Plan Overview

A Data Management Plan created using DMPonline

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

Creator: Diane Elizabeth Halliwell

Principal Investigator: Diane Halliwell

Data Manager: Diane Halliwell

Affiliation: University of Manchester

Template: University of Manchester Generic Template

Project abstract:

Vicky is a digitally-based online (web) intervention that aims to increase the uptake of cervical screening (previously known as a cervical smear) 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 4 focus groups to collect feedback on the acceptability and usability of Vicky that has been revised from the earlier study:

1. FOCUS GROUPS A and B 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 and E 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 approximately 24 participants overall with 4 to 8 participants in each focus group.

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Copyright information:

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'Vicky:' a draft psychology-based intervention to increase the uptake of cervical screening 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)?

- Funder
- Ethics

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
- Re-use existing data (please list below)

All focus groups will be conducted remotely online using Zoom.

FOCUS GROUPS A and B (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 two remotely conducted Zoom-initiated, cloud-based recording of each focus group (A and B; 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 once transcription is completed by Zoom.

FOCUS GROUPS D and E (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 cervical screening invite but have not attended yet
    2. Never had a cervical screening
    3. Been hesitant about going for a cervical screening by 6 months or more during the last 10 years
    4. Have attended a cervical screening 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 the uptake of cervical screening 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
- Cervical screening history (e.g., if they have ever attended, etc)
- Sexual orientation
- Religion
- Education level
- Employment status
- Postcode (first part only)
- Contact email collected only for the payment of electronic vouchers

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

The data items above are collected because uptake of cervical screening 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 is small (ideally around 24 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 and B.

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

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

Data type	Data production software	Storage handling during the study	Handling during analysis	Temporary files stored on researcher's PC	Long term storage
Consent					
Completed consent form (completed by participant)	Qualtrics provides secure server storage that is password protected and requires duo linked to the University's account and the secure Global Protect VPN to access the account provided directly to the researcher by the University of Manchester (UoM)	Downloaded to researcher's home PC, copy sent to participant; original encrypted password protected and stored on the secure server provided by UoM (researcher's P drive)	P drive	Deleted immediately after secure storage transfer to the p drive using Bitdefender and are non-recoverable	Transferred to data custodian on completion of the thesis for secure storage 5 years provided by UoM (in case of complaints)
Participant ID log					
This log contains a list of participants' unique ID numbers and initials only	Manual creation by researcher in Word	Encrypted, password protected and stored separately from screening/ demography data but together with the completed consent forms on researcher's p drive	P drive	Deleted immediately after secure storage transfer to the p drive using Bitdefender and are non-recoverable	Destroyed on completion of thesis

Screening and demography data	Data production software	Storage handling during the study	Handling during analysis	Temporary files stored on researcher's PC	Long term storage
Consent					
If NOT eligible for the study	Qualtrics provides secure server storage that is password protected and requires duo linked to the University's account and the secure Global Protect VPN to access the account provided directly to the researcher by the University of Manchester (UoM)	Destroyed immediately by the researcher using Qualtrics automatic delete data function	NA	NA	NA
Completed consent form (completed by participant)	Qualtrics	Downloaded to researcher's home PC, copy sent to participant; original encrypted password protected and stored on the secure server provided by UoM (researcher's P drive)	Anonymised data is analysed on the researcher's own home PC but transferred, encrypted and password protected at the end of each working day into Isilon	Deleted immediately after secure storage transfer to the p drive using Bitdefender and are non-recoverable	Transferred to data custodian on completion of the thesis for Destroyed on completion of the thesis
Participant ID log					
Email address for the participant: payment of vouchers only	Manual creation by researcher in Word Qualtrics	Encrypted, password protected and stored separately from screening/ demography data but together with the completed consent forms on researcher's p drive Qualtrics. The researcher already has a small bundle of vouchers to be use and has been advised to pay participants directly until these are used. For the payment of new vouchers, the email addresses will be used to complete the excel form to enable the Finance team to pay the voucher directly to the participant. The excel file will be encrypted and password protected and sent for processing to Doctoral Programmes Administrator. The researcher will send the password for the file separately to that containing the excel file.	P drive Qualtrics	Deleted immediately after secure storage transfer to the p drive using Bitdefender and are non-recoverable Deleted immediately after sending the payment information (from Outlook)	Destroyed on completion of thesis Destroyed on completion of the thesis
Screening and demography data					
Responses to Mickly during 1 week independent use by participants	Qualtrics	Destroyed immediately by the researcher using Qualtrics automatic delete data function	NA	NA	NA
If eligible for the study **Recordings of focus groups (24 hours after meeting)**	Qualtrics Qualtrics	Qualtrics Qualtrics	Anonymised data is analysed on the researcher's own home PC but transferred, encrypted and password protected at the end of each working day into Isilon	Deleted immediately after secure storage transfer to Isilon using Bitdefender and are non-recoverable	Destroyed on completion of the thesis
Email address for the participant: payment of vouchers only	Zoom – cloud based accessed through secure account provided by the UoM	Downloaded from Zoom's cloud, encrypted, password protected and transferred to Isilon / original files in Zoom's cloud deleted by researcher immediately after transfer to Isilon	Isilon	Deleted immediately after secure storage transfer using Bitdefender and are non-recoverable	Destroyed on completion of thesis
If eligible for the study 1 x combined video+audio file		Qualtrics. The researcher already has a small bundle of vouchers to be use and has been advised to pay participants directly until these			

Data type	Data production software	Storage handling during the study	Handling during analysis	Temporary files stored on researcher's PC	Long term storage
Consent					
1 x standalone audio file	As above	Download from Zoom's cloud and deleted by the researcher immediately using Bitdefender (researcher not aware of any method to only download the VA file and transcription; they are provided as a bundle). Original file in Zoom deleted by researcher after other files have downloaded	NA (not used in analysis)	Deleted immediately after secure storage transfer using Bitdefender and are non-recoverable	NA
Completed consent form (completed by participant)	Qualtrics provides secure server storage that is password protected and requires duo linked to the University's account and the secure Global Protect VPN to access the account provided directly to the researcher by the University of Manchester (UoM)	Downloaded to researcher's home PC, copy sent to participant; original encrypted password protected and stored on the secure server provided by UoM (researcher's P drive)	P drive	Deleted immediately after secure storage transfer to the p drive using Bitdefender and are non-recoverable	Transferred to data custodian on completion of the thesis for secure storage 5 years for long-term storage by UoM (in case of complaints)
1 x transcription file	As above	Anonymised by removing names and replacing the participant's name with their unique identifier; encrypted and password protected and transferred to Isilon	Isilon	Local files used on researcher's PC for transcription and analysis are deleted using Bitdefender at the end of each working day. Files are transferred back to Isilon encrypted and password protected	Transferred to data custodian on completion of the thesis for secure storage 5 to 10 years)
Participant ID log					
This log contains a list of participants' unique numbers and initials only	Manual creation by researcher in Word	Encrypted, password protected and stored separately from screening/ demography data but together with the completed consent forms on researcher's p drive	P drive	Deleted immediately after secure storage transfer to the p drive using Bitdefender and are non-recoverable	Destroyed on completion of thesis
Screening and demography data					
If NOT eligible for the study	Qualtrics	Destroyed immediately by the researcher using Qualtrics automatic delete data function	NA	NA	NA
If eligible for the study	Qualtrics	Qualtrics	Anonymised data is analysed on the researcher's own home PC and password protected at the end of each working day into Isilon	Deleted immediately after secure storage transfer to Isilon using Bitdefender and are non-recoverable	Destroyed on completion of the thesis
Email address for the participant: payment of vouchers only					
• Anonymised personal data		Qualtrics. The researcher already has a small bundle of vouchers to be use and has been advised to pay participants directly until these			

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)?

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

See previous sections.
Consent forms.
Participant ID log.
Demography and screening data
VA file and transcription data.
Email addresses of participants (for issuing the vouchers)
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)?

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

See table above.
*** Hard copy materials access**
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 (focus groups) will be conducted working remotely from the researcher's home office and the participants choice of location. 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. Participants will be offered the option of using a pseudonym name during the recordings instead of their own names.

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

- No

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?

- No

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).

2022-05-24

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 4 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. The p drive is a private and secure drive provided to the researcher during the course of the PhD by the UoM. It is accessible only to the researcher, is password protected and needs duo vpn activated to access it.
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.
Collection of email addresses for the payment of vouchers.

How will the data be collected or created?

Consent forms:
Collected Via Qualtrics.
Participant ID log:
Created manually by the researcher in Word
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 / participant ID Log) and a dedicated RDS (Isilon) space for the researcher.
Emails addresses are stored securely on Qualtrics during the project and will be deleted along with all other study relevant data on completion of the thesis; emails sent containing voucher information are deleted immediately in Outlook after the email is sent

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 RDS 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 are only available via the researcher's p drive and only accessible to the researcher (Diane E Halliwell).
Access to Qualtrics and any original data is accessible only through a secure account provided to the researcher by UoM

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.