TRIAL PROTOCOL

Eczema Monitoring Online

EMO

Eczema **M**onitoring **O**nline

Eczema Monitoring Online via Questionnaires

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Trial Co-ordinating Centre: Centre of Evidence Based Dermatology, University of Nottingham

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Synopsis

Title	Eczema monitoring online via questionnaires
Acronym	EMO
Short title	Eczema Monitoring Online (EMO)
Chief Investigator	Prof. Kim Thomas
Aims and Objectives	**AIM:** The overall aim of this study is to inform the design of eczema randomised controlled trials on whether regular monitoring of eczema symptoms affects patient-reported outcomes. **OBJECTIVES:** 1. To evaluate the effect of regular symptom monitoring on eczema severity 2. To evaluate the effect of regular symptom monitoring on adherence to eczema treatment use 3. To evaluate the effect of regular symptom monitoring on missing data
Trial Configuration	Online, two-arm, parallel group, randomised controlled trial.
Setting	The trial will be conducted online. Participants will be recruited via a variety of recruitment methods (including, but not limited to): social media, eczema charities, study participant recruiting websites and existing mailing lists of people who have taken part in previous eczema studies and consented to be contacted about future studies.
Sample size estimate	Assuming a standard deviation of 6.5, the estimated sample size to detect a between group difference of 2.5 in eczema severity score with 80% power and with a two-sided significance level is a total of 212 participants (106 per group). Allowing for 20% loss to follow up, the required total sample size for this trial is 266 participants (133 per group).
Number of participants	266 participants

Eligibility criteria	**Inclusion Criteria:** • Self-report or parent/carer report of eczema diagnosis by a healthcare professional • Person aged 1 year or older • Able and willing to provide informed consent • If under 16 years old, a parent/carer needs to provide informed consent on behalf of the child • Able to read and understand written English • Have access to the internet and to an internet-enabled device • POEM score of 3 or above at eligibility screening **Exclusion Criteria:** • Unable/unwilling to provide informed consent • Currently taking part in another eczema clinical trial
Description of the intervention	The intervention will be the online Patient Oriented Eczema Measure (POEM) questionnaire. Participants in the intervention group (Weekly group) will be asked to complete POEM weekly. The control group will not receive intervention.
Duration of study	The overall duration of the study is anticipated to be approximately 21 months and planned to start in June 2021. Each participant will be asked to participate in the trial for 8 weeks.
Randomisation and blinding	The randomisation schedule is based on computer generated random codes, using random permuted blocks of randomly varying size, stratified by age and baseline disease severity. The PhD student will deal with participant queries, thus she will have access to group allocation, but the other trial team members and the trial statistician will remain blinded.
Outcome measures	The primary outcome will be eczema severity measured by the self-reported or proxy (parent/carer reported) POEM at baseline and 8 weeks.
Methods of analysis	The primary outcome will be analysed according to randomised groups. The primary analysis of POEM scores will be performed using single linear regression and will adjust for stratification variables (age and baseline disease severity) and for other variables that appear to be imbalanced at baseline. Sensitivity analyses and other further exploratory analyses will be performed using appropriate statistical methods.

Abbreviations:

CEBD	Centre of Evidence Based Dermatology
CONSORT	CONsolidated Standards of Reporting Trials
CRF	Case Report Form
CI	Chief Investigator
CLOTHES	Clothes for the Relief of Eczema Trial
ECO	Eczema Care Online
GCP	Good Clinical Practice
GDPR	General Data Protection Regulations
HOME	Harmonising Outcome Measures for Eczema
MCID	Minimal Clinically Important Difference
PIS	Participant Information Sheet
POEM	Patient-Oriented Eczema Measure
REC	Research Ethics Committee
REDCap	Research Electronic Data Capture
RCT	Randomised Controlled Trial
SR	Systematic Review
SWET	Softened Water for Eczema Trial
UoN	University of Nottingham

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1. Background and Rationale

1.1 Background

Eczema (also known as atopic eczema, atopic dermatitis) is a common, chronic, inflammatory skin condition that causes itchiness, sleep loss and decreased quality of life, affecting children and adults (1). It is characterised by periods of relative remission and relapse with increased disease activity, indicating the fluctuating nature of the disease (2). This should be taken into account when designing clinical trials that evaluate the effectiveness of eczema interventions. In the last two decades a lot of randomised controlled trials (RCTs) in eczema have been conducted (3). Online questionnaires completed by participants are often used in eczema clinical trials to capture the views of participants about their eczema. This allows researchers to measure the effectiveness of different treatments (4). Findings of the CLOTHES and SWET eczema RCTs show that completing questionnaires regularly (known as monitoring) can change the way that people manage their eczema, indicating a behaviour change, resulting in improved eczema severity (5,6). This is a concern within clinical trials because completing regular questionnaires may make it harder to identify changes in the eczema resulting from the treatments being tested.

The effect of monitoring on trial outcomes is well described in other chronic conditions, such as cancer, asthma and HIV (7,8,9). One proposed mechanism of action of monitoring is associated with participants' behaviour change, as illustrated in recent systematic reviews (10,11). This online trial has been designed to test our primary hypothesised mechanism of action of participant behaviour change.

The Harmonising Outcome Measures for Eczema (HOME) initiative recognises the importance of monitoring and also the frequency of outcome measure collection (12,13). HOME is a global collaboration of patients, healthcare professionals, journal editors, regulatory authorities and the pharmaceutical industry, working collaboratively to standardise outcome measures in eczema clinical trials (14). In RCTs, a balance needs to be established between capturing accurate measurements of the outcome of interest, whilst not unduly altering the behaviour and attitudes of the trial participants.

Further research is needed to evaluate the effect of monitoring on outcomes. To date, to the best of our knowledge, no study has been conducted to capture the effect of monitoring in eczema. This methodological trial is specifically designed to investigate whether completing questionnaires is an effective intervention in improving eczema severity. This will allow us to evaluate the effect of regular monitoring on eczema severity and help to improve the design of future eczema clinical trials.

1.2 Trial Rationale

This study aims to assess whether completing questionnaires regularly changes participants' behaviour and affects adherence to standard treatment use and management of eczema. It is important to investigate the effect of monitoring on clinical outcomes as it can cause erroneous estimation of the treatment effect. The term 'monitoring' will be used to denote completion of self-reported or proxy (parent/carer) reported questionnaires. This online trial will help to evaluate whether monitoring affects disease severity and will inform future eczema clinical trial designs about the effect of monitoring on patient-reported outcomes.

1.2.1 Justification for Participant Population

Eczema is a common chronic skin condition, affecting both children and adults with varying disease severity (1). Adults and children with eczema with any disease severity (mild, moderate and severe) will be eligible to participate in this trial. The broad aim of this study is to inform the design of future eczema clinical trials therefore the eligibility criteria is diverse, which improves the generalisibility of the study.

1.2.2 Justification for Design

This is an online, two-arm, parallel group RCT. Participants with eczema will be randomised (1:1) to complete online questionnaires weekly (Intervention group) or at the beginning and end of study only (Control group). Online questionnaires are often used in eczema trials therefore we are replicating what is usually done in those trials; namely, asking participants to complete questionnaires online. This is not a treatment trial, therefore there is no need for face-to-face visits to take place. Moreover, it is feasible to conduct this remote study, especially under the current COVID-19 pandemic. The online design also allows this methodological study to be conducted efficiently.

1.2.3 Choice of Treatment

The intervention in this trial is questionnaire completion and therefore there is no treatment involved. Participants will be asked to complete questionnaires at different timepoints according to their randomised allocation. Participants will be able to continue to use their existing eczema treatments as usual.

2. Aims, Objectives and Outcome Measures

2.1 Aims:

The overall aim of this study is to inform the design of future eczema randomised controlled trials on whether regular symptom monitoring affects patient-reported outcomes.

2.2 Objectives:

1. To evaluate the effect of regular symptom monitoring on eczema severity
2. To evaluate the effect of regular symptom monitoring on adherence to eczema treatment use
3. To evaluate the effect of regular symptom monitoring on missing data

2.3 Outcome Measures:

Primary outcome:

- **Eczema severity:** change in eczema severity from baseline to 8 weeks assessed by the Patient Oriented Eczema Measure (POEM) score. POEM is a HOME

recommended core outcome set instrument for the patient-reported symptoms domain (15). It captures self-reported or proxy reported symptoms, including: frequency of itch, sleep disturbance, bleeding, weeping/oozing, cracking, flaking and dryness. It provides a score from 0 to 28, with higher score meaning more severe eczema (16).

Secondary outcomes:

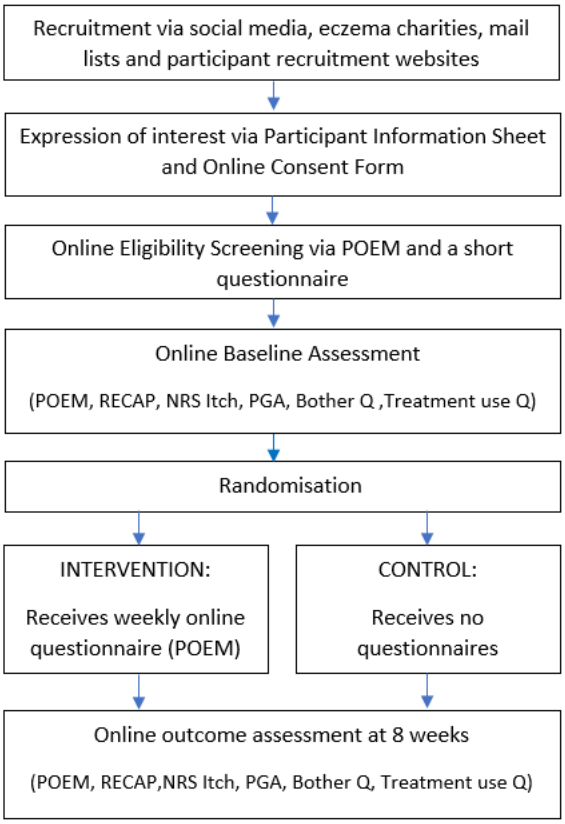
- **Adherence to eczema treatment use:** will be assessed in two ways:
  - Change in eczema treatment use from baseline to 8 weeks assessed by emollient and topical corticosteroid use over the last week.
  - Change in eczema treatment use from baseline to 8 weeks assessed by overall eczema treatment use over the last 2 months.
- **Missing data:** the proportion of fully completed questionnaires at 8 weeks.

3. Trial Setting

3.1 Trial Setting

This study will be conducted online. Participants will be recruited via various methods, including but not limited to: social media (e.g. Facebook, Twitter, Instagram), eczema charities (e.g. National Eczema Society), participant recruitment websites (e.g. www.callforparticipants.com) and existing mailing lists of people who have taken part in previous eczema studies and consented to be contacted about future studies. We aim to recruit both children and adults with eczema.

Figure 1. Participant flow through this trial:



4. Eligibility

4.1 Inclusion Criteria

- Self-report or parent/carer report of eczema diagnosis by a healthcare professional
- Person aged 1 year or older
- Able and willing to provide informed consent
- If under 16 years old, a parent/carer needs to provide informed consent to participate
- Able to read and understand written English
- Have access to the internet and to an internet-enabled device
- POEM score of 3 or above at eligibility screening

4.2 Exclusion Criteria:

- Unable/unwilling to provide informed consent
- Currently taking part in another eczema clinical trial

5. Consent

Adults and children with eczema will be recruited via various methods (including, but not limited to) social media, eczema charities, participant recruitment websites, existing mailing lists of people who have taken part in previous eczema studies and consented to be contacted about future studies. A link to the study website will be displayed in the advertisement/email/information/website about the study. People interested in the study will follow the link, which directs them to the study website. The Participant Information Sheet (PIS) will be displayed, which will contain the summary of the aim of the research, intervention, eligibility criteria and what will happen to their data upon withdrawal from the study. The PIS will stress that participation is voluntary and the potential participant may withdraw from the trial at any time without any negative consequences. It will also explain that participants can withdraw from the study by notifying us via sending an email to the study email address. There will be a statement that makes it clear that by clicking the NEXT button, that allows them to proceed to the consent form, they are agreeing to the information provided.

Upon clicking the NEXT button, the online consent form will be displayed, and potential participants will be required to read and complete the form and they will be asked to type their name. According to the UK Health Research Authority (17) this is an appropriate electronic method to seek and document consent for this type of study. If a child is below 16 years of age and wishes to participate in the study, the parent/carer will be asked to provide informed consent on behalf of the child. Potential participants will be informed that by proceeding to submit the online consent form, they are agreeing that they have read and understood the information provided, fulfil the eligibility criteria and are willing to voluntarily take part in this study. A completed online consent form from each participant will be always obtained prior to participating in this trial. Electronic data, including consent forms, will be managed, stored and organised according to the study Data Management Plan.

6. Enrolment and Randomisation

6.1 Enrolment

Potential participants will be recruited via different organisations and platforms (including, but not limited to):

- **Eczema charities:** e.g. National Eczema Society (http://www.eczema.org/), Eczema Outreach Support (https://www.eos.org.uk/), Nottingham Support Group for Carers of Children with Eczema (http://www.nottinghameczema.org.uk/index.aspx).

- **School of Medicine / Centre of Evidence Based Dermatology communication channels** (e.g. Twitter, website, existing mailing lists and newsletters).

- **Call for Participants website** (https://www.callforparticipants.com). An open platform that brings together researchers to promote their studies and potential participants interested in taking part in studies.

- **Social media:** the study will be advertised on a range of platforms e.g**.** Facebook, Twitter, Instagram.

- **Other organisations/online platforms/ individuals** e.g. resharing via social media.

Recruitment is expected to start in June 2021 and it is anticipated to last for approximately 9 months. Participant retention and completion of follow-up assessments will be promoted by using various methods (including, but not limited to): email reminders, text reminders, telephone calls. Newsletters and other appropriate communications may be used to aid retention. Upon completion of the follow up questionnaires at 8 weeks, participants will be able to enter an optional price draw for a chance to win one of six £20 vouchers to say thank you for taking part. The recruitment strategy will focus on the UK, as participation is online so it will not be restricted by geography.

6.2 Randomisation

Participants will complete the consent form followed by baseline characteristics and eligibility screening. All assessments and questionnaires will be developed by using the Research Electronic Data Capture (REDCap) software. Those who do not fulfil the eligibility criteria of a POEM score of 3 or above will be provided with information explaining that they were not eligible to take part in the study and will be signposted to other online resources.

Eligible participants will be randomised online to either the intervention group or to the control group, using the REDCap software. The randomisation schedule will be based on computer generated random codes, using random permuted blocks of randomly varying size, stratified by age and baseline disease severity.

6.3 Blinding

This is a methodological trial and there will be no treatment intervention involved.

The nature and the objectives of this study does not allow complete transparency towards participants about the purpose of this trial. If they knew the aim of the trial, it would likely influence their behaviour, which would completely undermine the trial objectives. Therefore, potential participants will be told that the aim is to evaluate how eczema changes over time. It appears to be an appropriate approach as this is a non-treatment intervention trial and participants will not be at disadvantage or risk because of taking part. After randomisation, participants will be informed about how often they will be asked to complete the questionnaires. The PhD student will deal with participant queries, thus she will have access to group allocation, but the other trial team members and the trial statistician will remain blinded.

7. Trial Intervention

7.1 Intervention

The trial intervention will be the POEM questionnaire. Only the intervention group will receive the POEM questionnaire (intervention) each week. This will allow participants to monitor their symptoms regularly.

Both groups, the intervention group and the control group will receive POEM at baseline and 8 weeks, as part of the primary outcome assessment, which will enable us to evaluate whether regular symptom monitoring affects eczema severity.

8. Trial Procedures and Assessments

8.1 Summary of Assessment

Table 1. Summary of Trial Assessments.

ASSESSMENTS	Week 0	From Week 1 to Week 7							Week 8
Baseline characteristics	✓								
Eligibility Screening	✓								
Informed Consent	✓								
Randomisation	✓								
Online Weekly POEM (Intervention Group)		◆	—	—	—	—	—	◆	
No intervention (Control Group)									
Disease severity (POEM)	✓								✓
Eczema control (RECAP)	✓								✓
Itch intensity measure (NRS Itch)	✓								✓
Treatment use Question	✓								✓
Patient Global Assessment (PGA)	✓								✓
Global bother Question	✓								✓

8.2 Schedule of Assessments

Enrolment (Week 0):

- Participant Information Sheet (PIS): interested individuals will be provided with a link to the study website that will take them to the PIS, which will include the summary of research aims, intervention and information about data handling. Upon reading it, they can proceed to the consent form.

- Informed consent: potential participants will be required to read, complete and submit the consent form, if they would like to take part in the study.

- Baseline characteristics: age, gender, ethnicity, country, postcode (UK only), self-report or parent/carer report of doctor's eczema diagnosis and what eczema treatment is currently used.

- Eligibility screening: eczema severity assessed by the POEM questionnaire.

- Randomisation: upon completion of the eligibility screening, eligible participants will be randomised online to either the intervention group or to the control group, using the REDCap software.

Baseline (Week 0):

The following online questionnaires will be completed by both study groups at baseline:

- POEM
- RECAP
- NRS Itch
- Patient Global Assessment (PGA)
- Bother question
- Treatment use question

Post randomisation (from Week 1 to Week 7): the intervention group will be sent weekly POEM questionnaires for completion. The control group will not receive questionnaires during this time-frame.

Follow-up (Week 8):

Both study groups will be sent the following questionnaires at week 8:

- POEM

- RECAP
- NRS Itch
- PGA
- Bother question
- Treatment use question

8.3 Trial Assessments

The only questionnaire that will be used to assess the primary outcome in this study is POEM.

- **Patient-Oriented Eczema Measure (POEM)** (16): a well-validated, reliable and simple tool that demonstrates good responsiveness to change and used for monitoring eczema severity in both children and adults. It is a seven item questionnaire that assesses self-reported or proxy reported symptoms over the last week, including: frequency of itch, sleep loss, bleeding, wheeping/oozing, cracking, flaking and dryness. It provides a score from 0 to 28, with higher score representing more severe eczema. Missing data will be handled in accordance with the instrument developer's recommendations.

- **Treatment use Question:** this will include three single item questions that will be asked at baseline and at week 8 to assess adherence to emollient and topical steroid use over the last week and also assess overall eczema treatment use over the last 2 months.

The following questionnaires are included in this study to be able to undertake validation studies based on this trial's dataset.

- **NRS Itch** (18): Peak Pruritus Numerical Rating Scale (NRS) a validated, reliable, widely-used measure that assesses the intensity of peak (worst) pruritus (itch) during the past 24 hours. It provides a score from 0 to 10, higher score means more intense itch.

- **Recap of Atopic Eczema (RECAP)** (19): a validated, seven item questionnaire that captures self-reported or proxy reported eczema control. It is a recently developed instrument and further validation studies are required to investigate how it performs in trials. The assessment of the minimal clinically important difference (MCID) study, a severity banding study or other needed validation studies will be conducted based on this trial's dataset, which will improve the interpretability of RECAP in eczema research.

- **Patient's Global Assessment (PGA):** single item global assessment of eczema. It is a six point Likert scale (clear, almost clear, mild, moderate, severe, very severe), used to gauge an overall sense of current disease severity. This might be used as an anchor in one of the validation studies.

- **Bother Question:** It is a global assessment of eczema in the preceding week to gain an insight into overall disease severity. This might be used as an anchor for the validation studies.

8.4 Withdrawal Procedures

Participants will be free to withdraw from the trial anytime, without having to give a reason. Participants will be informed that this will not have any negative consequences on them. The PIS and the consent form will make participants aware that should they withdraw from the trial, the data collected to date cannot be erased and may be still used and included in the analysis.

9. Adverse Event Reporting

This is a non-treatment intervention trial and the occurrence of an adverse event as a result of participation in this study is not expected and no adverse event data will be collected. The researchers will be unable to provide medical advice. Thus, if medical concerns arise the researchers will suggest participants contact their general practitioner or relevant healthcare professional to discuss their concerns. This information will be always provided in the form of written information at the end of the questionnaire completion.

10. Data Handling

10.1 Case Report Form

Traditional case report forms (CRFs) will not be used as such because data collection will be via online, patient-reported or proxy reported questionnaires as described in section 8. Each participant will be assigned a study identity code number for use on the electronic database. The study database and electronic documents will be treated as confidential and held securely in accordance with regulations.

10.2 Source Data

Source documents will include consent forms and all the online questionnaires used in this study. Only study staff shall have access to study documentation other than the regulatory requirements listed below. All source documents shall be made available at all times for review by the Chief Investigator (CI) and inspection by relevant regulatory authorities.

10.3 Data Management

Data will be handled in accordance with the study Data Management Plan.

11. Quality Control and Quality Assurance

11.1 Study Conduct

Study conduct may be subject to systems audit for inclusion of essential documents; permissions to conduct the study; CVs of study staff and training received; local document control procedures; consent procedures and recruitment logs; adherence to procedures defined in the trial protocol (e.g. inclusion / exclusion criteria).

11.2 Study Data

Monitoring of study data shall include confirmation of informed consent; source data verification; data storage procedures; local quality control checks and procedures, back-up and disaster recovery of any local databases. The CI or delegate (PhD student) shall carry out monitoring of study data as an ongoing activity. Study data and evidence of monitoring and systems audits will be made available for inspection by the REC as required.

11.3 Record Retention and Archiving

In compliance with the ICH/GCP guidelines, regulations and in accordance with the University of Nottingham Code of Research Conduct and Research Ethics, the CI will maintain all records and documents regarding the conduct of the study. These will be retained for at least 7 years or for longer, if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.

11.4 Statement of Confidentiality

Individual participant medical or personal information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted above. Participant confidentiality will be further ensured by utilising identification code numbers.

If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly. Data generated as a result of this study will be available for inspection on request by the University of Nottingham representatives, the REC and the regulatory authorities.

12. End of Trial Definition

The end of trial is defined in this study as once database has been locked and primary analyses conducted. The PhD student will notify the University of Nottingham's REC when the trial has ended, and a summary of the study report will be provided within 12 months of the end of trial.

13. Statistical Considerations

13.1 Sample Size Calculation

Assuming a standard deviation of 6.5, the estimated sample size to detect a between group difference of 2.5 in eczema severity score with 80% power and with a two-sided significance level is a total of 212 participants (106 per group). Allowing for 20% loss to follow up, the required total sample size for this trial is 266 participants (133 per group). These statistical assumptions are in line with the Eczema Care Online (ECO) trial (20), which is also an online trial that included a similar disease severity population to our study.

13.2 Definition of Outcome Measures

13.2.1 Primary outcome measure

- **Eczema severity:** change in eczema severity from baseline to 8 weeks assessed by the POEM score.

13.2.2 Secondary outcome measures:

- **Adherence to standard treatment use:** will be assessed in two ways:
  - Change in eczema treatment use from baseline to 8 weeks assessed by emollient and topical corticosteroid use over the last week.
  - Change in eczema treatment use from baseline to 8 weeks assessed by overall eczema treatment use over the last two months.
- **Missing data:** the proportion of fully completed questionnaires at 8 weeks.

13.3 Planned Final Analyses

Analysis will be performed using Stata (statistical data analysis software). Reporting of the trial will be performed in accordance with CONSORT (CONsolidated Standards of Reporting Trials) guidelines (21). Appropriate descriptive statistics will be applied to compare the randomised arms at baseline and 8 weeks.

The primary outcome will be analysed according to randomised groups. The primary analysis of POEM scores will be performed using single linear regression and will adjust for stratification variables (age and baseline disease severity) and for other variables that appear to be imbalanced at baseline. Sensitivity analyses and other further exploratory analyses will be performed using appropriate statistical methods. Missing POEM data will be handled in accordance with the recommendation of the developers of the instrument (18). A statistical analysis plan will be developed and agreed prior to database lock. Any changes to the planned statistical methods will be documented in the trial report.

14. Trial Organisational Structure

14.1 Trial Coordination

The trial is co-ordinated by the Centre of Evidence Based Dermatology, University of Nottingham.

14.2 Trial Management Group

The purpose of the Trial Management Group is to oversee the day-to-day management, overall conduct and progress of the trial. Meetings will be held regularly to keep the group up to date with the trial, to monitor progress and to identify problems at an early stage. During the trial set up period, the group will have more frequent meetings and it is anticipated to have monthly meetings thereafter.

The trial management group will include:

Arabella Baker (PhD Student): responsible for participant recruitment, data collection, data storage and data analysis, alongside other members of the research team.

Prof. Kim Thomas (Chief Investigator and Lead Supervisor): has overall responsibility for the trial and shall oversee the management of the trial. The Chief Investigator will be the data custodian.

Eleanor Mitchell (Co-Investigator and Co-supervisor): provides guidance and support on all elements of clinical trials, including but not limited to: design, management and conduct.

Dr Chris Partlett (Trial Statistician): will provide statistical support, when needed.

14.3 Funding

This trial is funded as part of a PhD studentship by the University of Nottingham (UoN).

15. Ethical Considerations

The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice and the UK Department of Health Policy Framework for Health and Social Care, 2017.
Relevant legal frameworks, including the General Data Protection Regulations (GDPR) and the EU Clinical Trials Directive will also be followed.

The trial will not be initiated before the study protocol, consent forms, PIS and data management plan have received approval from the UoN Faculty of Medicine and Health Sciences Research Ethics Committee (REC). In case of substantial protocol amendments, application will always be made to the REC to request authorisation prior to implementation.

Minor protocol amendments only for administrative changes may be implemented immediately, and the REC will be informed.

16. Confidentiality and Data Protection

Participant data will be regarded as confidential and will be handled and stored in accordance with GDPR regulations. All reasonable endeavours will be made to maintain confidentiality. The study data management plan will be followed, which describes the management, storage and protection of all data related to this study.

17. Insurance and Indemnity

The UoN is the sponsor of this trial. UoN has appropriate insurance coverage in place (including, but not limited to Clinical Trials, Professional Indemnity, Employer's Liability and Public Liability policies) in relation to the Institution's Legal Liabilities arising from the University's activities and those of its staff, whilst conducting University business and research activity. These include provision for indemnity in the event of successful litigious claim for proven non-negligent harm.

18. Publication Policy

Results of this trial will be submitted for publication in a relevant peer reviewed academic journal. Results will be also submitted for the doctoral work of Arabella Baker. The findings and trial methodology will be presented at conferences. Lay summaries for participants will be prepared and a copy will be sent to participants, unless they decline receiving it. All data will be reported anonymously, participants will not be identified in any publications.

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SIGNATURE PAGE

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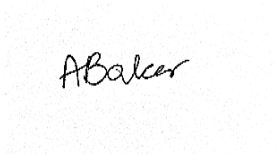
Signature: 

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