NIHR | National Institute for Health Research

MESARCH
Research supporting best practice in Sexual Assault Referral Centres

Multi-disciplinary Evaluation of Sexual Assault Referral Centres for better Health (MESARCH)

Lorna O'Doherty, Katherine Brown, Sarah Brown, Emma Sleath, Rachel Caswell, Millie Gant, Louise Jackson, Dianne Whitfield, Richard Morris, and Gene Feder

STUDY PROTOCOL

01/03/2019

PROTOCOL VERSION 1.0

SPONSOR: COVENTRY UNIVERSITY

FUNDER NUMBER: NIHR HS&DR PROGRAMME 16/117/04

NHS PARTNER: UNIVERSITY HOSPITALS BIRMINGHAM NHS FOUNDATION TRUST

CHARITY PARTNERS: SURVIVORS IN TRANSITION, SUFFOLK; RAPE AND SEXUAL VIOLENCE PROJECT (RSVP) BIRMINGHAM

HRA APPROVAL DATE: NOT APPROVED

IRAS NUMBER: N/A

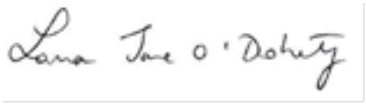
SIGNATURE PAGE

The undersigned confirm that the following protocol reflects the project we were contracted to undertake and that the Chief Investigator agrees to conduct the study in compliance with approved protocols and will adhere to the principles outlined in the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), amended regulations (SI 2006/1928) and any subsequent amendments of the clinical trial regulations, GCP guidelines, the Sponsor's (and any other relevant) SOPs, and other regulatory requirements as amended.

I also confirm that I will make the findings publicly 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 and serious breaches of GCP from the trial as planned in this protocol will be explained.

Chief Investigator:

Signature: Date: 1/3/2019



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Contents

i. LIST OF ABBREVIATIONS

DMEC	Data Monitoring and Ethics Committee
MESARCH	Multidisciplinary Evaluation of Sexual Assault Referral Centres for better Health
NIHR	National Institute for Health Research
PI	Principal Investigator
PPI	Patient and Public Involvement
PTSD	Post-traumatic stress disorder
PIS	Participant Information Sheet
SARC	Sexual Assault Referral Centre
SSC	Study Steering Committee
MSM	Men who have sex with men
LGBT	Lesbian, Gay, Bisexual and Transgender
BME	Black and minority ethnic
BDI	Beck Depression Inventory
WHOQoL-Bref	World Health Organisation quality of life measure
ACE	Adverse childhood experience
RCT	Randomised controlled trial
CDPLPG	Cochrane Developmental, Psychosocial and Learning Problems Group
CYP	Children and young people
GAD-7	Generalised Anxiety Disorder-7 tool
NPT	Normalisation Process Theory
CAPI	Computer-assisted personal interview
ISVA	Independent Sexual Violence Advisor
STI	Sexually transmitted infection
CSA	Child sexual abuse

ii. STUDY SUMMARY

Study Title	Multi-disciplinary Evaluation of Sexual Assault Referral Centres for better Health (MESARCH)	
Internal ref. no. (or short title)	MESARCH	
Phase	This protocol describes the full study	
Design	Evidence syntheses Mapping and case studies of SARCs Longitudinal observation with embedded qualitative study	
Study Participants	Mapping: SARC managers in England Case study: SARC professionals/stakeholders and service users of SARCs 16+ cohort: adults and young people (aged 16 years+) who are survivors of recent/non-recent sexual violence attending SARCs in England Children and young people 13-15 years who are survivors of recent/non-recent sexual violence attending SARCs in Eng	
Planned Sample Size	SARC managers – not specified 150 SARC staff, non-SARC professionals and service users 1500 service users aged 16+ (target enrolment) 30 service users aged 13-15 years	
Treatment duration	Not applicable	
Follow up duration	Cohorts: 6, 12 and 24 months	
Planned Study Period	September 2018-Feb 2022	
	Objectives	Outcome Measures
Primary	• Post-traumatic stress disorder- PTSD	• PCL-5
Secondary	• Depression • Quality of life • Sexual health • Sexual violence re-victimisation • Anxiety • Alcohol use • Resource use • Adverse Childhood Experience • Health-related quality of life	• Beck Depression Inventory (BDI • WHOQoL-Bref • Bespoke measure for sexual health Sexual Experiences Survey Revised–Short form • GAD-7 • AUDIT • Bespoke measure • ACE measure non-specified • EQ5D-5L

iii. FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this trial)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
National Institute for Health Research University of Southampton Science Park, SO16 7NS	Total research costs £1,286,677.20 Total NHS support & treatment costs £44,350.00

iv. KEY WORDS: Sexual assault, rape, child sexual abuse, sexual health, health services, PTSD

1 AIMS AND RESEARCH QUESTIONS

The primary aim of the MESARCH project is to produce a comprehensive and rigorous evaluation of sexual assault referral centres (SARCs) in England. Coventry University will lead an experienced, multi-disciplinary team that includes the University of Bristol, University of Birmingham, Coventry Rape and Sexual Assault Centre (CRASAC), Juniper Lodge SARC, University Hospitals Birmingham NHS Foundation Trust (as lead trust) together with two charities that support survivors of sexual violence - the Rape and Sexual Violence Project (RSVP) and Survivors in Transition (SiT). The objectives and approaches, developed through wide stakeholder and service user consultation, map to our 4 research questions (RQs; Table 1) but also to 3 of the 6 priority areas identified by the NIHR as central to the evaluation of SARCs. Using a range of established, best practice, and innovative methods, we will:

(i) evaluate national and global evidence on interventions for responding to sexual violence, including integrated models of care similar to SARCs [RQ1];

(ii) examine models of service delivery including the interventions delivered, through national mapping of SARCs and case analyses at 10 sites, informed by Normalisation Process Theory to examine integration of work practices, workforce, technology and the role of SARCs in the broader context of a health and community response to sexual violence [RQ2];

(iii) undertake a 2 year follow-up study in a diverse cohort of survivors of sexual violence to explore the impact of different models and health interventions delivered by SARCs on post-traumatic stress disorder, sexual health, depressive symptoms, quality of life, substance misuse, violence re-exposure, health service use, and costs [RQ3];

(iv) analyse the impact of delivering post-crisis trauma-focused counselling interventions in the third sector vs NHS mental health services on PTSD and other health outcomes [RQ3];

(v) drawing on the cohort sample using maximum variation sampling to ensure broad range of subgroups represented, and supplemented by a community sample, conduct a qualitative investigation of experiences and outcomes of SARCs and barriers and facilitators to access [RQ3];

(vi) synthesise findings from the 3 workstreams through collaboration across the research team, study steering committee, our collaborators and widespread evidence-user involvement to co-produce ‘messages’ for maximum impact – that is, to reach those who commission SARCs, deliver day-to-day SARC services, those who work with SARCs, and those who use SARCs or could benefit from attending SARCs but experience social barriers [RQ4].

Table 1 Research questions

Workstream 1 Evidence synthesis	RQ1 In individuals who have experienced (recent or non-recent) sexual violence, do health interventions (including integrated care interventions like those offered by SARCs) reduce the risk of post-traumatic stress disorder and other poor health outcomes? • What are providers' experiences of delivering health interventions for sexual violence? • What are the experiences of survivors of sexual violence in accessing help in health settings?
Workstream 2 Process evaluation	RQ2 What are the implications of four inter-related aspects of SARCs – the everyday work they do, the workforce, technology, and organisation – for the delivery of SARC services? • What is the work of SARCs including the types of interventions delivered? • Who is the SARC workforce? • What are the technologies that enable SARCs to get work done? • What is the organisational context of SARCs and to what extent are SARCs embedded within the overall response by health and third sector organisations to the needs of survivors of sexual violence?
Workstream 3 Outcomes evaluation	RQ3 What are the health and cost trajectories of those who attend SARCs? • How do these compare for different subgroups of survivors attending SARCs? • How do these compare for different interventions and SARC models? • How do these compare for different post-crisis counselling settings?
Workstream 4 Integration and knowledge transfer	RQ4 What recommendations based on the knowledge generated in this project can be offered for improving the effectiveness of SARCs, and how might the reach and response of SARCs to the needs of diverse and underrepresented groups be enhanced?

2 METHODS: EVIDENCE SYNTHESIS (Workstream 1)

This study will involve a Cochrane Review and a qualitative meta-synthesis and review of the grey literature to address RQ1: 'In individuals who have experienced (recent or non-recent) sexual violence, do health interventions, including integrated care interventions like those offered by SARCs, reduce the risk of post-traumatic stress disorder and other poor health outcomes?' We are further setting out to answer:

- What are providers' experiences of delivering health interventions for sexual violence?
- What are the experiences of survivors of sexual violence in accessing help in health settings?

2.1 Cochrane Review (CR)

The Cochrane Developmental, Psychosocial and Learning Problems Group (CDPLPG) has provided in principle support and we plan to register the title on confirmation of funding. For a wide range of ethical and practical reasons, it can be difficult to conduct RCTs, particularly when services and support are required quickly following sexual violence, and assigning survivors to a control/no intervention condition is problematic given the potential negative consequences for the survivors. Thus, if we find a lack of evidence from RCTs, we will consider inclusion of non-randomised studies according to guidance in the Cochrane Handbook for Systematic Reviews of Interventions [1]. Studies will be included if they meet the criteria set out in Table 2, although studies will not be excluded on the basis of the outcomes measured. PTSD will be the primary outcome of the review. Studies will be included where it is measured through an improvement from a diagnosis of PTSD determined by accepted clinical diagnostic criteria, or based on change in PTSD symptoms measured using scales that are based on diagnostic criteria and have published reliability and validity, e.g. the Children's PTSD Inventory [53]. The review will cover a range of secondary outcomes across mental, physical and sexual health, and behavioural outcomes. Different groups are affected by sexual violence in different ways and harms and benefits of care will be captured through a variety of outcomes. Thus, to ensure inclusiveness, and in line with our previous Cochrane Reviews [54, 55], we will not exclude studies on the basis of the outcomes selected. We will also report process outcomes such as provision of information and referrals.

Table 2 PICO

Population	Intervention	Comparison	Outcomes	Types of studies
Any person of any age or gender who has been a victim of sexual violence	Any intervention offered to victims of sexual violence in a health or community setting (e.g. medico-legal clinics) or that evaluates effectiveness based on health outcomes	Control (treatment as usual, waiting list controls or no treatment) Another medical treatment Another psychological therapy Other treatment	Mental, sexual and physical health; health care use*	Any study that allocates individuals, or clusters of individuals, by a random or quasi-random method to an intervention compared with a control**

*outcomes not used to select studies; **if necessary to include NRS, these will be non-randomized controlled trial; controlled before-and-after study; interrupted-time-series study; historically controlled study; cohort study [1]

2.1.1 Searches: The searches will be run by the Trials Search Co-ordinator of CDPLPG. The databases listed in Table 3 will be searched, along with the websites of the WHO (who.int/topics/violence/en/) and the Violence Against Women Online Resources (vaw.umn.edu/). We will include international peer-reviewed and non-peer-reviewed studies and published and unpublished studies. We will not apply any date or language restrictions to our search strategies. We will not use a randomised controlled trial (RCT) or methodological or analytical design filter as we want the search to be as inclusive as possible. We will hand-search a selection of journals and examine the reference lists of acquired papers and track citations forwards and backwards. We will email the authors of all primary studies included in the review about any omissions and, in particular, omissions of non-peer-reviewed studies. We will contact the WHO Violence and Injury Programme to inquire about any sexual violence intervention studies that might fit our inclusion criteria of which we were unaware, especially in low- and middle-income countries.

Table 3 Databases to be searched

- Cochrane Central Register of Controlled Trials, which includes the Specialised Register of the CDPLPG.
- Ovid MEDLINE(R) 1946 to current
- Ovid MEDLINE(R) In-process and other non-indexed citations
- Embase (Ovid) 1980 to current
- CINAHL PLUS (EBSCOhost) 1937 to current
- PsycINFO (Ovid) 1806 to current
- Sociological Abstracts (ProQuest) 1952 to current.
- Conference Proceedings Citation Index - Social Science and Humanities (CPCI-SS&H; Web of Science) 1990 to current
- Database of Abstracts of Reviews for Effectiveness (DARE), part of the *Cochrane Library.*
- Cochrane Database of Systematic Reviews (CDSR), part of the *Cochrane Library.*
- WHO International Clinical Trials Registry Platform (ICTRP) (who.int/ictrp/en/)
- ClinicalTrials.gov (clinicaltrials.gov).

2.1.2 Selection and extraction: Studies will be reviewed by title and abstract by two review authors. Full text articles will then be retrieved and studies will be further assessed against the inclusion criteria. Any disagreement about abstract/study inclusion will be resolved by reading the full paper followed by discussion with a third author. Two authors will independently extract the data from the included studies into electronic data collection forms. We will request any missing information or clarification from the first or corresponding authors of papers and will note all instances where additional statistical data are provided by study investigators. This data will be distinguished as such in the text (Effects of interventions). All relevant data will be entered into Review Manager (RevMan) software, V5.3 [56] and we will generate a 'Characteristics of included studies' table. Two authors will independently assess the risk of bias of all studies meeting the review criteria including the following domains: sequence generation; allocation concealment; blinding of participants and personnel; blinding of outcome assessment; incomplete outcome data; and selective outcome reporting and other sources such as protection against contamination; adequate baseline assessments and reliability of outcome measures.

2.1.3 Analysis: Continuous data will be analysed if: (i) means and SDs are available in the report/obtainable from authors, and (ii) the data are said to be normally distributed. For binary outcomes, we will calculate a standard estimation of the odds ratio (OR) or risk ratio (RR) as appropriate and 95% confidence intervals (CI) using a random-effects model [1]. A meta-analysis will be conducted where there are sufficient data and it was appropriate to do so. The decision to pool data in this way will be determined by the compatibility of populations, interventions (clinical heterogeneity), duration of follow-up (methodological heterogeneity), and outcomes. We will use random-effects models to take account of any identified heterogeneity of interventions. The Mantel-Haenszel method, a default program in RevMan, can take account of few events or small study sizes and can be used with random-effects models. Where it is inappropriate to combine the data in a meta-analysis, we will provide a narrative description of the effect sizes and 95% CIs or SDs for individual outcomes in individual studies. Subgroup analyses will facilitate comparisons across key user-groups: i) adult v child; (ii) recent v non-recent victimisation; (iii) under-served v mainstream survivors; (iv) male v female. If possible, we will also examine subsets of studies based on organisational differences (e.g. size of centre; service delivery model). The online Guideline Development Tool [57] will be used to develop 'Summary of findings' tables to summarise the amount of evidence, typical absolute risks for those who receive the intervention and do not, estimates of relative effect, and the quality of the body of evidence.

2.2 Systematic review and qualitative meta-synthesis

Survivors' experiences and perceptions of interventions are as important as outcomes. A service that has demonstrated effective outcomes in one group of survivors, might be perceived as unwelcoming to other groups, or may be difficult to access for certain groups. We know that some groups of survivors do not use SARCs [51], an issue we will explore in WS2 and WS3. Accordingly, some researchers have employed qualitative methods to examine SARCs and interventions (e.g., [13]. We will therefore also conduct a systematic review and qualitative meta-synthesis of studies that have examined the experiences and perspectives of survivors and intervention professionals. A thematic synthesis [58] will be used, since it was developed out of a need to conduct reviews that address questions relating to effectiveness, intervention need, acceptability and appropriateness and acceptability, without compromising on key principles of systematic reviews [59]. We will include qualitative studies that address the primary question on the impacts and experiences of different interventions for sexual violence exposure. We will address two further questions: 'What are providers' experiences of delivering health and social care interventions of sexual violence?' and 'What are the experiences of survivors of in accessing help in health and social care settings?' The review will look at the barriers and facilitators encountered across subgroups of survivors. Although sexual violence against women has produced a large body of literature, to date no synthesis of the qualitative research evidence on the support needs of all victims of sexual violence has been conducted.

2.2.1 Searches and selection of studies: We will include only qualitative research studies and exclude surveys or quantitative studies that contained descriptive free-text data. Our eligibility criteria are: empirical qualitative studies (standalone or discrete components of mixed-method studies) employing qualitative methods for data collection and analysis; studies focusing on the views/experiences of children, parents or adults receiving or delivering interventions following exposure to sexual violence, and those who did not access interventions; published articles or reports that have undergone some level of peer review [3, 4]. The research team will identify search terms by discussing the review

objectives and examining indexing of relevant papers in different search databases. Selecting articles for inclusion will follow a similar process to that described above.

2.2.2 Appraisal and analysis: Two review authors will independently use sensitivity analyses as designed and described by Thomas and Harden (2008) to assess the possible impact of study quality on the findings. All but one of the 12 criteria that were derived from existing sets of criteria proposed for assessing the quality of qualitative research and whether studies employed appropriate methods will be used. The 12th criteria based on the best practice principles in conducting research with children will be adapted to reflect best practice in relation to conducting research with survivors. As per the approach taken by [58], the findings sections of papers/reports will be entered verbatim into NVivo by the research assistant, which will be reviewed by the research associate to ensure that all data have been included and uploaded. The research associate and research assistant will then independently conduct free line-by-line coding; organise these free codes into related areas to construct descriptive themes; and develop 'analytical' themes. The development of these codes and themes will be reviewed by SB. The review authors will independently develop analytic themes and these will be discussed as a group. The analytic themes will be refined and discussed until the team reaches agreement that the themes best represent the findings of the studies included in review.

3 METHODS: MAPPING AND CASE STUDIES (Workstream 2)

Workstream 2 aims to identify the implications of four inter-related aspects of SARCs – the everyday work they do, the workforce, technology, and organisation – for the delivery of SARC services? It will address the following sub-questions:

- What is the work of SARCs including the types of interventions delivered?
- Who is the SARC workforce?
- What are the technologies that enable SARCs to get work done?
- What is the organisational context of SARCs and to what extent are SARCs embedded within the overall response by health and third sector organisations to the needs of survivors of sexual violence?

3.1 Mapping study design

The initial stage will be to map out service delivery by SARCs to adult and child survivors of sexual violence across England using adapted items from the COSAI tool [64]. Recruitment will be done by sending an official invitation from the project followed-up by a phone call from the project team. The tool will be administered to a consenting member of management staff at each SARC using a 30 minute computer-assisted personal interview (CAPI). This will gather data on variables such as funding and service delivery models; types of interventions offered (e.g. psychological, medical, forensic); coordination, response, referral pathways; user population characteristics; and police and legal services. To maximise coverage and account for variation, we will approach all SARCs to participate. We will enter and clean data, and conduct descriptive statistics to summarise the characteristics of SARCs. Mapping data will be used to stratify SARCs (e.g. on population, size, model) and provide a sampling frame from which to select SARCs to approach for the main process study (described in 3.2) but also to inform WS3.

3.2 Case studies

3.2.1 Conceptual framework

In-depth case studies at diverse SARC sites will address our 4 process-oriented sub-questions (see above). We selected Normalisation Process Theory (NPT) [7] as a conceptual framework to examine SARCs as these organisations are a product of process and of people coming together over time engaging in concerted cognitive and practical action. This theory has been used extensively within health settings to understand the complex interplay between different factors (e.g., actions of involved individuals, social environment, features of interventions) that can affect the successful implementation of processes and interventions [65]. NPT will be used to inform the selection of informants and sites, design of interview questions, and data analysis. NPT directs focus to how ways of working are implemented and become embedded or ‘normalised’ within an organisation [66] and relates to the work of WS2 in understanding the work practices, people and contexts of SARCs. Given this capability, NPT will also enable us to determine how SARCs sit within a broader context of sexual violence services, by directing attention to the processes and mechanisms by which SARCs interact with other agencies and sectors. There are four components to this theory: Coherence, Cognitive Participation, Collection Action, and Reflexive Monitoring [67]. Coherence relates to the role of individuals and organisations in sense-making and processing to either promote or inhibit the embedding of a process of system. Cognitive Participation refers to the process of engagement of participants (e.g., users, staff, external stakeholders) to embed practices. Collective Action has four sub-components: Contextual Integration (CI), Relational Integration (RI), Interactional Workability (IW), and Skill Set Workability (SSW). CI identifies the capacity of an organisation to allocate resources and control in implementing and integrating practices. RI identifies the relationship networks between staff,

users, and external stakeholders in relation to processes. IW specifies the way in which users, staff, external stakeholders interact to operationalise processes. SSW identifies the division of labour within the setting. Finally, Reflexive Monitoring relates to the appraisal and monitoring of the processes that have been implemented.

3.2.2 Participants and setting

Case studies will be conducted at 10 SARC sites. Sites will be selected using our mapping data, to ensure maximum variation. For each SARC site, we will involve up to 5 individuals involved in commissioning or delivering SARC services (managers; support workers; forensic medical examiners; ISVAs); 5 informants from third sector and other organisations that are part of the inward and onward referral 'landscape' for a given SARC (e.g. Rape Crisis Centres, NHS mental health services; (paediatric) ISVAs); and up to 5 former/current service users >18 years of age. The consent procedure for providers will be undertaken by a member of the project team and interviews will be conducted at their place of work. Service users, however, will be approached by a member of SARC staff known to them. With their permission, SARC staff will pass contact details to the researcher who will take consent, coordinate and conduct the data collection. This will provide the perspectives of up to 150 informants. We will use flexible methods across cases to explore individual and group experiences, e.g. one-hour face-to-face interview or opportunities to participate in group sessions using participatory methods as this may yield a wider range of perspectives and experiences [68]. Participants including service users will be purposively sampled.

3.2.3 Data collection and analysis

Service users will be offered options for being interviewed by a peer (PPI)/researcher and their preferences for interview locations will be taken into account (within the limits of researcher safety protocols). Interviews will be audio-recorded and follow a semi-structured format. For participatory methods, we will follow guidance [68] and arrange a local safe space away from SARCs to bring people together. Audio data will be transcribed verbatim and transcripts anonymised. Transcripts and other data types (e.g. visual materials as outputs from participatory methods) will be stored and organised in NVivo. Case studies will emphasis information-gathering in relation to context and mechanism [69] and we will be guided by NPT [6] and its application in the NHS [5]. Analysis of the data will be done using both inductive and deductive approaches to thematic analysis guided by NPT. Deductive analysis will focus on: sense-making or understanding the purpose of the work that happens in SARCs (Coherence); clarity and cooperation around who is responsible for the work of SARCs (Cognitive participation); the processes and mechanisms by which the work actually gets done including the use of key technologies; and organisation of services (Collective action). Inductive analysis will enable any constructs not highlighted in the above analysis to also be drawn out from the data. NPT will assist us to: examine the range of 'best practice' interventions and guidelines in use, and the extent to which SARCs are implementing them (Reflexive monitoring, Collective action); how they function internally (Coherence), as well as identifying the multi-sectoral and inter-agency mechanisms and protocols at play (Cognitive participation); and draw out strengths and gaps in provision. This analysis will initially focus on individual sites, but comparisons will be made across sites to determine similarities/differences in provision and how these impact on the work of the SARCs.

4 METHODS: 16+ COHORT AND CHILDREN/YOUNG PEOPLE COHORT STUDIES (Workstream 3)

The cohort study will be outcomes-focused, use mixed-methods and be underpinned by the question, 'What are the health and cost trajectories of those who attend SARCs?' (RQ3). Specifically, it will address:

- How do these outcomes compare for different subgroups of survivors attending SARCs?
- How do these outcomes compare for different interventions and SARC models?
- How do these outcomes compare for different post-crisis counselling settings?

4.1 Design and setting

The main design feature will be a cohort study of mental, physical and sexual health outcomes over two years in survivors of sexual violence who have received care through SARCs. Follow-up will be done at 6, 12 and 24 months.

4.2 Sampling and procedures for 16+ cohort study

We will stratify SARCs according to characteristics such as service delivery model, location and size, using data derived from our earlier mapping work (WS2). We will approach up to 15 SARCs in order to recruit individuals into the cohort study, attempting to maximise heterogeneity, and where possible, involve SARCs that have already expressed willingness to be in the research recognising that this will enhance feasibility. The WS lead will approach/invite sites until we secure the target number of organisational units. We will agree in advance (in collaboration with the SSC, PPI group and supported by information collated in WS2 about operations and mechanisms of service delivery) our service user recruitment strategy with all participating SARCs (e.g. agree on whom will approach individuals, and when). Ethical issues related to recruitment, data collection and retention of service users are addressed in Section 7.

Over 1 year, service users aged 16 years and above will be invited to participate. People will be excluded if in exercising judgement, the responsible member of SARC staff anticipates they may encounter difficulties in providing informed consent or understanding the content of surveys used in data collection due to mental or physical health issues, cognitive impairment, intellectual disability or poor English language skills. SARC staff will maintain records of the numbers excluded, strictly adhering to documentation developed for the study, recording a reason for any exclusions according to the areas identified in the project documentation along with some basic demographic data consistent with those collected routinely by SARCs. At the eligibility assessment stage, no identifying information such as DOB or names regarding ineligible persons will be conveyed to the project team.

The proposed steps for approaching service users are summarised in Table 4.

Table 4 Procedure for involving service users aged 16 years and above

1. Service user attends SARC
2. SARC crisis worker or other suitable staff member screens service user for eligibility. All eligibility information is conveyed to the project team.
3. Eligible service users are informed about the study at an appropriate point either at the SARC (or in weeks that follow based on individual needs and SARC preferences) by either an ISVA or SARC support worker.
4. Within 21 days, eligible service users will be approached by a SARC support worker or Independent Sexual Violence Advisor (ISVA) or SARC support worker who provides brief explanation about the project and officially invites service user to consider being involved in the study. Consent is requested to pass contact details to the project team only ('level 1' consent).
5. If service user consents to be contacted by research team, the consent form for making contacted is returned to research team and there is no more involvement of the SARC
6. Research team make contact within 1 week
7. When consent established over the phone ('level 2' or full consent), baseline data are collected using a structured telephone interview or the person is emailed a link to complete the data collection online
8. Follow up is undertaken according to the service users' preferences at 6, 12 and 24 months

Once phone contact is made by the project team at baseline, the project team will follow recruitment and safety protocols as set out in Section 7 to check eligibility, explain study purpose and gain full consent (level 2). There will be the option of either computer-assisted personal interview (CAPI) or having a weblink emailed which will grant access to the online system. Those submitting baseline (BL) data will be considered 'enrolled' in MESARCH. We will send reminders according to participant preferences for each follow-up, consistent with our previous work [70].

4.3 Number of participants required

At 15 SARCs, 2500 males and females ≥16 years will be invited into a longitudinal study of health and wellbeing in survivors of sexual trauma; we estimate an enrolment rate of 60% and an attrition rate of 40% over two years [10] leaving 900 individuals' data for the analysis at 24 months (see flow of participants in Figure 1). In estimating the sample size to test the hypothesis that there will be clinically meaningful differences in PTSD scores among service users attending SARCs e.g. between C1 (highly integrated SARCs) and C2 (poorly integrated SARCs), we assume a difference of 5 points in the PTSD score after 24 months, with a standard deviation of 12 points, following estimates from the PATH trial [17, 18] and a community sample of males and females reporting sexual violence and other trauma [19]. With 6 sites per group (i.e. C1 v C2) and 60 participants per site in each arm, there would be 87% power to detect a 5-point difference in change in PTSD score (ICC=0.03). In fact, we will recruit 15 sites, so the true power would exceed 87%. Assuming an attrition of 40% [10] we will need to enrol 600 into each group for the primary analysis. We have inflated the number of SARCs to be recruited to minimise risks associated with low enrolment and/or high LTFU however a further advantage is to enable exploratory analyses in subgroups (see 4.6).

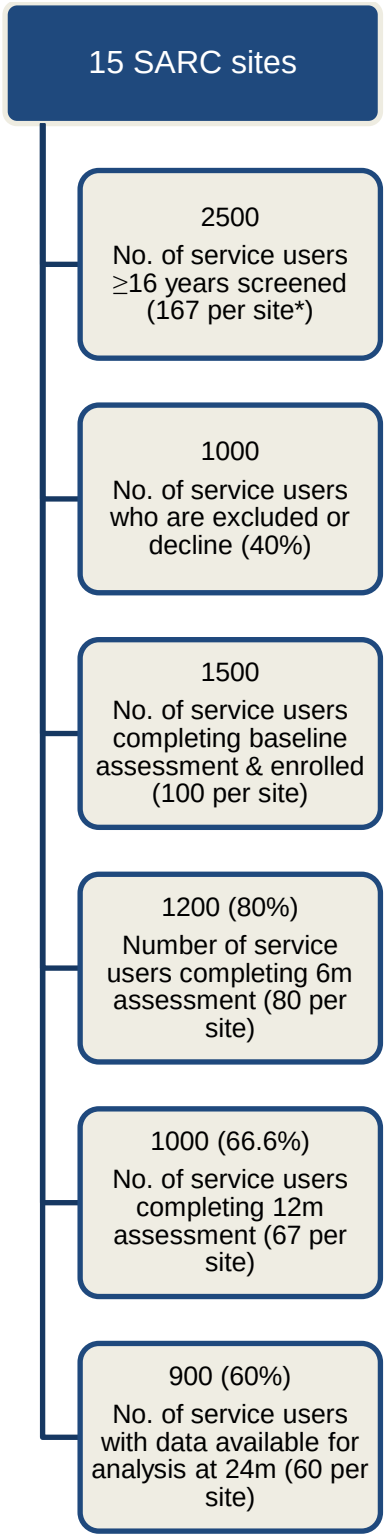

Figure 1 16+ cohort study flow chart

*These estimates are based on the Blue Sky Report (2013). Vast majority of SARC users will meet inclusion criteria.

4.4 Data collection

At baseline, we will collect demographic information on age; gender; education; employment status and income; ethnicity; sexuality and ACEs to enable us to describe the sample and conduct sub-group analyses. We will also seek permission from the participant to gain access to their NHS service use data to enable us to track service use objectively and undertake economic modelling at 1 and 2 years. Follow-up will be done on three occasions over the course of the project - at 6 months, 1 and 2 years. Our proposed methods for retaining participants are informed by a number of large studies of violence and health [71] including our own previous work in the health field [10] e.g. gathering a range of details from participants at baseline - safe telephone numbers, postal/email addresses; use of reminders; and providing a small incentive, with the value increasing over time (i.e. £5, £10, £15, £20).

4.5 Outcomes

The outcomes will be assessed at baseline, and again at each timepoint. The primary outcome is PTSD, widely endorsed in the literature [11, 12] and through our scoping work with PPI and service providers, as a primary health issue for survivors and an absence of diagnosis, or reduction in symptoms may mark improvement or recovery in a person who has experienced sexual violence. PTSD symptoms (PTSSs) will be assessed using the PCL-5 [16], the latest version of the PTSD Checklist (PCL). PCL-5 assesses the presence and severity of PTSD symptoms in the last month based on DSM-5 criteria. The PCL-5 asks about symptoms in relation to generic stressful experiences. Respondents are asked to rate how bothered they have been by each of 20 items in the past month on a 5-point Likert scale ranging from 0 (not at all) to 4 (extremely). Items are summed to provide a total severity score (range 0-80). The PCL is commonly used, and has demonstrated validity and excellent internal consistency reliability (.94 for the total scale and .82-.94 for subscales) [15, 72]. A total score of 33 or higher suggests the patient may benefit from PTSD treatment. Evidence suggests that a 5-10 point change is reliable and a 10-20 point change is clinically meaningful [73]. Depressive symptoms will be measured using the Beck Depression Inventory (BDI) [74]. Anxiety symptoms will be assessed using the GAD-7 [75]; quality of life will be assessed using the WHOQoL-Brief [76]; alcohol measured using the AUDIT-C [77]. We will develop a set of items to assess sexual health, including STI testing and diagnosis, pelvic pain; use of contraception, pregnancy outcomes and reproductive coercion [78, 79]; sexual violence will be assessed using the Sexual Experiences Survey Revised-Short Form [80]. Our approach to measuring health and other costs is outlined in 4.8.

We will work with our SSC and PPI groups in order to refine our choice of measures, in particular, appropriate ways to assess sexual violence exposure in this high-risk population [81].

4.6 Data analysis

Limited research has highlighted variation in models of service provision at SARCs [13] and there is lack of evidence on the effectiveness of SARCs to address the immediate and long-term consequences of sexual violence. Our analysis will examine the level of variation in service delivery models (identified in WS2) and determine if this variation is associated with different levels of trauma symptoms at 12 and 24 months. We will fit a multilevel regression model for PTSD. The mixed effects model will include a random effects term for centre and fixed effect terms for type of service (e.g. where post-crisis counselling care occurs in NHS mental health services v third sector/charity), as well

as for individual level covariates such as age, sex, ethnicity, and SES. Similar analyses will be carried out for the secondary outcomes.

Exploratory subgroup analysis on those minority groups (e.g. BME, men, different age groups) large enough to enable meaningful statistical comparison will be carried out, where evidence of interaction for type of service according to demographic subgroup will be regarded as statistically significant if p-values of 0.01 or smaller are found. Exploratory subgroup analyses will address the question 'How do trajectories compare for different subgroups of survivors attending SARCs?' In key user-groups that are sufficiently large to enable meaningful statistical comparison, we will compare outcomes for: i) recent v non-recent victimisation; (ii) male v female; (iii) migrant or Black and minority ethnic v non-BME survivors; (iv) LGBT v heterosexual; (v) disability v no disability; (vi) chronic mental health issues v mental wellness.

Conducting comparisons between those in the 16+ cohort and those in the 13-15 age range across these parameters will be limited by small numbers in the latter group. However, it will be possible to use the qualitative interview data (see section 4.10) to enable comparisons of adult and child journeys using this mixed approach. Similarly, we will draw on our qualitative data to explore experiences of other groups too small to capture in quantitative analyses. We will also examine if trajectories are influenced by other organisational aspects such as size of centre, location, and interventions available. The final subgroup analysis will examine the effect of setting of post-crisis counselling, a question originally stated in the HS&DR commissioning brief: Are there detectable differences in outcome according to the setting of post-crisis counselling care (NHS mental health services v third sector/charity)? Among the 15 SARC sites, we estimate that for around half the sites, SARC users will be referred to specialised third sector counselling, while in the remainder, users will be referred to mainstream mental health services. We estimate that if similar differences in 24 month outcome are seen between these two counselling types, we will still have up to 90% power to detect them. Other outcomes are depressive symptoms, sexual health, life quality, substance misuse, health service use, and cost effectiveness.

4.7 Our work with children and young people (CYP)

4.7.1 Design

We plan to undertake a cohort study with children and young people. This will involve recruiting a small number of children and young people attending SARCs and following them up over 2 years using quantitative measures.

4.7.2 Sample and recruitment

We will ensure any child participant can be carefully supported from recruitment and throughout the research process (see Section 7 on our approach to safeguarding participants).

A highly-selective strategy will be used for involving children and the recruitment will be at the discretion of the relevant SARC. We plan to enrol around 2 service users at each of the 15 sites where we are delivering the 16+ cohort study (total n=30; see Figure 2 for flow of children and young people through the study). For the children and young people study, we will only include SARC service users aged 13-15 years who do not meet exclusion criteria. Young people and children will be excluded if, in

exercising clinical judgement, the responsible member of SARC staff anticipates they may encounter difficulties in providing informed consent or understanding the content of surveys used in data collection due to mental or physical health issues, cognitive impairment, intellectual disability or poor English language skills. Where appropriate, parents/guardians will be asked for consent. The consenting process will be undertaken by the SARC and through the young person's key worker who will also support the data collection process (for example, to identify with the child a suitable place for baseline data collection and whether this is better done on the phone with a member of the project team or online).

4.7.3 Data collection

In child participants, we will not be measuring sexual trauma as we will know all children have an index experience of CSA. We will work with our collaborators and SSC/PPI on refining child outcomes. Informed by [45], we will likely examine the following areas: PTSD symptoms measured using the Children's PTSD Inventory [53] and depressive symptoms using the BDI (applied previously with adolescents [82]; and risk-taking behaviours [83].

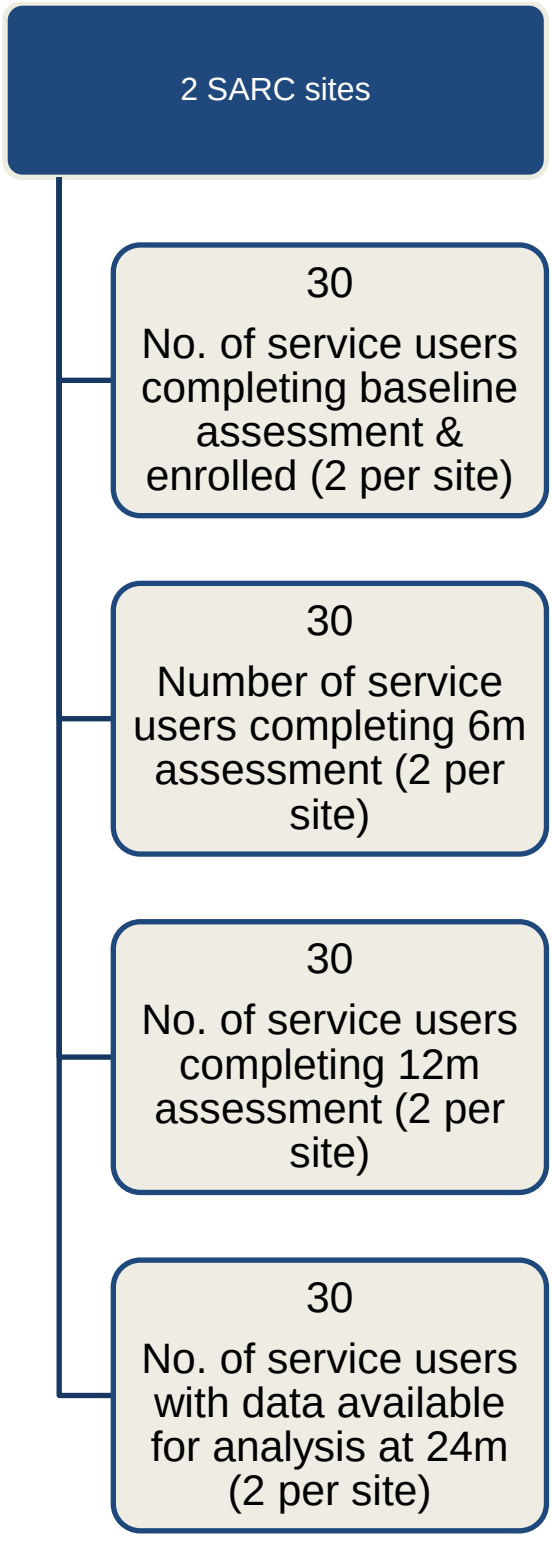

Figure 2 Children and young people (CYP; 13-15 years) cohort study flow chart

4.8 Economic evaluation (Workstream 3)

4.8.1 Design

The economic analysis has been added to the project since the outline was submitted. It will compare the costs and outcomes associated with different models of SARC service delivery. The main models of SARC service delivery will be identified as part of WS2. It is anticipated that 2-4 main models will be identified, which will then be compared within the economic evaluation. If SARCs are effective in reducing PTSD and improving quality of life and other mental, physical and sexual health outcomes, there are likely to be important cost implications for the healthcare sector, for the wider public sector, and for society as a whole. We believe it is essential to capture these.

4.8.2 Data collection

Resource use data will be collected prospectively to estimate the costs associated with different models of SARC service delivery. The resource use to be monitored will include: 1) the cost of service use within SARCs (e.g. consultations, treatment etc.); 2) NHS and other public sector resource use after initial attendance at SARCs (e.g. GP visits, SHC visits); 3) costs associated with the treatment of PTSD and other relevant conditions; 4) wider public sector resource use, for example in relation to social care, housing, and other social welfare systems; 5) costs experienced by service users and family members (e.g. travel costs and impacts on productivity). Information on unit costs or prices will be sourced to attach to each resource use item, to enable an overall cost per service user to be calculated (e.g. [84]). Other NHS and public sector resource use will be captured via a questionnaire for service users and we will also capture costs incurred by service users themselves. Health-related quality of life data will be collected using the EQ5D-5L instrument which is widely used for those with PTSD and related conditions [85]. The instrument will be administered to compare changes in health-related quality of life for different service delivery models, at 6 months and 12 months and 2 years.

4.8.3 Economic analysis

In order to compare the costs and benefits of different SARC service delivery models, both a within study analysis and a model based economic analysis will be undertaken. The within study analysis will primarily use the data collected within the cohort study. Initially, the base case analysis will be framed in terms of a cost-consequences analysis, and data will be reported in a disaggregated manner on the incremental cost and important consequences assessed in the cohort study. The main economic analysis will assess cost-effectiveness based on incremental cost per quality-adjusted life year (QALY) gained at 12 and 24 months, with a secondary analysis of cost per case of PTSD avoided at 12 months. If the results of the cohort study show that there are significant differences in the effectiveness of SARC delivery models, in terms of reducing PTSD and improving other health outcomes, it will be necessary to assess the cost-effectiveness of the SARC delivery models in the longer term, to take into account the impact on an individual's quality of life and productivity. Therefore, if deemed necessary, based on the results of the cohort study, we will use a decision-analytic model to evaluate the longer-term impacts of the different types of service delivery (for up to five years, if data allow). The model development process will use, as a starting point, other models developed for PTSD and related conditions (e.g. [86]). Assuming that a Markov model is found to be appropriate, it will be constructed using TreeAge Pro software. The evidence used in the model will be drawn from the cohort study, with data on longer term costs and outcomes derived from the literature.

Cost-effectiveness acceptability curves (CEACs) will be used to show the uncertainty surrounding the cost-effectiveness of the intervention, for a range of thresholds for cost-effectiveness [87]. We will use both deterministic and probabilistic sensitivity analyses to explore the effects of inherent uncertainty in the estimates on the results [88]. Drawing on the findings of WS2, further plausible variations in SARC service delivery will be explored as part of the sensitivity analysis. The economic evaluation will be conducted and reported in accordance with relevant guidelines [89]. For the longer term analyses, discounting will be undertaken to reflect recommendations by NICE and the Treasury.

4.9 Pilot and stop go decisions

Pilot studies will be conducted in the initial 6 months of WS3 at one SARC site. The purpose is to examine the feasibility of the methods for the main cohort study and identify required design modifications. In particular, we will assess the feasibility of our approach to inviting participants into the study, data gathering procedures, and retention (e.g. use of incentives). At the SARC, we will discuss the project with staff members, build awareness about the rationale, explain inclusion/exclusion criteria and use of the anonymous data form to record exclusions, and agree on the most appropriate staff member(s) to approach potential participants (as one feature of the research delivery that will vary from one SARC to another e.g. flagged by crisis workers at service entry, follow up by ISVA within 21 days). Once set up is complete, all eligible service users over a 3-month period will be invited into the pilot project by SARC workers and enrolment by the project team will proceed as described in 4.2. The pilot will include one follow-up only, at 3 months and an automated email reminder will be sent to the participants' safe email address notifying him/her that it is time to complete the follow-up. Participants who indicated a preference for the CAPI will be emailed to arrange a time. Data collection will include a set of questions about the experience of being invited into and participating in the study. We will require two-thirds of service users to be enrolled from the SARC (or 8 persons per month for 3 months, based on an annual estimate 150 service users >15 years [90] and require loss to follow-up to be <20% (around 4/24 at 3 months).

Indication of recruitment problems: If the study does not recruit at the rate projected in the flowchart at baseline (i.e. 60% of SARC users), we will work to make changes based on feedback from pilot participants and staff. It is also worth noting that nearly everyone attending a SARC will be eligible for inclusion (thus a higher rate of enrolment is possible) and we have already accommodated for the risk posed by a lower rate of enrolment than the projected 40% and/or sites dropping-out by planning to oversample SARCs – we have costed in recruiting 15 sites into WS3 however our sample size requires 60 SUs at 12 sites. If retention is the problem, we will work with pilot participants to improve the participation experience. We will review our numbers at 6 and 12 months in conjunction with the SSC, PPI members and the funder, to inform our decision to progress into the 2 year follow up, with a stop decision if the retention rate at 12 months is considered too low. Even if the retention rate falls to 50% at 24 months, this would leave 750 participants submitting data at 24 months which is consistent with other cohort studies in the area of health services and mental health [91].

To ensure we have success with recruiting SARCs, we already sought the in principle support of several SARCs. If necessary and SARCs were willing, we would be able to conduct WS2 and WS3 at the same sites.

4.10 Qualitative study (Workstream 3)

4.10.1 Design

There will be a nested qualitative, interview-based study to enable a greater depth of understanding of the factors associated with better outcomes for survivors of SV participating in the adult cohort study and the CYP cohort. In total we will include 55 individuals in the embedded qualitative study. This sub-study will address RQ3 and RQ4.

The study will employ narrative methods [92] as these provide participants with the opportunity to give their accounts of a particular experience, free of the assumptions of the interviewer or research team, and empowering them to structure the stories of what happened and their meanings as understood by them. Narrative methods have been applied extensively in explorations of experiences relevant to SV and rape (e.g. [93-95] and lend themselves well to gaining insight into the ways in which people get to grips with potentially devastating disruptions to their everyday lives (e.g. [96]).

4.10.2 Recruitment of participants from the 16+ cohort

Participants who have participated in the adult cohort study will be recruited in order to gain insight into factors that were experienced positively and negatively from a range of narratives. This will provide the project team with rich data about experiences outside of SARC models of care that were valued, as well as those within SARC models. In collaboration with our PPI group of survivors of sexual violence and professionals who support them, we will devise a sampling framework and detailed recruitment strategy that is sensitive to the needs of, and acceptable to, the target population. We propose that this will involve recruiting adult participants from the SARC cohort study between 12 and 24 months post enrolment. We will aim to recruit 30 cohort members in total and apply maximum variation sampling in order to over represent service users whose voices are not typically included in this type of research (e.g. sex workers, MSM, BME and LBGT).

4.10.3 Recruitment of non-SARC service users

We will also seek to recruit people via third sector partners (e.g. CRASAC, RSVP) and stakeholders (e.g. Terence Higgins Trust) who support survivors of SV to ensure their experiences are included in the data (n=15).This will provide data that will help the research team to better understand barriers to SARC access among those offered a referral by other services but who have not used SARCs.

4.10.4 Recruitment of participants from the CYP (13-15 years) cohort

Participants who were invited into the cohort study as children (aged 13-15 years) for the CYP study and who have turned 16 during will be eligible for the embedded qualitative study. We will invite 10 young people with experience of attending the SARCs included in the study, to participate in an interview. This will be guided by maximum variation sampling to ensure wide range of perspectives of young people are brought to bear on the qualitative sub-study. We will aim to interview these participants in the 12-24 month period.

4.10.5 Procedure

Participants who express an interest in being interviewed will be given time and support to prepare for the narrative interview having had a full explanation of what this involves and ensuring they are comfortable to provide their story about experience of services following SV. Participants will be

offered the choice of a face-to-face or telephone interview at a time and location convenient to them and either with or without the support of a person of their choosing. The interview guide will be developed in partnership with survivors of sexual violence and those who support them within our PPI group. It is likely to include an opportunity for the participants to talk generally about themselves and how they are, and to discuss any concerns they may have about the narrative interviews they are engaging with. The interviewer will discuss any concerns and ensure that the participant is happy to begin to tell his/her story. The interviewer will likely suggest the participant starts at an appropriate moment in discussions by saying that he/she is, 'interested in finding out about your experiences of accessing help or support after experiencing sexual violence and that you can begin to tell your story at the point immediately after your experience of sexual violence, or wherever it feels right to start'. It is hoped that this method will illicit talk about health and wellbeing without leading the participant in any particular direction. At the end of the storytelling however, if narratives about health and wellbeing have not been included participants will be asked to talk about the status of their health and wellbeing and views on whether their experiences of receiving support have helped or negatively affected this status. We will also ask them for detail about what health services and other types of support services, if any, they have accessed. Interviews will be audio-recorded with participants' permission and transcribed verbatim.

4.10.6 Analysis of qualitative data

Data will then be subject to narrative analysis (Murray, 2003) to draw out the meanings ascribed to participants' experiences and to identify both unique elements and commonality or themes across experiences. This process will be led KB and the project RA. Narrative analysis is divided into two distinct phases. The first is a descriptive phase which, following thorough reading and familiarisation with the transcripts, involves devising summaries of each narrative to pull out the key features and identify sub-plots as well as overarching story arcs. Similarity between different narrative summaries, as well as key differences, will also be identified at this stage to form the basis of a coding frame. In the second stage, a range of theoretical perspectives will be considered in order to interpret and make sense of the narratives and the coding frame. To achieve this we will work collaboratively with co-investigators and PPI group members, considering the range of options and the ways in which they may or may not aid interpretation of the data. This process will be used to support interpretation of quantitative findings from the cohort data.

5 METHODS: INTEGRATION (Workstream 4)

5.1 Aim and design

The final phase of the MESARCH project involves integrating of evidence from the reviews, process analyses and outcomes studies (Workstream 4). By combining the group's expertise, building on members' previous research and links with health sector and third sector domestic and sexual violence organisations, MESARCH will be able to deliver research that is ground-breaking and complex. WS4 will consolidate the findings, organising them according to a process (WS2)-outcome (WS3) framework with the work from WS1 providing a global and national context about the nature of the problem (sexual violence and its sequelae) and the current evidence on effectiveness of programmes and interventions to address it. Our WS2 'process' data will be drawn into WS3 as part of comparing different outcomes for users of different types of models of care and funding models and allow us to explore how degree of integration [5, 6] of SARCs might increase or reduce patient benefit. As described across the proposal, evidence users will play an active role across all workstreams to ensure appropriate and feasible methods. However, this contribution will be stepped up in WS4 as part of co-interpretation of findings and to enhance how we communicate about SARCs and sexual violence at local, regional and national levels. Our strategy is informed by evidence-based knowledge transfer and exchange (KTE) [21-23, 97, 98] to enhance the likelihood of uptake.

For example, Bokyo, Wathen and Kothari (2017) proposed a strategy for communicating about family violence, which can be adapted to sexual violence. Drawing on MESARCH and existing research, this strategy might focus on risk and protective factors, the impacts of violence across the lifespan and in different subgroups, including economic costs; physical, sexual, reproductive and mental health, and socio-occupational functioning. This information can be packaged for different groups using adapted evidence-informed approaches for communicating to specific groups; for example we may take into account messages for perpetrators as well as survivors, policy makers, providers/stakeholders in different sectors. We will engage in widespread knowledge exchange also; this will include working with stakeholders over 5 interactive workshops in WS4 to examine perspectives on the findings regarding SARCs and gain feedback prior to producing final guidance/recommendations.

From here we will deliver a dissemination programme that ensures widespread impact from the research. We are committed to ensuring that the outcomes of our research have impact in the context of policy-making and clinical practice, and address relevant questions and uncertainties in order that they might inform real-world decisions about which services to commission and to whom to offer them. Bokyo and colleagues also point to a number of approaches (e.g. internet based; face to face methods) that could be tailored to health and third sector and other relevant providers and build on a recent PreVAiL review of interventions to mobilise family violence evidence: they found that using a variety of strategies can be effective, at least in the short-term. The specific context of sexual violence in England would need to be considered. Section 6 sets out our planned outputs and dissemination plan and we will draw on and provide messages about sexual violence and its impact on health, the impact of different interventions and models of care on health and cost outcomes, and put forward user-centred [24] recommendations for SARCs that will be useful to stakeholders in different decision-making contexts. The final conference will mark the end of the project and showcase our findings.

6 DISSEMINATION AND PLANNED OUTPUTS

The main knowledge products from this research will be: (i) comprehensive and up-to-date knowledge about the most effective interventions and components of interventions for improving health and wellbeing outcomes for survivors of sexual violence; (ii) an understanding about the extent to which the current SARC infrastructure and service in England reflects that evidence in practice; and (iii) the ways in which services can be adapted or changed to improve health outcomes for survivors. A variety of different types of output are planned in order to translate these knowledge products into informative and usable formats. In planning the required outputs we have identified the range and scope of our audiences which include:

A Commissioning organisations (CCGs, public health, local authorities, NHS (E) in primary care, mental, sexual health, clinical/managerial leads with role in safeguarding, DV/SV, mental and sexual health);

B SARC management and staff;

C Patients, the public and survivors of sexual trauma;

D Specialist third sector (Rape Crisis; sexual offender rehabilitation; DV specialists);

E NHS services and decision-makers;

F External statutory organisations (DoH; NHS England; NICE);

G Police, and Police and Crime Commissioners;

H Researchers in violence, health and criminology;

I Health professionals in DV and SV; sexual, primary, mental health; emergency medicine; drug and alcohol.

The labelling A-I above is mapped into Table 5 below where we have illustrated how each output helping to deliver knowledge products is aligned to workstreams, knowledge transfer strategy, primary audience catered for and the expected year of delivery. Because our stakeholders, PPI group and SSC will be involved throughout the process they will help us ensure that the messages we present and the way they are presented are engaging for the intended audiences, motivating in relation to recommended action and considerate of the capacity and capability of the relevant audience for uptake. We will aim to be responsive to the feedback we receive in the dissemination process at earlier stages of the research so that we can learn how to optimise and maximise knowledge translation and impact moving forward.

Table 5 Outputs and knowledge transfer strategy

WS	Output	Description	Knowledge transfer strategy	Primary audience*	Expected delivery
WS1	Cochrane Review protocol	Protocol for systematic review of trials evaluating interventions for sexual violence Registered on PROSPERO	Journal publication, open access via Cochrane website with link from project website	H	Y2 Q4
WS1	Cochrane Review	Published review in Cochrane Database of Systematic Rev	Journal publication, open access via Cochrane website with link from project website	H	Y3 Q4
WS1	Systematic review and synthesis of qualitative studies	Published evidence synthesis on experiences & outcomes of care for sexual trauma; Register on PROSPERO	Journal publication (submit to NIHR Journals Library)	H	Y3 Q4
WS1	Evidence summary	Summarises key findings from Cochrane Review, qualitative meta-synthesis and UK grey literature	• Release 'Effectiveness Matters' through Centre for Reviews and Dissemination • Links on project website; shared in project newsletter	A, B, D, E, F, G, H, I NIHR	Y3 Q4
WS2	National SARC 'map' Mapping summaries	Based on mapping of all SARCs, each participating SARC receives a rapid report with comparisons	• Key facts & figures about SARCS on project website as infographic, shared via digital media and project newsletter • PDF tailored to each SARC (confidential)	A, B, C, D, E, F, G, I (map)	Y1 Q4
WS2	Making sense of SARCs	Findings from in depth case analyses about the work that SARCs do and how this fits with wider context of a	• MESARCH interim conference to around 100 delegates • Journal publication (submit to Health Services and Delivery Research)	A, B, D, E, F, G, H	Y2 Q3 (conf) Y4 Q3 (Pub)

		response to sexual violence			
WS3	Effectiveness and cost effectiveness of SARC provision of care for survivors of sexual violence: Publications and evidence briefings	From cohort study of survivors in SARCs, sexual health clinics and emergency departments - Publication of quantitative and qualitative findings on trajectories and outcomes Brief version of the evidence released following publications	• Journal publication baseline/6m data (submit to a BMC Public Health journal) • Journal publication 12m (submit to Sexual Health) • Journal publication 24m (submit to Lancet or BMJ Open) • Journal publication of qualitative findings (consider a violence journal) • Journal publication of economic evaluation (Social Science and Medicine) • Evidence briefings, available in electronic format from website and leaflets after pub • Confidential evidence briefings for commissioners, prior to publication • Conference	A, B, D, E, F, G, H, I NIHR	Y4 Q3+
WS3	Participant cohort	A 'live' cohort of participants for future research	Database of participant contact details for those who consented to follow up after project	H, NIHR, other funders	Y4 Q3
WS4	Resource for survivors, families, friends, public	'How do I find support for an experience of sexual assault for myself or someone I know?'	• Leaflets distributed to NHS settings and community • Info available on project website	C, D, E	Y4 Q2
WS4	Best practice guidance	Best practice guidance and transferable recommendations to improve service provision, with focus on hard to reach groups	• 5 interactive KTE nationwide workshops on implementation of good practice A5 laminated poster, leaflets • Infographic hosted on website and distributed via newsletter • MS PowerPoint slides	A, B, D, E, F, G, H NIHR	Y4 Q2
All WS	Summary reports	5x progress reports	• PDF	NIHR	Y1Q2-Y4Q3
WS4	End of project report	A report integrating findings	• PDF • Full, executive and plain English summary available on website • International conference • MESARCH final conference	A, B, C, D, E, F, G, H NIHR	Y4 Q3

7 ETHICS

We have allowed 6 months before the project start date to enable us to submit an ethics application to Coventry University Ethics Committee and apply to the HRA via IRAS. The initial ethics application will cover the pilot study and all workstreams. We will submit an amendment if any changes are required based on the pilot work. The physical and emotional safety of participants in the project is a primary concern. We will adopt many safety features [99], and procedures used successfully (i.e. trials reported no adverse events) in our previous research [10, 17]. All research staff, including PPI staff, will be trained in the use of these safety procedures. We expect the most significant risk faced by participants will be the psychological distress caused by being in a project about a recent or non-recent experience of sexual trauma; service users may be at risk of further victimisation and the research could increase this; there may have been no prior disclosure among a small number of participants in the community-based qualitative study (although given that they will be recruited through services, this is unlikely) and people may see the project as an avenue to support; answering lots of questions may be experienced as burdensome; particular issues exist in relation to conducting research with vulnerable groups within an already vulnerable population (e.g. children, immigrants, sex workers); project staff may find some of the information gathered through interviews and other data collection methods distressing, and project staff may face risks during field work; asking people with a recent assault to share information could jeopardise criminal justice proceedings.

Many steps will be taken to minimise the likelihood of these risks:

1) At SARCs a stepped process in WS3 will be used with an initial flagging of the project by a support worker when a service user first presents, and a follow-up discussion (30 mins per service user) by trusted support worker to explain the project/request consent within 21 days. The project team will then follow-up as per service user preferences to collect baseline data.
2) The SARC worker will emphasise the voluntary and confidential nature of the research and the option to withdraw at any time; that decisions about participation will not affect care received, that the project is for research and not treatment and confidentiality would only be breached if there was indication of harm to self or others.
3) We will speak to every potential participant and 'safe' contact information provided by the participant will be used in communication about the project or if there are safeguarding issues we need to follow up.
4) At the end of the project people will be asked for their consent to be followed up at in the future and to potentially enable access to routine data about them and use of linkage (e.g. GP or HES data).
5) Project materials sent to people's homes will not reference the true nature of the project (e.g. "A study about your health"). For those opting for online data collection, we will provide a username and password for accessing the site. Information will be provided regarding the safe (private) use of computers and the Internet. As necessary, the RA will help participants brainstorm a safe location to assess a computer or tablet. The website will be equipped with a 'quick escape' bar.
6) There will be a structured debriefing at the end of data collection session (by phone or online) to remind participants that he/she might experience a stress reaction after the session, that this is a normal response and we will provide options for managing it. Interactions between the research process and the person's support/recovery journeys will be minimised to maintain the 'naturalistic' element of the research. However, our previous experience shows that being in a research study may be beneficial to service users [100]. Part of this is due to all participants at all stages being made aware of the options for getting support. We will have links for SARCs, CRASAC, RSVP and SiT and a range of other local and national services tailored to the site of recruitment.
7) We will develop very clear procedures around the involvement of children aged 13-15 years in WS3 and seek wide input on this prior to rolling out through SARC workers. We will ensure familiar support staff take consent and also are available during all data collection points (until the young person is 16 and then they may opt not to have the support worker present). SARC staff will be encouraged to use highly selective approaches to identifying just 2 participants per site, and consent from guardians will be sought. Our qualitative interviews with young participants will only include those that have turned 16 years and they will have option of being interviewed by PPI staff member with lived experience of sexual trauma.

8) The language and content of the surveys will be carefully drafted and reviewed to ensure inclusiveness and so that people can see themselves in the study, and to avoid phrasing that could be interpreted as blaming or stigmatising. To increase participants' sense of comfort, we will use an informal, conversational tone, include messages that acknowledge when questions or activities might create distress, and encouraged participants to take a break if needed.
9) We will undertake risk assessments with staff around processing participants' trauma and circumstances using university guidelines but also in conjunction with advice from CI Whitfield and the collaborator SiT which routinely trains survivors for conducting peer interviewing.
10) We will use brief measures of sexual violence to avoid re-traumatisation and prevent interference with any criminal justice processes.
11) All of the above strategies will be refined in conjunction with the SSC, PPI team and our three collaborators including gaining feedback in the pilot study about perceived duration and nature of questions in the pilot study and making appropriate adjustments before the main study and involving young people in processes around child participation.
12) There will be ongoing monitoring of the data by the project team, with a triage system in place for identifying concerning patterns or dealing with any concerning phone, email or text contact. Risk of suicidality is heightened in people with sexual violence [101]. Although we do not anticipate that study participation will increase this risk, we will integrate safety programming.
13) We will convene an independent Data Monitoring and Ethics Committee (DMEC) to coincide with completion of 6 and 12 month data timepoints. The 3-member Committee will be further convened in the event of an unintended/adverse consequence. Although less often a feature of non-intervention research, the investigators considered it was important to have a DMEC given that the research involves vulnerable populations, and participants with significant potential risk of harm, or unknown or uncertain risks. In line with national guidance [102], the purpose will be to review reports of potential harms (e.g. exposure to abuse, risk of suicide) and adherence to safety study protocols prepared by the project team, and data analyses to show trends by subgroup prepared by our statistician. The DMEC will recommend investigations and/or follow-up actions about any safety concerns which they identify to the investigators.

8 PATIENT AND PUBLIC INVOLVEMENT

This research is an active partnership between service providers, community organisations, researchers, NHS and members of the public. PPI will enhance the effectiveness, credibility and cost effectiveness of this work; we also believe it is important that the research is underpinned by broader democratic principles of citizenship, accountability and transparency. In the application form, we addressed how PPI shaped the proposal. Here, we describe how PPI has been authentically embedded into workstreams. Involving people with lived experiences of sexual violence along with other members of the community will ensure the activities and outputs are 'acceptable'. Participants will feel supported, validated and understood which will be balanced against methodological rigour. PPI will test assumptions throughout implementation as we have already seen in the development phase. This input will enhance the potential for producing high quality research, with outputs that are relevant to all evidence- and end-users. CI Feder's previous PPI work (e.g. used in INVOLVE case study) will inform PPI and CI Whitfield will be an expert advisor on promoting the wellbeing of PPI contributors.

Our strategies, informed by INVOLVE [103] will comprise the following:
(i) immediate appointment of a Public Involvement Coordinator (0.5FTE) as a central point of contact for PPI members during planning and WS activities and to assist with identifying and implementing PPI as per our protocol;
(ii) members of the public, patients and survivors will have permanent positions (n=5; 33%) on our Study Steering Committee (SSC), which will meet twice a year. We will provide for preparation time (1/2 day) prior to the 7 SSC meetings to enable PPI members to read materials sent to them prior to the meeting and prepare comments/feedback for us. Incumbents will act as critical friends in the preparatory work, delivery and monitoring of each stream of activity. Participants will be invited from different settings at different times to enable broad perspectives and expertise to be brought to bear at key junctures (n=35). The approach will ensure the voices of marginalised survivors have a firm say in our work. Locating members will be facilitated by our nomination of a wide range of community organisations to the SSC and our two collaborating charities (RSVP; SiT). We also built in a SSC meeting prior to project kick-off to gain PPI perspectives in designing project logos, promotion materials and website, to contribute to the development of the Cochrane Review protocol as well as input into key ethics issues for ethics applications;
(iii) we will offer 5-day research training opportunities to five PPI representatives so that we have a pool of expertise from which to invite survivors and service users to contribute via 'research' work days (see below). Training will be undertaken by the PI and CI Sleath, in line with good practice outlined in case studies on the INVOLVE website and with input from SiT which is experienced a training survivors for research practice. Our PPI representatives will be able to access support if they wish through our partner, CRASAC. CI Whitfield will be available to advise on handling any complex issues for the PI and other WS leads;
(iv) PPI 'research' days will be costed across 3 WS. Those with appropriate training will be asked to help with piloting & feasibility testing; refining of research materials; peer interviewing as part of the SARC case studies (WS2) and qualitative investigation of community members' help-seeking and views on impact of different service provision along with input into analysis and interpretation of qualitative findings (WS3); and will have a key role in the integration phase, in the co-production of messages and knowledge sharing and exchange where appropriate.

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