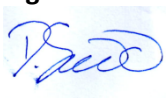
FULL/LONG TITLE OF THE STUDY
The Development of Measures to Assess the Long-Term Support Needs of Adult Sexual Assault Survivors

PROTOCOL VERSION NUMBER AND DATE
This protocol's version is 1.0.

RESEARCH REFERENCE NUMBERS

IRAS Number: 281719
Sponsors Number: R124724
Funder's Number: N/A
Short Title/Acronym: LTSNQ

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.
I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor
I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:
Signature:
.....
Date: ...../...../....
..
Name (please print):
.....
Position: .....
.....
Chief Investigator:
Signature: 
Date: ....03../06....
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Name: (please print): David Gadd
.....

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KEY STUDY CONTACTS

Insert full details of the key study contacts including the following

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STUDY SUMMARY

This research aims to identify and understand the long-term needs of adult sexual assault survivors, following their disclosed assaults to Saint Mary's Sexual Assault Referral Centre in Manchester. The findings from this study will improve understanding of the needs of survivors of sexual assault and have the potential to directly impact the way in which these services respond to their needs. This research is much needed, especially in the context where understanding the short, medium and long-term needs of survivors has become a priority for the NHS.

Study Title	The Development of Measures to Assess the Long-Term Support Needs of Adult Sexual Assault Survivors
Internal ref. no. (or short title)	The Long-Term Support Needs of Adult Sexual Assault Survivors
Study Design	Qualitative study using an online questionnaire
Study Participants	We will recruit participants who have disclosed an assault and attended a Forensic Medical Examination at Saint Mary's SARC in Manchester. We will only recruit participants over the age of 18 years who are able to speak and understand written English.
Planned Size of Sample (if applicable)	For this study we aim to recruit 50 participants.
Follow up duration (if applicable)	There are follow up questionnaires at 6, 12 and 24 months. The participant's consent will be sought before each of these stages.
Planned Study Period	June 2020- June 2022
Research Question/Aim(s)	The principal research question is: What are the long-term needs of adult sexual assault survivors? This study also has two secondary questions: How do survivors' needs vary according to: their social demographic characteristics; the nature of the original assault and their prior relationship (if any) with the alleged perpetrator; the kinds of social support they access? What are the resource implications for SARCs and other partner organisations that aim to support survivors in the immediate and long term?

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
Violence, Abuse & Mental Health Network (VAMHN), UK Research and Innovation	**£30k**
Saint Mary's Sexual Assault Referral Centre	**Dr Majeed's time is given pro-bono**

ROLE OF STUDY SPONSOR AND FUNDER

As the sponsor of this project, The University of Manchester is directly responsible for initiating and managing the research study. The University assumes responsibility for the training of its staff, their health and safety, the study design, conduct, data analysis and interpretation of the data, and the production and dissemination of results. The University controls the final decision regarding any of these aspects of the study.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Study Steering Groups

The steering group comprises of 8 members. The group met every week to discuss the progress of the IRAS application and the feedback from stakeholder meetings. Five members are employed by the University of Manchester, 4 of whom were co-applicants. Two are employed by Saint Mary's SARC. One member is a survivor of sexual assault and ISVA (Independent Sexual Violence Advisor) who directly engaged with the team on the feasibility of the questionnaire.

- Professor David Gadd, University of Manchester, is the principal investigator.
- Dr Rabiya Majeed, Saint Mary's SARC, is the co-director.
- Dr Maria Pamapaka, University of Manchester, is the statistics expert of our research team.
- Dr Laura Watt is responsible for uploading the questionnaire on a secure online platform. She is affiliated with The University of Manchester. She has offered extensive feedback on the design of the questionnaire and relevant documents to the ethics application.
- Dr Filippo Varese has been offering guidance on the use of mental health assessment questionnaires as well as the IRAS application. He is affiliated with the University of Manchester.
- Dr Catherine White is the Clinical Director at Saint Mary's SARC. She has provided feedback on the questionnaire.
- Anne Marie Jones is a survivor of sexual assault and ISVA (Independent Sexual Violence Advisor) who directly engaged with the team on the feasibility of the questionnaire.

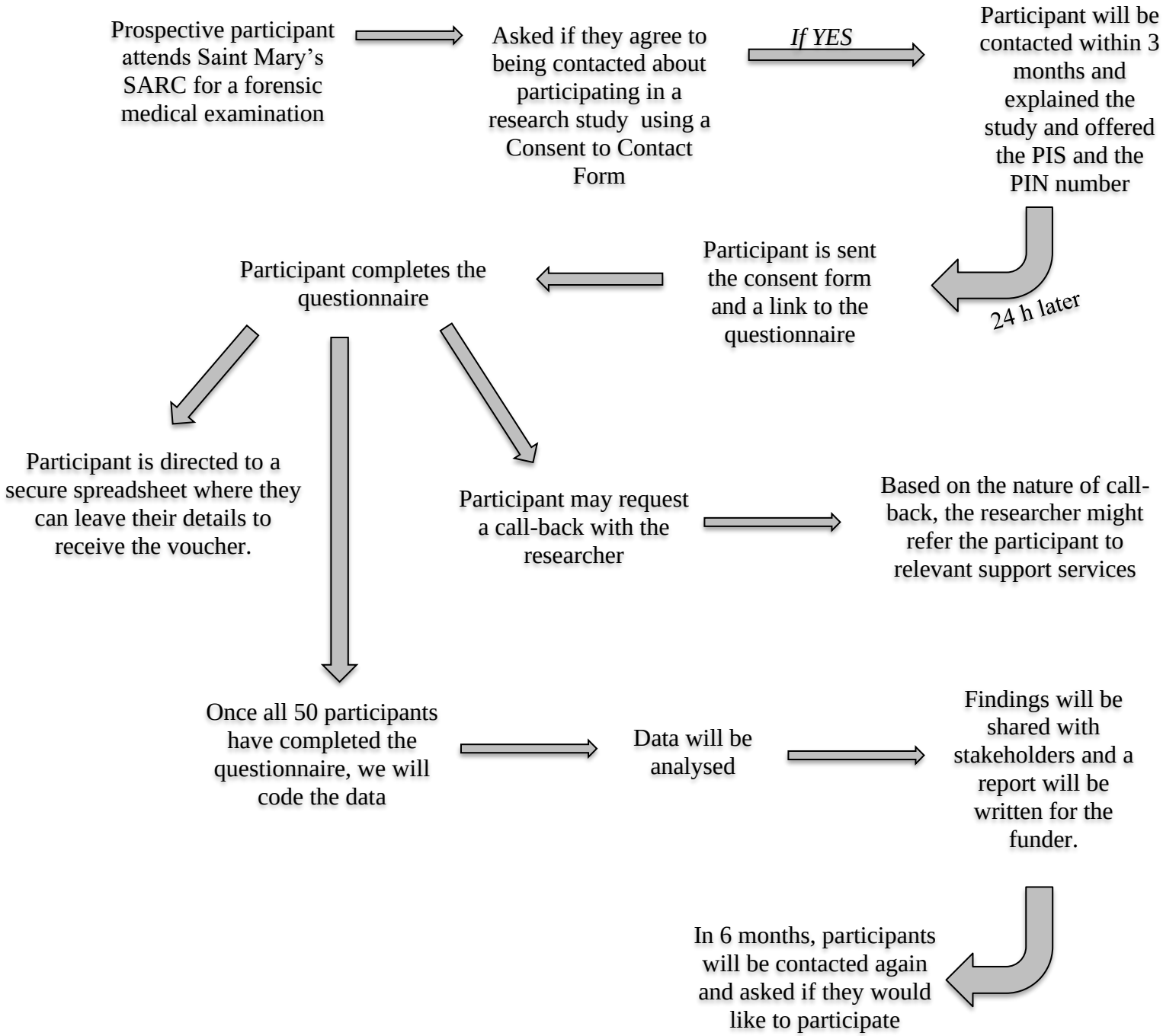
PROTOCOL CONTRIBUTORS

The sponsor of this study (The University of Manchester) is responsible for ensuring the research study unfolds as agreed upon in the sponsoring letter and ethics application. In accordance with University of Manchester's Information Governance Office Records Retention Schedule, all research data will be kept for a minimum default period of five years after publication.

In designing the questionnaire, we have reached out to 6 different stakeholders to request their feedback on the feasibility of the study. These organisations (Manchester Action on Street Health, Men's Room, Manchester People First, the Lived Experience Advisory Panel from Manchester Complex Trauma Research Unit, Sahara and Saint Mary's SARC team) directly support vulnerable people, some of whom are victims of sexual assaults. We have taken on feedback from these experts to ensure that the questionnaire is appropriate for the targeted sample. We have also taken in direct feedback from a member of ISVA and sexual assault survivors regarding the feasibility of the questionnaire.

KEY WORDS: long-term needs, assessment, adult, sexual assault survivors.

STUDY FLOW CHART



STUDY PROTOCOL

Long-Term Support Needs of Adult Sexual Assault Survivors

1 BACKGROUND

NHS England (2018) has reoriented priorities for sexual assault services so that they focus on 'lifelong care' for victims and survivors and that Sexual Assault Referral Centres (SARCs), in particular, become effective at meeting the medium and long term needs of victims and survivors of sexual assault, as well as their short term needs. This ambition raises questions both of those *service providers* whose focus is variously on crisis management and forensic medical examinations in the aftermath of sexual assault and of *survivors* themselves whose needs evolve in ways that follow personal trajectories that are inflected by criminal justice interventions, repeat victimization, secondary victimization in the courtroom (Majeed-Ariss et al., 2019a), entering new relationships, having children, subsequent encounters with perpetrators or others victimized by them, as well as the impact of the abuse on their own physical and mental health. As the World Health Organisation's review of the literature summarises, there is substantial evidence that those exposed to sexual violence suffer long term mental health consequences, including 'guilt, anger, anxiety, depression, post-traumatic stress disorder, sexual dysfunction, somatic complaints, sleep disturbances, withdrawal from relationships and attempted suicide' (Krug et al, 2014: 154). But it is often assumed that such consequences are straightforwardly caused by the original trauma, with insufficient attention paid to the ways in which the social contexts of the aftermath of violence (Gadd, 2016) such as family break-up, having to move home, inability to work or study and responses to trauma including stigma, counselling, support, isolation, friendship also generate and assuage crises of the self (Hydén et al, 2016; Hydén et al., forthcoming).

Some of those crisis points that are pre-empted by the limitations of the criminal justice response are quite predictable. For example, it takes the police on average 73 days after an assault has been reported to decide whether a criminal case can be presented to the Crown Prosecution Service (CPS), during which time over half are dropped for evidential reasons and a third of victims withdraw their complaint. It takes the CPS on average a further 78 days to decide whether to prosecute a case and it is usually around 470 days after an assault has occurred that court cases conclude, two fifths of which result in acquittal (ONS, 2018). Very little, however, is known empirically about the extent to which the support offered by Sexual Assault Referral Centres (SARCs) and Independent Sexual Violence Advisers (ISVAs) helps mitigate the trauma this prolonged cycle of inquisition, discrediting and disappointment causes many victims. Consequently, the focus of political intervention tends, simplistically, to equate 'supporting survivors' with 'improving prosecution rates', with limited recognition that drives to improve justice outcomes often place heavy demands on victims.

In practice, the factors behind survivors' disengagement with services are often obscured. For example, service users of Saint Mary's SARC in Manchester are over four times more likely than members of the general population to report mental health complaints that *predate* their assault (Manning et al., 2019). Perhaps due to the impact of anxiety and depression on well-being, service users with mental health complaints generally take longer to present to the service than those without (Manning et al., 2019). Moreover, while SARCs have become adept at meeting many of the immediate needs survivors present with (Majeed-Ariss et al., 2019b; Massey et al., 2019), what they provide varies considerably by region – not all offering 24-hour services – and few providing the fully integrated range of services that was initially envisioned for them (Lovett et al., 2004). Historically, SARCs have proved better at reaching out to women and children who are white and English-speaking than those who are not (Robinson et al., 2009). Men and

boys (Majeed-Ariss et al., in press), the elderly (Lee et al., in press), people from black and minority ethnic groups (Karsna & Majeed-Ariss, 2019), people with learning disabilities (Olsen et al., 2017; Majeed-Ariss et al., in press), and those who are unsure whether they were assaulted (possibly because their drinks were 'spiked' or they willingly consumed substances that rendered them unconscious) tend to be regarded as 'special' service user groups who are not universally well- served by SARCs. Consequently, some survivors engage little, if at all with SARCs shortly after they have been assaulted, while others develop new needs but have only sporadic or superficial. The main aim of this research is to gain a better understanding of adult sexual assault survivors' needs and consider the effectiveness of current interventions and support

2 RATIONALE

This proposed research aims to lay the groundwork needed to facilitate the development of measures that would be used in a longitudinal study of adult sexual assault survivors' support and service needs. Its focus is on the social, emotional and physical well-being of those who have previously disclosed assaults to Saint Mary's SARC in Manchester. In 1986 Saint Mary's became the first SARC to be established in the UK, with an initial remit to provide a medico-legal response to sexual assaults. There are now over 40 SARCS in the UK. Saint Mary's SARCs remains the busiest site, seeing over 1200 clients in 2018/9 for a forensic medical examination (FME). SARCs perform forensic medical examinations which involve the collection and preservation of forensic evidence which may be of use in future court cases. Today, Saint Mary's SARC has a unique service delivery model whereby it provides a comprehensive and coordinated forensic, ISVA and counselling service to males and females, children and adults who have reported sexual assault or rape. Most clients come to Saint Mary's via the police, but about 10% of adults contact SARC directly and attend without police involvement. The project will pilot a set of measures designed to assess how survivors' needs are tempered and changed following access to support and service provision.

3 THEORETICAL FRAMEWORK

In this research study we will use a Long-Term Needs Questionnaire designed by this research team for the purposes of this project, which is to assess the long-term needs of survivors of sexual assault. Due to the lack of literature in this area, this study is hypothesis generating rather than hypothesis testing. At the moment very little is known about the extent to which the support offered by legal, health, and social care agencies including SARCs helps mitigate the trauma in the longer term. Our study has designed a questionnaire that can assess the impact that the sexual assault has had on the person's physical and mental well-being as well as the type of social support he/she has accessed or would find useful to access. To ensure the study is appropriate for the population, we held 6 stakeholder meetings with various local NGOs and healthcare professional groups who are already supporting vulnerable people, who provided extensive feedback on the questionnaire. All participants in the research will be asked to fill in a self-report online questionnaire. Where access to online is hindered, other options will be set in place to ensure accessibility.

The project will pilot a set of measures designed to assess how survivors' needs are tempered and changed following access to support and service provision. Assuming the feasibility of the project is confirmed by this pilot study, a larger mixed method grant application will be developed with the stakeholders and survivors as potential co-leads the following year.

4 RESEARCH QUESTION/AIM(S)

The principal research question is: Is it feasible to assess the long term needs of adult sexual assault survivors using a questionnaire?

This study also has three secondary research questions:

1. What are the Long-Term Support Needs of Adult Sexual Assault Survivors?
2. How do survivors' needs vary according to: their social demographic characteristics; the nature of the original assault and their prior relationship (if any) with the alleged perpetrator; the kinds of social support they access?

3. What are the resource implications for SARCs and other partner organisations that aim to support survivors in the immediate and long term?

4.1 Objectives

The main objective of the study is to gain a better understanding of the long-term needs of survivors of sexual assault.

4.2 Outcome

The primary outcome of the study involves measures that capture survivors' long-term needs. The study will enable the validation of such measures with a novel questionnaire which also includes three questionnaires on mental health: General Anxiety Disorder 7 (GAD-7), Patient Health Questionnaire (PHQ-9) and the International Trauma Questionnaire (ITQ). All three questionnaires are used by mental health services to help establish whether someone meets the criteria for a clinical condition.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

In this research study we will use a Long-Term Needs Questionnaire designed by this research team for the purposes of this project, which is to assess the long-term needs of survivors of sexual assault. Due to the lack of literature in this area, this study is hypothesis generating rather than hypothesis testing.

Our research methodology includes the testing of the feasibility of the Long Term Needs Questionnaire. This is to ensure that the questionnaire accurately captures survivors' long-term needs in ways that: are rigorous enough to speak compellingly to those who commission services; recognise survivors' rights to privacy and to forget; and do not compromise service users' relationships with professionals. The questionnaire has included 3 robust validated questionnaires on mental health (General Anxiety Disorder 7, Patient Health Questionnaire 9 and International Trauma Questionnaire) which are widely used in mental health services to help understand whether someone is clinically suffering from anxiety, depression and/or post-traumatic stress disorder. These are all mental health conditions associated with sexual violence.

As part of the Long Term Needs Questionnaire development process, we have held 6 stakeholders' meetings with a number of health care and third sector organisations to discuss the suitability of the questionnaire with the population that they are supporting. These organisations (Manchester Action on Street Health, Men's Room, Manchester People First, the Lived Experience Advisory Panel from Manchester Complex Trauma Research Unit, Sahara and Saint Mary's SARC team) directly support vulnerable people, some of whom are

victims of sexual assaults. We have taken on feedback from these experts to ensure that the questionnaire is appropriate for the targeted sample.

Following this process, the questionnaire was securely uploaded online. This will allow prospective participants to fill in the questionnaire at a time convenient to them, on a device of their choosing. Acknowledging not everyone is computer literate or has access to technology, we have agreement from the aforementioned organisations to make hard copies available at their organisations. Participants who are unable to complete the questionnaire online, or who do not have a fixed address where we can send the questionnaire, can request that the questionnaire is sent to one of the stakeholder organisations to be completed there. This is available for participants who are already receiving support from these organisations, such as Manchester Action on Street Health (MASH). Three prepaid, sign for envelopes will be provided to participants completing the questionnaire in hard copy, enabling them to send consent forms, voucher requests and questionnaire answers separately.

Each participant will be asked to complete the questionnaire using a PIN number, which will ensure their anonymity. Following the completion of the questionnaire, the participants will be offered a £20 voucher (sent electronically or in the post as preferred) as a gesture of thank you. For this pilot study we aim to recruit 50 participants. The recruitment process is done with the support of Saint Mary's SARC.

Following a forensic medical examination, survivors of sexual assault at Saint Mary's Sexual Assault Referral Centre are routinely asked to complete a feedback questionnaire. They will also now be offered a consent to contact form that invites them to give their consent to be contacted about the study. (Copies of the participant information sheet will also be available for those who want further information). If they consent to this, someone on the research team will contact them and send them the participant information sheet and assign them a PIN number. Participants will be given at least 24hours to consider the project, before they are sent a link to the online consent form and the questionnaire.

Saint Mary's Sexual Assault Referral Centre which is based within Manchester University NHS is a research site within this study.

All the documents that the participant has filled in (including initial feedback questionnaire) have been uploaded in support of this application.

Recruitment will take place via NHS services, in particular Saint Mary's SARC in Manchester.

We will undertake a psychometric analysis for the validation of the constructs within the questionnaire. This will be conducted within the Rasch measurement framework– with appropriate models depending on the type of data, for example, the Rasch rating scale model, for common Likert type scale items. Within this framework decisions about the validity of the measures are based on a range of statistical indices, such as item fit statistics, differential item functioning tests and person item maps. Item fit statistics indicate how accurately the data fit the model, and thus provide evidence for fulfilment of the unidimensionality assumption, supporting the development of one-dimensional scales. Person – item maps and the item difficulty hierarchy provide evidence for substantive, content and external validity. Differential Item Functioning (DIF) and person fit statistics suggest group differentiation of the constructed measure, which is an important aspect of validity when an instrument is used with different groups of persons or on different occasions to ensure measurement invariance. We also intend to compare the measures developed with the above techniques with results of established norms (for the 3 established measures).

6 STUDY SETTING

The questionnaire has been uploaded online on a secure server using REDCAP, a University of Manchester approved software. Participants will be able sent the link to the questionnaire and can fill it in whenever suits them best. For participants who would prefer completing a paper copy of the questionnaire, special provisions will be put in place to ensure this is possible and that all data will be kept securely.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

The study aims to recruit 50 adult sexual assault survivors who have attended Saint Mary's for a forensic medical examination.

7.1.1 Inclusion criteria

The participants must be 18 years old and above. The participants should have attended Saint Mary's Sexual Assault Referral Centre in Manchester for a forensic medical examination following a claim for sexual assault. The participants should be able to read and understand written English.

7.1.2 Exclusion criteria

We would exclude any participant who is under the age of 18 and who has not received a forensic medical examination at Saint Mary's SARC in Manchester. We would exclude any participants who are unable to read and understand written English.

7.2 Sampling

Potential participants will be identified and recruited from the single research site, Saint Mary's Sexual Assault Referral Centre which sits within Manchester University NHS Foundation Trust. Participants will be recruited from people who attend Saint Mary's SARC for a forensic examination, following a report of sexual assault.

As a procedure, following each forensic medical examination, Saint Mary's SARC provides each service user with a feedback sheet. They will now also be given a consent to contact form inviting them to indicate if they can be contacted within the next 3 months to take part in a research study. If they agree, they will be asked to provide contact information. Ideally, we would want participants to give an email address, though we can also use a phone number (for sms) or postal address.. This information will be securely stored in a password protected file on one of Saint Mary's drives by the research team member who works at Saint Mary's. All of these potential participants will be contacted by someone on the research team who will offer them more information including the information sheet if they would like it, and give them a chance to ask any questions and consider the information sheet before deciding whether or not to participate.

7.2.1 Size of sample

This sample size was chosen as appropriate for the psychometric analysis to be performed for the validation of this instrument as it provides enough responses to pilot the initial questionnaire and explore the construct validity of the main measures.

7.2.2 Sampling technique

As this is a pilot study, we think that 50 is a good number to demonstrate feasibility.

7.3 Recruitment

Potential participants will be identified and recruited from the single research site, Saint Mary's Sexual Assault Referral Centre which sits within Manchester University NHS Foundation Trust. Participants will be recruited from people who attend Saint Mary's SARC for a forensic examination, following a report of sexual assault.

7.3.1 Sample identification

Participants will be first approached by the staff at Saint Mary's SARC, following the forensic medical assessment, using a consent to contact form that asks if they would like to consent to being contacted in the following 3 months about a research project. It will be made clear to the participants that there is no obligation to consent to being contacted and that this will not impact their ability to access the service.

If the prospective participant agrees to being contacted, they will be asked to provide an email address, or if not, a phone number or postal address. Prospective participants will then be contacted within three months' time. If the participant wishes, they can request that the researcher explains the project to them, shares the participant information sheet and answers any questions they may have about the study.

7.3.2 Consent

All participants will be presented with an information sheet and a consent form which will explain to them in detail the purpose of the study, any potential risks and benefits involved, their rights and the research procedure. All participants will be given at least 24 hours to consider the information presented on the information sheet, before being introduced to the questionnaire and consent form. All participants will be asked to give consent that they agree to taking part in the study. The consent form will be presented to them electronically, and we will assume consent by ticking of relevant boxes.

8 ETHICAL AND REGULATORY CONSIDERATIONS

All the research team members in this study have received appropriate training on managing data and confidentiality according to the GDPR guidelines. This will ensure the prevention of any risk regarding information management and prevent any breaches of confidentiality. There is no risk of disclosure of sensitive information as all information that participants give will be anonymised and kept safely.

We have a distress protocol for managing personal information that arises when participants requested a call back, and the circumstances in which disclosures of risk of harm will be shared by the researcher based at St Mary's with the clinical team.

One challenge associated with this research study is the linking of some participant data (including participant demographics, alleged perpetrator data, assault details, sexual orientation, employment status and service data collected by Saint Mary's SARC with participants' responses to the questionnaire. To manage this challenge we have put in place the following steps. Firstly, the participant's personal file will only be accessible by the researcher at Saint Mary's. She will ensure that each participant receives a PIN number, which will allow them to complete the questionnaire anonymously. The PIN number and identifying information will be stored on a password protected drive at St Mary's SARC. Only after the data from the questionnaire and the personal file is anonymised will the researchers at the University of Manchester be able to access it in order to carry out the data analysis.

It is important to note that all participants will have the choice over whether or not their questionnaire data is linked with any SARC data, and it will be made explicit what this data will include. Participants who choose not to have data linked will be asked for some participant demographics (gender, age and ethnicity) within the questionnaire, however data on alleged perpetrator, assault details and service data will not be asked for.

It is possible that participants may become upset by some of the questions asked in the questionnaire. If participants become upset at any point they have the right to stop and withdraw their consent to participate further in the study. Before taking part in the research, participants will be made aware of their right to withdraw without providing a reason and the right to have their data removed as long as it has not been anonymised.

In the eventuality that participants are distressed, the research team has set up a partnership with Saint Mary's SARC, who will help provide emotional support to the participants. At the end of the questionnaire, participants are presented with a question asking them whether they would like to be contacted by the researcher or staff at Saint Mary's to further discuss the research or any concern they might have in regards to their participation in the study. All contact information that participants may provide will be kept safe and deleted shortly after the call. Contact details will only be kept if and while the researcher considers that the participant requires further support and thus may need to refer them to external support organisations. Nonetheless, any referral will be made only with the consent of the participant.

This research study presents an opportunity for adult sexual assault survivors to voice their needs in regard to the support they feel would be most helpful to them to cope with the aftermath of the traumatic incident. Being involved in this study might have a cathartic benefit to the participants as well as knowing that their involvement will support the understanding of the long term needs of sexual violence survivors. In turn, this knowledge will have the potential to influence policy and practice in this area

As a gesture of thank you, the participants will receive a £20 voucher for taking part in the study.

To receive the sponsorship from The University of Manchester, this research project underwent a review process carried out by the members of the ethics committee. The objectives of the Committees are to maintain ethical standards of practice in research, to protect participants of research and researchers from harm, to preserve the participants' rights and to provide reassurance to the public and to outside bodies that this is being done. It is also the aim of the Committees to facilitate, not hinder, valuable research, and to protect researchers from unjustified criticism. This sponsorship letter is then used alongside the IRAS application to obtain the ethics approval of NHS Health Research Authority.

By undergoing ethical review, we ensure that our research follows the UK Policy Framework for Health and Social Care Research. The aim of these principles is to protect and promote the interests of patients, service

users and the public in health and social care research, by describing ethical conduct and proportionate, assurance-based management of health and social care research, so as to support and facilitate high-quality research in the UK that has the confidence of patients, service users and the public.

8.1 Assessment and management of risk

It is possible that participants may become upset by some of the questions asked in the questionnaire. If participants become upset at any point they have the right to stop and withdraw their consent to participate further in the study. Before taking part in the research, participants will be made aware of their right to withdraw without providing a reason and the right to have their data removed as long as it has not been anonymised.

In the eventuality that participants are distressed, the research team has set up a partnership with Saint Mary's SARC, who will help provide emotional support to the participants.

- At the end of the questionnaire participants are provided with the option to request a call back with a member of the research team, if they would like to speak to someone about the research or if they feel distress following the completion of the questionnaire.

- If the participant wants a call back, they will make an online booking with Rabiya Majeed via youcanbookme.com. A hyperlink in the questionnaire will direct the participant to this site, which is autonomous of the research project and used for all kinds of diary bookings.

- Participants will be told at the outset of the call that any risk of harm information identified during the phone call will be communicated to the health care team at St Mary's. This will be done in collaboration with the participant, where possible.

- If risk to self or others, including minors, is disclosed during a telephone contact, the individual will be informed that confidentiality will need to be breached.

- Two additional instances that may require passing on information to the participants' clinical team are suicidal ideation (even in the absence of current intent) and disclosure of previously undisclosed historic risk information (e.g. disclosure of a suicide attempt in the past that the care coordinator did not mention during the referral process).

- We will remind participants of their right to withdraw from the study, during this call.

- We will encourage participants to use provided support numbers detailed on our participant information sheet if they continue to feel distressed.

- Participants who would like a voucher payment will be directed by the questionnaire to another autonomous site where they can indicate any email address they wish the voucher to be sent to and provide an electronic signature. Dr Maria Pampaka (UoM) will receive these voucher requests and refer them to the UoM School of Social Science purchasing team, who will keep a record of the transactions and signatures for HMRC purposes only.

Since the questionnaire mostly requires self-report responses to multiple choice questions, we do not expect the participants to make any disclosure of risk to self or others during the study. There are, however, a few

open-text response questions. These comprise some questions where the category 'other, please specify' is offered and two questions where respondents are able to add further comments to their chosen categorical response. In the highly unlikely event that a participant discloses a risk of harm in these open responses we would breach confidentiality and advise St Mary's accordingly.

In the eventuality of a risk of harm disclosure, several protocols have been put in place. The actions depend on the type of risk.

1. *In case there is a disclosure of risk to child/vulnerable person*

In the eventuality that the individual discloses that a child / vulnerable adult may be in danger, the Child / Adult Safeguarding Team should be contacted, either via St Mary's, or if this not possible by the research team. If it is outside of 9am –5pm and there is considered to be imminent risk to a child / vulnerable adult, the police should be informed.

2. *In case there is a disclosure of a crime*

If a participant discloses that they or someone else has committed a crime, then it may be necessary for the research team to phone the police as soon as possible. Consultation with clinical members of staff is always recommended in such cases.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

The study will receive ethical review and approval via the IRAS system.

- Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.
- All correspondence with the REC will be retained.
- It is the Chief Investigator's, David Gadd's responsibility to produce the annual reports as required.
- The Chief Investigator, David Gadd, will notify the REC of the end of the study.
- An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.
- If the study is ended prematurely, the Chief Investigator, David Gadd, will notify the REC, including the reasons for the premature termination.
- Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

Regulatory Review & Compliance

Before any patients can be enrolled into the study, David Gadd and Rabiya Majeed will ensure that ethical approvals are in place as well as appropriate approvals from the single study site, Manchester University Hospital Trust. For any amendment to the study protocol, David Gadd and Rabiya Majeed, in agreement with the University of Manchester will submit information to the appropriate body in order for them to issue approval for the amendment. David Gadd and Rabiya Majeed will work with R&D department at the NHS study site as well as the study delivery team to put the necessary arrangements in place to implement the amendment and to confirm support from all parties for the study amendments.

Amendments

If UoM wishes to make a substantial amendment to the REC application or the supporting documents, they will submit a valid notice of amendment to the REC for consideration. The REC will provide a response regarding the amendment within 35 days of receipt of the notice. It is UoM responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC.

Amendments also need to be notified to the national coordinating function of the UK country where the lead NHS R&D office is based and communicated to the participating organisations (R&D office and local research team) departments of participating sites to assess whether the amendment affects the NHS permission for that site. Note that some amendments that may be considered to be non-substantial for the purposes of REC still need to be notified to NHS R&D (e.g. a change to the funding arrangements).

David Gadd will be responsible for the decision to amend the protocol and, following consultation with the steering group and Dr Rabiya Majeed, decide whether an amendment is substantial or non-substantial. Substantive changes will be reported to the project steering group and VAHMN. The *amendment history will be tracked using version numbers and dates to identify the most recent protocol version. A cover sheet will accompany the protocol to list all versions.*

8.3 Peer review

The funder, VAMHN, subjected the project application to anonymous peer review, using anonymous, independent experts.

8.4 Patient & Public Involvement

To ensure the study is appropriate for the population we held 6 stakeholder meetings with various local NGOs and healthcare professional groups (Manchester Action on Street Health, Men's Room, Manchester People First, the Lived Experience Advisory Panel from Manchester Complex Trauma Research Unit, Sahara and Saint Mary's SARC team) who are already supporting vulnerable people, who provided extensive feedback on the questionnaire. In providing the feedback some of these organisations consulted with survivors in their own management group.

We also invited a member of the public with lived experience and relevant knowledge as an Independent Sexual Violence Advisor to two of our steering group meetings to discuss the feasibility of the questionnaire.

8.5 Protocol compliance

Accidental protocol deviations will be reported to David Gadd and the University of Manchester, REC immediately and recorded in the minutes of the project steering group. These are highly unlikely given the project depends exclusively on an online questionnaire. But should they recur, the project will be suspended, while the advice of the NHS Trust is sought.

8.6 Data protection and patient confidentiality

To collect data, we will use an online questionnaire tool that is approved by the University of Manchester. Data will be stored in accordance with the General Data Protection Regulation (GDPR) and Data Protection Act 2018. All investigators and study site staff will comply with the requirements of 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.

Participants will complete the survey anonymously. Participant anonymised data will be stored securely on the University of Manchester's computer system. Any documents containing participant information that are not in electronic format will be kept securely in locked filing cabinets at the university. Information regarding participant names and contact details will be stored separately at Saint Mary's SARC while anonymous research data will be kept at the University of Manchester. In accordance with University of Manchester's Information Governance Office Records Retention Schedule, all research data will be kept for a minimum default period of five years after publication. For this research project the data custodian is Professor David Gadd.

Participant confidentiality will be maintained following this protocol:

1. Participants' names and contact details (for the purpose of recruitment in the study) will be kept separate from the other data and stored only by St Mary's. St Mary's will allocate a PIN number for each participant. Participants will complete the questionnaire anonymously using a PIN number.

2. Consent forms will be collated by the CI and stored on a password protected file on the University P Drive.

3. The record of PIN allocations will be shared only between the researcher, Rabiya Majeed and the CI, David Gadd, using an encrypted file. This file will be destroyed once data collection concludes.

4. Anonymized data collected via a university approved system will automatically be held on a secure network at the University. The university will not store participant contact details. All data will be referenced according to the anonymous PINs. This will ensure that their answers cannot be traced back to them.

5. Anonymized dashboard data from participants medical records will be associated with PIN numbers and shared from St Mary's to the University of Manchester, where it will be linked – in instances where participants have consented to this – with questionnaire answers.

6. Where the questionnaire is emailed or mailed to the participants from St Mary's, participants will be instructed not to add names to their data and to only return answers with the PIN number affiliated to the University.

7. Participants who would like a voucher payment will be directed by the questionnaire to another autonomous site where they can indicate any email address they wish the voucher to be sent to and provide an electronic signature. Maria Pampaka (UoM) will receive these voucher requests and refer them to the UoM School of Social Science purchasing team, who will keep a record of the transactions and signatures for HMRC purposes only. Once the study is complete the project copy will be overwritten and permanently deleted.

8.7 Indemnity

The University of Manchester will arrange insurance for research involving human subjects that provides cover for legal liabilities arising from its actions or those of its staff or supervised students, subject to policy terms and conditions. No Party shall be liable to another in contract, tort/delict, breach of statutory duty or otherwise for any loss of profits, revenue, reputation, business opportunity, contracts, or any indirect, consequential or economic loss arising directly or indirectly out of or in connection with this Agreement. If one or more Parties are NHS Foundation Trusts and the Party incurring the Loss is not responsible for all or part of the Loss and is not indemnified in respect of the Loss by one of the indemnity schemes then the Party incurring the Loss shall be entitled to recover the Loss from the other Party pursuant to the provisions of this Agreement.

8.8 Access to the final study dataset

In accordance with University of Manchester's Information Governance Office Records Retention Schedule, all research data will be kept for a minimum default period of five years after publication. The research team will be responsible for the storage of research data. Electronic data will be stored at the University of Manchester on the university's secure computer network. Hard copy data will be stored in locked cabinets at the University of Manchester.

The anonymized data set will be stored and preserved to enable a 24-month follow up of participants. All data will be stored on UoM secured drives. It will not be downloaded to unencrypted devices. The dataset will be completely anonymized and comprise numerical/categorical information. It will thus not contain confidential information.

The funders have not requested archiving, but we will review whether to approach the UK Data Service for archiving at the end of the project.

8.9 Data monitoring and quality assurance

The study will be subject to the audit and monitoring regime of the University of Manchester. Consequently, individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to the research participant.

9 DISSEMINIATION POLICY

9.1 Dissemination policy

Details of the study including justification and findings will be sent in an accessible format to organisations where participants were recruited from identified stakeholders. The researchers will also offer to present the findings at team meetings or other in-house events.

Professor David Gadd will act as the data custodian. Intellectual property will reside with the University of Manchester. All background intellectual property rights (including licences) and know-how and their improvements used in connection with the Study shall remain the property of the Party introducing the same and the exercise of such rights for purposes of the Study shall not knowingly infringe any third party's rights. Our intellectual property agreement reflects this.

9.2 Authorship eligibility guidelines and any intended use of professional writers

Authorship of the final study report will be granted to the applicants and Dr Filippo Varese.

10 REFERENCES

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Olsen A, Majeed-Ariss R, Teniola S and White C. (2017). Improving service responses for people with learning disabilities who have been sexually assaulted: an audit of forensic services. *British Journal of Learning Disabilities.* 45, 238-45. DOI: 10.1111/bld.12200

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11. APPENDICIES

11.1 Appendix 1- Required documentation

Participant Information Sheet (PIS)

Consent Form

Distress Protocol

11.2 Appendix 2 – Schedule of Procedures

Procedures	Baseline	3 months later	6 months later	12 months later	24 months later
Attends Saint Mary's SARC	x				
Gives Consent to be contacted	x	x	x	x	x
Participant receives PIS and PIN number	x	x	x	x	x
Participant receives Consent Form and Questionnaire	x	x	x	x	x
Participant is given the option to request a call back	x	x	x	x	x
Participant is directed to accessing the voucher.	x				

13.3 Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	0.1	02.06.2020	O.P.	A draft of the protocol was created
2	0.1	03.06.2020	D.G.	The protocol was reviewed. Guidance was given on particular issues.
3	0.2	04.06.2020	O.P.	Feedback was actioned.
4	1.0	03.07.20	DG	Revised for HRA submission
5	1.1	10.07.20	DG	Revised following minor queries from sponsor

This protocol has regard for the HRA guidance and order of content.

- All draft versions should be numbered 0.1, 0.2 etc.
- The final version for submission should be numbered 1.0
- The changes made relative to the previous protocol version should be listed after submission