Testing video information about mammography screening in a randomized design

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Principal Investigator (PI): Manja Dahl Jensen, MD, PhD-student.
Supervisors: John Bordersen, Volkert Dirk Siersma, Kasper M. Hansen.
Sponsor: University of Copenhagen, Faculty of Health and Medical Sciences
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STATEMENT OF COMPLIANCE

The study will comply to “The Danish Code of Conduct for Research Integrity” (see webpage: *https://ufm.dk/en/publications/2014/the-danish-code-of-conduct-for-research-integrity*)

INVESTIGATOR'S SIGNATURE

The signature below constitutes the approval of this protocol and provides the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements.

Principal Investigator or Clinical Site Investigator:

Signed: _____ Date: 2020-05-28

Name: Manja Dahl Jensen
Title: Medical doctor, PhD-student

Investigator Contact Information
Affiliation: University of Copenhagen, Department of Public Health
Address: Oester Farimagsgade 5, 1014 Copenhagen, Denmark
Telephone: 0045 26804803
Email: madj@sund.ku.dk

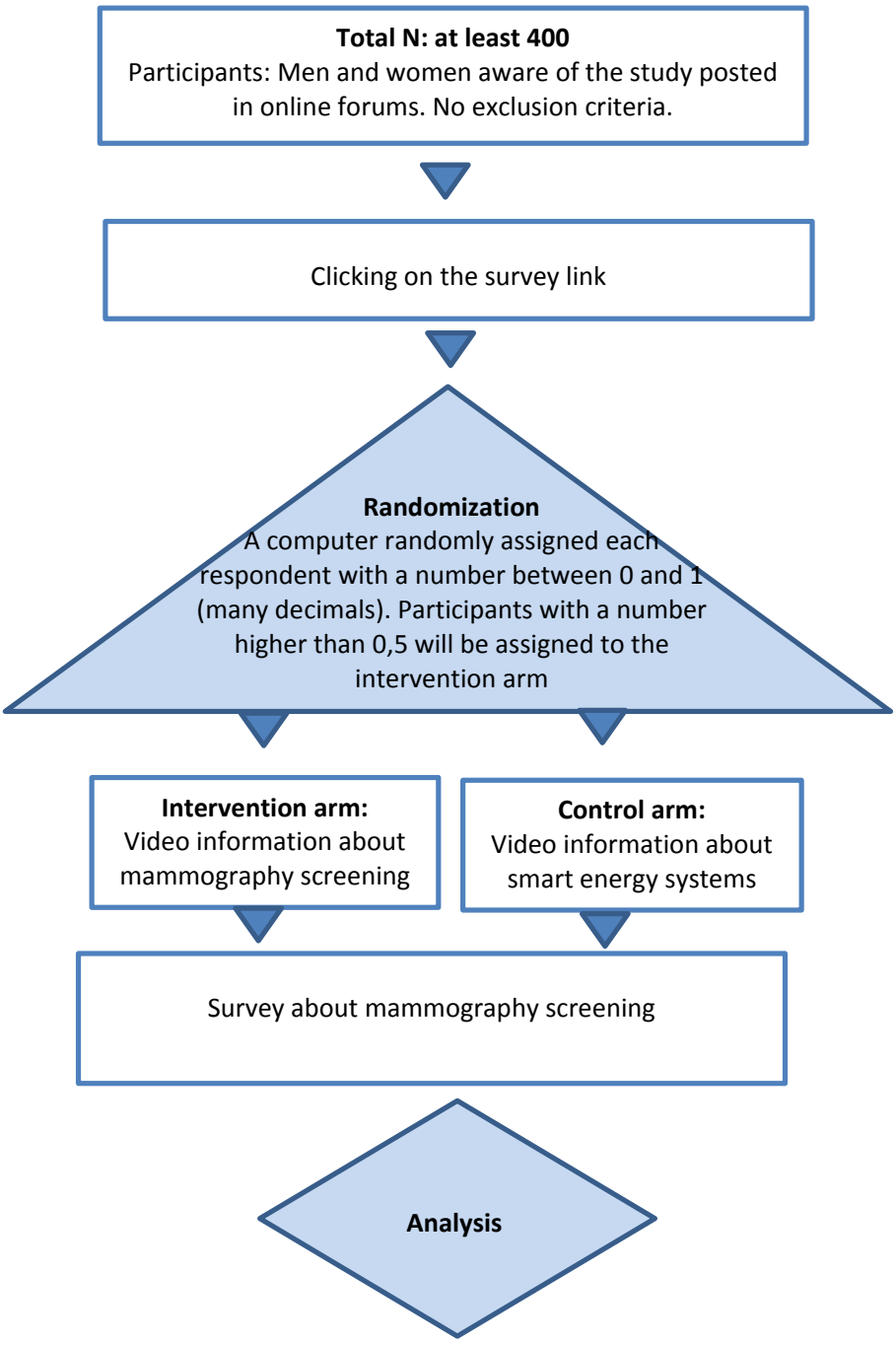
1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title:	Testing video information about mammography screening in a randomized design
Study Description:	This study tests video information about mammography screening using a randomized comparison and a quantitative survey. Primary hypotheses: Video information about mammography screening change people's choice. Less people will be in favor of screening in the intervention group compared with the control group.
Objectives:	Primary Objective: - No.1: To examine whether video information changes choice (e.g. individual and societal) about mammography screening. - No.2: To examine whether video information about mammography screening increases knowledge. - No.3: To examine whether video information changes opinions related to mammography screening. Secondary Objective: To determine the feasibility and acceptability of using an online video informing about mammography screening together with an online survey designed to access choice, knowledge and opinions.
Endpoints:	Primary Endpoint: No.1: Choice, No.2 Knowledge, No.3: Opinion change. Secondary Endpoints: Response duration and acceptability of the video.
Study Population:	An open convenience sample mainly consisting of a diverse set of students, however we will open up for other respondents.
Phase or Stage:	Not applicable
Description of Sites:	Depending on number of respondents the survey will be uploaded at one or more online forums in Denmark.
Description of Study Intervention/Experimental Manipulation:	The intervention comprises a video informing about mammography screening. The video is based on best available evidence about important outcomes of mammography screening over 20 years (breast cancer mortality reduction, overdiagnosis, false positives, false negatives and living longer as a patient) compared with no screening.
Study Duration:	Estimated study duration is one month from the study opens to enrollment until completion of data collection.
Participant Duration:	We assume that each participant will use 30 minutes completing the survey.

1.2 SCHEMA

Flow Diagram



1.3 SCHEDULE OF ACTIVITIES

The schedule below is provided as an example and should be modified or replaced as appropriate.

Tasks	Preparation before study	May 2020	May-June 2020	June 2020
Development of video information	x			
Development of survey	x			
Identification of relevant online forums to post the survey		x		
Administration of the survey including:				
- Randomization			x	
- +/- Intervention			x	
- Data collection			x	
Data analysis				x

2 INTRODUCTION

2.1 STUDY RATIONALE

To our knowledge no study has tested the possibilities of educating the public about mammography screening through video information. This study test whether video information reflecting best available evidence increase knowledge and whether or not it is feasible to educate about this complex issue through video information posted online.

2.2 BACKGROUND

Screening for disease can lead to intended benefits and unintended harms. Among the most important benefits are: reduced mortality, morbidity and incidence of disease. Among the harms are: overdiagnosis, overtreatment and more years as a patient. It is not easy to evaluate whether benefits exceed harms or vice versa as they do not have the same unit.

Studies have demonstrated limited public awareness and understanding of the key harm in screening: overdiagnosis (1, 2). In addition, public beliefs in the benefits of screening are in general exaggerated and their beliefs in the harms understated (3).

This study will contribute with knowledge regarding the use of video information about mammography screening in education of the public. Can video information increase knowledge and does the information change opinions and choice about this complex issue?

2.3 RISK/BENEFIT ASSESSMENT

2.3.1 KNOWN POTENTIAL RISKS

This study does not include any potential physical, social, legal or economic risks. Participants might be surprised of the limited benefits of mammography screening as literature have revealed that most people overestimate the benefits. In addition, participants might be surprised that screening can cause harm.

2.3.2 KNOWN POTENTIAL BENEFITS

If participants gain in depth understanding of key concepts of screening it might help them in the decision-making process (deciding whether or not to undergo screening) in the future.

2.3.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

The risk that participants might be surprised by the information is addressed by the provision of the PI's email address in the survey. If participants want clarification of any aspects of information presented in the video they have the ability to contact the PI for further information and clarification.

3 OBJECTIVES AND ENDPOINTS

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Primary		
No.1: To examine whether video information changes choice (e.g. individual and societal). No. 2: To examine whether video information increases knowledge about mammography screening. No. 3. To examine whether video information changes opinions about mammography screening.	Primary endpoint no. 1: Choice A possible effect on choice will be examined by comparing the proportion of participants in favor of screening (on the individual level and societal level respectively) between the intervention arm and the control arm. Primary endpoint no. 2: Knowledge It will be examined whether the scale is responsive to a possible effect of the intervention. Effect on knowledge will be measured by the differences in correct answers to knowledge questions (conceptual and numerical) between the intervention arm and the control arm. The marking scheme is designed to assess whether participants are approximately correct in their numeric estimates, thereby capturing their 'gist' of the quantitative information. Marks for conceptual and numeric questions will be summed for each participant. Primary endpoint no. 3: Opinion change Among other analysis a "relative importance analysis" will be performed to know which of the opinions (e.g. worry, anticipated regret, screening history ect.) are most important in relation to "choice" (e.g. individual choice and having screening in the society).	It is currently unknown how informed laypeople in Denmark evaluate benefits and harms of mammography screening on the societal level.
Secondary		
To determine the feasibility of using an online video informing about mammography screening together with an online survey designed to access knowledge and opinions.	Secondary endpoints: As this part of the study test the acceptability and feasibility of the intervention and survey no formal hypothesis are available. Descriptive statistics will be calculated. - Response duration: mean response duration. - Acceptability of the video: percentages of the participants finding the video to be neutral, in favor of or against mammography screening.	Acceptability of the video and response duration may affect knowledge and opinions.

4 STUDY DESIGN

4.1 OVERALL DESIGN

This study will be conducted as a single site parallel-arm, 1:1 randomized controlled trial (RCT) through a web-based quantitative survey uploaded in online forums. Participants will be randomized to either the intervention group (video information about mammography screening followed by a survey about mammography screening) or the control group (video information about energy systems followed by the same survey). The survey computer programme will randomly assign each respondent to either the intervention arm or the control arm in the beginning of the survey. Each time a participant click on the survey the programme will generate a random number between 0 and 1 (with many decimals). If the number is higher than 0,5 the survey will display the video informing about mammography screening before the participant have the opportunity to answer questions. If the number is 0,5 or less the participant will be presented with a video about energy systems before answering the same questions. The allocation will be concealed to all researchers conducting the trial until the survey is completed. The statistician doing the analysis will not be aware of the allocation. Participants will of cause know if they have been presented with a video informing about mammography screening or not but they do not know about the intervention and control design of the study.
The rationale behind using a randomized design compared to a before- and after comparison is that we expect participants to find it hard using long time answering questions about this complex issue as they are not necessarily target group for mammography screening.

Hypothesis related to the primary outcome:

- No.1: Video information about mammography screening change people's choice. Less people will be in favor of screening in the intervention group compared with the control group.
- No.2: Video information about mammography screening increases knowledge.
- No.3: Video information about mammography screening changes opinions.

Hypothesis related to the secondary outcome:

- Survey response time/duration is expected to be around 30 minutes.
- Most participants will find the video about mammography screening to be neutral with some finding it to be against mammography screening.

No stratification is planned. Sub-studies are described in section 9.4.7.

4.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

The control group provide the study with a baseline. The randomized design reduces the likelihood that any possible difference in knowledge levels between the two study arms occur due to factors outside the experiment assuring internal validity. Using the randomized design instead of a before-and after comparison is timesaving.

4.3 JUSTIFICATION FOR INTERVENTION

The survey will be uploaded in online forums. This mode of delivery will make participants completely anonymous and make the study free of costs. The intervention group will be asked to view a video about mammography screening lasting 22 minutes. The length of the video-intervention was informed by the legal requirements regarding information provision related to healthcare interventions as well as "think-aloud test" of the storyboard preformed on 10 laypeople.

4.4 END-OF-STUDY DEFINITION

A participant is considered to have completed the study if he or she has completed the survey. The study is completed when at least 400 participants have completed the survey.

5 STUDY POPULATION

5.1 INCLUSION CRITERIA

Participants eligible for the study includes all men and women age 18-75.

5.2 EXCLUSION CRITERIA

None.

5.3 LIFESTYLE CONSIDERATIONS

N/A.

5.4 SCREEN FAILURES

N/A

5.5 STRATEGIES FOR RECRUITMENT AND RETENTION

Recruitment is planed through online forums at the University of Copenhagen as well as online forums at other institutions. No interview or run-in period will be used to identify eligibility as all men and women coming across the survey is eligible.
At first page of the survey it will be explicitly stated that participation is voluntarily. Participants will not be compensated or provided any incentives to participate.
The survey will be accessible until the target enrolment size is reached. This study does not specify specific enrollment sample size by gender, race and ethnicity, or age. No retention plan is included.

6 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S)

6.1 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S) ADMINISTRATION

6.1.1 STUDY INTERVENTION OR EXPERIMENTAL MANIPULATION DESCRIPTION

The study intervention is a video informing about mammography screening. This video was developed prior to the study with the goal of informing about mammography screening in a societal perspective using best available evidence. Only the intervention arm will be provided with the video before answering questions in the survey. The control arm will be provided with a video informing about smart energy systems before answering the same questions.
The study intervention is directly linked to the primary endpoint (choice, knowledge and opinions about mammography screening).

6.1.2 ADMINISTRATION AND/OR DOSING

It will be possible for the participants in the intervention arm and control arm to play the video as many times as wanted as well as to stop and rewind the video if needed.

6.2 FIDELITY

6.2.1 INTERVENTIONIST TRAINING AND TRACKING

As the online survey is programmed to deliver the intervention no problems relating to fidelity of delivery is expected.

6.3 MEASURES TO MINIMIZE BIAS: RANDOMIZATION AND BLINDING

This study will be conducted as a parallel-arm, 1:1 randomized controlled trial.
As the observations in this study is captured by an online survey immune to observer bias the PI will be blinded. The statistician conducting the analysis will be blinded to the group allocations during analysis.
As no adverse events can occur in this trial blinding will not be broken for any participants.

6.4 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION ADHERENCE

All participants will be asked whether or not the saw the video. A test-question for the intervention group is included in the questionnaire that can only be answered if participants saw the video. However, we are not able to objectively evaluate whether or not participants adhere and study the hole video.

6.5 CONCOMITANT THERAPY

N/A.

6.5.1 RESCUE THERAPY

N/A.

7 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

7.1 DISCONTINUATION OF STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

No events can be thought of that would result in discontinuation. Nor the PI will have reasons to discontinue a participant from the study.
As the study involves a single reply to a survey no efforts will be made to follow-up participants who discontinue the study (only reply to part of the survey).
If a participant discontinues from study intervention (reply that he or she has not viewed the video) but still answer the survey he or she will be kept in the study.

7.2 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Participants are free to withdraw from participation in the study at any time without request.
The reason for participant discontinuation or withdrawal from the study cannot be assessed in this trial design.

7.3 LOST TO FOLLOW-UP

N/A as the study involves a single reply to a survey.

8 STUDY ASSESSMENTS AND PROCEDURES

8.1 ENDPOINT AND OTHER NON-SAFETY ASSESSMENTS

Procedures, measures and assessments to be done to fulfill the objectives:

1. Administration of the survey through uploading in online forums.
2. Termination of data collection when (at least) 400 participants have answered the survey.
3. Scoring knowledge questions
4. Statistical analysis of data

8.2 SAFETY ASSESSMENTS

N/A.

8.3 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

N/A.

8.3.1 DEFINITION OF ADVERSE EVENTS

N/A.

8.3.2 DEFINITION OF SERIOUS ADVERSE EVENTS

N/A.

8.3.3 CLASSIFICATION OF AN ADVERSE EVENT

8.3.3.1 SEVERITY OF EVENT

N/A.

8.3.3.2 RELATIONSHIP TO STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

N/A.

8.3.3.3 EXPECTEDNESS

N/A.

8.3.4 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

N/A.

8.3.5 ADVERSE EVENT REPORTING

N/A.

8.3.6 SERIOUS ADVERSE EVENT REPORTING

N/A.

8.3.7 REPORTING EVENTS TO PARTICIPANTS

N/A.

8.3.8 EVENTS OF SPECIAL INTEREST

N/A.

8.3.9 REPORTING OF PREGNANCY

N/A.

8.4 UNANTICIPATED PROBLEMS

8.4.1 DEFINITION OF UNANTICIPATED PROBLEMS

This protocol uses the definition of Unanticipated Problems as defined by the Office for Human Research Protections (OHRP). OHRP considers unanticipated problems involving risks to participants or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

8.4.2 UNANTICIPATED PROBLEMS REPORTING

N/A.

8.4.3 REPORTING UNANTICIPATED PROBLEMS TO PARTICIPANTS

N/A.

9 STATISTICAL CONSIDERATIONS

9.1 STATISTICAL HYPOTHESES

Primary Endpoint no.1:
We hypothesize that, compared to participants in the control arm, participants receiving video information about mammography screening will be less likely to be in favor of mammography screening. Our null hypothesis is that there will be no difference in the proportion of participants in favor of screening between the control and the intervention arm.

Primary Endpoint no.2:
We hypothesize that, compared to participants in the control arm, participants receiving video information about mammography screening will have increased knowledge about mammography screening. Our null hypothesis is that there will be no difference in the knowledge levels between the control and the intervention arm.

Primary Endpoint no.3:
We hypothesize that, there will be differences between the relative importance of different opinion items in relation to choice comparing the intervention arm and the control arm. Our null hypothesis is that there will be no difference in opinions between the control and the intervention arm.

Secondary endpoints:
As this part of the study test the acceptability and feasibility of the intervention and survey no formal hypothesis are available. Descriptive statistics will be calculated related to the response duration, drop-out rate and acceptability of the video.

9.2 SAMPLE SIZE DETERMINATION

Calculation of sample size was based on the primary endpoint "societal choice". Sample size was determined to be 400 participants. The calculations are based on the following:

Robust evidence has revealed that laypeople are overestimating the benefits and ignoring or underestimating the harms of screening thereby basing the positive attitudes on wrong assumptions. It would therefore be expected that fewer laypeople would favour screening after the intervention compared with before.

We assume 90% to be in favour mammography screening in the public. We consider 10 percentage points (pp) change in choice to be a difference we want to be able to detect in our study.

If 400 people participate in the study we are able to detect a decrease from 90% to 80% in favour of screening, or larger, with 80% power at a 5% significance level.

9.3 POPULATIONS FOR ANALYSES

Concerning the primary endpoint no. 1 and no. 2 (e.g. comparison of choice and knowledge between the two study arms) three analysis will be performed:

- An Intention-to-Treat (ITT) analysis including all randomized participants.
- A modified Intention-to-Treat analysis including all participants in the intervention arm who stated they saw at least some of the video.
- A per-protocol analysis including only those participants in the intervention arm who saw the hole video and answered the hole survey.

9.4 STATISTICAL ANALYSES

9.4.1 GENERAL APPROACH

Baseline characteristics (e.g. sociodemographic) will be compared between the intervention and control arm using descriptive statistics. Each of the three primary endpoints will be analyzed and check of assumptions will be made. The secondary outcomes will be assessed with descriptive statistics.

9.4.2 ANALYSIS OF THE PRIMARY ENDPOINT(S)

No.1: Comparison of choice: We will compare the proportion of participants in favor of screening (on the individual level and societal level respectively) between the intervention arm and the control arm. Results will be presented as the likelihood that (a possible) difference in proportion of people in favor of screening between the two study arms are due to chance.

No.2: Comparisons of knowledge score between the intervention group and control group will be conducted using the independent sample t-test.

No.3: Comparisons of opinions: Among other analysis a "relative importance analysis" will be performed to know which of the opinions (e.g. worry, anticipated regret, screening history ect.) are most important in relation to choice (e.g. individual choice and having screening in the society).

9.4.3 ANALYSIS OF THE SECONDARY ENDPOINT(S)

The secondary endpoints will be assessed using descriptive statistics:

- Response duration: mean response duration.
- Acceptability of the video: percentages of the participants finding the video to be neutral, in favor of or against mammography screening.

9.4.4 SAFETY ANALYSES

N/A.

9.4.5 BASELINE DESCRIPTIVE STATISTICS

Baseline characteristics (e.g. sociodemographic) will be compared between the intervention and control arm using descriptive statistics.

9.4.6 PLANNED INTERIM ANALYSES

None.

9.4.7 SUB-GROUP ANALYSES

Sub-studies planned: We will explore possible heterogeneous effects on choice across gender, age, knowledge, educational level, experience with the programme and the sector. We will also explore possible heterogeneous effects on knowledge gain across the subgroups.

9.4.8 TABULATION OF INDIVIDUAL PARTICIPANT DATA

Individual participant data will be completely anonymous and listed according to date and time of survey completion.

9.4.9 EXPLORATORY ANALYSES

N/A.

10 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

10.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

10.1.1 INFORMED CONSENT PROCESS

10.1.1.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO PARTICIPANTS

As the study does not contain any GDPR related information and does not impose any risk to the participants informed consent is not necessary according to Danish law.

10.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

N/A.

10.1.2 STUDY DISCONTINUATION AND CLOSURE

There are no reasons for this study to be terminated or temporary suspended before “end of study”.

10.1.3 CONFIDENTIALITY AND PRIVACY

The data collected in this survey will be totally anonymous. Investigators will not have any possibility of identifying the participants. The responses to the survey will be stored according to date and time of completion. The survey does not contain sensitive personal information.

10.1.4 FUTURE USE OF STORED SPECIMENS AND DATA

Data collected for this study will be analyzed and stored at the University of Copenhagen.

10.1.5 KEY ROLES AND STUDY GOVERNANCE

Principal Investigator	**Medical Monitor or Independent Safety Monitor**
Manja Dahl Jensen, MD, Phd-student	N/A
University of Copenhagen	
Oester Farimagsgade 5, 1014 Copenhagen, Denmakr	
0045 26804803	
madj@sund.ku.dk	

10.1.6 SAFETY OVERSIGHT

N/A.

10.1.7 CLINICAL MONITORING

N/A.

10.1.8 QUALITY ASSURANCE AND QUALITY CONTROL

N/A.

10.1.9 DATA HANDLING AND RECORD KEEPING

10.1.9.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Data collection will be the responsibility of the PI. The PI will be responsible for ensuring the accuracy, completeness, legibility of the data reported.

10.1.9.2 STUDY RECORDS RETENTION

The survey replies will be archived until May 2050.

10.1.10 PROTOCOL DEVIATIONS

This protocol defines a protocol deviation as any noncompliance with the clinical trial protocol.
It will be the responsibility of the PI to use continuous vigilance to identify and report deviations. All deviations will be addressed in study source documents reported at ClinicalTrials.gov.

10.1.11 PUBLICATION AND DATA SHARING POLICY

This study is intended for publication in a peer-reviewed journal such as BMJ open or BMC Pilot and Feasibility Studies. When the study is completed, access to study data will be provided by the PI on request.

10.1.12 CONFLICT OF INTEREST POLICY

Any conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed.

10.2 ADDITIONAL CONSIDERATIONS

N/A.

10.3 PROTOCOL AMENDMENT HISTORY

Version	Date	Description of Change	Brief Rationale

11 REFERENCES

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