

Investigating the use of behavioural science informed messages to facilitate attendance at Breast Cancer Screening

Version 1.2 15/02/2022

MAIN SPONSOR: Imperial College London

FUNDERS: Imperial College London, NIHR Patient Safety Translational Research Centre

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IRAS Project ID: 311717

REC reference: **xxx**

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Name & Role

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Sponsor

Imperial College London is the main research Sponsor for this study. For further information regarding the sponsorship conditions, please contact the Head of Regulatory Compliance at:

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Funder

This work is being funded through an NHS England grant (London region) awarded to the study team at the NIHR Patient Safety Translational Research Centre (PSTRC).

This protocol describes the study and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the study. Problems relating to this study should be referred, in the first instance, to the Chief Investigator.

This study will adhere to the principles outlined in the UK Policy Frame Work for Health and Social Care Research. It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

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GLOSSARY OF ABBREVIATIONS

BCT	Behavioural Change Technique
ICL	Imperial College London
NHS	National Health Service
NHSBSP	NHS Breast Screening Programme

NHSE	NHS England
RCT	Randomised Controlled Trial
SMS	Short Message Service

KEYWORDS

Breast cancer screening, uptake, behavioural science, SMS messaging

STUDY SUMMARY

TITLE Investigating the use of behavioural science informed messages to facilitate attendance at Breast Cancer Screening

DESIGN Randomised Controlled Trial

AIMS To determine the impact of SMS messages, and a video developed using behavioural science upon the uptake

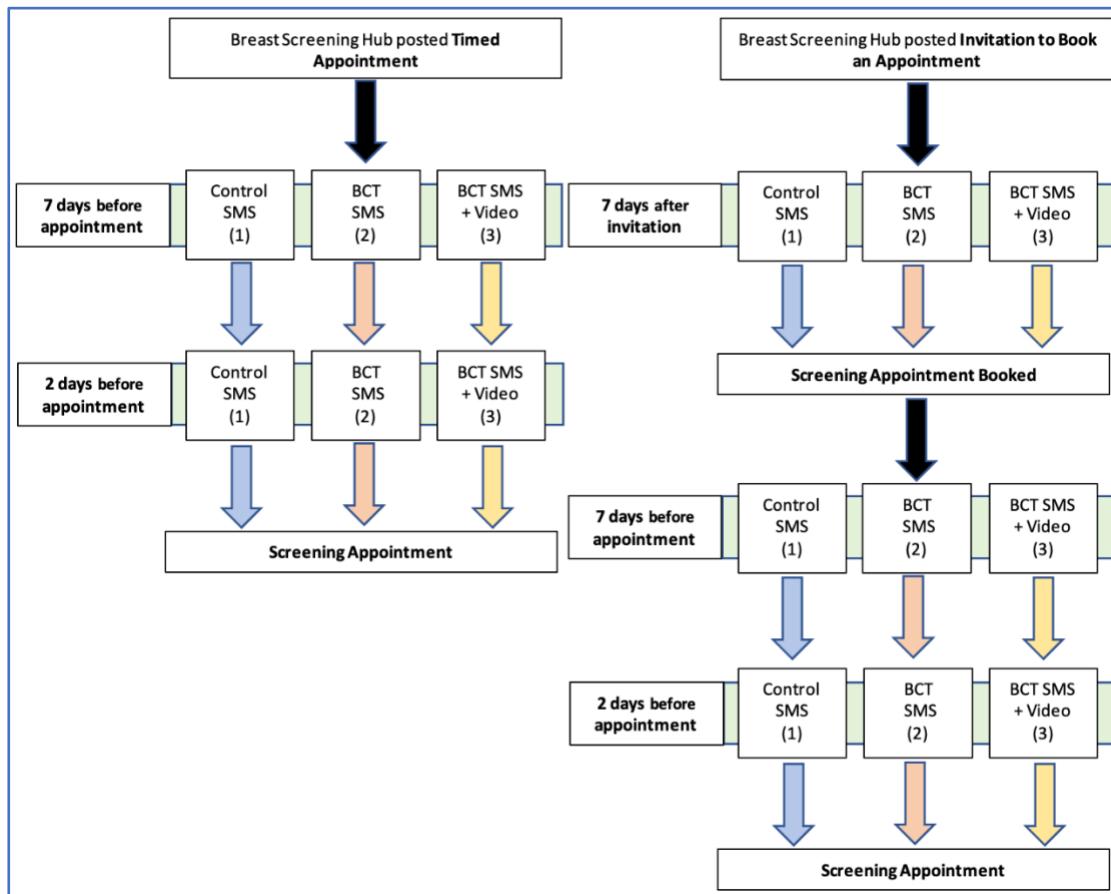
OUTCOME MEASURES Primary: percentage uptake of the invitation to screen. Secondary: percentage uptake of the invitation to screen amongst population subgroups (e.g. by demographic factors, and by invitation type).

POPULATION All women aged between 50 and 70, invited to screen in the London breast cancer screening region.

ELIGIBILITY Eligible to attend the NHSBSP in London during the study period.

DURATION 6 months

REFERENCE DIAGRAM



1. INTRODUCTION

1.1. BACKGROUND

Breast cancer is the most common cancer in the UK, with 1 in 8 women affected during their lifetime(1). Whilst survival rates are high, the 5-year survival rate is 72% higher with the earliest stage breast cancer, compared to the latest disease stage(2). The NHS Breast Cancer Screening Programme (NHSBSP) invites women aged 50 to 70 years old every three years to a mammogram. By enabling earlier detection, it is estimated that the NHSBSP saves 1300 lives per year(3).

Despite the potential benefits of breast cancer screening, attendance is falling. Coverage rates have fallen nationally by 1.3% between 2016 and 2020. London has shown particularly poor rates (67.3%), with coverage in 2020 below the acceptable target of 70%(4). The COVID-19 pandemic has exacerbated these trends with an estimated 1 million mammograms missed, due to the cessation of screening to minimise transmission risk (5)(6). Counteracting these trends is a significant public health priority.

Furthermore, there is increasing concern regarding the socio-demographic inequalities in breast screening uptake. For example, the odds of attendance amongst those from the most

deprived areas is 5% lower than those from less deprived areas (7)(8). In addition, in one study in London, the adjusted odds of attendance were almost three times higher amongst White British, compared to Asian women, and six times higher than Black women(9). The barriers faced by these groups need to be appreciated, and any intervention to increase attendance ensure that inequalities are not widened(10).

Behavioural Science is a field of study concerning understanding the processes underpinning human action(11). Behavioural theories, such as the Capability Opportunity Motivation-Behaviour (COM-B) model (12, 13), have been used to understand the determinants of several health behaviours including handwashing and smoking (14, 15). Recent studies have shown the application of behavioural science to screening may also facilitate uptake of invitations (16). In one study by Kerrison et al. the use of a reminder prompt SMS increased uptake by 5% (17). However, the use of plain text messages limits which behavioural determinants can be feasibly addressed, and what techniques can be used. Video messages can allow for more complex and a broader range of behavioural change techniques (BCTs) to be incorporated, and therefore have greater impact upon attendance.

1.2. RATIONALE FOR CURRENT STUDY

Whilst behavioural science-informed messages have previously been trialled by groups to facilitate breast screening attendance, their effectiveness has been variable (18). One of the reasons for this, is that SMS messages are of limited length and formatting capability, thus restricting the number of BCTs that can be included. Moreover, some behavioural techniques are more complex than others, and plain text can limit the extent to which these can be feasibly incorporated. Video messaging provides a delivery mechanism that may enable more complex, and different combinations to be trialled. There is however, a paucity of data regarding the impact of sending a video-based behavioural science message upon attendance rates at breast cancer screening programmes. This study looks to investigate the impact of a video-message, compared to behavioural science-based SMS messages and standard reminder SMS.

2. STUDY OBJECTIVES

The primary object is to determine the impact of behavioural science informed (1) video and (2) SMS messages compared to usual care, upon uptake of breast cancer screening. Secondary objectives involve how this impact on attendance differs between population subgroups including people from differing demographic groups and people invited to open, as opposed timed appointments (see Study Design).

3. STUDY DESIGN

This study will be conducted as a randomised control trial (RCT) in the London screening region of the NHSBSP. The study will last over 6 months. The administrative hub for the NHSBSP in London is based at the Royal Free Hospital, who will oversee invitation scheduling, message delivery and outcome data collation through their existing delivery systems.

Participants will be randomised using simple randomisation method in a 1:1:1 fashion to either intervention arm or usual care. Randomisation will utilise a computerised system in which each participant who is due for screening in the study period is randomly allocated a

number corresponding to the message they will receive. This will be undertaken by the screening hub, and will be passed on to the message delivery service who will ensure the correct template is sent.

Written invitations are sent, as standard practice, by the NHSBSP to invite women to either (1) an appointment at a set time, date and location (so-called timed invitations) or (2) to call and book an appointment (or open invitation). Following this, as part of usual care, those selected for open invitations will receive a first SMS 7 days post written invitation. They will then receive two SMS reminders, 7 days and 2 days prior to the appointment, once it has been booked. Those who receive timed invitations will just receive the two reminder messages, 7 and 2 days prior to the appointment. The decision to offer an individual a timed or open invitation is made by the screening service based on their covid-19 recovery process, and will not be altered by this project.

This RCT will involve randomising participants to receive the usual care messages (according to the timings outlined above), a plain text SMS incorporating BCTs or the BCT SMS with a new link to a video incorporating more BCTs (see **figure 1 for message content in each of the three trial arms**).

The content of the intervention messages, and the video have been developed through extensive Patient and Public Involvement and Engagement work including 10 interviews, 2 focus groups and 2 co-design workshops. Members of the public have been consulted throughout the process, especially regarding the representations of individuals in the video, and the message content. The feedback received has been used to alter the materials, and further feedback received. Through this iterative approach we have ensured content is appropriate. We have also sought feedback from members of the Oremi centre (a mental health day service specifically for African Caribbean and Arabic Speaking adults) and Gendered Intelligence (a trans-led organisation to improve the quality of life of trans people) to ensure individuals from these groups are happy with representations. Screening commissioners, led by Dr Kathie Binysh (NHS England Breast Screening Lead, London), have also approved this content. The NHS Identity team have provided approvals for the use of NHS logos/branding, and the team at London Northwest Healthcare NHS Trust approved the use of their name.

The video will be hosted on a private page on the Imperial College London website, which will be available only to those who have been sent the link. The video will be translated into several languages, with voice overs also available in different languages, to ensure people from a diverse background are able to understand the content.

After 3 months from the initial written invitations, data will be collated from the breast screening hub regarding whether an individual attended an appointment and whether the messages were successfully sent. This will be repeated at 6 months corresponding to the key performance indicator of the service.

Figure 1. Message content for timed and open invitations for the trial arms (a) control, (b) plain text SMS with BCTs and (c) BCT SMS with new link to BCT video.

Reminders at 7 and 2 days prior to appointment		
a) Control	b) Behavioural SMS	c) Behavioural SMS + Video

<p>Don't forget your breast screening appointment is at 10:36 am on 26/10/2021 at Edgware Community Hospital. To re-arrange or cancel your appointment call 0203 758 2024 or visit www.london-breastscreening.org.uk For further info please click here: https://youtu.be/7CAJqKnxKa4</p>	<p>Following the breast cancer screening letter you received, don't forget your appointment is at 10:36am on 26/10/2021 at Edgware Community Hospital. Detecting breast cancer early gives you the best chance to fully recover. To find out why we're inviting you and what to expect watch this video: https://youtu.be/7CAJqKnxKa4 To re-arrange or cancel your appointment call 0203 758 2024</p>	<p>Following the breast cancer screening letter you received, don't forget your appointment is at 10:36am on 26/10/2021 at Edgware Community Hospital. Detecting breast cancer early gives you the best chance to fully recover. To find out why we're inviting you and what to expect watch this video: https://imperial.ac.uk/ABBS To re-arrange or cancel your appointment call 0203 758 2024</p>
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Message sent 7 days after the open invitation to book an appointment		
a) Control	b) Behavioural SMS	c) Behavioural SMS + Video
<p>Breast Screening appointments have changed. You will have received a letter on how to book an appointment. Please call the London Breast Screening Hub on 020 3758 2024 or visit www.london-breastscreening.org.uk to arrange an appointment at your nearest location. For further info please click here: https://youtu.be/7CAJqKnxKa4"</p>	<p>Breast Screening appointments have changed. You will have received a letter on how to book an appointment. Please call the London Breast Screening Hub on 020 3758 2024 or visit www.london-breastscreening.org.uk to arrange an appointment locally.</p> <p>Detecting breast cancer early gives you the best chance to fully recover. To find out why we're inviting you and what to expect watch this video: https://youtu.be/7CAJqKnxKa4</p>	<p>Breast Screening appointments have changed. You will have received a letter on how to book an appointment. Please call the London Breast Screening Hub on 020 3758 2024 or visit www.london-breastscreening.org.uk to arrange an appointment locally.</p> <p>Detecting breast cancer early gives you the best chance to fully recover. To find out why we're inviting you and what to expect watch this video: https://imperial.ac.uk/ABBS</p>

3.1. STUDY OUTCOME MEASURES

The primary outcome of this study is the percentage uptake of breast cancer screening, three months after the initial invitation letter. This will be reported as both intention-to-treat and per protocol, according to whether the SMS messages were received. Currently it is estimated that the screening service has access to 80% of mobile numbers of invitees.

Secondary outcomes will involve how the uptake differs according to:

- demographics (e.g. ethnicity, deprivation)
- invitation type (open and timed invitation)
- attendance history (previous non-attendee, recurrent attendee, first-time invitee)

We will also repeat the primary analysis to determine the uptake at 6 months. These timepoints were chosen firstly from the literature which suggests the impact of behavioural interventions occurs in the acute decision phase, but also following discussion with the screening service where 6 monthly reporting coincides with a key performance indicator.

4. PARTICIPANT ENTRY

4.1. PRE-REGISTRATION EVALUATIONS

As participants will be those invited as part of the NHSBSP, no additional pre-registration evaluations will be required.

4.2. INCLUSION CRITERIA

The inclusion criteria will match those used by the NHSBSP, as all invitations will come directly from the programme, as per usual care. These include:

- Aged between 50 to 70 at the time of invitation
- Lives within London screening region
- Registered as female with GP

4.3. EXCLUSION CRITERIA

The exclusion criteria will match those used by the NHSBSP, as all invitations will come directly from the programme, as per usual care. These include:

- Previous attendance at breast screening in the current (3-year cycle)
- Opted out of receiving SMS messages
- Opted out of screening
- Previous bilateral mastectomy

4.4. WITHDRAWAL CRITERIA

As messages will be sent through the NHSBSP and undertaken as part of the usual care process the withdrawal criteria will match those of the screening service. Individuals can opt-out of both messaging or screening at any time throughout the process and will be excluded. No data for those who highlight opt-outs will be held or analysed by researchers. The opt-out decision will be retained by screening services, and they will not be contacted with the messages. This process involves either indicating opt-out through the national data opt-out (should they wish not for their data to be used) or by contacting the London breast cancer screening service using the details provided on their invitation letter. Those who have opted out will not have data passed to researchers for analysis. However, following pseudo-anonymisation it will not be possible for researchers to identify individuals who wish to have their data withdrawn.

5. ADVERSE EVENTS

5.1. DEFINITIONS

Adverse Event (AE): any untoward medical occurrence in a patient or clinical study subject.

Serious Adverse Event (SAE): any untoward medical occurrence or effect that:

- **Results in death**
- **Is life-threatening** – refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe
- **Requires hospitalisation, or prolongation of existing inpatients' hospitalisation**
- **Results in persistent or significant disability or incapacity**
- **Is a congenital anomaly or birth defect**

Medical judgement should be exercised in deciding whether an AE is serious in other situations. Important AEs that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above, should also be considered serious.

5.2. REPORTING PROCEDURES

All adverse events should be reported. Depending on the nature of the event the reporting procedures below should be followed. Any questions concerning adverse event reporting should be directed to the Chief Investigator in the first instance.

5.3.1 Non serious AEs

All such events, whether expected or not, should be recorded- it should be specified if only some non-serious AEs will be recorded, any reporting should be consistent with the purpose of the trial end points.

5.3.2 Serious AEs

An SAE form should be completed and emailed to the Chief Investigator within 24 hours. However, relapse and death due to breast cancer, and hospitalisations for elective treatment of a pre-existing condition do not need reporting as SAEs.

All SAEs should be reported to the <name of REC> where in the opinion of the Chief Investigator, the event was:

- 'related', ie resulted from the administration of any of the research procedures; and
- 'unexpected', ie an event that is not listed in the protocol as an expected occurrence

Reports of related and unexpected SAEs should be submitted within 15 days of the Chief Investigator becoming aware of the event, using the NRES SAE form for non-IMP studies. The Chief Investigator must also notify the Sponsor of all related and unexpected SAEs.

Local investigators should report any SAEs as required by their Local Research Ethics Committee, Sponsor and/or Research & Development Office.

Contact details for reporting SAEs

RGIT@imperial.ac.uk

CI email (and contact details below)

Fax: xxx, attention xxx

Please send SAE forms to: xxx

Tel: xxx (Mon to Fri 09.00 – 17.00)

6. ASSESSMENT AND FOLLOW-UP

The end of the study will be 6 months after initiation. Following this period, we will undertake an assessment of the uptake of screening by participants. At two time-points (during and at the end of the study period) feedback from participants who have watched the video will be sought. This will involve anonymised feedback regarding an individual's opinions on the content, characters, and style of the video. This feedback will be hosted on the video website and will be optional. Informed consent will be sought for the completion of this anonymous

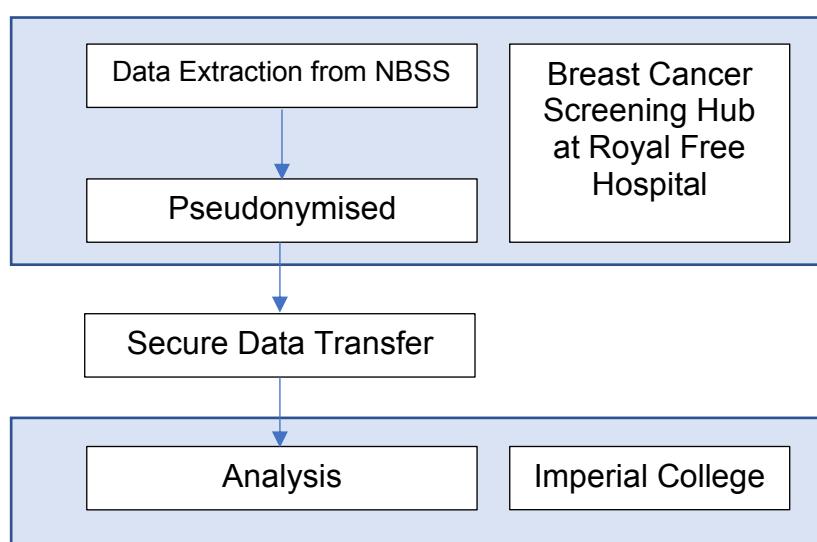
questionnaire. The questionnaire is available at this link:
https://imperial.eu.qualtrics.com/jfe/form/SV_1YPMnU1vvyeNDxA

7. STATISTICS AND DATA ANALYSIS

There will be three trial arms in this RCT. Based upon previous studies, and what would constitute a clinically meaningful effect size a power calculation has been conducted (18). Assuming 5% type 1 error probability, 80% power, and an effect size of 3%, results in a minimum sample size of 2797 people per study arm (8391 in total). Chi-squared non-parametric statistic will be used to determine whether effects are significant. Secondary outcomes will examine the impact upon attendance amongst subgroups including those with different invitation type and from different demographic groups. A regression model will be developed to test these secondary hypotheses.

Data flow for this project is demonstrated in **figure 2**.

Figure 2 Demonstrating data flow of project.



Variables that will be extracted for analysis will include:

1. Demographics
 - Age at invitation
 - Index of Multiple Deprivation (derived from postcode)
 - Ethnicity
 - Previous attendee/non-attendee/first-time invitee
2. Invitation
 - Invitation type (open or timed)
 - Screening service location
3. Outcome
 - Attendance at booked appointment

Data and all appropriate documentation will be stored for a minimum of 10 years after the completion of the study, including the follow-up period.

8. REGULATORY ISSUES

8.1. ETHICS APPROVAL

The Study Coordination Centre has obtained approval from the **xxx** Research Ethics Committee (REC) and Health Research Authority (HRA). The study must also receive confirmation of capacity and capability from each participating NHS Trust before accepting participants into the study or any research activity is carried out. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

8.2. CONSENT

No consent will be sought from participants, as the act of alerting them to differing message contents can impact upon their behaviour and may bias results. For example, alerting participants to a breast screening project using messages to improve uptake, may act as a prompt for individuals who may have not attended to attend. Furthermore, there is a need to test such messaging as a population-level intervention, to see if it has an overall effect. Basing such testing on small groups that have explicitly consented, will likely bias findings, and ignore the impact upon under-represented groups. Moreover, the current project is simply changing the wording of messages and incorporating a different video intervention, which has been approved by NHSE. Screening services have the capacity to autonomously change the content of screening reminders, for example in response to fluctuating uptake or change health policies on a local level. Explicit consent therefore is not being sought for this project, as it does not diverge from the existing care that individuals currently receive. Not requiring consent is in keeping with existing projects that have received ethical approval and been conducted in England on the use of behavioural science messaging (16,17).

On the other hand, written consent will be sought from the online feedback form for the video intervention. Participants will be free to withdraw from completing this questionnaire at any time, or not to undertake the survey at all should they wish. Consent to enter the study will be sought from each participant only after a full explanation has been given, an information leaflet offered, and time allowed for consideration. An online participant consent will be obtained. The right of the participant to refuse to participate without giving reasons will be respected.

8.3. CONFIDENTIALITY

The Chief Investigator will preserve the confidentiality of participants taking part in the study and is registered under the Data Protection Act.

Data will be pseudo-anonymised, with the code retained by the NHS Screening Service for their purposes, researchers will not have access to this so will not be able to de-anonymise data. It will be extracted from the NBSS system with identifiers removed and transferred to the Big Data Analytical Unit (BDAU) at Imperial College London for analysis. The BDAU is the data science facility within the Centre for Health Policy (CHP) at Imperial College. Its mission is to ensure the maximum use, impact and dissemination of research using healthcare data. Our secure environment (BDAU SE) was the first ISO 27001 certified research environment within the College. It is also 100% compliant with NHS IG Toolkit Version 14.1 (EE133887)

and holds a “Standards Met” status for DSP Toolkit (EE133887-BDAU). The BDAU has years of experience hosting and analysing sensitive healthcare data for research. These include datasets from CPRD, NHS Digital, NHS England, and NHS Improvement.

8.4. INDEMNITY

Imperial College London holds negligent harm and non-negligent harm insurance policies which apply to this study.

8.5. SPONSOR

Imperial College London will act as the main Sponsor for this study. Delegated responsibilities will be assigned to the NHS trusts taking part in this study.

8.6. FUNDING

The Patient Safety and Translational Research Centre (PSTRC) at Imperial College London will fund this study through an NHS England grant received by the research team. No renumeration will be provided to participants, as the sending of messages will encompass usual practice. Message costs above the existing limits will be covered by the research team to ensure the screening service does not incur a deficit due to this study.

8.7. AUDITS

The study may be subject to audit by Imperial College London under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the UK Policy Framework for Health and Social Care Research.

9. STUDY MANAGEMENT

The day-to-day management of the study will be co-ordinated through Amish Acharya.

10. PUBLICATION POLICY

A robust publication policy is envisaged with aggregated unidentifiable data published in peer review journals and in conference presentations. To ensure widespread dissemination of the work to relevant stakeholders, dissemination will also include non-academic means such as blog posts. This work will also be incorporated into a PhD thesis. No identifiable data will be used in any publication.

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