
'Vicky' a draft psychology-based intervention to increase cervical cancer screening: Part 2 Focus Group

A Data Management Plan created using DMPonline

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Project abstract:

Vicky is a digitally-based intervention that aims to increase engagement with cervical cancer screening (CCS) 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."

This second, present study (13350) aims to gather data to address the same research questions but within a focus group setting, using a semi-structured approach. This setting has several differences to those of the 'think aloud' individual sessions in that:

1. It permits organised discussion to gain information about their views and experiences of Vicky as a whole rather than separate parts of the intervention.
2. It permits an insight into people's shared understanding of Vicky.
3. It permits an insight into the ways of how individuals are influenced by others within a group situation.

We feel that the above approach is relevant and justified at this stage of piloting Vicky for 3 main reasons:

- a) It allows us to observe the everyday use of language and culture in relation to Vicky and identify issues of conflict.
- b) It allows us to explore the degree of consensus about Vicky.

c) It permits the collection of a large body of data in a shorter period of time.

Research question:

Q1: Does 'Vicky' reflect the diversity of barriers to CCS uptake 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?

A researcher from the project team will act as moderator of the focus group, which will be conducted remotely via Zoom and audio and video recorded, and automatically, transcribed by the software.

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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)?

- Acquire new data

***Personal data:**

We will collect the following data:

1. Electronically signed consent forms (hosted by Qualtrics).
2. Screening and demography data (two-part online questionnaire hosted by Qualtrics).
3. Audio+video plus transcription data.

1. Consent forms

A link to an online digital consent form hosted by Qualtrics is provided to prospective participants. Once they have completed their details, the researcher prints the form to PDF, adds in their details and issues the completed form back to participants for their records. An encrypted, password protected copy of the consent form is stored on the researcher's p drive. The original consent forms are retained on Qualtrics only until the study has been published, after which they are permanently deleted.

2. Screening and demography:

Participants will be asked to complete an online questionnaire which is divided into two parts. **A unique participant ID number is generated automatically by Qualtrics during the participant's completion of the following forms. This ID number is used to identify the participants to other team members:**

The first part is composed of screening questions to check their eligibility. These will

collect responses on:

Confirmation of:

1. ***Age (between 25 and 64 years)***
2. ***Cervix status (full or partial)***
3. ***Current residency in the UK (must be Yes)***
4. ***Current registration with a GP in the UK (must be Yes)***
5. ***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)***
6. ***If applicable, that they are not currently receiving treatment for pre-cancerous cervical lesions (must be No or not applicable)***
7. ***Fall into one of the following groups:***
8. ***Never attended cervical cancer screening (CCS) (eligible)***
9. ***Have attended CCS but have been hesitant/delayed screening by 6 months or more in the last 10 years (eligible)***
10. ***Have attended CCS in last 10 years but not every 3 or 5 years as recommended (eligible)***
11. ***Regularly attends CCS every 3 or 5 years and has not delayed by more than 5 months (screening failure)***
12. ***Currently taking part in any research study designed to increase engagement in CCS (must be NO)***

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
- CCS 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 CCS 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 CCS take up.

As the study population of small (8 to 10 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>

The Covid-19 question is collected because people who are shielding have particular barriers to CCS. The email is collected for follow up of any questions related to the transcript file (see below). It is also used to inform them that their participation is complete and provide the link to the Amazon voucher given as a thank you for their

participation.

3 Audio+video, transcription data:

The University of Manchester will be conducting one, Zoom-initiated, cloud-based recording of a focus group, moderated by the researcher. This will take place following a 2-week period where each participant has been provided with the latest version of Vicky and asked to review all part of the intervention. The focus group will be conducted using a semi-structured questionnaire designed to prompt feedback and enable discussion amongst the participants.

Zoom produces three types of files during recordings (i.e., a combined video+audio (VA), audio only file, and a transcription file). However, only the combined VA recording and the transcription file will be retained for the study. The stand-alone audio file is automatically deleted by Zoom after 30 days and is not used in the study.

The transcript and associated combined VA recording will be anonymised at the end of the session by assigning unique IDS generated by Qualtrics for each participant. this will replace their names in the transcript whenever it occurs.

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)

1. Consent form:

The completed electronic, digitally signed consent form by both the participant and the researcher will be encrypted, password protected and stored on the researcher's p drive provided by the University of Manchester for the duration of the study.

Any consent form details retained on Qualtrics will be deleted on publication of the study. Consent forms will be transferred to the data custodian on publication of the study for long-term storage.

2. Screening and demography (eligible participants):

During the study: Participants are automatically assigned a unique participation number by Qualtrics when they begin the screening and demography questionnaire. ***This number will be used to identify the participant to other members of the research team.***

The original unanalysed screening and demographic data are collected and stored for the duration of the study by Qualtrics software. During analysis, this data will be downloaded, encrypted and password protected and transferred to RDS allocated to the researcher by the University of Manchester.

After the study: The original raw data screening/demography data hosted by Qualtrics will be deleted on publication of the study.

Screening and demography data (screening failures): Partially completed screening and demography data collected from participants and stored by Qualtrics who fail screening is deleted as soon as possible by the researcher. No data is retained for long term storage.

3. Qualtrics data collected during exposure to intervention (Vicky): Parts of the intervention are designed to promote planning etc and require input from the participants during use. No formal analysis of this data is planned.

4. Focus group session:

Focus group (Live session): Zoom produces 3 types of files when recording:

A combined video+audio (VA) file;
A stand-alone audio file.

A transcript of the recording (a voice to text report).

Only the combined VA and transcript will be used for this study. The standalone audio file is deleted automatically by Zoom after 30 days and is not used in the study.

The combined VA file will be used to help check the transcript which will be anonymised by assigning each participant's unique ID (generated previously by Qualtrics) to their part of the transcript. The transcript will be encrypted, password protected and stored on the RDS provided for the researcher by the University of Manchester.

The VA file will be destroyed on publication of the study.

Summary: Consent forms, anonymised transcript, analysis of screening/demography are destined for long-term secure storage at the University of Manchester.

Local data files on Qualtrics will be deleted on publication on the study. zoom files are automatically deleted after 30 days.

Files stored temporarily:

Copies of files downloaded and stored on the researcher's PC are destroyed once copies have been transferred to the University of Manchester. Bitdefender software is used to permanently delete files and are non-recoverable.

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

Audio, video and transcription data.

Any hard copy notes (e.g., made during the focus group) will be written-up on word processing software and originals shredded. text files will be encrypted, password protected and transferred to the researcher's dedicated secure storage (ision) provided by the University of Manchester.

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

- Impose suitable data sharing and collaboration agreements
- 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

*** 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**

The researcher will take precautions to ensure the privacy of participants during the live recording. These include wearing 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.

*** University servers storage**

Personal identifying information relating to participants (i.e., consent forms) will be stored and accessed via the researcher's p drive. All files will be encrypted and password protected and only accessible to the researcher. these will be transferred to the data custodian at the end of the study.

All transcripts will be fully anonymised as well as interview notes taken by the researcher during the focus group session. The combined VA recording will anonymised and retained until after publication in case of queries during the publication process.

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 in relation to follow up queries and if they wish their details to be entered onto a database for future research.

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).

2021-11-24

Project details

What is the purpose of your research project?

This is Part 2 of a two-part piloting stage to evaluate a digital intervention called Vicky designed to increase engagement with CCS during and beyond 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 2-week period with an updated version of Vicky (based upon feedback from Part 1), using a focus group approach and a semi-structured questionnaire to prompt discussion. The focus group session will review all parts of Vicky.

The research questions are:

RQ1: Does 'Vicky' reflect the diversity of barriers to CCS uptake 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
Policy <http://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
Policy <http://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.

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 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 the focus group.

A copy of the questionnaire.

Ethics and Legal Compliance

How will you manage any ethical issues?

The consent forms explicitly request 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's 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?

*** Consent forms:**

Qualtrics-generated consent forms, signed by both parties, will be encrypted, password protected and stored on the researcher's p drive. These will be transferred to the data

custodian for long-term storage on publication of the study. Original electronic consent forms will be stored on Qualtrics until the study is published, after which time they will be deleted using the software.

*** Personal identifying meta-data (screening data and demographic data for those confirmed as eligible for the study):**

Each participant is automatically assigned a unique identifier (participant number) by the Qualtrics software when they begin the screening and demography questionnaire. This data and their responses are stored securely within the Qualtrics platform until needed for analysis. The raw data will be downloaded, encrypted and password protected and transferred to the researcher's RDS server. The original raw data on qualtrics will be deleted on publication of the study.

*** Video+audio recording x 1:**

The combined VA file will be downloaded, encrypted and stored on the researcher's RDS until after the publication of the study. At this point, the VA file will be permanently deleted. The associated transcript will be anonymised, by assigning the unique ID to each participant's part of the transcript. The transcript will be encrypted, password protected and stored on the researcher's RDS.

Zoom original cloud based files are automatically deleted by the software after 30 days. Any locally downloaded files to the researcher's PC is deleted using Bitdefender software and is not recoverable.

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.

Access to the consent forms is provided via will be stored on 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:

1. Consent forms (in case of complaints).
2. Anonymised screening and demography data.
3. Anonymised transcript from the VA recording of the focus group session.

These data will be passed to the data custodian for long term storage (5 - 10 years) after the publication of the study.

As the data is specific and unique to the development of the intervention itself, which may or may not attract IPR later, no re-sue is anticipated other than to support any IPR it may attract.

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 and the researcher is currently looking into whether the intervention could attract IPR. 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.