstrual kit. All participants will be followed up for six months and at the end of the study we will collect all liners. Participants have microbiology and process data collected over six months. Following completion of this WP, we will understand 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. All participants will be provided with replacement liners at the end of the study. This work is to primarily confirm replication of laboratory findings within two community settings in Nepal (one rural and one urban), rather than focus on real-world implementation.

Prior to this, we have confirmation that our product meets ISO10993 requirements, which demonstrates that our pads have passed cytotoxicity (ISO10993-5), vaginal irritancy (ISO10993-23), and sensitisation (ISO10993-10) tests. We have also undertaken a preliminary study in the United Kingdom which assessed comfort, useability, and safety. Findings were presented to the Data Safety Monitoring Committee on Wednesday 15th October 2025. No safety concerns were reported. On this basis, the independent Data Safety Monitoring Committee were willing to endorse the team's plans to conduct a pilot study using the SunPad reuseable menstrual product in Nepal

5 Study objectives / endpoints and outcome measures

5.1 Overall study objective

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.

5.2 WP3.3b Pilot Study objectives

- To determine the bacterial load on SunPad coated liners compared to identical uncoated menstrual liners over a 6-month period.
- 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.

5.3 WP3.3b Pilot study outcomes measures

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 susceptibly 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

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 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
- 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.

6 WP3.3b Pilot Study design

A parallel groups individually randomised controlled pilot trial. Participants will be randomly allocated (1:1) to receive a menstrual kit either containing SunPad or uncoated reuseable menstrual pads. We will follow-up participants for six-months. We will maintain allocation concealment by developing a centralised randomisation process in Cardiff University and providing sequentially numbered anonymised "Pack IDs" without revealing the allocation to those recruiting, participating, or analysing data while the trial is being conducted. This process also maintains blinding.

6.1 Target population

Women based in Kaski District, Nepal who currently use reusable menstrual pads (experienced users). Some study participants may be recruited from WP3.1 (NHRC Ref No: 47).

6.2 Setting

Two wards within the Kaski District; one rural and one urban. (Reevan (ward no.5) and Batulechaur (ward no. 16)). This setting has been the location for work packages 3.1 (NHRC Ref No: 47) and 3.2. (NHRC Ref No: 2504) so for research integrity purposes this work package will be conducted here.

6.3 Participants

Women who use reusable/washable menstrual pads who are willing to use and return the pads and engage in data collection processes for the duration of the study. Participants will be provided with a new set of reusable pads when they return the product at the end of the study, to encourage retention. Local community healthcare workers will be briefed on the study.

6.4 Eligibility criteria

Inclusion criteria:

- Currently using reusable menstrual health pads
- Able to provide informed consent
- Agree to follow recommended instructions regarding cleaning and drying processes for the product
- Willing to provide information regarding experience and satisfaction using the product 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 product uncovered in direct daylight)
- Identified as known or suspected to be experiencing urinary/reproductive infection at time of study initiation (pain with urination, cramping, abnormal discharge). Symptoms could include:
    i. A need to urinate more often than usual
    ii. Pain or discomfort when urinating
    iii. Sudden urges to urinate
    iv. Feeling as though the bladder is unable to be emptied fully
    v. Lower abdominal pain:
    vi. Urine that is cloudy, foul-smelling or contains blood
    vii. Abnormal discharge
    viii. 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).

6.5 Sample size, randomisation, and blinding

We will recruit 70 participants in total. As this is a pilot study, we will not be testing any hypotheses and instead focus our analysis on estimation. For outcomes where the estimate is a proportion (for example), we will be able to calculate a 95% confidence interval around our estimate to within +/- 12.2%.

Global Action Nepal (GAN) field researchers will recruit 70 participants from the Kaski district of Nepal. 35 will be from a rural area (ward 5) and 35 from an urban location (ward 16). As with the work package 3.2, participants must meet the eligibility criteria and provide informed consent prior to enrolment. As randomisation is on a 1:1 basis, 35 participants will be allocated to receive SunPad and 35 will be allocated to uncoated reuseable menstrual pads. Our randomisation process will be based on randomly permuted blocks, stratified by ward. Menstrual kits will be identical in appearance and labelled centrally with sequential "Pack IDs". These will maintain blinding (as well as allocation concealment). We will additionally maintain blinding by standardising washing and drying instructions across arms and ensuring that both SunPad and uncoated liners have no discernible features.

6.6 Recruitment

Women will be recruited by the delivery team based in Global Action Nepal (GAN), via signposting by local outreach workers. There will be three recruitment routes:

- Potentially eligible women will be approached during planned educational visits or contacted (via text/WhatsApp) by a local outreach worker about the study and, if interested, will provide consent (in writing or using a fingerprint (with a neutral witness) if written consent is not an option for the participant) to contact by a member of GAN
- Potentially eligible women collecting reusable menstrual health pads from local outreach workers will be informed about the study and, if interested, will provide consent to contact by a member of GAN
- Some participants may be identified during WP3.1 (NHRC Ref No: 47) and will be directly approached by GAN facilitator.

This flexible recruitment strategy enables a combination of proactive and opportunistic recruitment.

6.7 Informed consent

An informed consent discussion will be undertaken by an appropriately trained and delegated member of the GAN team. Potentially eligible participants will be provided with verbal and/or written information about the study. Consent will be obtained either in writing or using a fingerprint (with a neutral witness) if written consent is not an option for the participant once there has been sufficient time to consider the participant information and ask questions. Consent forms will clearly state that the participant is free to withdraw at any time without any obligation to give a reason and without any impact on future support (e.g. future access to reusable menstrual health products from NGO or community outreach partners).

6.8 Data collection

We will use REDCap software as our study database. Participants will be registered on the database and assessed for eligibility. Once the participant has consented and been deemed eligible for the study, a member of the GAN research team will administer a baseline questionnaire to participants and support

its completion. The data collection forms will be developed in REDCap and the different forms will be access-controlled (via password and through a CU developed and maintained delegation log) to ensure that users only see forms that are relevant to them (e.g. the laboratory staff would only see the forms that would be completed by them). The REDCap app via a tablet or mobile device allows for data to still be collected if there is no/unreliable Wi-Fi, and data can be uploaded to the database when a Wi-Fi or internet connection is re-established. The database will be robustly tested before being used in a live environment. Cardiff University will act as the data controller for the study. The REDCap database will be hosted on Cardiff University servers (based in the UK). From the outset, we will establish a data sharing agreement with GAN to facilitate sharing of data with the local team in Nepal.

6.9 Baseline data

Following consent, we will collect the following data:

- Demographics, such as age, living circumstances (e.g. location, type of residence, number of people living in the household, primary source of water for drinking / washing), self-reported height and weight, age at menarche, parity, time since delivery, contraception.
- Information regarding previous use of reusable menstrual products (e.g. length of time, wearing habits, acceptability, washing habits, quality and overall satisfaction of the product).

6.10 Intervention

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, we have confirmation that our product meets ISO10993 requirements, which demonstrates that our 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. Participants will be provided with 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). 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.

6.11 Control

The control product will be an uncoated reuseable menstrual pad. 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). The control product will be indistinguishable from the SunPad product, as the same fabric, stitching and packaging has been used, and they have been produced by the same manufacturers. Participants assigned the control product will be provided with 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). 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. These instructions will be identical to those in the intervention arm.

6.12 Study procedures

- Potential participants will be approached by the researcher
- They will then be provided information on the study and given the opportunity to ask questions and discuss the study with the researcher
- The participant will be screened for eligibility
- On confirming eligibility, informed consent will be obtained by a researcher
- The baseline questionnaire will be completed, supported by the researcher
- The researcher will then provide the participant with the next consecutive numbered study pack.
- Participants will be supplied with 16 reusable menstrual liners, three shields (pad holders), one storage bag, user instructions, plastic zip lock dry bag, soap and a daily diary.
- The daily diary will allow participants to quickly record the data required for the follow up questionnaire.

Participants will be followed up for six months. Follow-up data collection will allow us to measure:

- Via a monthly questionnaire administered face-to-face or over the telephone by a member of the GAN research team:
    - 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)
    - Any concerns or conditions they may have experienced

- At final follow-up (6 months post randomisation); questionnaire administered face-to-face or over the telephone by a member of the GAN research team:
    - 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

- Via the returned products:

- Proportion of catalyst retained on product;
- Stain profile on the product as assessed by amount of blood on fabric
- Microbial profiling of the product (liners) and assessed by 16S RNA sequencing, total viable/coliform counts and antibiotic susceptibility profiling.

Furthermore, we will also begin exploring the feasibility and acceptability of study measurement processes.

Table 1 Schedule of recruitment, delivery and follow-up[1]

Procedures	**Visits (insert visit numbers as appropriate)**				
	Screening	**Baseline**	**Randomisation**	**Follow up**	**End of study (6 months)**
Eligibility	X				
Informed consent	X				
Baseline QA		X			
Randomisation outcome			X		
Follow up month 1				X	
Follow up 2				X	
Follow up 3				X	
Follow up 4				X	
Follow up 5				X	
Final follow up (6)				X	

[1] Taken from the HRA CTIMP protocol template (2016).

6.13 Exploratory Virology Analysis

In vitro virology analysis will be conducted out of Tribhuvan University, supported by School of Pharmacy in Cardiff University. The aim of these analyses is to explore whether viruses can be extracted from SunPad and to develop a methodology protocol to inform future works.

As no human samples (i.e. from donated pads) will be used in this work, no ethical approval for this component is required. Therefore, details of this *in vitro* work will be specified in a separate protocol.

7 Risk Assessment

A Study Risk Assessment has been completed to identify the potential hazards associated with the study and to assess the likelihood of those hazards occurring and resulting in harm. This risk assessment includes:

- The known and potential risks and benefits to human subjects

[1] Taken from the HRA CTIMP protocol template (2016).

- How high the risk is compared to standard practice
- How the risk will be minimised/managed

This study has been categorised as a low risk, where the level of risk is comparable to the risk of standard medical care. A copy of the study risk assessment may be requested from the Study Manager. The study risk assessment is used to determine the intensity and focus of monitoring activity (see section 18.1).

8 Screening logs

A screening log will be kept detailing all women who have been approached for the study. We will include women who were assessed for eligibility but were deemed not eligible and also women who declined to take part in the study and the reason for their nonparticipation. The screening log will be completed at site and uploaded to the study Teams space. No identifiable information will be included on the log.

9 Withdrawal and lost to follow-up

9.1 Withdrawal

Participants have the right to withdraw consent for participation in any aspect of the study at any time. The participants care or services will not be affected at any time by declining to participate or withdrawing from the study.

If a participant initially consents but subsequently withdraws from the study, clear distinction must be made as to what aspect of the study the participant is withdrawing from. For this work package, the participant will be withdrawing from the pilot study (e.g. collection of survey/diary data, collection of used materials, and/or use of the intervention).

The withdrawal of participant consent shall not affect the study activities already carried out and the use of data collected prior to participant withdrawal. The use of the data collected prior to withdrawal of consent is based on informed consent before its withdrawal.

In all instances participants who consent and subsequently withdraw should complete a withdrawal form (see Withdrawal Form in study pack) or the withdrawal form should be completed on the participant's behalf by the researcher/PI based on information provided by the participant. This withdrawal form should be sent to sunpad@cardiff.ac.uk. Any queries relating to potential withdrawal of a participant should be forwarded to sunpad@cardiff.ac.uk.

9.2 Lost to follow up

Participants will be identified as lost to follow-up if after three attempts to contact the researcher is unsuccessful. The researcher will use the following approaches to obtain missing data:

- Call at a different time of day e.g. morning or evening.
- Call on a different day e.g. a weekend
- Wait a week and then try calling again

If all three attempts are unsuccessful the participant will be recorded as lost to follow up. Any data which has been collected to date will contribute to the analysis. If we are unable to reach the participant for any of the follow-ups we will not be attempting to follow up the participant in the next round of follow ups. For example, if unable to follow up at follow up one, we will not then contact at follow up two, the participant will be recorded as lost to follow up from follow up one.

10 Statistical considerations

10.1 Sample size

In WP3.3b

we will recruit 70 participants in total. As this is a pilot study, we will not be testing any hypotheses and instead focus our analysis on estimation. For outcomes where the estimate is a proportion (for example), we will be able to calculate a 95% confidence interval around our estimate to within +/- 12.2%.

10.2 Missing, unused and spurious data

Detail provided in the Statistical Analysis Plan (SAP).

10.3 Procedures for reporting deviation(s) from the original SAP

These will be submitted as amendments where applicable and recorded in subsequent versions of the protocol and SAP.

10.4 Termination of the study

There are no ‘stopping rules’ or ‘discontinuation criteria’ for individual participants in this study.

10.5 Inclusion in analysis

The study population will be all participants who are eligible and consent to participate in this study.

11 Analysis

11.1 Main analysis

A detailed statistical analysis plan will be written prior to analysis. Statistical analysis will be performed in Stata (version 16 or higher) or similar. As this is a pilot study to understand prototype field performance within the target setting, the statistical analysis will be mainly descriptive in nature.

11.1.1 Describing recruitment and follow-up

We will report the number of women approached for the study, assessed for eligibility, agree to take part (participants) and are randomised, as well as describing women that are deemed not eligible (and reason), and those that decline to take part in the study and the reason for their nonparticipation. The number of women lost to follow-up throughout the course of the study (with incomplete/no survey data), and the number not returning the products for testing will be described. These numbers will be depicted in a flow chart. We will report this both overall and by trial arm. As this is a pilot study, no hypothesis testing will take place, and our focus will be on estimation only. Differences between arms will be accompanied by associated 95% confidence intervals.

11.1.2 Describing the study participants

From the baseline questionnaire we will describe study participants with respects to their age, living circumstances (e.g. location, type of residence, number of people living in the household, role in the household, primary source of water for drinking/washing), calculated/self-reported BMI, age at menarche, parity, time in months since delivery, contraception. Summary statistics (frequency, proportion, mean alongside standard deviation, or median alongside interquartile range) will be used. We will also describe the participants previous use of reusable menstrual products (e.g. wearing habits, acceptability, washing habits, quality and overall satisfaction of the product). Similarly, we will report this both overall and by trial arm to demonstrate comparability of participants in each of the arms.

11.1.3 Questionnaire data returned over participant follow-up

Participants will be followed up for six months from recruitment/baseline questionnaire. To determine initial levels of acceptability of the product among its users we will describe product use, cleaning, drying, stain and odour on the product, and storage, issues experienced, over all cycles and for each cycle of use. As well as comparing these process measures between arms, we will examine how these outcomes vary by participant demographics and baseline characteristics including frequency, flow and duration of menstrual bleeding and over time, and examine any differences in product use over monsoon periods compared to non-monsoon periods. Free text questions (e.g. ‘how did you clean and dry the product?’ will be categorised and/or reported narratively. At the final follow-up we will describe the satisfaction of the product (look, ease of use) and usual product cost including acceptability of costs and well as detailing any overall feedback on the product.

11.1.4 Data on microbial contamination/bioburden of used products

We will compare outcomes from the products returned for microbial contamination testing (e.g. Proportion of catalyst retained on product, blood and microbial profiling) between arms. Similar to the above paragraph, we will also explore how these outcomes vary by participant demographics and

baseline characteristics, reported use, cleaning and drying, use in monsoon period or not, estimated usage of pads flow and duration of menstrual bleeding over the period of use.
use.

11.1.5 Study processes

Furthermore, we will also begin exploring the feasibility and acceptability of study measurement processes. For this we will report the number of women who do not engage at follow-up (lost to follow-up), withdraw from the study, and request additional reusable products. We will also report the completeness of each question asked at baseline and at each follow-up. These will also be reported overall and by trial arm.

11.1.6 Sub-group and interim analysis

None planned.

12 Data Management

Source data for the participant facing questionnaire is intended to be online, but with the backup of a paper version of the CRF if there is a strong preference by the participant or there are connectivity issues. Once the participant has consented and been deemed eligible for the study, a member of the GAN research team will administer a baseline questionnaire to participants and support its completion.

CRFs will only contain a unique participant identification (PID), initials and date of birth (partial so not identifiable; month and year only). No other identifiable information will be recorded on the CRFs/questionnaires.

Access to the REDCap database will be via username and password and restricted to appropriately trained personnel only. The database will be housed on local servers managed by Cardiff University staff in accordance with all appropriate legislation.

The GAN team will keep any identifiable data (name, address etc.) separately from the study database and this will not be made available to anyone in Cardiff University.

Wherever possible data will be validated at point of entry, thereby reducing the opportunity for missing or unexpected data. All changes made to the data will be recorded and visible via an audit log within the database.

The planning, development, testing and maintenance of the database will be performed in line with CTR SOPs, as will the data management function.

A data management plan will be developed to outline the details of how data will be collected, transferred stored and accessed by the team.

Table 2: Data origin

Study data	Source Data			
	Eligibility Form	Consent Form	Baseline Questionnaire	Follow up Questionnaire
Eligibility	X			
Consent		X		
Demographics			X	
Menstrual products knowledge / use (prior to use of reusable pads)			X	
Information regarding use of reusable pads				X
Problems regarding use of reusable pads				X

12.1 Completion of case report forms (CRFs)

12.1.1 Paper CRFs

If a paper copy of the CRF is used, then the data contained in it should be entered onto the REDcap database and then stored at the GAN offices.

If missing or questionable data are identified, a data query will be raised on a Data Clarification Form (DCF). The DCF will be sent to the relevant participating site. The site shall be requested to respond to the data query on the DCF. The CRF pages should not be altered.

All answered data queries and corrections should be signed-off and dated by a delegated member of staff at the relevant participating site. The completed DCF should be returned to the CTR and a copy retained at the site along with the participants' CRFs.

The CTR will send reminders for any overdue data. It is the site's responsibility to submit complete and accurate data in timely manner.

12.1.2 Electronic CRFs

The preference of this study is that data is entered directly onto the REDCap database.

This is a secure encrypted system accessed by an institutional password and complies with the General Data Protection Regulation 2016. The system can be accessed on:

https://redcap.ctr.cardiff.ac.uk/redcap/index.php

A user password will be supplied to Investigators upon completion of all processes required prior to opening.

12.1.3 Data completeness

If missing or questionable data are identified, a data query will be raised on a Data Clarification Form (DCF). The DCF will be sent to the relevant participating site. The site shall be requested to respond to the data query on the DCF.

All answered data queries and corrections should be signed-off and dated by a delegated member of staff at the relevant participating site. The completed DCF should be returned to the CTR and a copy retained at the site along with the participants' CRFs.

The CTR will send reminders for any overdue data. It is the site's responsibility to submit complete and accurate data in timely manner.

13 Protocol / GCP non-compliance

The PI should report any non-compliance to the study protocol or the conditions and principles of GCP to the CTR in writing as soon as they become aware of it.

14 End of study definition

The end of the study is defined as the date of final data capture to meet the study endpoints.

CI or Study Manager must notify the main REC of the end of a clinical study within 90 days of its completion or within 15 days if the study is terminated early.

15 Archiving

The Study Management File and any files containing essential documents will be archived at an approved external storage facility for 15 years as per Cardiff University's policy. Essential documents pertaining to the study shall not be destroyed without permission from Cardiff University. Any paper CRFs used can be archived in GAN.

16 Regulatory considerations

16.1 Ethical and governance approval

This study protocol will be submitted through the relevant permission system for global governance review. Approval has been obtained from the School of Medicine Research Ethics Committee at Cardiff University (reference: 23/94) on 21st November 2025. Ethical approval will subsequently be obtained

from Nepal Health Research Council in Nepal. The study will also be subjected to Governmental support in Nepal. The Research Governance approval must be obtained before recruitment of participants.

16.2 Data protection

The CTR will act to preserve participant confidentiality and will not disclose or reproduce any information by which participants could be identified, except where specific consent is obtained. Data will be stored in a secure manner and will be registered in accordance with the General Data Protection Regulation 2016. We must ensure that it is in the public interest when we use personally identifiable information (such as date of birth) from people who have agreed to take part in research and that we are using it properly in accordance with the General Data Protection Regulations (GDPR).

Participants will always be identified using a unique PID. All other identifiable information (name, address etc,) will not be stored with collected data.

16.3 Indemnity

Negligent harm: The Sponsor shall indemnify the site against claims arising from the negligent acts and/or omissions of the Sponsor or its employees in connection with the study (including the design of the Protocol to the extent that the Protocol was designed solely by the Sponsor and the Site has adhered to the approved version of the Protocol) save to the extent that any such claim is the result of negligence on the part of the Site or its employees.

Non-negligent harm: This study is an academic, investigator-led and designed study, coordinated by Cardiff University. Cardiff University may provide compensation to participants who may have been harmed or injured as a direct result of taking part in this study.

16.4 Funding

The SunPad Study is funded by the Bill and Melinda Gates Foundation, funder reference: **INV-048434**. The funder will have no direct role in study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results. The funder has no direct control over the final decision regarding any of these aspects of the study, but the CI will communicate any concerns or issues to the funder accordingly.

17 Study management

This protocol relates only to WP3.3b, this WP is managed by the study management group. Overall study responsibility lies with Dr Jennifer Edwards, the CI. Details of the SMG is addressed in 17.1.

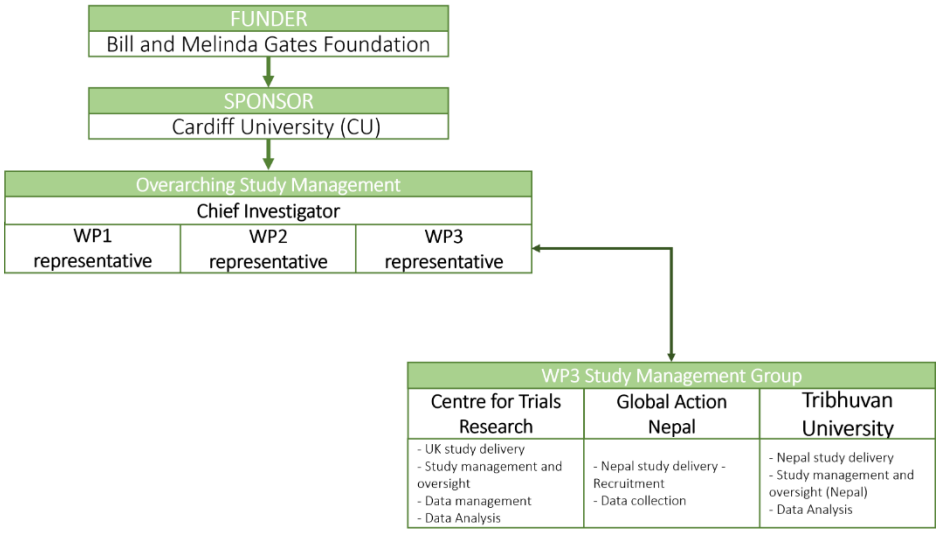

Figure 1: Study Management (WP3)

17.1 Study management group (SMG)

A Study Management Group (SMG), comprising the CI, co-applicants, CU, GAN and University of Tribhuvan representatives will meet every month online to regularly review study milestones. SMG members will be required to sign up to the remit and conditions as set out in the Terms of Reference, which will include confidentiality agreements and conflict of interests as well as member / organisational responsibilities. The study manager will chair the SMG meetings; input will be sought from each team member.

18 Quality control and assurance

18.1 Monitoring

The study risk assessment has been used to determine the intensity and focus of central and on-site monitoring activity in The SunPad Study. Low remote monitoring levels will be employed and are fully documented in the study monitoring plan.

Investigators should agree to allow study related monitoring, including audits by providing direct access to source data/documents as required. Findings generated from monitoring will be shared with the relevant study team members.

18.2 Audits and inspections

The study may also be participant to inspection and audit by Cardiff University or funder.

19 Patient and public involvement and engagement

A patient and public involvement and engagement group will be established for SunPad once the funding is in place, and there are the resources to support the PPIE representatives. The study team in Nepal have existing networks with Days for Girls or The Social Changemakers and Innovators (SOCHAI). The long term intended aim is to establish a PPIE global panel to support this study in progression and transition into other countries.

20 Publication policy

A publication policy will be agreed at the start of the WP to determine who leads the publications arising from each WP, in line with CRediT taxonomy (https://credit.niso.org/) as a way of standardising the attribution of contribution. It is integral that we ensure we mobilise all researchers within the study team and ensure opportunities are available for lead publications to come from both Nepal and the UK. All publications will be reviewed and approved by the SMG.

21 References

1. Shrestha S, Tuladhar NR, Basnyat S, Acharya GP, Shrestha P, Kumar P (2011). Prevalence of vaginitis among pregnant women attending Paropakar Maternity and Women's Hospital, Thapathali, Kathmandu, Nepal. Nepal Med Coll J. 13(4):293-6.

22 Appendices

Document type	Work package	Document title
Participant information sheets	WP3.3b Pilot Study	SunPad Pilot PIS v1.5 22025
Posters	WP3.3b Pilot Study	SunPad Pilot Poster v1.3 23102025
Consent forms	WP3.3b Pilot Study	SunPad Pilot Consent Form v1.5 23102025