Plan Overview

A Data Management Plan created using DMPonline

Title: 'Vicky:' a draft psychology-based intervention to increase uptake of smear tests during and after the COVID-19 pandemic: FOCUS GROUP

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Template: University of Manchester Generic Template

Project abstract:

Vicky is a digitally-based online intervention that aims to increase the uptake of cervical smears during and beyond the COVID-19 pandemic.

The present study (ethics application 13350) is a follow up study on an earlier study (11246), which was a 'think aloud' study conducted to gather data (i.e., thoughts, feelings, views) from individual participants to address the research questions in relation to Vicky.

We will be conducting 8 focus groups to collect feedback on the acceptability and usability of Vicky that has been revised from the earlier study:

1. FOCUS GROUPS A, B, and C will be conducted with participants who have had previous exposure to Vicky through the above study. These groups will enable the researcher to pilot the approach and data collection tools, and unless significant changes are made to the research design following these focus groups, the data from these groups be used alongside the other groups detailed below.

2. FOCUS groups, D, E, F, G and H will be conducted with participants who have had no prior exposure to Vicky.

Participants in all focus groups will have unlimited access to Vicky for one week before the meeting.

Recruitment of 12 to 18 participants overall for both focus

groups.

ID: 89228

Start date: 01-06-2022

End date: 01-08-2022

Last modified: 16-05-2022

Copyright information:

'Vicky:' a draft psychology-based intervention to increase uptake of smear tests during and after the COVID-19 pandemic: FOCUS GROUP

Manchester Data Management Outline

1. Will this project be reviewed by any of the following bodies (please select all that apply)?

- Ethics
- Funder

2. Is The University of Manchester collaborating with other institutions on this project?

- No - only institution involved

3. What data will you use in this project (please select all that apply)?

- Re-use existing data (please list below)
- Acquire new data

FOCUS GROUPS A, B and C (comprised of new data and reuse of previously acquired data):

1. Electronic consent (new data)

2. Screening and demography data from the fist study (think aloud) will be re-used in the present study to summarise demography etc (re-use of already acquired data)

3. Audio+video (VA), transcription data from one Zoom-initiated, cloud-based recording of each focus group (new data). Only the combined VA file and the transcription file will be retained for the study. The stand-alone audio file is deleted by the researcher after the meeting.

FOCUS GROUPS D, E, F, G and H (all new data):

1. Electronic consent.

2. Screening and demography data (two-part online questionnaire hosted by Qualtrics).

The first part is composed of screening questions to check their eligibility. These will collect responses on:

Confirmation of:

1. *Cervix status (full or partial)*
2. *Age (between 24 and 64 years)*
3. *Fall into one of the following groups:*
    1. Received your first smear test invite but have not attended yet
    2. Never had a smear test
    3. Been hesitant about going for a smear test by 6 months or more during the last 10 years
    4. Have attended a smear test in the past but NOT every 3 or 5 years as recommended according to age during the last 10 years
4. *Current residency in the UK (must be Yes)*
5. *Current registration with a GP in the UK (must be Yes)*
6. *Able to speak, read and write English independently of someone helping them (this is based on B1 (intermediate competency in English as defined by: https://www.efset.org/english-score/) (must be Yes)*
7. Be resident in the UK at the time of recruitment into the study (must be a Yes)
8. Be registered with a GP at the time of recruitment into the study (must be a Yes)
9. Not currently receiving treatment for precancerous cervical lesions or cervical cancer at the time of recruitment into the study
10. Not currently taking part in a research study designed to increase uptake of smear tests at the time of recruitment into the study
11. Have returned to a normal screening schedule (every 3 years if aged 25 to 49; every 5 years if aged 50 to 64 years) if you have received treatment for cervical lesions/cancer in the past
12. Be able to speak, read and write English independently of someone helping you
13. Able to give fully informed consent

If the participant does not meet the screening criteria, they are informed immediately via the software underpinning the form, thanked for their time, and their screening data will be deleted by the researcher.

Demographic details if confirmed eligible:

If and only if, participants meet all the eligibility criteria will the second part of the form be released for them to complete. This is demographic part and will collect additional information to complement the screening data including:

- Martial status or living arrangements (including the number of dependent children)
- Ethnicity
- Smear test history (e.g., if they have ever attended, etc)
- Sexual orientation
- Religion
- Education level
- Employment status
- If they are currently shielding themselves or others during COVID-19
- Postcode
- Contact email

NB: IP addresses and location data are disabled in Qualtrics for this study.

The data items above are collected because uptake of smear tests is influenced by a number of factors including religion, ethnicity, etc. The postcode is collected to assign a deprivation score which is another factor influencing uptake.

As the study population of small (12 to 18 participants) and we are collecting postcodes, only a deprivation score will be assigned to individual postcodes using the following government tool:

http://imd-by-postcode.opendatacommunities.org/imd/2019

3. As per above for Focus groups A, B, and C.

4. Where will the data be stored and backed-up during the project lifetime?

- Other storage system (please list below)
- P Drive (postgraduate researchers and students only)
- University of Manchester Research Data Storage Service (Isilon)

Data type	**Data handling**	**Storage during study**	**Long term storage (after the study is completed)**
Consent form			
Completed consent form (completed by participant)	Encrypted, password protected	Secure server provided by UoM	Transferred to data custodian on completion of the thesis for secure storage 5-10 years provided by UoM
Participant log ID			
This log contains a list of participants' unique ID numbers and initials only	Encrypted, password protected and stored separately from screening/ demography data but together with the completed consent forms	Secure server provided by UoM	Destroyed on completion on thesis
Screening/demography data			
If not eligible for the study	Destroyed immediately by the researcher using Qualtrics automatic delete data function	NA	NA
If eligible for the study	Qualtrics provided secure server storage that is password protected	Qualtrics	Destroyed on completion of the thesis
Responses to Vicky during 1-week independent use before meeting	Qualtrics collected responses	Qualtrics	Destroyed on completion of the thesis

Focus group recorded session			
1 x combined video+audio (VA) file	Encrypted, password protected	Secure server provided by UoM	Destroyed when transcription considered complete
A stand-alone audio file	Not used/destroyed immediately after the meeting	NA	NA
A transcription file (i.e., voice to text file).	Anonymised/ encrypted, password protected	Secure server provided by UoM	Transferred to data custodian on completion of the thesis for secure storage 5-10 years provided by UoM

Files stored temporarily: Any local copies of files stored on the researcher's PC are destroyed once copies have been transferred to the University of Manchester. Files stored to Zoom's cloud are deleted by the researcher once they have been downloaded and checked for completion.

5. If you will be using Research Data Storage, how much storage will you require?

- 1 - 8 TB

During the study plus long-term storage: RDS as indicated above.

6. Are you going to be working with a 3rd party data provider?

- No

7. How long do you intend to keep your data for after the end of your project (in years)?

- 5 - 10 years

Questions about personal information

Personal information, also known as personal data, relates to identifiable living individuals. Special category personal data is more sensitive information such as medical records, ethnic background, religious beliefs, political opinions, sexual orientation and criminal convictions or offences information. If you are not using personal data then you can skip the rest of this section.

Please note that in line with data protection law (the General Data Protection Regulation and Data Protection Act 2018), personal information should only be stored in an identifiable form for as long as is necessary for the project; it should be pseudonymised (partially de-identified) and/or anonymised (completely de—identified) as soon as practically possible. You must obtain the appropriate ethical approval in order to use identifiable personal data.

8. What type of personal information will you be processing (please select all that apply)?

- Anonymised personal data
- Audio and/or video recordings
- Pseudonymised personal data
- Personal information, including signed consent forms
- Special categories and criminal convictions

See previous sections.

Consent forms

Demography and screening data

VA file and transcription data.

If applicable, researcher hand written notes will be transferred to hard copy via word processing and stored within the secure server. Originals will be shredded. Researcher notes will not contain any identifying information on participants.

9. How do you plan to store, protect and ensure confidentiality of the participants' information (please select all that apply)?

- Anonymise data
- Control access to buildings, rooms and filing cabinets where data, computers, devices or hardcopy materials are held
- Encrypt files, folders, computers and devices where personal data is held
- Pseudonymise data and apply secure key management procedures
- Where needed, follow The University of Manchester guidelines for disposing of personal data
- Store data on servers, computers or devices that are not connected to an external network, including the internet
- Store data on servers or computers that are approved by The University of Manchester and securely backed up

See table above.

*** Hard copy materials access**

Data collection will be conducted working remotely from the researcher's home office. All hard copy study materials and data will be secured in a study-specific secure document box at the researcher's home. The box and key will be stored separately.

*** Privacy during recordings**

Data collection will be conducted working remotely from the researcher's home office. The researcher will ensure the privacy of participants during the live recording through earing headphones so that a participant's responses cannot be heard; closing doors in the household and arranging with other members of the family not to interrupt the session.

10. If you are storing personal information (including contact details) will you need to keep it beyond the end of the project?

- Yes – Other

Participants are informed and explicitly consented to allow the research team to retain the email address they have provided to be used to contact them if they have consented to be contacted about future researcher involving the development of Vicky.

11. Will the participants' information (personal and/or sensitive) be shared with or accessed by anyone outside of the University of Manchester?

- No

12. If you will be sharing personal information outside of the University of Manchester will the individual or organisation you are sharing with be outside the EEA?

- Not applicable

13. Are you planning to use the personal information for future purposes such as research?

- Yes

14. Who will act as the data custodian for this study, and so be responsible for the information involved?

Professor Emma Banister (main supervisor)

15. Please provide the date on which this plan was last reviewed (dd/mm/yyyy).

2022-04-05

Project details

What is the purpose of your research project?

This is Part 2 of a research pipeline evaluating a digital intervention called Vicky designed to increase the uptake of smear tests during and after the COVID-19 pandemic. Part 1 involved interviewing individual participants during 'think aloud' interviews.

Part 2 involves collecting feedback after participants have been allowed to interact over a 1-week period with an updated version of Vicky (based upon feedback from Part 1), using a focus group approach and a discussion guide to prompt discussion. We are planning to conduct 8 focus groups in total. The focus groups will aim to assess the usability and acceptability of Vicky within the intended population.

The research questions are:

RQ1: Does 'Vicky' reflect the diversity of barriers to uptake of smear tests among different groups of people eligible for screening?

RQ2: Does 'Vicky' offer people who are eligible for screening rapid, workable solutions to those barriers and what improvements can be made?

RQ3: Is 'Vicky' easy to use and navigate?

RQ4: Is 'Vicky' acceptable as an intervention within this target population?

What policies and guidelines on data management, data sharing, and data security are relevant to your research project?

The University of Manchester Data Protection Policy
Policyhttp://documents.manchester.ac.uk/display.aspx?DocID=14914

The University of Manchester Records Management Policy
http://documents.manchester.ac.uk/display.aspx?DocID=14916

The University of Manchester Publications Policy
http://documents.manchester.ac.uk/display.aspx?DocID=28526

The University of Manchester Research Data Management Policy
http://documents.manchester.ac.uk/display.aspx?DocID=33802

The University of Manchester Research Data Management Standard Operating Procedures
http://documents.manchester.ac.uk/display.aspx?DocID=42605

The University of Manchester Intellectual Policy
Policyhttp://documents.manchester.ac.uk/display.aspx?DocID=24420

The University of Manchester It Policies and guidelines
https://www.itservices.manchester.ac.uk/aboutus/policy/

Guidance on the use of Zoom for Researchers
https://documents.manchester.ac.uk/DocuInfo.aspx?DocID=48888

Responsibilities and Resources

Who will be responsible for data management?

Diane Elizabeth Halliwell for the University of Manchester (all data capture, data quality, data storage and backup, data archiving).
Data custodian: Professor Emma Banister.

What resources will you require to deliver your plan?

Access to p drive off campus.
Access to study secure research Data Storage off campus.
Physical document safe for study-specific documents.

Data Collection

What data will you collect or create?

Consent forms.
Collection of screening, personal and demographic data.
Collection of visual, audio and transcription data.

How will the data be collected or created?

Consent forms:
Collected Via Qualtrics.
Screening/demography form:
Collected via Qualtrics.
Recorded sessions:
Visual, audio and transcription via Zoom remotely.

Documentation and Metadata

What documentation and metadata will accompany the data?

A document will be maintained to outline how the dataset was collected. This will be a in the form of a README file (i.e., a basic text) file providing detailed information on the methods used to generate the data that can be read alongside the dataset

This will include:

The dates that Vicky was issued to participants.

The date of each focus group.

A copy of the discussion guide.

Ethics and Legal Compliance

How will you manage any ethical issues?

The consent forms explicitly requests consent for a participant's data to be used anonymously for teaching and publication purposes.

The retention, storage and sharing of data related to this study is described in detail elsewhere in this document.

Encryption will be performed using 7-Zip as recommended by the University of Manchester. Passwords are created simultaneously to protect encrypted files.

Qualtrics: access to the software is provided through the University of Manchester VPN and duo authentication, which is accessed only by the researcher.

Data storage includes the researcher p drive (consent form only) and a dedicated RDS space for the researcher.

How will you manage copyright and Intellectual Property Rights (IPR) issues?

Copyright of publications is normally owned by publishers.

Data generated during the study will be owned by the funder (AMBS).

Design and content of 'Vicky' jointly shared between researcher and University of Manchester.

Storage and backup

How will the data be stored and backed up?

Please refer to the above table.

How will you manage access and security?

*** Access**

Access to the study specific DBB provided by the University of Manchester will be provided by the main supervisor through the provision of passwords. The password is known only to the researcher.

Access to the consent forms / ID log is only available via the researcher's p drive and only accessible to the researcher (Diane E Halliwell).

Selection and Preservation

Which data should be retained, shared, and/or preserved?

For retention and curation, please refer to the above table.

What is the long-term preservation plan for the dataset?

Data will be placed into RDS for long-term storage and preservation of data, to be accessed by others only for research purposes.

Consent forms should be retained for a minimum of three years after the end of study.

Data Sharing

How will you share the data?

Data sharing will occur only between research team members.

The data is unique and specific to the intervention being designed. We are planning to evaluate the intervention further through a RCT. For these reasons, no data sharing is anticipated at present.

Are any restrictions on data sharing required?

See above. It's not possible to decide on whether a non-disclosure agreement is suitable at this stage.