Plan Overview

A Data Management Plan created using DMPonline

Title: The acceptability and feasibility of compassion-focused therapy groups for women with perinatal mental health difficulties

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Template: University of Manchester Generic Template

Project abstract:

Background: The perinatal period (the time around pregnancy and birth) is a time when women are at increased risk of psychological difficulties. Women experiencing moderate-severe mental health difficulties in the perinatal period are looked after within specialist services in the community or as an inpatient on a Mother and Baby Unit. Psychological therapies are recognised as being an important part of the treatment for mental health problems in this period. There is a need, however, to develop the evidence-base regarding suitable psychological interventions for this population. Compassion-focussed therapy (CFT) is a promising psychological intervention which has been found to improve psychological well being in diverse participant samples. Methods: This study will use quantitative (service data and routinely collected outcome measures) and qualitative (interviews, analysis of open-ended questions from evaluation forms collected by services) methods to examine the feasibility and acceptability of a specially tailored, group-based Compassion Focused Therapy intervention currently offered by UK Perinatal Mental Health Services. Routinely collected outcome data includes measures of psychological distress, self-compassion and parent-infant bonding. Service-level data will be gathered to examine client retention to the intervention. In interviews participants will be asked questions about the content of the course (e.g. what they found most helpful/ relevant, what they found easy/ harder to understand), aspects of its delivery (e.g. venue, timing, the approach/ communication style of the group facilitators), and also about any changes that they noticed as a result of taking part in the intervention. Analysis: Questionnaire and service-level data will be examined using descriptive statistics; interview data using inductive thematic analysis. Outcomes: It is hoped that findings from this study will be useful for refining this promising intervention, and help inform the design of larger-scale studies of effectiveness.

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The acceptability and feasibility of compassion-focused therapy groups for women with perinatal mental health difficulties

Manchester Data Management Outline

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

- 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)

New data will be acquired from interviews. The service data we are analyzing (on referrals, engagement, retention to CFT groups, data on demographic/ clinical characteristics of attendees and their scores on routinely collected outcome measures) is data that has already been collected by the service/ teams for the purposes of monitoring and evaluation. Individual level data will be pseudonymised before its transfer to the research team.

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)

The pseudonymisation key for interview participants will be stored using the University of Manchester secure network and P Drive, which is backed up daily. Digital data will be securely stored to the University of Manchester Research Data Storage (RDS) will be used which is automatically backed up regularly.
Hard copies of confidential documents that contain personal identifiable information will be stored in a locked cabinet in a member of the research teams office.
When the office is not occupied, it will be locked with appropriate physical security in place. The building the office is located in is securely locked in and out-of office hours.

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

- 1 - 8 TB

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

- Yes

Researchers will obtain data from community and inpatient perinatal mental health teams within Greater Manchester Mental Health NHS Foundation Trust on the following variables for each CFT group that has been undertaken in the team to date: number referred, number screened, number screening positive, number screening negative, reasons for service users screening negative, number beginning the intervention, number completing intervention, number completing at least 50% of the intervention, and session by session attendance. A data collection form will be provided by the research team for clinicians to enter this data. This data is not identifiable as it does not concern individual participants, but rather is summary data.

Researchers will also obtain individual-level data on the demographic and clinical characteristics of group participants, and their scores on the pre and post-intervention questionnaire measures routinely collected by the service (community settings) or evaluation forms (inpatient setting). Specifically, for each group participant, researchers will obtain data on the following variables: (mental health) diagnosis/ diagnoses, age, parity, ethnicity, martial status, education and employment status, as well as pre and post intervention item by item scores on the CORE-10 (a self-report measure of psychological distress), the OAS (a self-report measure which assesses people's beliefs about how others perceive them), the FSCRS (a self-report measure of self-compassion), the HONOS (a clinician-rated measure of health and social functioning) and post-intervention on the Perinatal POEM (a measure of patient satisfaction with the services they have received). This data will be entered by clinicians into another specially-designed data collection form. Another data collection form has been prepared for clinicians in the inpatient/ MBU team for entering data from evaluation forms. Data will be pseudonymised by clinicians prior to being transferred to the researcher, which will be done as a password-protected, encrypted file sent from the clinician's secure NHS e-mail account to the researcher's secure NHS e-mail account. The procedure for pseudonymisation is that the clinicians will assign numbers to each of the participants in a particular group. They will keep a key of the names that correspond with each number for each group as a password-protected, encrypted file on their NHS computer. The researcher has created an excel template for this purpose. The researcher will not have access to the pseudonymisation key or any other information that could identify these service users at any point during or after the study and the pseudonymisation key will be destroyed by the clinician after data is analysed.

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)?

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

Interview participants

As part of the recruitment process, participants who express interest in the study will be asked to sign a consent to contact form where they will be asked to leave personal identifiable information (e.g. name, contact number, email address, address).

Prior to being involved in the study, all participants will be asked to complete a consent form which will include personal identifiable information (e.g. name) and their signature.

Interview participants will be asked to complete a demographic questionnaire which will collect personal data as well as sensitive personal data (e.g. age, marital status, living arrangements, country of origin, recent mental health diagnosis/diagnoses, ethnic background, education and employment status for both the woman & her partner, family finances, mental health of woman & her partner, date of birth, age of youngest child, and sex and age of other children). Women will also be asked to provide the name and contact details of their GP (their date of birth is also collected for this purpose).

The interviews will be audio-recorded onto an encrypted, password-protected device provided by the University of Manchester. All personal identifiable information will be removed during the transcription process. Participants will be assigned a pseudonym. To reduce bias and increase participant involvement, participants will be asked at interview to provide a pseudonym they would like to be referred to as during write up.

Participants can consent to the research team retaining the contact details so a summary of the overall findings can be sent. Participants will indicate this on the consent form. This is optional- a person can still participate in the study if they do not wish to do this.

Service data relating to CFT groups

Researchers will obtain individual-level data on the demographic and clinical characteristics of CFT group participants, and their scores on the pre and post-intervention questionnaire measures routinely collected by the service (community settings) or evaluation forms (inpatient setting). Specifically, for each group participant, researchers will obtain data on the following variables: (mental health) diagnosis/ diagnoses, age, parity, ethnicity, martial status, education and employment status, as well as pre and post intervention item by item scores on the CORE-10 (a self-report measure of psychological distress), the OAS (a self-report measure which assesses people's beliefs about how others perceive them), the FSCRS (a self-report measure of self-compassion), the HONOS (a clinician-rated measure of health and social functioning) and post-intervention on the Perinatal POEM (a measure of patient satisfaction with the services they have received). As described under question 6, this data will be pseudonymised prior to being transferred to the research team, with the pseudonymisation key stored in a secure location on NHS computers. The researcher will not have

access to this key at any time.

9. Please briefly outline how you plan to store, protect and ensure confidentiality of the participants' information.

The interviews will be recorded onto a password-protected University of Manchester recording device. This device will be stored in a locked bag and then transferred to the principal researcher's University of Manchester secure storage as soon as possible.

Electronic data will be stored in the following way:

- P: Drive:
  - Key matching participants details with IDs and pseudonyms (password protected & encrypted)
- Research Data Storage (RDS):
  - Separate storage of electronic/audio consent (filename must not include pseudonym or participant ID)
  - Temporary storage of pseudonymised audio recordings (these will be deleted after they have been transcribed and checked)
  - Pseudonymised transcripts
  - Demographic data
  - Participant contact details
  - (Anonymous) summary data on CFT groups (referrals, attendance etc.)
  - Pseudonymised demographic/clinical data and pre-post intervention questionnaire data for group attendees

The key will link the participant's name and contact details with their participant ID number and pseudonym. This file will be password protected and encrypted. It will be stored separately from the questionnaires, audio recordings, and transcripts on the Principal Researcher's P Drive as recommended by the University of Manchester's SOP. Only the Principal Researcher and the Chief Investigator will have access to this information.

Additional security will be applied to the RDS, such as limiting read access to only the necessary researchers. Audio consent will be recorded separately to the interview data and will be stored separately on the RDS from all other research data (e.g., anonymised transcripts, anonymised demographic & questionnaire data). Each audio consent file will individually be password protected.

Audio recordings of the interviews will be temporarily stored on the RDS. The audio data will be stored in an mp3 format using password protection which will only be known by the research team. Each of the audio recordings will be individually password protected and encrypted. The password will contain a minimum of 7 characters, have a mixture of upper- and lower-case letters, symbols and numbers. The files will be encrypted (e.g., 7-zip software, or whatever recommended encryption software is recommended by the University of Manchester Research IT department at that time); the encryption key will only be shared with research team members who require access to the raw audio recordings for the adequate execution of their role within the study. Once transferred to university storage (RDS), the recordings will be checked and then deleted from the audio recording device.

As well as the Principal Researcher, transcription of interviews may be undertaken by a member of University staff or university-approved transcription service. If transcription is undertaken by a member of University staff they will sign a confidentiality agreement prior to completing any transcription. To receive university approval, transcription services will have already signed a contract with the university containing confidentiality clauses. Audio files will be transferred to the member of university staff and transcription company securely, as password-protected and encrypted files. All interviews will be transcribed in a secure location where the data will not be visible or audible to others (for the Principal Researcher and member of University staff this would either be a secure, confidential space on campus or via the University VPN).

As previously mentioned, interview data will be transcribed in a pseudonymized format, meaning any personally identifiable information will be removed by the transcriber at the point of transcription. Participants will have been allocated their own participant ID by which they will be referred to from this point in all further documentation.

Pseudonymized transcriptions will be saved in a Microsoft Word document and saved in a separate location on the University of Manchester's RDS system. This will ensure that confidential data is stored separately from anonymous and anonymized data. Once more, this folder will be password protected and encrypted. Each transcript will be individually password protected. The file name will be saved with the date of transcription, a letter to represent the participant, and a number (i.e., DD_MM_YY_P_1). Once the transcription is complete, the Principal Researcher will review the transcript and then delete the audio of the interview.

Physical data

If used, paper records, such as consent forms, consent to contact forms, questionnaires and interview notes, will be retained. They will be kept in a locked, secured filing cabinet in the office of a member of the research team. When the office is not occupied, it will be locked with appropriate physical security in place. The building is securely locked in and out of office hours. These documents will be transferred to this location as soon as possible. The consent form will not contain the participant study ID number.

Long-term storage of data

The essential documents and the interview transcripts will be stored in line with the University of Manchester's Record Retention Schedule for a minimum of 5 years following publication or 10 years following the end of the study depending on which one is greater. Consent forms and electronic recording of consent will also be destroyed at this time. The Chief Investigator will be the data custodian and will destroy all data securely at the end of the specified time frame. The paper information will be destroyed via shredding using Redshore shredding consoles. Digital data will be permanently erased from the computer drives. This will be performed in accordance with University of Manchester procedures for the disposal of confidential waste.

If the participant gives consent, their anonymised data will be shared in order to support additional research, in accordance with the UK Policy Framework for Health and Social Care Research https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/uk-policy-framework-health-and-social-care-research/.Agreeing for their data to be used is optional for participants in this study (i.e. they can still take part if they do not agree to this). If they do agree and consent, their anonymised data will be deposited in an open data repository where it will be permanently stored. Figshare at the University of Manchester Library (https://figshare.manchester.ac.uk/) will be used for this.

Participants will also be given the option of their contact details being retained for up to 5 years in order to inform them about future studies they may be interested in. If they provide consent for this, their details will be stored securely on UoM servers in a digital folder only accessible to the study team and used only for this purpose. Women can still participate in the study if they do not choose to do this.

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?

- Yes - Private organisations with contractual arrangements

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?

- No

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?

Dr Anja Wittkowski, Senior Lecturer in Clinical Psychology, University of Manchester

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

2021-11-16

Project details

What is the purpose of your research project?

Background: The perinatal period (the time around pregnancy and birth) is a time of increased risk of psychological difficulties for women. Women experiencing moderate-severe mental health difficulties in the perinatal period are looked after within specialist services in the community or as an inpatient on a Mother and Baby Unit. Psychological therapies are recognized as being an important part of the treatment for mental health problems in the perinatal period. There is a need, however, to develop the evidence-base regarding suitable psychological interventions for this population. Compassion-Focused Therapy (CFT) is a promising psychological intervention that has been found to improve psychological wellbeing in diverse participant samples. A specifically tailored version of CFT for women with perinatal mental health problems (delivered in a group format) has been developed and is now being delivered by Perinatal Community Mental Health Teams in Greater Manchester. The feedback received on the intervention, which was initially developed and delivered by an NHS service in Derby, has been positive. However, the intervention has not yet been evaluated formally.

Methods: This study will use quantitative (service data on referrals and retention to groups and attendees scores on routinely collected outcome measures) and qualitative (interviews, analysis of open-ended questions from evaluation forms collected by services) methods to examine the feasibility and acceptability of providing a specially tailored, group-based Compassion Focused Therapy intervention within UK Perinatal Mental Health Services. Routinely collected outcome data includes

measures of psychological distress, self-compassion and parent-infant bonding. Service-level data will be gathered to examine client retention to the intervention. In interviews, participants will be asked questions about the content of the course (e.g. what they found most helpful/ relevant, what they found easy/ harder to understand), aspects of its delivery (e.g. venue, timing, the approach/ communication style of the group facilitators), and also about any changes that they noticed as a result of taking part in the intervention.

Analysis: Quantitative data collected by the service will be examined using descriptive statistics; interview and open-ended evaluation form question data using thematic analysis.

Outcomes: It is hoped that findings from this study will be useful for refining this promising intervention, and may help inform the design of larger-scale studies of effectiveness.

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

The University of Manchester's policies and guidance on the following will be relevant to this research project:
- Research Data Management Policy
- Records Management Policy
- Data Protection Policy
- Standard Operating Procedure for Taking Audio Recording of Participants for Research Projects
- Standard Operating Procedure for Information Security, Classification, Ownership and Secure Information Handling
- The University of Manchester Publications Policy
http://documents.manchester.ac.uk/display.aspx?DocID=2852
- The University of Manchester Intellectual Property Policy
http://documents.manchester.ac.uk/display.aspx?DocID=24420
- ESRC Research Ethics Framework
- IT Policies and Guidelines
As the principal researcher is a Trainee Clinical Psychologist, the project will adhere to the British Psychological Society's Code of Ethics and Conduct'

Responsibilities and Resources

Who will be responsible for data management?

The principal researcher (Charlotte Garrett) will ensure that the Data Management Plan is adhered to and updated as required.
The research team will be responsible for the design, processing and analysis of data.
The primary academic supervisor (Anja Wittkowski) will be responsible for the secure storage of hard copies of data.
The principal researcher will share responsibility for the transcription of data with an approved university employee.

What resources will you require to deliver your plan?

- The University of Manchester will provide an encrypted audio recorder to safely record the interviews
- The University of Manchester computers and secure network (Pdrive, RDS). This is already accessible to the principal researcher.
- The principal researcher to have a locked box for holding personal, identifiable and sensitive data (e.g. consent forms, dictaphone, demographic questionnaire) in between transfer to the University of Manchester's secure locations.

Data Collection

What data will you collect or create?

Digital data created/ collected will be of the following types:

i) *Information from consent to contact forms* - Electronic copies of consent to contact forms containing participant names and contact details, details from which may also be entered into an electronic spreadsheet.

ii) *Summary data from teams/the service about CFT groups* - Data will be collected from community and inpatient teams within Specialist Perinatal mental health services on the following variables in relation to CFT groups that have already taken place: number of service users referred, screened, screening positive, screening negative, reasons for service users screening negative, number of service users beginning the intervention, completing the intervention, completing at least 50% of the intervention, and session by session attendance. This data will be collated by clinicians. An electronic data collection form (excel file) and SOP has been prepared to facilitate this process. This data is not identifiable as it does not concern individual participants but rather is summary data. The file containing this data will be password-protected and transferred to the researcher via secure NHS e-mail.

ii) *Data from teams/ services concerning CFT-group participants*- Individual-level data on the demographic and clinical characteristics of group participants, and their scores on the pre and post-intervention questionnaire measures routinely collected by the service (community settings) or evaluation forms (inpatient setting) will also be obtained from teams. Specifically, for each group participant, researchers will obtain data on the following variables: (mental health) diagnosis/ diagnoses, age, parity, ethnicity, marital status, education and employment status, as well as pre and post-intervention item by item scores on the CORE-10 (a self-report measure of psychological distress), the OAS (a self-report measure which assesses people’s beliefs about how others perceive them), the FSCRS (a self-report measure of self-compassion), the HONOS (a clinician-rated measure of health and social functioning) and post-intervention on the Perinatal POEM (a measure of patient satisfaction with the services they have received). This data will be entered by clinicians onto another specially-designed electronic data collection form (excel file) which will also be accompanied by an SOP to promote consistency and accuracy of data entry. Another electronic data collection form (excel file) and SOP has been prepared for clinicians in the inpatient/ MBU team for entering data from evaluation forms.

This individual-level data will be pseudonymized by clinicians prior to being transferred to the researcher, which will be done as a password-protected, encrypted file sent from the clinician’s secure NHS e-mail account to the researcher’s secure NHS e-mail account. The procedure for pseudonymization is that the clinicians will assign numbers to each of the participants in a particular group. They will keep a key of the names that correspond with each number for each group as a password-protected, encrypted file on their NHS computer. The researcher has created an excel template for this purpose (Pseudonymisation key for teams V.1.). The researcher will not have access to the pseudonymization key or any other information that could identify these service users at any

point during or after the study and the pseudonymization key will be destroyed by the clinician after data is analyzed.

iii) Interview data - Data will be created/ collected from qualitative interviews conducted with between 10 and 20 participants. Interviews will be conducted either face to face or via videoconferencing or telephone call. Only University of Manchester approved video conferencing platforms will be used (Zoom or Teams) and will be accessed via the Principal Researcher's university account. The recording function on the videoconferencing platform will not be used. The interviewer will have the audio recording device nearby and record just the audio of the interview.

For the interview component of the study, digital data will include audio data of consent procedures and interviews in an encrypted mp3 format. Additionally, transcriptions of audio data will be produced on Microsoft Office Word which will be digitally created through an unencrypted, uncompressed file format. Transcripts may be analysed using NVivo software (Castelberry, 2014).

Non-digital data created/ collected will be of the following types:

i) Hard copies of consent to contact forms - if potential participants chose to complete these forms as hard copies.

ii) Hard copies of consent forms

ii) Questionnaire data from interview participants- Before completing their interview, participants will complete two questionnaires with the researcher - the Client Satisfaction Questionnaire-8 (CSQ-8; Attkisson, Greenberg, 2004; Larsen, Attkisson, Hargreaves, Nguyen, 1979) and the Family Background Questionnaire (FBQ, Tsivos, Calam, Sanders & Wittkowski, 2018). Questionnaires will be completed first in a non-digital format (paper copy) whether interviews are conducted virtually or face-to-face. Scores will then be inputted into an excel file and thereafter into a statistical software programme (e.g. SPSS) for analysis (as for all quantitative data collected).

Digital data is expected to require 1-8 TB of storage total.

How will the data be collected or created?

Organisation of data:

Summary data relating to CFT groups, individual-level data on group attendees and data from evaluation forms will be obtained from health professionals in perinatal mental health teams (inpatient and outpatient). Electronic data collection forms with associated SOPs will be used to aid consistency and accuracy in data entry. The completed forms/ files will be transferred to the principal researcher in password-protected documents via secure NHS e-mail. It will then be safely transferred to the University of Manchester's secure storage as soon as possible. The file name format will be standardised including the name of the team, the number of the data collection form, and the date the file was sent (e.g. Cluster_1_Community Team_Data_Collection_Form_1_DD_MM_YY). This information will then be collated by the Principal Researcher into a single database containing all the data obtained from the various teams.

Audio digital files will be recorded as the interviews take place. These will be safely transferred to the University of Manchester's secure storage as soon as possible. Archive files will be created to keep track of older versions of documents, if necessary. Once transferred to the University secure network, the audio digital files will be named using the same system which will include the participant number and date of interview (e.g. 1_P_DD_MM_YY). The transcribed data will be allocated a corresponding number. They will be saved using the date of the transcription and the allocated corresponding number (i.e.DD_MM_YY_P_1)

Questionnaire data from interview participants will be completed first in a non-digital format (paper copy) either by the experimenter on the participant's behalf (if interviews are virtual) or by the participant themselves (if interviews are face-to-face). Scores will then be inputted into an excel file and thereafter into a statistical software programme (e.g. SPSS) for analysis (as for all quantitative data collected).

Consistency and quality of data:
It will be important to monitor the consistency and quality of the data. The consistency of the data will be controlled and documented through the following processes: calibration; standard data capture; recording, data entry validation; peer review. The quality of data collection will be ensured by the research team via regular supervision meetings where these processes will be reviewed. Prior to submission of publication, all data will be internally peer-reviewed.

Documentation and Metadata

What documentation and metadata will accompany the data?

This study fulfils the large-scale research project component of the University of Manchester's Doctorate in Clinical Psychology programme. The study will be written up as a journal format thesis as well as being published in a published journal (to be decided upon at a later date). As part of this process, the principal researcher will outline relevant information to ensure for replication of the project. This will involve a comprehensive methodological and data analysis section with information about how the data was gathered, stored, analysed and interpreted.
A basic text document will be created to collect metadata during the project. This will include dates of when the interviews took place, any changes to the original data (e.g. corrections to transcriptions/notes).

Ethics and Legal Compliance

How will you manage any ethical issues?

The project will follow GDPR regulations and adhere to the principles outlined in the Declaration of Helsinki, University of Manchester Standard Operating
Procedures and Good Clinical Practice.
The following ethical issues relating to data management have been identified as relevant to this project:

Ethical approval:

Participants will be recruited from NHS sites. Therefore, the study will have been reviewed and approved by the HRA/HCRW, NHS REC and relevant NHS Trust and R&D before recruitment into the study begins. This will ensure that the project achieves NHS and the University of Manchester's ethical standards.

Consent of participants:

Potential participants in the interview part of the study will be identified by health professionals in specialist perinatal (inpatient and outpatient) mental health services and will be women who are due to take part in, are currently taking part in, or have recently taken part in a CFT group run by that team/ service. Interested participants will give their consent to be contacted via the completion of a consent-to-contact form. Participants will be encouraged and provided with multiple opportunities to ask relevant questions about the study: during initial contact; prior to the interview taking place as well as being informed that they can contact the research team if any additional questions arise.

All participants will be given a participant information sheet to read prior to consent being taken.

Participants will have a minimum of 24 hours to digest and consider this information so an informed decision can be made regarding their participation. This will include details of the research project including how participants' data will be used, stored, disseminated, published, and archived.

Informed consent will be taken from all participants that agree to participate. The principal researcher will hold in mind issues of capacity when considering an individual's eligibility.

Participants will be informed that they have the right to withdraw from the study at any stage and with no detriment to them. Participants will be informed that once their data has been anonymously transcribed, it can no longer be withdrawn from the study. The principal researcher will request verbal consent for data already collected to be used for the purposes of the study and then, no further data will be collected. If the participant withdraws their full consent, including any previous data collected, the principal researcher will inform the participant that HRA guidance expects all data collected up to the point of withdrawal to be retained to ensure the validity of the study.

Data protection and patient confidentiality

The research team and study site staff will comply with the Data Protection Act (2018) with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles. This will involve the following:- Depersonalising data, removing participants' personal identifiable information and replacing this with participant identified number and pseudonym's

- Pseudonymisation key will be stored separately on the Principal Researcher's P: Drive
- The names of identifiers (e.g. locations, other names) will be replaced with 'X' when data is transcribed.
- All participants will be provided with a unique identifier that is recorded on questionnaires and completed tasks.
- The secure maintenance of data using encrypted digital files with password protection folder and storage media on the University of Manchester's RDS.
- All completed consent forms and electronic consent will be stored separately from other research data either in a locked filing cabinet or in a password protected folder.
- Participants will choose a pseudonym of their choice at interview. At the point of analysis all personal identifiable information will be removed. No identifying details will be reported in the write up or publication.
- The secure storage of personal, identifiable information in locked cabinets, in offices with appropriate physical security in place.
- Limiting access to the minimum number of individuals necessary for quality control, audit, and analysis.
- Personal identifiable information will be destroyed as soon as it is no longer required. Essential documents will be retained for five years in line with The University of Manchester's policy.

The research team will also comply with The University of Manchester's data policies and SOP's.

Summary data supplied by services on numbers referred/ retained etc. to CFT groups does not raise data protection or confidentiality issues as this information does not relate to individual participants. Individual-level data supplied by services (demographic and clinical characteristics, questionnaire/ outcomes data, and data extracted from evaluation forms) will be pseudonymised prior to being transferred to the research team. The pseudonymisation key for this data will be retained securely by the professionals entering the data on NHS computer systems and will not be accessed by the researcher at any time during or after the study.

It is possible that audio files from interviews will be accessed by a party outside the research team in order to be transcribed. This party will either be a member of University of Manchester staff or a University of Manchester approved transcription service. In the case of the former, a confidentiality agreement with this employee will be signed prior to their undertaking any transcription. In the case of the latter, in order to obtain University of Manchester approval, the company is required to sign a contract containing confidentiality clauses. In all cases, audio files will be transcribed in secure and confidential settings. When transferring audio/ transcription files, care will be taken to ensure that this is done in a manner that protects client's confidentiality i.e. files will be password-protected and encrypted. Audio files will be pseudonymised before being sent to be transcribed.

Data storage:
All data will be stored in secure locations on the University of Manchester RDS and in securely locked cabinets and offices of the research team with appropriate physical security. Research data will be stored for a period of five years. As this study is a non-interventional low risk study, consent forms will be retained for 2 years once the study has ended which is in line with The University of Manchester Record Retention Schedule. Beyond this point, hard files will be destroyed via shredding (Restore shredding consoles will be used to dispose of confidential paper) and any digital data will be permanently deleted from computer drives.

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

The University of Manchester will own the copyright and Intellectual Property Rights (IPR) of the data. The data will not be licensed for re-use.

Storage and backup

How will the data be stored and backed up?

All data will be transferred to the University of Manchester's Research Data Service (RDS) as soon as possible after collection. The RDS is regularly and automatically backed-up.

Audio data will be transferred from the encrypted audio recorder to the RDS. It will then be permanently deleted from the audio recorder. Once the audio recording has been transcribed, it will be checked and then the audio file will permanently deleted from the computer drive.

Consent audio recordings will be transferred to the University of Manchester's RDS. It is important to note, that they will be stored separately from all other research data (e.g. pseudonymised transcripts, anonymous demographic data). Each individual consent audio recording will be password protected and encrypted. They will be stored securely until it has reached the five year retention period. After this point, the file will be permanently deleted.

Hard copies of documents containing personal, identifiable and sensitive information (e.g. consent forms, demographic questionnaires) will be kept in a locked cabinet in a member of the research teams locked office, with appropriate physical security in place. The office will be locked when it is not occupied. The building in which the office is located is securely locked in and out of office hours.

The University of Manchester's Record Retention Schedule states that research data such as transcripts are classed as essential documents and therefore, should be retained for a minimum of 5 years following publication or 10 years following the end of study depending on which one is greater. As this study is a non-interventional low risk study, consent forms will be retained for 2 years once the study has ended which is in line with The University of Manchester Record
Retention Schedule. Once this time has elapsed, hard copy, non-digital files will be permanently destroyed via shredding.Restore shredding consoles will be used to dispose of confidential paper. Digital data will be permanently deleted from the computer drives and recycle bins emptied.

How will you manage access and security?

Access to data
The research team will have access to audio and transcribed data. The audio recordings will only be

heard by members of the research team or by one additional University of Manchester employee who helps with the transcription process. This employee will be reminded of the guidelines regarding confidentiality and will be asked to sign a copy of the 'Confidentiality Agreement'.

The primary academic supervisor/Chief Investigator will be responsible for the storage of the hard copy data. This will only be available to the research team.

Data will not be shared or made accessible to any additional or third-parties.

Security of data:

Physical security:

- Once data has been collected, the principal researcher will store it in a locked box. The data will be transferred to the intended location (e.g. secure network drive, RDS, locked filing cabinet) of a research team members office as soon as possible.
- Hard copies of data will be stored in a lockable office of a member of the research team. The office will be locked when it is not occupied with appropriate physical security in place. The office is located in a secure building that is locked in and out of office hours.
- Participant information will be stored separately; this means that consent forms will be stored separately form interview notes.
- If members of the research team wish to access this data, a process of signing in and out documents will be put in place to ensure the appropriate tracking of information. Members of the research team will be expected to sign when the information was taken and and when it was returned.

Network security:

- The University of Manchester has a secure network where personal, sensitive information may be stored. This network has appropriate firewall protection and relevant security updates.

Security of digital data on computer systems and files:

- The pseudonymisation key for interview data will be stored on the University of Manchester's secure PDrive which is backed up daily.
- Digital data (audio recordings, transcripts, service summary and pseudonymised individual level data from CFT group participants) will be stored on the RDS.
- For the longer term storage of data (e.g. audio consent recordings) of data, the University of Manchester's RDS drive will be used which is backed up regularly and automatically.
- Audio interview recordings will be stored on the principal researcher's RDS. These will be stored separately to audio consent recordings. Each individual file will be password protected.
- All audio digital data will be stored in an mp3 format and will be password protected. The password will be a minimum of seven characters, contain upper and lower case letters, symbol and a number. The password will only known by the research team.
- The audio recordings will be checked by the principal researcher before they are permanently deleted from the recording device.
- Interviews will be transcribed verbatim by the Principal Researcher or by a professional transcription service within the University of Manchester (with whom a confidentiality agreement will be signed) from a secure location where the data is not visible or audible to anyone else. Transcripts will be anonymised meaning all personally identifiable information will be removed.
- Transcripts will be checked and then the audio file will be permanently deleted. Transcriptions will be saved as a Microsoft Word document to the principal researcher's secure RDS. To ensure a level of confidentiality and to prevent confusion amongst transcripts, each file will be saved with the date of transcription and allocated a number (i.e. DD_MM_YY_P_1).
- Participants will assign themselves a pseudonym which will be used for thesis and publication write-up. If direct quotations are used, participants will be referred to by their pseudonym.

Selection and Preservation

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

In line with the University of Manchester's retention policy, documents and audio recordings of informed consent will be kept for five years. As this study is a non-interventional, low risk study, consent forms will be retained for 2 years once the study has ended which is in line with The University of Manchester Record Retention Schedule. The data will not be used of future research projects therefore, all other documents will be securely destroyed (e.g. via Redshore shredding consoles) or permanently deleted when they are no longer required.

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

As the data is part of a time-limited Doctorate in Clinical Psychology. The primary academic supervisor (Dr Anja Wittkowski) will be responsible for the preservations/archiving of data once principal researcher completes the course.

Data Sharing

How will you share the data?

A multidisciplinary (i.e. University of Manchester Institutional Repository) data repository or a discipline-specific data repository (i.e. Psychdata) will be used to publish and share the research data. The University of Manchester's policy will be adhered to when sharing data and metadata via the repository. Participants are required to give their consent for their anonymised data to be deposited.

To reference data in publications, published outputs will be given a Digital Object Identifier (DOI)

The research data will be fully anonymised and publicly available via the student thesis and peer-reviewed journal publications.

Are any restrictions on data sharing required?

All participants will have chosen a pseudonym of their choice that they will be referred to in all publications. Service level and routine outcomes/ evaluation form data is already anonymous or is pseudonymised before it is transferred to the researcher.