PROTOCOL

The Effectiveness of Sexual Assault Referral Centers with regard to Mental Health and Substance Use: A National Mixed Methods study

Mixed Methods Study of SARCs (MiMoS)

SHORT Protocol v2_11.11.2019

IRAS Number	238240
ISRCTN Number	TBC
FUNDERS Number	HS&DR - 16/117/03

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

1. SIGNATURE PAGE

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, GCP guidelines, 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 Trial Sponsor:

Signature: Date:
..../...../.....

Name (please print):
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Position:
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Chief Investigator:

Signature: Date:
..../...../.....

Name: (please print):
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Statistician:

Signature: Date:
..../…../…..

Name: (please print):
.....

Position:
.....

2. KEY STUDY CONTACTS

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Funder(s)	National Institute for Health Research (NIHR HS&DR 16/117/03)
Co-Investigators and Work Package Leads	Work Package 1 Lead, Dr Brynmor Lloyd Evans: b.lloyd-evans@ucl.ac.uk Work Package 2 Lead, Professor Charlie Brooker, charlie.brooker@rhul.ac.uk Work Package 3 Lead, Dr Rebekah Shallcross, r.shallcross@leeds.ac.uk Work Package 4 Lead, Dr Kylee Trevillion, kylee.trevillion@kcl.ac.uk and Dr Steven Ariss, s.ariss@sheffield.ac.uk Work Package 5 Lead, Dr Kylee Trevillion, kylee.trevillion@kcl.ac.uk Work Package 6 Lead, TBC
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Committees	Project Management Group (PMG) Independent Oversight Group Program Steering Committee (PSC) Lived Experience Advisory Group (LEAG)

3. LIST of CONTENTS

4. LIST of ABBREVIATIONS

AE	Adverse Event
CI	Chief Investigator
GCP	Good Clinical Practice
ICF	Informed Consent Form
IOG	Independent Oversight Group
IAPT	Increasing Access to Psychological Therapies
ISF	Investigator Site File (This forms part of the TMF)
ISRCTN	International Standard Randomised Controlled Trials Number
LEAG	Lived Experience Advisory Group
MiMoS	Mixed Methods of SARCs
NHS R&D	National Health Service Research & Development
PI	Principal Investigator
PIS	Participant Information Sheet
PMG	Programme Management Group
PSC	Programme Steering Group
REC	Research Ethics Committee
SAE	Serious Adverse Event
SARC	Sexual Assault Referral Centre
SOP	Standard Operating Procedure
SSI	Site Specific Information
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee
WP	Work Package

5. STUDY SUMMARY

Study Title	The Effectiveness of Sexual Assault Referral Centres with regard to Mental Health and Substance Use: A National Mixed Methods study
Internal ref. no. (or short title)	MiMoS study
Study Design	Realist Evaluation using Mixed Methods
Study Participants	Sexual Assault Referral Centre's (SARCs) and related service's staff, service users and stakeholders
Planned Study Period	01.06.2018 – 31.05.2021
Research Questions	1. What programmes are identified in published and grey literature to inform how mental health and substance use can be best addressed in SARCs? 2. What models can be identified across the SARC services in terms of addressing mental health and substance use? 3. What is the prevalence and nature of mental health and substance use in people who attend SARCs? 4. What types of services are accessed by people with a range of needs following attendance at a SARC, and how satisfied are they with those services? 5. What are the barriers and facilitators to accessing the right support at the right time for people who have attended a SARC? 6. How do outcomes differ between a bespoke psychological therapies service at a SARC and mainstream mental health?

Research Objectives	1. To undertake an evidence review of SARC provision for health outcomes (including mental health and substance use) (Work Package 1) 2. To identify what models of SARCs currently exist in England (Work Package 2) 3. To identify the mental health and substance use needs of attendees of SARCs (Work Package 3) 4. To identify what services are available, and to explore satisfaction with care, barriers to access and gaps in provision (Work Packages 2, 3 and 4) 5. To understand from the perspective of the workforce and their current practice, skills and training needs in terms of recognition of, and referral for, mental health and substance use issues (Work Package 4) 6. To obtain the survivor view on how they felt their emotional well-being was addressed by the SARC as well as external services (Work Package 4) 7. To compare health outcomes for people who experience sexual assault and access bespoke SARC psychological therapies provision compared to those who experience sexual assault and are in mainstream mental health services (Work Package 5) 8. To produce a range of lay and academic outputs that will aim to identify and share good practice in SARC services related to substance use and mental health in order to have an impact on care delivery (e.g. training materials, new methods of screening, local partnerships etc.) (all Work-Packages, and specifically Work Package 6)

6. FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organizations providing funding and/or support in kind for this trial)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
National Institute for Health Research (NIHR)	Total research costs requested (not including NHS Support & Treatment Costs): **£1,161,567.21** Total NHS support & treatment costs / (savings): **£3,384.00**

7. ROLE OF TRIAL SPONSOR AND FUNDER

ROLE OF TRIAL SPONSOR: The sponsor (The University of Leeds) is responsible for ensuring before a study begins that arrangements are in place for the research team to access resources and support to deliver the research as proposed and allocate responsibilities for the management, monitoring and reporting of the research. The Sponsor also has to be satisfied there is agreement on appropriate arrangements to record, report and review significant developments as the research proceeds, and approve any modifications to the design.

ROLE OF TRIAL FUNDER: The funder (National Institute for Health Research (NIHR) HS&DR 16/117/03) is the entity that will provide the funds (financial support) for the conduction of the study. Funders are expected to provide assistance to any enquiry, audit or investigation related to the funded work.

ROLE OF CHIEF INVESTIGATOR (CI): The person who takes overall responsibility for the design, conduct and reporting of a study. If the study involves researchers at more than once site, the CI takes on the primary responsibility whether or not he/she is an investigator at any particular site.

The CI role is to complete and to ensure that all relevant regulatory approvals are in place before the study begins. Ensure arrangements are in place for good study conduct, robust monitoring and reporting, including prompt reporting of incidents, this includes putting in place adequate training for study staff to conduct the study as per the protocol and relevant standards.

The Chief Investigator is responsible for submission of annual reports as required. The Chief Investigator will notify the REC of the end of the study, including the reasons for the premature termination. Within one year after the end of study, the Chief Investigator will submit a final report with the results, including any publications/abstracts to the REC.

ROLE OF WORK PACKAGE LEADS: Individually or as leader of the researchers at a site; ensuring that the study is conducted as per the approved study protocol, and report/notify the relevant parties – this includes the CI of any breaches or incidents related to the study.

8. ROLES AND RESPONSIBILITIES OF TRIAL MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Programme Management Group (PMG)

The PMG will meet every 2-3 months to ensure all practical details of the trial are progressing and working well and that the project is progressing along its timelines. This group will be formed of the CI, WP Leads and the researchers on the study.

Programme Steering Committee (PSC)

The PSC will meet around every 6 months and includes all members of the PMG as well other stakeholders such including PPI representation, NHS England and Trust PIs. It will provide the overall supervision of the wider programme of research.

Independent Oversight Group (IOG)

The IOG will assess, at intervals, the progress of the research and safety data, to ensure that the continuing trial is safe for those participating. It is completely independent of the investigators, their employing organizations, funders and sponsors. This committee will meet once every 6 months and be available in order to oversee any decisions regarding ethical considerations that occur throughout the trial.

Lived Experience Advisory Group (LEAG)

The Lived experience advisory group will provide expert-by-experience opinion to the research team via face-to-face meetings and through email contact. The committee will comment on research material and protocol and will meet reguarly throughout the study.

9. PROTOCOL CONTRIBUTORS

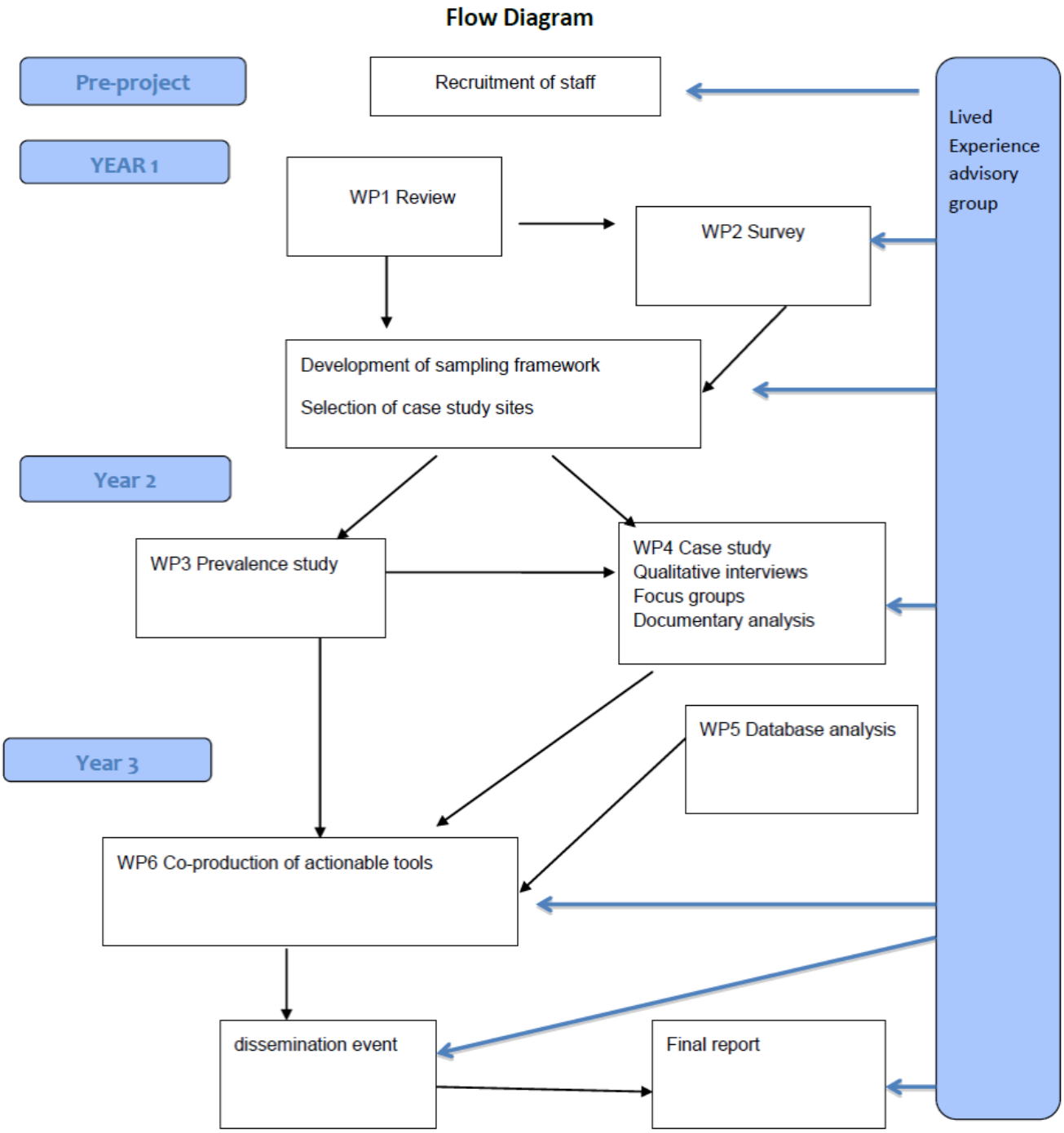
All co-applicants (outlined in key contacts) contributed to the development of the protocol of work to be conducted. Liz Hughes (CI) has expertise in leading trials, evaluations and mixed methods focusing on complex needs including sexuality and sexual health. Charlie Brooker (WP2 Lead) has undertaken needs assessments in SARCs and has published papers on the links between sexual violence, mental health and SARCs. Brynn Lloyd-Evans (WP1 Lead) is a mental health services researcher. Rachael Hunter is a health economist, will advise on service use data and calculation of service use costs. Kylee Trevillion (WP 4 & 5 Lead) is a mixed-methods researcher who specialises in women's mental health, specifically violence and abuse. She is experienced in qualitative and quantitative literature reviews, and surveys and interviews. Steve Ariss is a realist evaluation expert. Gail Gilchrist is a mixed methods researcher in addictions research focusing on the epidemiology of substance use and its relationship with mental health, intimate partner violence (IPV), childhood abuse and sex work. Mike Lucock has extensive experience of research on the effectiveness of psychological therapies in routine practice. This includes process and outcomes research and working with service user researchers. He will focus on access to psychological therapies. Sarah Kendal is experienced in child and adolescent mental health research using qualitative and participatory methods, and will lead on PPI, ensuring meaningful input throughout the research. Rebekah Shallcross (WP3 Lead) is a research clinical psychologist with experience in women's mental health; conducting research into domestic and sexual violence, and will work full time in years 2 and 3 coordinating all aspects of the project. Fay Maxted is a national expert and advocate for survivors of sexual assault and will ensure

that the survivor perspective and best interests is included throughout the research. Karen Tocque is an epidemiologist and will provide statistical expertise as a collaborator.

10. KEY WORDS

Sexual Assault; Mental Health; Substance Misuse; Rape; SARC

11. TRIAL FLOW CHART



12. THE EFFECTIVENESS OF SEXUAL ASSAULT REFERRAL CENTRES WITH REGARD TO MENTAL HEALTH AND SUBSTANCE USE: A NATIONAL MIXED METHODS STUDY

Mixed Methods Study of SARCs (MiMoS)

12.1. Background

Sexual assault referral centres (SARCs) are a one-stop shop for the treatment of people who have experienced sexual assault. They bridge criminal justice and health services in recognition of the range of needs that are presented. This includes forensic medical examinations, physical and mental health checks, safeguarding and risk assessment, as well as psychosocial support. SARCs are also able to refer or signpost to other agencies in the local area should a need be identified. The HS&DR has commissioned this research to examine how SARCs are responding to the mental health and substance use needs of its service users.

Mental ill health is common in people who attend SARCs. In Holland (Bicanic et al., 2014), the United States (Brown et al., 2013), and England (Brooker and Durmaz, 2015), approximately 40% of SARCs attendees have been estimated to have a mental health problem. In a recent audit of Thames Valley SARCs, Brooker et al (under review) found: that 69% of attendees could be defined as experiencing a mental health problem; 20% had a history of admission to a psychiatric unit; 32% were drinking at 'hazardous' levels; and 45% had previously self-harmed. In a secondary analysis of data from the Adult Psychiatric Morbidity Survey, Brooker and Tocque (2016) found that there was a consistent relationship between risk of mental health and substance use problems and the level of sexual violence experienced. They concluded that having mental health expertise in SARCs was crucial. However, the National Service Specification for SARCs (NHS England, 2015) whilst acknowledging mental health issues are common, states only that SARCs should ensure the provision of appropriate psychosocial support according to need, and where this exceeds what Increasing Access to Psychological Therapies (IAPT) can support, then they will be referred to secondary mental health services.

In the first national survey of SARCs Brooker and Durmaz (Brooker and Durmaz, 2015) reported that only half of SARCs routinely assessed mental health needs of attendees, and where it was assessed it was completed by a Forensic Medical Examiner (FME). Substance misuse issues were not always included. Almost two-thirds of SARC services report problems in referring on to mental health services for a variety of reasons. The paper argued that more research was needed in this important area and that NHS England should fully describe the skills required to undertake a mental health risk assessment when someone has been the victim of rape or sexual assault.

12.2. Rationale

Despite the high levels of mental health and substance use needs of those who attend SARCs, there is limited evidence regarding the specific needs of people who attend SARCs, what works for whom, in what context, and where resources could be allocated to obtain maximum benefit. In order to do this, we need to identify models of identifying and assessing mental health and/or substance use problems; what subsequent referral pathways are available for a range of people; the views and preferences of people who use SARCs; the workforce needs not only for SARC staff but for the network of agencies that work with survivors (including mental health, third sector counselling and substance use services); and the costs and benefits of different models of service provision.

The aim of the MiMoS study is to generate evidence related to the mental health and substance by addressing the following questions:

1. What programmes are identified in published and grey literature to inform how mental health and substance use can be best addressed in SARCs?

2. What models can be identified across the SARC services in terms of addressing mental health and substance use?

3. What is the prevalence and nature of mental health and substance use in people who attend SARCs?

4. What types of services are accessed by people with a range of needs following attendance at a SARC, and how satisfied are they with those services?

5. What are the barriers and facilitators to accessing the right support at the right time for people who have attended a SARC?

6. How do outcomes differ between a bespoke psychological therapies service at a SARC and mainstream mental health?

12.3. Assessment and management of risk

Conducting research in this population is not without risk to the participants, the researchers and the programme facilitators. The potential risks associated with this trial and more widely in our research group have been considered and guidance has been produced to minimise/mitigate these risks. Safety standard operating procedures will be developed, which all relevant staff (researchers, CRN staff, recruiting SARC staff) will be trained on. All research staff will be familiarised with this protocol and the SOP prior to conducting any trial-related procedure.

12.4. Research objectives

1. To undertake an evidence review of SARC provision for health outcomes (including mental health and substance use) (Work Package 1)
2. To identify what models of SARCs currently exist in England (Work Package 2)
3. To identify the mental health and substance use needs of attendees of SARCs (Work Package 3)
4. To identify what services are available, and to explore satisfaction with care, barriers to access and gaps in provision (Work Packages 2, 3 and 4)
5. To understand from the perspective of the workforce and their current practice, skills and training needs in terms of recognition of, and referral for, mental health and substance use issues (Work Package 4)
6. To obtain the survivor view on how they felt their emotional well-being was addressed by the SARC as well as external services (Work Package 4)

7. To compare health outcomes for people who experience sexual assault and access bespoke SARC psychological therapies provision compared to those who experience sexual assault and are in mainstream mental health services (Work Package 5)

8. To produce a range of lay and academic outputs that will aim to identify and share good practice in SARC services related to substance use and mental health in order to have an impact on care delivery (e.g. training materials, new methods of screening, local partnerships etc.) (all Work-Packages, and specifically Work Package 6).

In order to address these questions and objectives, we will undertake a multi-method study comprising of 6 work packages (WPs). This will include a review of the literature to identify models of good practice in working with mental health and substance use (WP1), then a national survey of all 47 SARCs to identify the ways in which they are recognizing and addressing mental health and substance use (WP2). These two work packages will inform and refine an emerging programme theory that we will further test in work packages 3 and 4. We will select around 6 SARCs to act as case study sites based on a sampling framework established by WP1 and 2. In WP3, we will endeavour to identify the nature of the needs of SARC attendees by undertaking a prevalence study as well as "what works for whom" in a follow-up survey asking about service use and satisfaction following an attendance at SARCs. In WP4 we will undertake more in-depth qualitative work refining and testing patterns that emerge as we undertake and analyze the data. This will comprise of focus groups with providers, individual interviews with service users and their significant others, and documentary analysis. By the end of WP4 we will have a more refined programme theory and will have some conclusions about what works for certain groups of people, what the contexts and mechanisms by which this works as well as recommendations for policy practice and further research. In work package 5 we will interrogate anonymized data sets of routine data for a specific psychological therapies service attached to a SARC as well as a data set of people identified as experiencing a sexual assault but who are within a mental health service. We will work with survivors and practitioner advisors throughout the whole study to ensure that our research is meaningful for those end users, and that we are producing work that has use and relevance to survivors, practitioners and

commissioners. To this end, we have added a specific work package (WP6) to co-produce actionable tools based on the emerging findings working in partnership with survivors and practitioners. As such, the Work Packages will help achieve the research objectives.

A Data Management Plan [MiMoS_23240_Data Management Plan_v1_16.08.2019] has been developed for WP 3, 4 and 5 to compliment this protocol.

This protocol will outline each work package in detail.

13. WORK PACKAGE 1: THE IDENTIFICATION AND TREATMENT OF MENTAL HEALTH AND SUBSTANCE MISUSE PROBLEMS IN SARCS: A SYSTEMATIC REVIEW

WP1 is a systematic review of previously reported studies and will require no ethical approval, or additional consent from participants and is near completion. As such, it is not detailed here. It aims to systematically review the comparative evidence for SARCs regarding mental health and/or substance misuse outcomes and has been registered on Prospero: PROSPERO 2018 CRD42018119706 Available from: http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42018119706

14. WORK PACKAGE 2: THE NATIONAL SURVEY OF SARCS AND MENTAL HEALTH/SUBSTANCE MISUSE

WP2 is a national survey of SARCs examining how they currently respond to mental health and substance misuse which required no ethical approval, or additional consent from participants. As such it is not detailed here. The survey has now been closed. The results have been used to inform case study sampling in WP3 and 4.

15. WORK PACKAGE 3: MENTAL HEALTH, SUBSTANCE MISUSE AND SARC ATTENDEES: A PREVALENCE STUDY

15.1. Aims

Work Package 3 has the following aims:

1.) To estimate the prevalence of mental health and substance use difficulties in cohort of people attending SARCs

2.) To assess how the identified mental health and substance misuse needs have been met at a 6month follow-up point

3.) To calculate quality adjusted life years (QALYs) over the 6 months

15.2. Study Design

Cross-sectional prevalence study, with a prospective follow-up cohort study of service use and satisfaction.

15.3. Setting

Participating SARCs at 6 sites across England, with the possibility of adding further sites if needed

15.4. Sample

Adults over the age of 18 who attend SARCs and who consent to participate within the recruitment period (or until sample size is reached).

The Inclusion Criteria are as follows:

1.) Aged 18 or older

2.) Can read and understand English (or there are suitable confidential translation services available

The Exclusion Criteria are as follows:

1.) Lack of capacity to provide informed consent.

2.) Where participation is deemed to significantly increase risk to self or others.

3.) Attendee of a SARC not participating in the study

To meet power requirements, a total sample size of n=360 across the six sites should be obtained (n=60 at each site). With an estimated population of 4000 across 6 sites per year, we estimate attendees at each SARC will be 40-60 referrals per site, per month. In a recent 12-month audit of mental health needs in Thames Valley SARCs (Brooker et al., under review) the SARC staff obtained

consent and collected data on 42% of attendees and 38% declined to participate (with limited support to recruit). Therefore we are confident that we should be able to obtain consent from 50% of attendees to participate which means 20-30 per site, per month. If we assume 20 per month (~50%) consent to participate x 6 sites= 120; therefore, sample size would be reached in 3 months; 120 x 3 =360, with 3 months leeway for variation. Extra sites may be added as necessary.

15.6. Measures

The following self-complete outcome measures will be used to assess relevant aspects of mental health and substance misuse.

- Demographics questionnaire
- Mental Health symptoms CORE 10 (Connell and Barkham, 2007) (MAIN OUTCOME)
- Alcohol Screening Tool (AUDIT-C) (Bush et al., 1998)
- The Primary Care PTSD Screen for DSM-5 (PC-PTSD-5) (Prins et al., 2015)
- ReQoL (Quality of Life for mental health) (Keetharuth et al., 2018)
- Drug use (DAST) (Skinner, 1982)
- Standard assessment of personality – a brief screen for personality disorder (SAPAS) (Moran et al., 2003)

These measures (with the exception of demographic questionnaire and SAPAS), will be completed again 6 months following recruitment into the study. At the 6 month follow-up, participants will also complete a bespoke service receipt inventory - designed to collect information on the proportion of different mental health, substance misuse and counselling services used by people in contact with SARCs, along with questions regarding participant's satisfaction and perceptions of unmet need. At this time point, participants will also be asked for meta-feedback about how they felt about the recruitment process and their participation in the study.

15.7. Procedure

A period of engagement with each SARC site will be undertaken in order to fully brief the staff about all aspects of the study and training on how to raise awareness of the subject of the study with attendees.

15.7.1. Recruitment & Consent

The following recruitment strategy and procedures have been developed in order to empower participants to have control over the decision about their capacity to participate in the research (Perot, Chevous & Survivors' Voices Research Group, 2018). Through engagement with our LEAG group we have developed a variety of recruitment strategies, recognizing that not all potential participants may want to come into the study in the same way. Participants will be able to first engage with the study in several ways:

1.) Upon presentation at a SARC participants may give verbal consent to contact to a member of SARC staff. This verbal consent will be recorded in the participant's notes or on the verbal consent to contact form provided to trusts, depending on the preference of the service. This verbal consent to contact will enable the participant to hear about the research from a researcher at a later date, at a time that is acceptable/convenient to them.

2.) Participants may give verbal consent to contact via any member of staff at any follow-up time point within the 6 weeks of attending the SARC. Once verbal consent to contact has been given (and documented), the participant can hear about the study from a researcher at a time that is acceptable/convenient to them.

3.) Researchers may sometimes be present at SARCs and available to talk with participants at their request. Researchers will be able to provide participants with information about the study (specifically suggested by the LEAG group).

4.) Clinical Studies Officers may sometimes be present at SARCs and available to talk with participants at their request. CSOs will be able to provide participants with information and with verbal consent, pass their details onto the researcher who will be able to speak with the participant in more detail about the research

5.) Participants may refer themselves to the study. The study will be advertised to eligible participants through social media and posters in relevant areas (for example, within SARCs, third sector organisations) and adverts on relevant websites (survivors trust etc; this was specifically suggested by the LEAG group)

6.) Leaflets will be given to all eligible people attending SARCs so that they may self-refer to the study following their visit (this was specifically suggested by the LEAG group).

After the participant has referred themselves to the study or given verbal consent to be contacted by a researcher, researchers will follow the following processes:

1.) Participants name and preferred method(s) of contact will be recorded by the research team. The researcher will contact the participant via phone (or post, email or text) to speak with the participant and if they so wish, provide them with all the information necessary for them to make fully informed consent (1-4 weeks after the presentation at SARC). Written information will be provided if safe to do so in the form of a PIS and this will also be verbally discussed. Participants will be given at least 24 hours (or longer if needed/requested) to consider the information before deciding whether or not to take part.

2.) If the participant decides to take part in the study, then fully informed consent will be obtained and the baseline study questionnaires will be completed, usually via a link emailed to the participant using University of Leeds approved online survey provider (e.g. 'Online Surveys'). However, if participants prefer, they can also complete the consent forms and questionnaires by post. In this instance, 2 copies of the consent forms signed by the researcher will be sent to participants along with the questionnaire and a stamped addressed envelope. Participants will be instructed to complete the consent forms and questionnaire, returning 1 consent and the questionnaire in the stamped addressed envelope provided. A further option for completing the questionnaires is over the phone with a researcher. In this

instance, the researcher will complete the online consent form and questionnaire over the phone with the participant, obtaining text or email confirmation of consent.

3.) Participants will be followed up 6 months later (using contact preferences obtained at baseline) in order to complete the follow-up questionnaires and service use questions. Participants will also be asked for meta-feedback about how the felt about the recruitment process and their participation in the study.

When attempting to contact the service user, researchers will use contact preferences upto 5 times before we record as 'unable to contact', in these instances, personal data will be deleted from the database.

The participants will receive £10 for participation in the prevalence study and follow-up, and if required, reimbursement for any additional travel expenses

15.8. Analysis

The demographics of our prevalence study sample, both non-recent and recent cases, will be initially compared to routine data collected from the 6 sites over the course of the national survey (WP2) in order to assess representativeness of our sample. The final dataset will then be weighted for demographics (e.g. age, gender, deprivation).

A direct estimate of the prevalence of mental health within SARC attendees will be determined from the sample and weighted estimates produced for the 6 SARC sites. Additionally, a further weighted national estimate will be produced (if demographic data can be obtained for all 47 SARC sites). Analysis of other health, wellbeing and behavioral measures will follow the same principle to produce direct (and site-specific and national weighted) estimates. Prior to producing these estimates, the dataset will be analyzed to determine how/if demographics, site or method of data collection have influenced prevalence measures. A logistic multivariate analysis will be undertaken to determine predictors of mental health and/substance use diagnosis. Participant's feedback on satisfaction with services and any gaps/unmet need will also be analyzed descriptively and themed in order to glean qualitative insights.

15.9. Health Economics

Little is known about what services SARC attendees use and the related costs. The aims of the health economics analysis in WP3 will be to:

(i) Provide descriptive statistics of resource use and costs for adult SARC attendees at recruitment and 6 months;

(ii) Calculate quality adjusted life years (QALYs) over 6 months;

(iii) Calculate the predictors of costs and QALYs; and

(iv) Quantify the relationship between costs and QALYs using general linear models.

Resource use will be costed using nationally published sources. In addition to reporting descriptive statistics of service use and costs we will use general linear models using appropriate family and link functions to provide descriptive statistics of predicted costs for different patient characteristics. In particular, we will evaluate the relationship between patient care pathway, costs and quality of life outcomes such as CORE and ReQoL to identify if engagement with services is predictive of better or worse quality of life. QALYs will be calculated from the ReQoL using algorithms currently under development by The University of Sheffield to calculate the area under the curve. We will use the AIC to decide the model structure which variables to include in the models (Barber and Thompson, 2004). For people missing data at 6 months we will evaluate baseline predictors of missing data and use these to construct multiple imputed datasets using chained equations. Final analyses will be conducted on the imputed data datasets.

15.10. Data Handling & Management

The information provided by participants will be confidential, and, in accordance with the Data Protection Act (2018) and GDPR (2018), any personal data (identifiable details) will be stored separately from the research data (i.e. answers given during on the questionnaire). Research data will be pseudonymised using a study number. The only exception to this confidentiality is if the research team have concerns about current or future risk of serious harm to the participant or to anybody else. Similarly, confidentiality may be broken if participants disclose details of intention to commit a crime or

if participants share details of a crime for which they have not been convicted. If this happens, the research team will follow standard operating procedures (SOPs) which will cover things like informing the participants GP or other relevant services (on a need to know basis only). Researchers will always try and discuss this with participants first where possible.

As well as being used to support the current research, data that has been pseudonymised and/or anonymized (i.e. questionnaire data that has had your identifiable information removed and been given a study number) may also be used to support relevant future research and/or training and may be shared anonymously with other researchers (subject to relevant research governance processes such as confidentiality and data access agreements). Anonymised data may also be made available indefinitely on database repositories for publication purposes to increase transparency of research process.

Identifiable, personal data will be kept for 2 years and then securely destroyed. If participants consent their identifiable information will be used to let them know about relevant future research opportunities (including WP4). Participants do not need to consent to further contact in order to participate in WP3. Monitors and auditors, the sponsor and regulatory inspectors may require access to personal data to verify or cross check data. They will be bound by the same confidentiality as the researchers on the study.

Participant's rights to access, change, or move their information are limited. If participants withdraw from the study or lose capacity to consent, we will keep their information that we have already obtained. To safeguard their rights, we will use the minimum personally-identifiable information possible. More about University of Leeds's privacy notice can be found here: https://dataprotection.leeds.ac.uk/wp-content/uploads/sites/48/2019/02/Research-Privacy-Notice.pdf

A Data Management Plan [MiMoS_23240_Data Management Plan_v1_16.08.2019] has been developed for WP 3, 4 and 5 to compliment this protocol.

16. WORK PACKAGE 4: CASE STUDIES USING REALIST EVALUATIONS

We will use a realist evaluation approach (Pawson, 1997), employing mixed methods, to develop, refine and test programme theories. These programme theories will consist of mid-range theories that explain how the SARCs and related services are intended or expected to achieve specific outcome patterns. These will encapsulate the diversity of experiences and explain what works, for whom, in what circumstances and why. The programme theories will be developed iteratively using tools such as logic models, if-then statements and context, mechanism and outcome conjectures (CMOCs) and supported by triangulating data from a range of sources including WP1-5:

Whilst each work package will produce its own discreet outputs, we will take an iterative approach; each stage will be informed by the findings of the previous stages, as well as within each stage (for example, qualitative interview schedules will be modified as we identify patterns and develop theories which we will then test at the next interview).

16.1 Research Questions

The overarching research questions for this workpackage are:

> How do service designs and organizational processes of SARCs and associated services address mental health and substance use needs, and what are people's experiences of SARC responses to these needs?

16.2 Aim and objectives

The aim of this workpackage is to:

- Provide a detailed understanding of the core components of effective SARC provision in relation to mental health and substance use problems and how to support these within the context in which programmes are delivered;
- To identify what services and referral pathways for mental health problems and substance abuse are provided by SARCs, and to explore satisfaction with care, barriers and facilitators to access, and gaps in provision

- To understand from the perspective of the SARC workforce and partner agencies their current organizational, practice, skills and training needs in terms of recognition of, and referral for, mental health and substance use issues
- To obtain the survivor view on how they felt their emotional well-being was addressed by the SARC as well as external services

We want to better understand the contexts and mechanisms resulting in the key process outcome patterns involved in the identification and management (including referral pathways) for substance use and/or mental health. This will include how (and if) and for whom the need for mental health and substance use services are identified. We will also expect to examine decision-making processes with SARC staff regarding referral to external agencies, and how this works for different needs (such as post-traumatic stress disorder; anxiety and depression; substance use problems; those with prior mental health problems).

16.3 Methods

We will use a comparative realist evaluation approach comprising detailed investigation of the relationship between organizational processes and contexts (Baker, 2011) which will generate a holistic understanding of the phenomenon under investigation (Easton, 2010). Using this methodology, this study seeks to explain and understand current SARC service provision by considering how variations in service provision and processes interplay with important aspects of individual service users, thereby influencing how mechanisms work and produce different outcome patterns (Pawson, 2004). This will be achieved by developing, refining and testing hypotheses (programme theories) that describe how various outcome patterns (O) are observed depending on whether the contexts (C) allow specific mechanisms (M) to operate. These hypotheses are called Context, Mechanism, Outcome conjectures or CMOCs. A simple example could be the following:

- Mechanisms= Identification of need and referral to external mental health services
- Context= Previous experience of mental health services
- Outcome patterns= Attending mental health services and longer-term expected outcomes such as improved wellbeing, reduced risk of further assault etc

A CMOC incorporating these elements could be constructed as follows:

It is expected that identifying a mental health need and referral to external mental health services (M) will result in improved wellbeing (O). However, if the service user has had previous adverse or unsatisfactory experiences of these services (C) and as a result does not take-up the referral then the anticipated mechanism will fail to 'fire'. Not only will the anticipated benefits of attending these services not be realized (O), but the service user might experience adverse outcomes such as despair or lack of hope (O), thereby potentially leading to worsening of psychological state and higher risk of further assault.

In this CMOC, the key elements that influence outcome patterns (O) are the referral process mechanisms (M) and whether they operate as expected, which is dependent on the context (C) of previous experiences of referral to these (or similar) services.

In the testing of the programme theories, we start by clearly defining the case study and what is to be included in each site. The SARC will be seen as the hub of the case study with all the partner agencies that both refer into the SARC as well as serve the local population that attend that SARC.

16.4 Study Design

A case study analysis of six SARCs (with the option of adding more if necessary). Selection of the SARCs will be based on a maximum variation, theoretical sampling framework established using evidence from other studies in the research programme (i.e. WP1 - the systematic review, and WP2 – the survey of SARCs).

16.5 Study Components

This work-package will consist of three main elements:

1. Programme theory development, integration and collaboration and consensus across the study workstreams
2. Realist interviews with SARC service users and carers and focus groups with SARC staff and partner agencies

3. Documentary review of SARC guidelines and policies, protocols and procedures on mental health and substance use problems.

Element 1: theoretical development, integration and collaboration

We will develop, test and refine a set of key programme theories in collaboration with and

based on a synthesis of findings from workpackage 1 (a review of evidence), workpackage 2 (a national survey of SARCs), and workpackage 3 (a prevalence survey of SARC users). These theories will be tested within and between the case study sites. Our overarching initial theory suggests that SARC attendance is a critical point that has great potential to identify pre-existing or emerging mental health and substance use problems and provide appropriate interventions. However, there is limited guidance as to how this should be operationalized, and evidence that service provision is highly variable.

These theories will be based on a taxonomy of SARC services, focused on a set of key characteristics, with specific reference to service designs and processes for SARCs and associated mental health and substance abuse services. Further theoretical development will describe how these organisational characteristics might present barriers and facilitators for the identification of mental health and substance use needs and service provision. We have developed an initial logic model (see appendix) and this workpackage will focus on testing out the elements of the model focused on "immediate outcomes/experience of service" and "outcomes".

Element 2: realist focus groups and individual interviews

Sampling
Inclusion:

- Aged 18 or over
- Can read and understand English or there are suitable confidential translation services available
- Have identified a mental health or substance use need to take part in the interview (service users only)

Exclusion:

- Lacks capacity to provide informed consent
- Where participation is deemed to significantly increase risk to self or others
- SARC attendee, significant other of attendee, or staff of a SARC not participating in the study

We will conduct individual semi-structured interviews with approximately 30 SARC service users (5 per SARC). We will also aim to recruit up to 30 significant others (e.g. partners, friends or family members of the service user), if possible (5 per SARC). We will conduct two focus groups per site with around 6-10 participants each, one with SARC staff and one with staff from partner agencies.

Similar to other qualitative work with people with mental health needs (Jones et al., 2009), we will recruit a purposive sample of service users and significant others across the six SARC case study sites, to ensure diversity with respect to gender, age, ethnicity, mental health status and recentness of abuse.

We will also recruit a purposive sample of SARC staff and staff from relevant external agencies across the six case study sites, to ensure representation within the workforce of SARCs and partner agencies (e.g. within SARCs to ensure representation from management, Forensic Medical Examiners and Nurses, Independent Sexual Violence Advisors (ISVA), / within external agencies to ensure representation from third sector partners including sexual and domestic violence sector services and sexual violence counsellors, mental health services, and local substance use services).

We will invite representatives of SARC staff, as well as key partner organizations within each case study site and will directly contact these services to explain the study and seek participation from those services.

Study materials

Both the individual interviews and focus groups will use a topic guide, which will be developed based on the refined programme theories. We want to know how this process works, for whom, in what circumstances and why, from the point of identification to accessing treatment and whether people are able to access the right support at the right time.

The topic guides will be formed from a combination of theory-seeking, theory-refining and theory testing questions and will develop iteratively with our increased understanding; to move from open (seeking) questions to explicitly testing hypotheses. Overall, the interviews will seek to understand the mechanisms by which interventions are intended to achieve certain outcomes and the individual and organisational contexts that modify these outcomes.

The topic guides for service users will seek to understand: what people perceive their needs are in relation to their mental health and substance use; how they view the identification and assessment of mental health problems and/or substance use; their views on the referral pathway; satisfaction with the services they received and outcomes. The topic guides for significant others' will seek to explore the impact on them of the service-user's contact with SARCs, any specific needs that they might have and opinions about the effectiveness of the SARCs and related services.

The topic guide for SARC staff and staff from partner agencies will seek to: understand how staff work with a range of mental health issues experienced by service users; to explore staff experiences of offering support to people who have experienced sexual assault and have mental health problems; to explore how staff identify those who have a high risk of mental health problems or pre-existing mental health problems; to explore staff experiences of ensuring service users access appropriate ongoing care; to explore the workforce training and skills needs of staff in regard supporting people with mental health needs and experiences of trauma.

Study procedures

The service users for WP4 will be a sub-sample of those who have taken part in WP3. We will refer to the record of participants who consented to be contacted for future research when they took part in

WP3. Those who agreed will be contacted by a researcher with further information about WP4, be provided with WP4 PIS (with at least 24 hours to consider the information), have an opportunity to ask any questions, and then if still interested arrangements to conduct the interview will be made. In order to ensure that we are able to meet the aims of the study (i.e. to explore the effectiveness of SARCS in relation to mental health and substance use needs) we will employ purposive sampling - we will use data obtained from WP3 to contact those service users who have an identified mental health or substance use need.

In the unlikely event that we are not able to recruit a large enough sample of service users through this route, we will also have the option of recruiting people directly to WP4, who have not taken part in WP3. In this case, researchers will use the same methods of recruitment as described in WP3 i.e. posters and leaflets will be displayed in SARCs, SARC staff will tell people about the study, and service users can self-refer to complete WP4.

Following written consent, individual interviews with service users will take place in person, or via skype or telephone (whichever is the preference of participants) at a time and place mutually agreed by the participant and the researcher to ensure the location is easy to travel to, provides privacy, and is safe and comfortable. Where interviews take place face to face, this might be at the SARC site, at another community venue, or, where deemed safe, at the service user's home. Any participant travel costs will be reimbursed or paid for in advance.

The study team will also ask service users to consider significant others (such as partners, family members, and friends) who might be interested in participating in the “significant other” interviews, and they will be given a specifically designed leaflet to pass on to their significant others. These interviews will be conducted as per the interviews with service users.

Researchers will adhere to local lone-working procedures (e.g. ‘checking-in’ phone calls upon completion of the interview). All service user and significant other interviews will be conducted by an experienced health researcher (someone with experience of conducting interviews of a sensitive nature).

All participants will be given £20 cash to thank them for their time.

When attempting to contact potential participants/participants, researchers will use contact preferences upto 5 times before we record as 'unable to contact', in these instances, personal data will be deleted from the database.

For the focus groups, we will invite representatives of SARC staff, as well as key partner organizations within each case study site and will directly contact these services to explain the study and seek participation from them. Focus groups will be conducted at the sites by members of the research team.

Consent will be sought from participants to audio-record the interviews. All interviews will be digitally recorded on encrypted devices and data transcribed verbatim. All identifiable information will be deleted from the transcripts to ensure that personal information is de-identified. Caution will be taken in choice of quotes to ensure that participants can't be recognized by the content.

Analysis

A within and between case analysis will be conducted for SARC staff, partner agencies and service user, significant other/carer interviews in order to identify and explore themes that are the same across services and those which vary between services. A deviant case analysis, where individual transcripts or site transcripts will be interrogated for information that seems discrepant with the overall analysis, will also be undertaken

Data will be analysed in two stages; stage one will involve using NVIVO to identify key theoretical themes, to explore the testing and refinement of hypotheses and develop a thematic framework for stage two. In stage two, NVIVO will be used for Framework Analysis (Ritchie, 2013) for refinement of Context, Mechanism, Outcome conjectures (CMOCs) (e.g. (Adams et al., 2016) Framework analysis comprises: (a) familiarization with the data; (b) identification of a thematic framework, (c) revision and refinement of the thematic framework, (d) charting of the thematic framework, and (e) systematic mapping and interpretation of the thematic framework, both within- and between-cases, to facilitate new insights and understandings at the individual and group level.

Consensus across the study team workstreams will be sought at key points in the investigation; for instance development of initial theories to be refined and tested and construction of the coding framework. This will be achieved through a combination of workshops, meetings and discussion documents circulated by email.

Element 3: documentary analysis

The refined programme theories will inform the development of the documentary analysis. This element will comprise a document review of SARC guidelines on the identification, referral and provision of care for people with mental health and substance use needs. The document review will critically examine the policies, protocols and procedures on mental health and substance use problems across six SARC services and explore how they relate to the Context, Mechanism, Outcome conjectures being developed through the study.

Identification of data sources

Service managers and personnel have been asked for their consent to support the identification of eligible documentation during work package 2 (national survey of SARCs). During the case study site visits SARC staff and/or researchers will identify any eligible materials, through hand searches and SARC service intranet searches.

Data extraction

Data from policies and protocols will be extracted by a researcher for all included documentation using a standardized extraction form, developed by researchers and based on SARC national service and NHS England guidance. This will be used to extract data on any good practice guidance/indicators reported in policies, protocols and procedures. Material will also be explored for evidence relating to the complex patterns of contexts, mechanisms and outcomes emerging from this and other work-packages (Pawson, 2004). A second reviewer (another member of the research team) will

independently extract data from a random sample of 20% of documents as a check. All data will be extracted into Microsoft Excel.

Document appraisal

Included documentation will be appraised using a standardized critical appraisal checklist, adapted from the Joanna Briggs Institute critical appraisal tool for narrative, opinion and text.

16.6 DATA MANAGEMENT

Data management will follow the same principles as WP3 i.e. the information provided by participants will be highly confidential, in accordance with the Data Protection Act (2018) and GDPR (2018). Names and contact details of potential participants will be passed to the research team via telephone or encrypted email, with the participants' verbal consent. These details will be kept on a suitable database on University of Leeds, University College London and Kings College London approved cloud based storage with relevant encryption and access restrictions applied. On entering the study participants will be assigned a unique study ID. This will be used on all interview data i.e. audio files and transcripts. Interviews will be audio recorded on encrypted devices. This data will be transferred to a password-protected computer as soon as possible and will be deleted from the recording device. Paper consent forms will be stored in locked filing cabinets, and audio files and transcripts will be kept on password protected computers.

At the end of the study data will be transferred to the University of Leeds for archiving.

A Data Management Plan [MiMoS_23240_Data Management Plan_v1_16.08.2019] has been developed for WP 3, 4 and 5 to compliment this protocol.

17. WORK PACKAGE 5: HISTORICAL COHORT STUDY COMPARING THE CLINICAL OUTCOMES OF PEOPLE WITH EXPERIENCES OF SEXUAL ASSAULT WHO RECEIVE DIFFERENT MODELS OF PSYCHOLOGICAL TREATMENT

17.1 Aim

To assess changes in psychological well-being among males and females [aged ≥ 13 years] with experiences of sexual assault [recent vs. non-recent] that receive psychological treatments from a mainstream mental health service compared to different psychological treatments received from a sexual assault referral centre.

17.2 Study design

A retrospective cohort study using anonymised data

Sample

Males and females who report any sexual assault: recent and/or non-recent sexual assault, and who receive psychological treatment from a mainstream mental health service or SARC service.

Procedure

Datasets

Data from this study will be collected from anonymised clinical datasets at a mainstream mental health service in London and a SARC service in Kent. The reason for selecting the mainstream mental health service in London is because it has the most well established anonymised health records system in England to date, providing data on a diverse sample of over 250,000 patients accessing mental health services, including substance misuse treatment, across four boroughs in London. The Kent SARC is also chosen is because it is only one of the 47 SARCs in England to have an established comprehensive multi-agency psychological treatment pathway with specialist third-sector organizations. As part of this pathway, Kent SARC has established a central database system for the reporting of demographic and clinical data of service users, and since 2016 the service has been obtaining consent from service users to the sharing of their anonymised data for research purposes.

Clinical Dataset Mental Health Service (CRIS Dataset)

Data from the mainstream mental health service - the South London and Maudsley National Health Service Foundation Trust (SLaM) – will be collected from the Biomedical Research Centre Case Register Interactive Search (CRIS) system (22). This CRIS system comprises anonymized health records of the Trust's unique bespoke, single, integrated electronic clinical record system. The CRIS system provides comprehensive records of all clinical information recorded throughout patients' journeys, including demographic information, details of referrals and transfers, detailed clinical assessments and care plans. It provides data on mainstream secondary, substance misuse and primary mental health services (the latter from Improving Access to Psychological Therapies (IAPT) services) and specifies type of treatment provided e.g. Cognitive Behavioural Therapy (CBT), guided self-help, Eye Movement Desensitization and Reprocessing (EMDR) etc.

This CRIS system records allows in-depth secondary analysis of both numerical, string and free text data, whilst preserving anonymity through technical & procedural safeguards. Free-text searches and natural language processing will be used to identify patients whose care team have documented that they have experienced sexual assault and whose clinical notes provide before- and after-therapy CORE Outcome Measures [CORE-OM]. This unique data set can only be accessed by King's Health Partners students and staff after approval by the CRIS oversight committee.

Clinical Dataset SARC service

The Kent SARC provides the only bespoke psychological therapies service in partnership with the local mental health NHS Trust and two third-sector organizations [Family Matters and East Kent Rapeline]. The SARC treatment model utilizes specialist third-sector organizations, which offer counselling, alongside an NHS psychological therapy service. The third-sector organizations provide an alternative therapeutic model to the mainstream mental health model of SLaM, through the provision of specialist trauma-focused counselling for males and females reporting sexual assault via the Kent SARC. The SARC service and its partners have established a central database system for the reporting of clinical data of service users. The database includes detailed demographic and clinical information, including before- and after-therapy CORE Outcome Measure (CORE-OM) scores. The

research team will work with the SARC providers (DUFFY and CLARK) to generate an anonymized clinical dataset of key demographic and clinical information and CORE outcome assessments for the purposes of this study.

Cases from each dataset will be matched on key clinical and demographic information, including age, gender, ethnicity and timing of assault (i.e. recent vs. non-recent).

17.3 Pilot work

Pilot searches of the clinical dataset for the mental health service (CRIS system), since its year of inception in 2006 to the end of 2016, indicate that there are CORE-OM outcome data on more than 3,000 women who have been raped or have experienced other forms of sexual assault. From this we estimate around 300 women per year receiving psychological treatment who have a document of sexual assault on the CRIS system, therefore approximately 900 cases for 2016 to 2019.

We have already been in discussions with the Kent SARC staff, two of whom are our collaborators (Duffy and Clark) and they have confirmed that they are able to provide us with an anonymized clinical dataset for the purposes of this study; the SARC service already has in place permission agreements from service users to the sharing of their anonymized data for research purposes. Pilot searches of the referral rates with the Kent SARC indicate that around 4-6 referrals per week are referred to the psychological treatment pathway per week (approximately 16-20 a month); before- and after-treatment assessment are taken for everyone in treatment. In 2016, the Kent SARC established the central database system for the reporting of clinical data of service users and, therefore, cases can be analysed from this date.

17.4 Permissions

For analysis of the CRIS data, ethical approval will need to be obtained from the CRIS database oversight committee. For analysis of the Kent SARC data, relevant ethical approvals will be sought.

17.5 Analysis

All analyses will be conducted in STATA version 14 (23). Descriptive statistics – proportional for categorical variables and means and standard deviations for quantitative variables – will be calculated to describe the sociodemographic and clinical characteristics of the sample. Main statistical analyses

will examine changes in psychological well-being (based on CORE outcome assessments before and after treatment) following psychological treatment from a mainstream mental health service compared to a SARC. We will examine the socio-demographic and clinical characteristics of the cohorts to explore whether there are systematic differences e.g. history of previous psychiatric contact such as admission. We will then address these using appropriate statistical techniques. We will stratify by gender and seek to match cases on socio-demographics such ethnicity.

17.6 Health Economics

We will assess the feasibility of comparing the cost of mental health care treatment for patients receiving treatment from mainstream mental health services compared to a SARC. Mental health resource use for patients attending traditional mental health services will be obtained from CRIS and costed using nationally published sources. The cost of the SARC will be calculated from the Kent SARC data, information collected from WP4 and the analysis conducted as part of WP3. We will conduct a cost-consequences analysis, reporting costs alongside outcomes for the two service types along with 95% confidence intervals to allow for evaluation of significant differences between the two service types. We will ensure the information reported is useful to policy makers and commissioners service planning and delivery through ongoing dialogue with key stakeholders.

18. WORK PACKAGE 6: DEVELOPMENT OF ACTIONABLE TOOLS

In work package 6, we will co-produce a set of actionable tools based on the emerging findings and in co-production with the LEAG as well as representatives from commissioning and providers.

18.1. Dissemination and outputs

We have a multifaceted strategy to disseminate our research findings. We will produce outputs for each work package (co-produced with the LEAG and PPI). These will be available to download on our project specific website www.mimosstudy.org.uk . We will use social media to engage with a range of people in relation to our findings, such as Twitter (e.g. using Twitter chats). We will coordinate press releases from our respective institutions and organisations to maximise visibility of our findings, and we will publish in open access peer reviewed journals, and present our findings at relevant conferences. In terms of the survivor and third sector we will be able to work with Fay Maxted at the Survivors Trust and Concetta Perot at Survivor's Voices and use their networks to disseminate.

19. GENERIC CONSIDERATIONS ACROSS WORK PACKAGES

19.1. Data Management, Permissions and Contracts

A Data Management Plan has been developed [MiMoS_238240_Data Management Plan_v1_16.08.2019]. All data will be stored in accordance with GDPR and the Data Protection Act (2008) on University of Leeds, University College London and Kings College London approved cloud based storage with relevant encryption and access restrictions applied. Relevant Data Sharing/Collaboration/Confidentiality agreements will be in place between all University collaborators, transcribers, translators and analytic companies. Similarly, relevant management permissions will be sought from all non-NHS organizations that we will be advertising or recruiting through.

19.2. Provider & Commissioner Involvement

We have engaged with a range of providers and commissioners in the development of the proposal and we will convene a "programme steering group" which will include SARC commissioners, SARC Clinicians and Medical Directors, Public Health England regional commissioner(s).

19.3. Patient & Public Involvement (PPI)

The Survivor voice and perspective is very important to our research plans, and as such we intend to work in partnership with survivors for all aspects of the study. The lead coordinator of our involvement approach will be Dr Sarah Kendal.

We convene a Lived Experience Advisory Group (LEAG). The LEAG will work closely with the researcher(s) on all aspects of the study – planning, data collection, and being part of the synthesis phase as well as the overall study analysis phase integrating data from all work packages. LEAG members can participate in a number of ways including face to face meetings, telephone calls, Skype and email. The research will also draw upon 'Turning Pain into Power: A Charter for Organizations Engaging Abuse Survivors in Projects, Research & Service Development'. Similarly, Fay Maxted of Survivor's Trust is part of the core research team, and Concetta Perot from Survivor's Voices is a key contributor, and advisor, to the research.

19.4. Ethical Considerations

We will develop comprehensive Standard Opertaing Procedures (SOP) which outline in more detail how to manage ethical considerations such as those outlined briefly below (i.e. to assess and manage distress and risk/ data management etc). Researchers should ensure they are up-to-date on relevant training such as Good Clinical Practice (GCP) and specifically trained to work with survivors. Please speak to your WP Lead if you feel you are not up-to-date with relevant training.

19.5. Assessment & Management of Risk

We will have clear distress and risk management standard operating procedures (SOPs) to ensure that people are safe within the study, so that timely and appropriate help is received should issues of concern be identified. A senior clinically trained member of the research team will be "on call" by phone during all data collection periods.

While many people find talking about their experiences to be helpful, some people may find that completing the questionnaire / taking part in the interview brings up issues that cause emotional distress. In this case the researcher will provide immediate emotional support to the participant, offer to pause or postpone the data collection, and, if the participant asks, will contact a person of the participant's choice (e.g. current care coordinator, carer, friend, family member, or colleague) for them.

If service users or carers report any untoward feedback, the researcher conducting the data collection / interview will confirm with the participant whether or not they would like the researcher to pass this on to the service or other relevant person. If the untoward feedback is of a nature that leads the researcher to be concerned for the safety of the participant or that of others, the participant will be informed that the feedback will be passed on to the relevant service or person to be addressed, but that if desired and possible they will remain anonymous.

In the event that the researcher feels concerned for their own safety they will be advised to bring the interview to an end. All face-to-face interviews will be conducted on NHS/SARC premises or other suitable spaces, and local safety policies and protocols should be adhered to by all researchers (e.g. informing local staff at the start of an interview, and again once the interview has been completed). All staff conducting research relating to the trial will be familiar with and have copies of the trial SOPs. Please refer to the SOPs for more details

19.6. Recording & Reporting of Events & Incidents

19.6.1. Definitions of Adverse Events

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a patient or study participant, which does not necessarily have a causal relationship with the procedure involved.
Serious Adverse Event (SAE).	Any adverse event that: • results in death, • is life-threatening*, • requires hospitalisation or prolongation of existing hospitalisation**, • results in persistent or significant disability or incapacity, or • consists of a congenital anomaly or birth defect
*A life- threatening event, this refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe. ** Hospitalisation is defined as an in-patient admission, regardless of length of stay. Hospitalisation for pre-existing conditions, including elective procedures do not constitute an SAE.	

19.6.2. Assessments of Adverse Events

Each adverse event will be assessed for severity, causality, seriousness and expectedness as described below.

Severity

Category	Definition
Mild	The adverse event does not interfere with the participant's daily routine, and does not require further procedure; it causes slight discomfort
Moderate	The adverse event interferes with some aspects of the participant's routine, or requires further procedure, but is not damaging to health; it causes moderate discomfort
Severe	The adverse event results in alteration, discomfort or disability which is clearly damaging to health

Causality

The assessment of relationship of adverse events to the procedure is a clinical decision based on all available information at the time of the completion of the case report form.

The differentiated causality assessments will be captured in the AE Log and SAE form.

The following categories will be used to define the causality of the adverse event:

Category	Definition
Definitely:	There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out.
Probably:	There is evidence to suggest a causal relationship, and the influence of other factors is unlikely

Possibly	There is some evidence to suggest a causal relationship (e.g. the event occurred within a reasonable time after administration of the study procedure). However, the influence of other factors may have contributed to the event (e.g. the participant's clinical condition, other concomitant events).
Unlikely	There is little evidence to suggest there is a causal relationship (e.g. the event did not occur within a reasonable time after administration of the study procedure). There is another reasonable explanation for the event (e.g. the participant's clinical condition).
Not related	There is no evidence of any causal relationship.
Not Assessable	Unable to assess on information available.

Expectedness

Category	Definition
Expected	An adverse event which is consistent with the information about the procedure listed in this protocol.
Unexpected	An adverse event which is not consistent with the information about the procedure listed in this protocol.

19.6.3. Recording adverse events

All adverse events will be securely documented by the researcher.

19.6.4. Procedures for recording and reporting Serious Adverse Events

All adverse events will be recorded in the study AE form, and the sponsor's AE log.

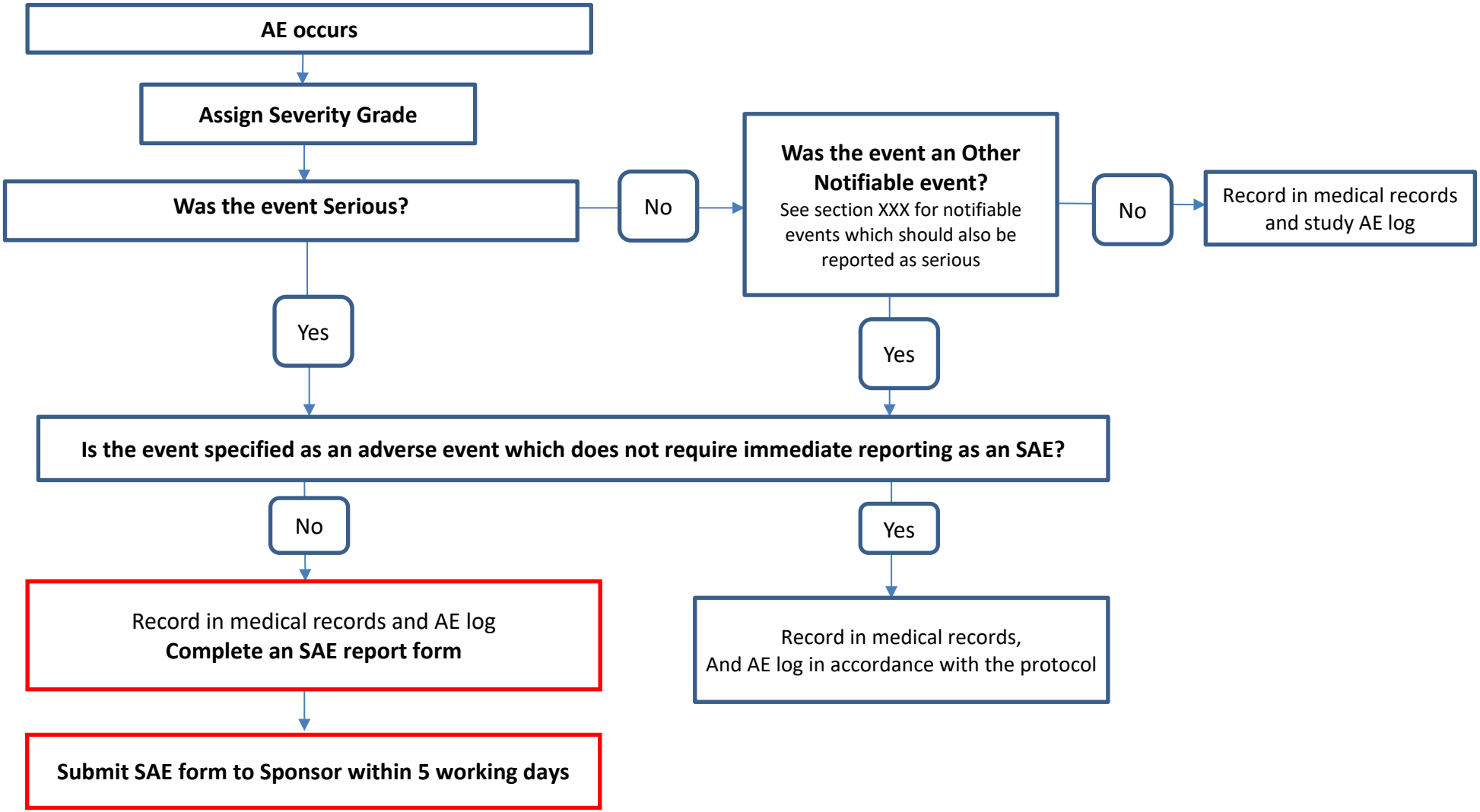
All SAEs must be recorded on a serious adverse event (SAE) form. The CI/Work Package Lead or designated individual will complete an SAE form and the form will be preferably emailed to the Sponsor within 1 working day of becoming aware of the event. The CI or WP Lead will respond to any SAE queries raised by the sponsor as soon as possible.

Where the event is unexpected and thought to be related to the procedure this must be reported by the Investigator to the Health Research Authority and REC within 15 days of research team awareness of the event. You will find information on SAE reporting to the REC on the HRA website, https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/safety-reporting/.

Completed forms for unexpected SAES must be sent within 1 working day of becoming aware of the event to the Sponsor

Email forms to: governance-ethics@leeds.ac.uk

Flow Chart for SAE reporting (this simple flow chart is for single site study, please amend in line with study specific requirements)



19.6. Reporting Urgent Safety Measures

If any urgent safety measures are taken the CI/ PI shall immediately and in any event no later than 3 days from the date the measures are taken, give written notice to the relevant REC and Sponsor of the measures taken and the circumstances giving rise to those measures.

19.7. Protocol deviations and notification of protocol violations

A deviation is usually an unintended departure from the expected conduct of the study protocol/SOPs, which does not need to be reported to the sponsor. The CI will monitor protocol deviations.

A protocol violation is a breach which is likely to effect to a significant degree –

(a) the safety or physical or mental integrity of the participants of the study; or

(b) the scientific value of the study.

The CI and sponsor will be notified immediately of any case where the above definition applies during the study conduct phase.

19.8. Monitoring and Auditing

The Chief Investigator will ensure there are adequate quality and number of monitoring activities conducted by the study team. This will include adherence to the protocol, procedures for consenting and ensure adequate data quality.

The Chief Investigator will inform the sponsor should they have concerns which have arisen from monitoring activities, and/or if there are problems with oversight/monitoring procedures.

19.9. Peer and Regulatory Review

The Sponsor considers the procedure for obtaining funding from the NIHR to be of sufficient rigor and independence to be considered an adequate peer review.

19.10. Funding and Supply of Equipment

The study funding has been reviewed by the UoL Research Office, and deemed sufficient to cover the requirements of the study. NHS costs will be supported via the Local Clinical Research Network.

The research costs for the study have been supported by the NIHR HS&DR programme grant 16/117/03.

19.11. Training

The Chief Investigator will review and provide assurances of the training and experience of all staff working on this study. Appropriate training records will be maintained in the study files.

19.12. Intellectual property

All intellectual property rights and know-how in the protocol and in the results arising directly from the study, but excluding all improvements thereto or clinical procedures developed or used by each participating site, shall belong to UoL. Each participating site agrees that by giving approval to conduct the study at its respective site, it is also agreeing to effectively assign all such intellectual property rights ("IPR") to UoL and to disclose all such know-how to UoL, with the understanding that they may use know-how gained during the study in clinical services and teaching to the extent that such use does not result in disclosure of UoL confidential information or infringement of UoL IPR.

19.13. Indemnity arrangements

University of Leeds (UoL) holds insurance against claims from participants for harm caused by their participation in this clinical study. Participants may be able to claim compensation if they can prove that UoL has been negligent. However, the trust/provider continues to have a duty of care to the participant of the clinical study. University of Leeds does not accept liability for any breach in the trust/provider's duty of care, or any negligence on the part of trust/providers employees. This applies whether the SARC is an NHS Trust or otherwise. collaboration agreements will be in place with Kings College London and University College London and they will have indemnity in place to cover the conduct of the research by researchers employed at those Universities.

19.14. Archiving

UoL and each participating site recognize that there is an obligation to archive study-related documents at the end of the study. The Chief Investigator confirms that she will archive the study master file at UoL in line with all relevant legal and statutory requirements.

19.15. Publication and dissemination policy

Dissemination will be carefully planned with the NIHR to ensure high quality peer review of our outputs and stakeholder engagement and information sharing. We will provide the usual full scientific reports, peer reviewed papers, powerpoint presentations, conference talks, and web output. We will also

consult with our LEAG, PSC and PMG groups to disseminate our findings across a range of NHS, health and other provider platforms. We will produce our summary documents in a range of formats suitable for different audiences.

We have developed a MiMoS website hosted at UoL. All SARCs will be sent links to the website. Twitter will be used for distributing publications to a variety of audiences and findings more widely once published in open access journals. We will hold an expert consensus meeting/conference in the final months of the project (estimated to be in March 2021).

20. REFERENCES

1. Bicanic I, Snetselaar H, De Jongh A, Van de Putte E. Victims' use of professional services in a Dutch sexual assault centre. European journal of psychotraumatology. 2014;5.

2. Brown R, Du Mont J, Macdonald S, Bainbridge D. A comparative analysis of victims of sexual assault with and without mental health histories: acute and follow-up care characteristics. Journal of forensic nursing. 2013;9(2):76-83.

3. Brooker C, Durmaz E. Mental health, sexual violence and the work of Sexual Assault Referral centres (SARCs) in England. Journal of forensic and legal medicine. 2015;31:47-51.

4. Brooker C, Tocque K, Paul S. Assessment of the mental health status of a one year cohort attending two Sexual Assault Referral Centres in England. under review.

5. Brooker C, Tocque K. Mental health risk factors in sexual assault: What should Sexual Assault Referral Centre staff be aware of? Journal of forensic and legal medicine. 2016;40:28-33.

6. NHS England. Sexual Assault Services Provider Service Specification and Commissioning Framework for Paediatric Sexual Assault Referral Centre (SARC) Services.; 2015 10th August 2015.

7. Connell J, Barkham M. CORE-10 User Manual, Version 1.1. : CORE System Trust & CORE Information Management Systems Ltd; 2007.

8. Bush K, Kivlahan DR, McDonell MB, Fihn SD, Bradley KA. The AUDIT alcohol consumption questions (AUDIT-C): an effective brief screening test for problem drinking. Ambulatory Care Quality Improvement Project (ACQUIP). Alcohol Use Disorders Identification Test. Archives of internal medicine. 1998;158(16):1789-95.

9. Prins, A., Bovin, M.J., Kimerling, R., Kaloupk, D.G., Marx, B.P., Pless Kaiser, A., & Schnurr, P.P. (2015). *Primary Care PTSD Screen for DSM-5 (PC-PTSD-5)* [Measurement instrument]. Available from https://www.ptsd.va.gov

10. Keetharuth AD, Brazier J, Connell J, Bjorner JB, Carlton J, Taylor Buck E, et al. Recovering Quality of Life (ReQoL): a new generic self-reported outcome measure for use with people experiencing mental health difficulties. The British Journal of Psychiatry. 2018;212(1):42-9.

11. Skinner HA. The drug abuse screening test. Addictive behaviors. 1982;7(4):363-71.

12. Moran P, Morven L, Tennyson L, Walters P, Thornicroft G, Mann A. Standardised Assessment of Personality – Abbreviated Scale (SAPAS): preliminary validation of a brief screen for personality disorder. The British Journal of Psychiatry. 2003;183:228-32.

13. Campbell L, Keegan A, Cybulska B, Forster G. Prevalence of mental health problems and deliberate self-harm in complainants of sexual violence. Journal of forensic and legal medicine. 2007;14(2):75-8.

14. Hunter RM, Reilly C, Atkinson P, Das KB, Gillberg C, Chin RF, et al. The health, education, and social care costs of school-aged children with active epilepsy: A population-based study. Epilepsia. 2015;56(7):1056-64.

15. Barber J, Thompson S. Multiple regression of cost data: use of generalised linear models. Journal of health services research & policy. 2004;9(4):197-204.

16. Baker GR. The contribution of case study research to knowledge of how to improve quality of care. BMJ quality & safety. 2011;20 Suppl 1:i30-5.

17. Easton G. Critical realism in case study research. Industrial marketing management. 2010;39(1):118-28.

18. Jones IR, Ahmed N, Catty J, McLaren S, Rose D, Wykes T, et al. Illness careers and continuity of care in mental health services: a qualitative study of service users and carers. Social science & medicine (1982). 2009;69(4):632-9.

19. Ritchie J, Lewis, J., Nicholls, C.M. and Ormston, R. . Qualitative research practice: A guide for social science students and researchers.: Sage.; 2013.

20. Adams A, Sedalia S, McNab S, Sarker M. Lessons learned in using realist evaluation to assess maternal and newborn health programming in rural Bangladesh. Health Policy and Planning. 2016;31(2):267-75.

21. Pawson RT, N. Realist Evaluation2004 17/11/17. Available from: http://www.communitymatters.com.au/RE_chapter.pdf

22. Stewart R, Soremekun M, Perera G, Broadbent M, Callard F, Denis M, et al. The South London and Maudsley NHS Foundation Trust Biomedical Research Centre (SLAM BRC) case register: development and descriptive data. BMC Psychiatry. 2009;9:51.

23. StataCorp. Stata Statistical Software: Release 14. . College Station, TX: StataCorp LP; 2015.

24. Legerski J-P, Bunnell SL. The risks, benefits, and ethics of trauma-focused research participation. Ethics & Behavior. 2010;20(6):429-42.

25. Campbell R, Adams AE. Why Do Rape Survivors Volunteer for Face-to-Face Interviews? Journal of Interpersonal Violence. 2009;24(3):395-405.

26. Brooker C, Tocque, K, and Paul, S. Assessment of the mental health status of a one year cohort attending a two Sexual Assault Referral Centres in England. under review.

21. APPENDICES

21.1. APPENDIX 1: Protocol Amendments

Version:	Ethics approval date:	Not

Details of previous amendments: