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, Millicent Gant, Louise Jackson, Dianne Whitfield, Richard Morris, and Gene Feder

**STUDY PROTOCOL**

**PROTOCOL VERSION 3.1**

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| Version | Changes | NIHR acceptance | HRA approval date | IRAS number |
|---|---|---|---|---|
| 3.1 | Additional sample and recruitment details for the children and young people's study | 26/05/2020 | 04/06/2020 | 265220 |
| 3.0 | TFEQ-R21 replaced by BEDS-7; assessment of height and weight added; suicidality and self-harm items from the APMS added | 12/5/2020 | 11/12/2019 (excluding APMS items) | 261455 |
| 2.2 | Enrolment period extended; removal of GAD-7, replaced HARK-4 with the ACTS; reduced TFEQ-R21 to select items; addition of SCOFF; removal of SES | 14/08/2019 | 30/07/2019 | 261455 |
| 2.1 | Refined focus of Cochrane review to adult experiences of sexual violence and abuse; expanded strategies for recruitment; addition of assessment of eating disorder; change in minimum age for inclusion to 18 years; application of short form of CES-D; assessment of 'capability'; HARK screening tool, EQDL5 and DUDIT. | 01/05/2019 | N/A | N/A |
| 1.0 | Original Approved Protocol | 01/03/2019 | 21/12/2018 | 243148 |

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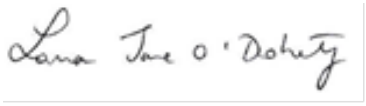
## SIGNATURE PAGE

The undersigned confirms 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: 15th May 2020



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# Contents

**i. LIST OF ABBREVIATIONS**

| | |
|---|---|
| ACE | Adverse childhood experience |
| ACTS | Afraid, Controlled, Threatened, Slapped Screening Measure |
| APMS | Adult Psychiatric Morbidity Study |
| BDI | Beck Depression Inventory |
| BEDS-7 | Binge Eating Disorder Screener-7 |
| BME | Black and minority ethnic |
| CAPI | Computer-assisted personal interview |
| CDPLPG | Cochrane Developmental, Psychosocial and Learning Problems Group |
| CSA | Child sexual abuse |
| CYP | Children and young people |
| DMEC | Data Monitoring and Ethics Committee |
| ISVA | Independent Sexual Violence Advisor |
| IPV | Intimate partner violence |
| LGBT | Lesbian, Gay, Bisexual and Transgender |
| MESARCH | Multidisciplinary Evaluation of Sexual Assault Referral Centres for better Health |
| NIHR | National Institute for Health Research |
| NPT | Normalisation Process Theory |
| PI | Principal Investigator |
| PIS | Participant Information Sheet |
| PPI | Patient and Public Involvement |
| PTSD | Post-traumatic stress disorder |
| QOL | Quality of life |
| RCT | Randomised controlled trial |
| SAAS | Sexual assault and abuse services |
| SARC | Sexual Assault Referral Centre |
| SSC | Study Steering Committee |
| STI | Sexually transmitted infection |
| WHOQoL-Bref | World Health Organisation quality of life measure |

**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<br>Mapping and case studies of SARCs<br>Longitudinal observation with embedded qualitative study | |
| Study Participants | Mapping: All SARC managers in England invited to participate in survey<br>Case study: SARC professionals, SAAS stakeholders and SARC service users/family members<br>Adult cohort: Adult (18 years+) survivors of recent/non-recent sexual violence attending SARCs in England<br>Children and young people (CYP) cohort: individuals aged 13-17 years, survivors of recent/non-recent sexual violence and attending SARCs in England | |
| Planned Sample Size | Mapping: SARC managers – not specified<br>Case study: 150 SARC staff, non-SARC professionals and service users and family members at adult (8) and paediatric (2) SARCs<br>1500 service users aged 18+ (target enrolment) attending 15 SARCs (adult cohort)<br>40 service users aged 13-17 years attending 2 paediatric SARCs (CYP cohort) | |
| Treatment duration | Not applicable | |
| Follow up duration | Adult and CYP cohorts: 6, 12 and 24 months | |
| Planned Study Period | September 2018-May 2022 (45 months) | |
| | Objectives | Outcome Measures |
| Primary outcomes | • Post-traumatic stress disorder- PTSD | • PCL-5 |
| Secondary outcomes | • Depression<br>• Quality of life<br>• Sexual health<br>• Sexual abuse and violence re-victimisation<br>• Alcohol use<br>• Drug use | • Centre for Epidemiologic Studies-Depression Scale (CESD-R-10)<br>• WHOQoL-Bref<br>• Bespoke measure for sexual health<br>• Bespoke measure sexual violence (follow-up only)<br>• AUDIT-C<br>• DUDIT |

| | | |
|---|---|---|
| | • Eating behaviours | • SCOFF measure<br>• BEDS-7<br>• Height and Weight |
| | • Resource use<br>• Health-related QoL<br>• Capability | • Bespoke measure<br>• EQ5D-5L<br>• ICECAP-A |
| | • Adverse Childhood Experiences | • WHO ACE International Questionnaire |
| | • Intimate partner violence | • ACTS screen (baseline)<br>• Composite Abuse Scale (follow-up) |
| | • Suicidality and self-harm | • APMS items |

**iii. FUNDING AND SUPPORT IN KIND**

| **FUNDER(S)**<br>(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<br>University of Southampton Science Park,<br>SO16 7NS | Total research costs £1,286,677.20<br>Total NHS support & treatment costs £44,350.00 |

**iv. KEY WORDS:** Sexual assault, rape, sexual abuse, 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, Rape Crisis England and Wales, 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<br>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?<br>• What are providers' experiences of delivering health interventions for sexual violence?<br>• What are the experiences of survivors of sexual violence in accessing help in health settings? |
| Workstream 2<br>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?<br>• What is the work of SARCs including the types of interventions delivered?<br>• Who is the SARC workforce?<br>• What are the technologies that enable SARCs to get work done?<br>• 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<br>Outcomes evaluation | RQ3 What are the health and cost trajectories of those who attend SARCs?<br>• How do these compare for different subgroups of survivors attending SARCs?<br>• How do these compare for different interventions and SARC models?<br>• How do these compare for different post-crisis counselling settings? |
| Workstream 4<br>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 psychosocial interventions 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 supported us to undertake a Cochrane Review entitled 'Psychosocial interventions for survivors of rape and sexual assault during adulthood'. 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.. 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 aged 18 years and above who has been a victim of sexual violence in adulthood | Any psychosocial or psychological 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)<br>Another psychological or psychosocial therapy<br>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 (CENTRAL; current issue) in the Cochrane Library.
- Cochrane Common Mental Disorders Controlled Trials Register (CCMDCTR) (https://cmd.cochrane.org/specialised-register )
- MEDLINE Ovid (1950 to present) - search strategy listed in Appendix 1.
- MEDLINE In-Process & Non-Indexed Citations Ovid (1966 to present).
- MEDLINE(R) Epub Ahead of Print Ovid (1946 to present).
- Embase Ovid (1980 to present).
- CINAHL EBSCO (Cumulative Index to Nursing and Allied Health Literature; 1982 to present).
- PsycINFO Ovid (1806 to present).
- ASSIA (Applied Social Sciences Index and Abstracts).
- ERIC (Education Resources Information Center).
- Social Science Abstracts EBSCO (1971 to present).
- Criminal Justice Abstracts EBSCO (all years).
- Proquest Published International Literature on Traumatic Stress (PILOTS; 1871 to present).
- ClinicalTrials.gov (www.ClinicalTrials.gov).
- WHO International Clinical Trials Registry Platform (ICTRP; apps.who.int/trialsearch).
- Cochrane Database of Systematic Reviews (current issue), part of the Cochrane Library
- Epistemonikos (www.epistemonikos.org).
- ZETOC (zetoc.jisc.ac.uk).
- Conference Proceedings Citation Index - Social Science & Humanities (Web of Science; 1990 onwards).

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 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. 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. We will also examine the effects by setting and characteristics of the providers. 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

We will undertake a review entitled: Survivor, family and professional perspectives of psychosocial interventions for sexual abuse and violence: A qualitative evidence synthesis. This will be undertaken through the CDPLPG and therefore be linked to the quantitative review.

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 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 do not contain 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 interventions and professionals delivering interventions following exposure to sexual abuse and 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 in 2.1.1 and 2.1.2.

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 one review author, and reviewed by another author to ensure that all data have been included and uploaded. Two co-authors 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 a third author. 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 collaborate with the NIHR-funded MIMOSA project (The Effectiveness of Sexual Assault Referral Centres with regard to Mental Health and Substance Use: A National Mixed Method Study; 16/117/03) to map out service delivery by SARCs to adult and child survivors of sexual violence across England drawing on several sources including the COSAI tool [64]. Recruitment will be done by sending an official invitation by NHS England on behalf of the two project teams asking a consenting member of management staff at each SARC to complete an online survey or having the option of a 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, and 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 offer a £10 Amazon voucher as an incentive to all those approached. 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. We will also access the SARC Indicators of Performance (SARCIPs) data held by NHS England to reduce burden on SARCs in the amount of data we request and to enhance the information we have to hand to inform mapping and other processes.

## 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 on diverse characteristics of SARC including organisational, client and service characteristics. 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. members of the police; staff at Rape Crisis Centres and other charity settings such as independent sexual violence advisors; general practitioners and health professionals of the NHS); 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 researcher (e.g. a member of the study Lived Experienced Group trained to conduct interviews) 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 and differences in provision and how these impact on the work of the SARCs.

# 4 METHODS: ADULT COHORT AND CHILDREN/YOUNG PEOPLE'S STUDY (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 adult and child survivors of sexual abuse and violence who have received care through SARCs. Follow-up will be done at 6, 12 and 24 months.

## 4.2 Sampling and procedures for the adult 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, lived experience group and supported by information collated in WS2 about context 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 18 years and above presenting in person at the SARC will be invited to participate (i.e. we will not include those whose only contact with the SARC is by telephone or those in prison settings). 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. We will also work with the voluntary sector to aid recruitment by making services aware of the research project and the option to enable recruitment. To achieve this, for each recruitment site, we will identify agencies that work with the SARC. In situations where Form A has been completed and the person has been referred on to support in the voluntary sector (this may especially be the case at SARCs where follow up support sessions are not routinely offered), the SARC will make a note about the referral and we will get in touch with the charity agency. The staff will then have the option of completing Form B for the individual service user and consent form in the same way as is done by the SARC.

Table 4 Procedure for involving service users aged 18 years and above

| |
|---|
| *1. Service user is seen by SARC staff in person* |
| *2. SARC staff member screens service user for eligibility. All eligibility information is anonymous and conveyed to the project team using secure sharing platform.* |
| *3. Eligible service users are briefly informed about the study at an appropriate point at the SARC or in weeks that follow, based on the individual's needs and SARC preferences, by a SARC staff member.* |
| *4. Eligible service users will be approached by a SARC staff member or Independent Sexual Violence Advisor (ISVA) who provides brief explanation about the project and officially invites service user to consider being involved in the study. Recruiting SARC service users through the third sector requires the SARC to pass on the service user's unique project ID in order to enable the recruitment process to continue beyond the SARC setting. Consent is requested to pass contact details to the project team ('Level 1' consent completed).* |
| *5. Additional approaches for enabling recruitment include (i) placing a trained member of the project team at the SARC to respond to opportunities to invite service users as they visit the SARC for after care; (ii) having members of the project team ready to speak by phone or video link to a service user if the SARC worker believes this is an appropriate approach for a particular service user; (iii) showing a short video message of invitation co-produced with our Lived Experiences Group which could be used by SARC staff to explain about the project (available on our project website).* |
| *6. Once the contact information has been passed on, there is no more involvement of the SARC except in circumstances such as the participant requires support and has agreed for us to notify the SARC.* |
| *7. A trained project team member makes contact within 1 week of receiving the research referral consent form from the SARC or third sector worker, and contact is made in line with service user preferences for example by email, text or phone call.* |
| *8. Once contact is made by the project team at baseline, the project team will follow recruitment and safety protocols, explain study purpose and gain full consent ('Level 2' consent).* |
| *9. When consent to take part in the study is established (using email or text or signed consent form), baseline data are collected using a range of options. These include offering a structured telephone interview, a weblink to complete the data collection online, an interview in person or via Skype (or alternative). Those submitting baseline data will be considered 'enrolled' in MESARCH.* |
| *10. Follow-up is undertaken according to the service users' preferences at 6, 12 and 24 months consistent with our previous work [70]* |

4.3 Number of participants required

At 15 SARCs, 2500 individuals aged ≥18 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 people 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).

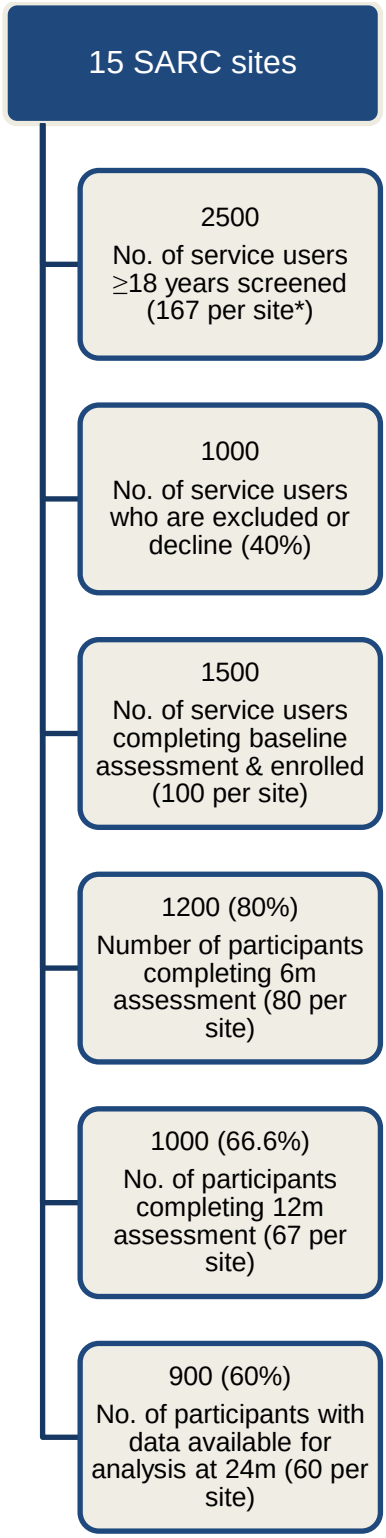



Figure 1 Adult cohort study flow chart

*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; and sexual identity. We will enquire about adverse childhood experiences (ACEs) and screen for past year domestic violence to enable us to describe the sample and conduct sub-group analyses. All other baseline measures will focus on standardised time frames according to the measure or the period since participants attended the SARC. 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. £10 following baseline completion, £10 at 6 months, £10 at 12 months, and £20 at the 24-month follow-up).

4.5 Outcomes

Table 5 shows the measures at each timepoint. The primary outcome is PTSD, widely endorsed in the literature [11, 12] and through our scoping work with individuals with lived experience 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 CES-D-R-10 [74]. Quality of life will be assessed using the WHOQoL-Brief [76]; alcohol measured using the AUDIT-C [77]. Eating behaviours using the SCOFF [75], BEDS-7 [109] and height and weight; drug use will be measured using the DUDIT [110]. 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 measured through bespoke screen items at follow up only. This is not assessed at baseline as it is not appropriate given the point participants may be at in their journey and we will have some data from the SARC about the nature of the assault such as, the type of assault, approximately how long ago the assault took place, the perpetrator of the assault and the use of substances in the assault. We will screen for domestic violence using the ACTS [80]; at follow up we will also assess exposure to domestic violence and abuse using the Composite Abuse Scale [104]. Our approach to measuring health and other costs using the ICECAP-A [111] and EQ5D-5L [112] is outlined in 4.8. Suicidality and self-harm will be assessed using brief items from the Adult Psychiatric Morbidity Study [113].

We will work with our study steering committee and lived experience group in order to refine our choice of measures, in particular, appropriate ways to assess sexual violence exposure in this high-risk population [81].

Table 5 Cohort outcomes measures at each timepoint

| Outcome | Measure | Timepoint |
|---|---|---|
| PTSD | PCL-5 | Baseline, 6 months, 12 months, 24 months |
| Depression | CESD-R-10 | Baseline, 6 months, 12 months, 24 months |
| Quality of life | WHOQoL-Bref | Baseline, 6 months, 12 months, 24 months |
| Eating issues | SCOFF<br>BEDS-7 | Baseline, 6 months, 12 months, 24 months |
| Health related quality of life | EQ5D-5L | Baseline, 6 months, 12 months, 24 months |
| Capability | ICEpop CAPability measure for Adults (ICECAP-A) | Baseline, 6 months, 12 months, 24 months |
| Sexual health | Bespoke measure | Baseline, 6 months, 12 months, 24 months |
| Alcohol use | AUDIT-C | Baseline, 6 months, 12 months, 24 months |
| Drug use | DUDIT | Baseline, 6 months, 12 months, 24 months |
| Resource use | Bespoke measure | Baseline, 6 months, 12 months, 24 months |
| Adverse Childhood Experience | WHO ACEs | Baseline |
| Intimate Partner Violence | ACTS 4 item screen<br>CAS | Baseline<br>6 months, 12 months, 24 months |
| Sexual violence | Bespoke measure | 6 months, 12 months, 24 months |
| Suicidality and self-harm | APMS | Baseline, 6 months, 12 months, 24 months |

4.6 Data analysis for the adult and CYP cohorts

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 abuse and 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/transgender male v female/transgender 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 the adult cohort and CYP service users across these parameters will be limited by small numbers in the latter group. However, it will be possible to use the qualitative interview data from the embedded study with adults and the widespread interviews with our 40 CYP participants to enable comparisons of adult and child journeys. 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 study with children and young people. This will involve recruiting children and young people at two paediatric SARCs and following them up over 2 years using a range of participatory methods.

#### 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 and/or third sector organisation who has been supporting the individual CYP e.g. it has been agreed that initial consideration of suitability / 'screening' will be done by the paediatric medical doctor who will make a note on the referral form to the third sector that they consider the service user to be suitable for being invited into the study at a later point in their care journey. Depending on when it is appropriate, the third sector organisation (usually the Children’s Independent Sexual Violence Advisor) will introduce the study to CYP or there could be follow up by a member of the SARC team (e.g. the doctor that saw the young person initially). We plan to enrol around 40 service users attending two paediatric SARC sites where we will firstly conduct our case studies as per WS2 and training with staff in preparation for WS3 including establishing our understanding of their systems and processes and subsequently undertake the follow up study (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 13-17 years who do not meet exclusion criteria. Young people and children will be excluded if it is less than one month since the assault/experience, or 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 interviews/ surveys used in data collection due to mental or physical health issues, cognitive impairment, intellectual disability or poor English language skills, although we will strive to overcome barriers to participation. All participants aged 13-15 years will require parental/guardian consent to take part; young people aged 16-17 years can provide consent themselves based on Gillick Competency. CYP aged 13-15 years will be excluded if their history is such that gaining consent from parents/guardians is not appropriate. . Finally, CYP will be excluded if they are in an unstable or unsafe situation.

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/ lived experience group on refining the CYP study. Informed by [45, 53], we will primarily undertake qualitative interviews with this cohort and follow the participants up at 6, 12 and 24 months examining key aspects of young people's mental health including PTSD symptoms depressive symptoms, substance misuse and risk-taking behaviours as well as impacts on daily life, social and intimate relationships and schooling. At baseline, we will strive to understand their experiences of using SARCs and other services.

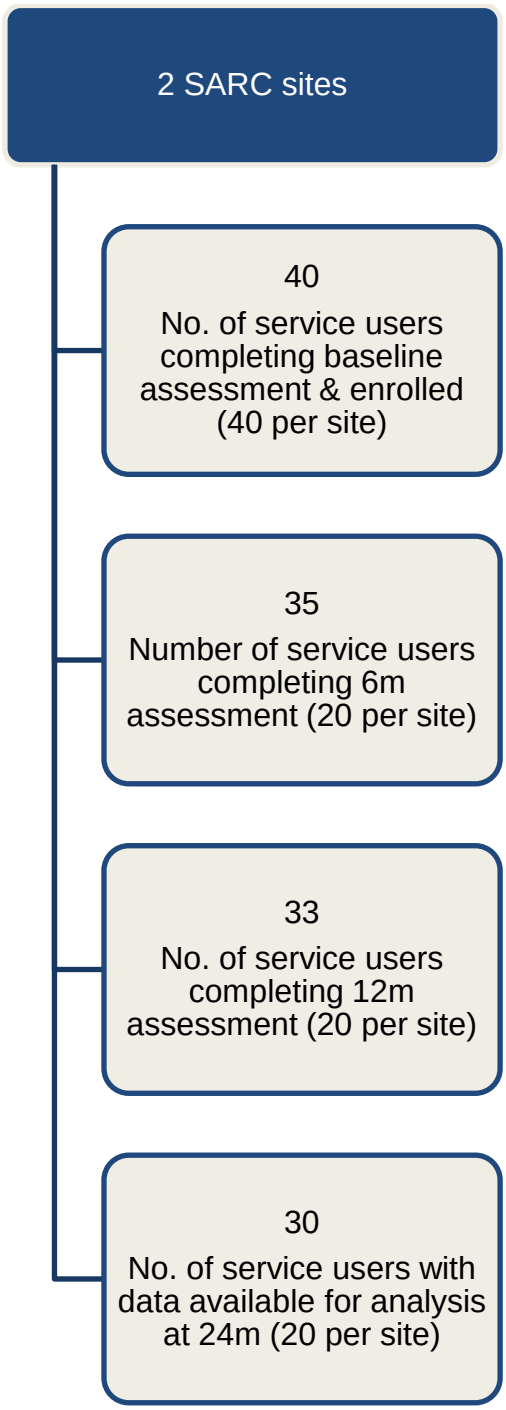
Thus, the CYP sub-study will look at very similar domains to the adult study but will use more fluid, creative and developmentally appropriate ways of engaging young people and children to share their views and experiences. This may involve engaging CYP through drawings, stimulus materials, and life narrative techniques [82]. We are mindful that the approach taken will need to be sensitive, taking into account the needs of participants and the setting in which the research takes place [83]. Engaging with CYP through qualitative and participatory methods can facilitate children sharing their interpretation of events, as they tell their personal accounts in their own voice [53].

The United Nations Convention on the Rights of the Child [105] states that all children have the right to make their voices heard in matters that concern them, whilst also having the right to protection from harm and exploitation [106]. Reflecting the philosophical underpinnings of the UNCRC, and recognising important theoretical developments in the sociology of childhood [107], we acknowledge that CYP are competent social actors who have the right to make contributions to issues which affect them, rather than viewing children as 'objects' of enquiry [108]. Therefore, we recognise the importance of conducting the CYP study sensitively and ethically to ensure that children are empowered to decide whether to take part in the study, whilst tailoring the methods used to engage directly with CYP whereby they are comfortable in how they share their experiences of SARC and key aspects of their mental health.

As well as inviting CYP to be involved in the study as research participants, we acknowledge the importance of CYP contributing the study in several other ways. We have worked with CYP to inform the design of the proposed CYP study, by inviting CYP who already form part of a local advisory group to take part in a CYP lived experience focus group. This group will is invited to share their views about the design and methods of the study, and this includes receiving feedback about the range of ways in which a qualitative interview could be conducted with future participants of the CYP study. Similar to

the adult lived experiences group, there may be additional opportunities for individuals in the CYP group to contribute as peer-researchers, whereby they are involved in conducting the research and/or assisting in the analysis of data. Data will be analysed according to the approaches preferred by participants. We expect the majority of participants will choose to be interviewed, with the procedures and analyses approximating approaches set out in 4.10.

Figure 2 Children and young people (CYP) cohort study flow chart




4.8 Economic evaluation

### 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, Data Monitoring and Ethics Committee Lived Experiences Group 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

### 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 will include a community-based comparison sample. We will include around 50 individuals aged 18 years and above 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 adult 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 Lived Experiences Group and professionals who support survivors, 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 adults from the SARC cohort study between 12 and 24 months post enrolment. We will aim to recruit around 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. people affected by sex work, members of BME and LBGT communities).

### 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 (approximately 20 individuals).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 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 lived experience 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.

#### 4.10.5 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 Lived Experience 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

### 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 6 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, Lived Experience 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 6 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 | 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 protocol and evidence synthesis on experiences & outcomes of care for sexual trauma | Journal publications (Cochrane Database of Systematic Reviews) | 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<br>• Links on project website; shared in project newsletter | A, B, D, E, F, G, H, I<br>NIHR | Y3 Q4 |
| WS2 | National SARC 'map'<br>Mapping summaries | Based on mapping of all SARCs, each participating<br>SARC receives a rapid report with comparisons | • Key facts & figures about SARCS on project website as infographic, shared via digital media and project newsletter<br>• PDF tailored to each SARC (confidential) | A, B, C, D, E, F, G, I<br>(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 response to sexual violence | • MESARCH interim conference to around 100 delegates<br>• Journal publication (submit to Health Services and Delivery Research) | A, B, D, E, F, G, H | Y2 Q3 (conf)<br>Y4 Q3<br>(Pub) |

| | | | | | |
|---|---|---|---|---|---|
| WS3 | Effectiveness and cost effectiveness of SARC provision of care for survivors of sexual violence:<br>Publications and evidence briefings | From cohort study of survivors in SARCs, sexual health clinics and emergency departments -<br>Publication of quantitative and qualitative findings on trajectories and outcomes<br>Brief version of the evidence released following publications | • Journal publication baseline/6m data (submit to a BMC Public Health journal)<br>• Journal publication 12m (submit to Sexual Health)<br>• Journal publication 24m (submit to Lancet or BMJ Open)<br>• Journal publication of qualitative findings (consider a violence journal)<br>• Journal publication of economic evaluation (Social Science and Medicine)<br>• Journal publication on CYP study outcomes<br>• Evidence briefings, available in electronic format from website and leaflets after pub<br>• Confidential evidence briefings for commissioners, prior to publication<br>• Conference | A, B, D, E, F, G, H, I<br>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<br>• 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<br>• Infographic hosted on website and distributed via newsletter<br>• MS PowerPoint slides | A, B, D, E, F, G, H<br>NIHR | Y4 Q2 |
| All WS | Summary reports | 5x progress reports | • PDF | NIHR | Y1Q2-Y4Q3 |
| WS4 | End of project report | A report integrating findings | • PDF<br>• Full, executive and plain English summary available on website<br>• International conference<br>• MESARCH final conference | A, B, C, D, E, F, G, H<br>NIHR | Y4 Q3 |

## 7 ETHICS

The team will seek ethics approvals and amendments as appropriate from the host institution and the Health Research Authority at different junctures over the life of the project (pilot study, main study, embedded qualitative study, CYP study). 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 lived experience group 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; finally, 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 by trusted support worker to explain the project/request consent. The project team will then follow-up as per service user preferences to collect full consent and 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 significant harm to self or a vulnerable adult or child.
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/Skype/in person/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 13-17 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 20 participants per site, and consent from parents/guardians will be sought after the individual themselves has consented. Our qualitative interviews with young participants will only include

those that have turned 16 years and they will have option of being interviewed by a peer researcher, that is, a trained researcher 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, lived experience group 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 or the involvement of those with lived experiences 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 abuse and 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. Our members have requested to be known as the MESARCH Lived Experiences Group. They will test assumptions throughout implementation as in development phases. 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 how we develop and work with our Lived Experiences Group and CI Whitfield will be an expert advisor on promoting the wellbeing of those contributors.

Our strategies, informed by INVOLVE [103] will comprise the following:
(i) immediate appointment of a Public Involvement Coordinator as a central point of contact for the lived experience group members during planning and WS activities and to assist with identifying new members and implementing PPI as per our protocol;
(ii) members of the public, patients and survivors will have permanent positions 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 Lived Experience Group 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. 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 lived experience 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 Lived Experience Group 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 Lived Experience Group 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) Lived Experience Group '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.

## 9 REFERENCES


1. Higgins, J.P.T. and S. Green, Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [Updated March 2011]. 2011: The Cochrane Collaboration.
2. Centre for Reviews and Dissemination, Systematic Reviews: CRD's guidance for undertaking reviews in health care. 2009.
3. Howarth, E., et al., IMPRoving Outcomes for children exposed to domestic ViolencE (IMPROVE): an evidence synthesis. Public Health Research, 2016.
4. Khelaifat, N., et al., Identifying the needs of migrant women exposed to domestic abuse, sources of support and the role of primary care: a protocol for a qualitative meta-synthesis. PROSPERO, 2014(CRD42014008718).
5. Turnbull, J., et al., The work, workforce, technology and organisational implications of the '111' single point of access telephone number for urgent (non-emergency) care: a mixed-methods case study. 2014: Southampton (UK).
6. May, C.R., M. Johnson, and T. Finch, Implementation, context and complexity. Implement Sci, 2016. 11(1): p. 141.
7. May C., F.T., Implementing, embedding, and integrating practices: an outline of normalization process theory. Sociology, 2009. 43(3): p. 535-554.
8. Macdonald, S., et al., Illness identity as an important component of candidacy: Contrasting experiences of help-seeking and access to care in cancer and heart disease. Soc Sci Med, 2016. 168: p. 101-110.
9. Tarzia, L., C. May, and K. Hegarty, Assessing the feasibility of a web-based domestic violence intervention using chronic disease frameworks: reducing the burden of 'treatment' and promoting capacity for action in women abused by a partner. BMC Womens Health, 2016. 16(1): p. 73.
10. Hegarty, K., et al., Screening and counselling in the primary care setting for women who have experienced intimate partner violence (WEAVE): a cluster randomised controlled trial. Lancet, 2013. 382(9888): p. 249-58.
11. Pietrzak, R.H., Goldstein, R. B., Southwick, S. M., & Grant, B. F., Prevalence and Axis I comorbidity of full and partial posttraumatic stress disorder in the United States: results from Wave 2 of the National Epidemiologic Survey on Alcohol and Related Conditions. . Journal of Anxiety Disorders, 2011. 25(456-465).
12. WHO, Global and regional estimates of violence against women: prevalence and health effects of intimate partner violence and non-partner sexual violence. 2013, World Health Organization: Geneva.
13. Lovett, J., Regan, L., & Kelly, L. , SARCs: Developing good practice and maximising potentials. 2004: London.
14. NHS England, Public health functions to be exercised by NHS England. . 2016.
15. Blevins, C.A., et al., The Posttraumatic Stress Disorder Checklist for DSM-5 (PCL-5): Development and Initial Psychometric Evaluation. J Trauma Stress, 2015. 28(6): p. 489-98.

16. Weathers, F.W., Litz, B.T., Keane, T.M., Palmieri, P.A., Marx, B.P., & Schnurr, P.P. . The PTSD Checklist for DSM-5 (PCL-5). 2013; Available from: https://www.ptsd.va.gov/professional/assessment/adult-sr/ptsd-checklist.asp.

17. Brierley, G., et al., Psychological advocacy toward healing (PATH): study protocol for a randomized controlled trial. Trials, 2013. 14: p. 221.

18. Ferrari, G., et al., Domestic violence and mental health: a cross-sectional survey of women seeking help from domestic violence support services. Glob Health Action, 2016. 9: p. 29890.

19. Mullerova, J., et al., Dissociative features in posttraumatic stress disorder: A latent profile analysis. Psychol Trauma, 2016. 8(5): p. 601-8.

20. Bhopal, K. and R.E. Deurchar, Researching Marginalised Groups 2015, London: Routledge.

21. Boyko, J.A., A. Kothari, and C.N. Wathen, Moving knowledge about family violence into public health policy and practice: a mixed method study of a deliberative dialogue. Health Res Policy Syst, 2016. 14: p. 31.

22. Boyko, J.A., C.N. Wathen, and A. Kothari, Effectively engaging stakeholders and the public in developing violence prevention messages. BMC Womens Health, 2017. 17(1): p. 35.

23. Kothari, A. and C.N. Wathen, Integrated knowledge translation: digging deeper, moving forward. J Epidemiol Community Health, 2017. 71(6): p. 619-623.

24. Dalton, J., et al., Potential value of systematic reviews of qualitative evidence in informing user-centered health and social care: findings from a descriptive overview. J Clin Epidemiol, 2017.

25. CSEW, Violent crime and sexual offences-Intimate personal violence and serious sexual assault. . 2015, Office for National Statistics.

26. ONS, Overview of violent crime and sexual offences (year ending March, 2015). . 2016.

27. Bentley, H., O'Hagan, O., Raff, A., & Bhatti, I. , How safe are our children? . 2016, NSPCC.

28. Radford, L., et al., Child abuse and neglect in the UK today. 2011, NSPCC.

29. World Health Organization, Preventing child maltreatment: a guide to taking action and generating evidence. 2006, WHO Department of Injuries and Violence Prevention: Geneva.

30. Walby, S., J. Towers, and B. Francis, Is violent crime increasing or decreasing? A new methodology to measure repeat attacks making visible the significance of gender and domestic relations British Journal of Criminology, 2016. 56(6): p. 1203-1234

31. Campbell, J.C., Health consequences of intimate partner violence. Lancet, 2002. 359: p. 1331-36.

32. Tewkesbury, R., Effects of sexual assaults on men: Physical, mental and sexual consequences. . International Journal of Men's Health, 2007. 6: p. 22-35.

33. Coxell, A.W., & King, M. B. , Male victims of rape and sexual abuse. . Sexual and Relationship Therapy, 2010. 25: p. 380-391.

34. Walker, J., Archer, J., & Davies, M. , Effects of rape on men: A descriptive analysis. Archives of Sexual Behavior, 2005. 34: p. 69-80.

35. Liu, H., Petukhova, M. V., Sampson, N. A., Aguilar-Gaxiola, S., Alonso, J., Andrade, L. H., . . . Kessler, R. C. , Association of DSM-IV Posttraumatic Stress Disorder with traumatic experience type and history in the World Health Organization World Mental Health Surveys. JAMA Psychiatry, 2017. 74(3): p. 270-281.

36. Guina, J., et al., Are Gender Differences in DSM-5 PTSD Symptomatology Explained by Sexual Trauma? J Interpers Violence, 2016.

37. World Health Organisation, World Health Report Reducing Risks, Promoting Healthy Life. 2002.

38. NSPCC, Child Sexual Abuse: An NSPCC Research Briefing. . 2013.

39. Allnock, D. and P. Miller, No one noticed, no one heard: a study of disclosures of childhood abuse. 2013, NSPCC.

40. Dubourg, R., Hamed, J., & Thorns, J. , The economic and social costs of crime against individuals and households 2003/04. 2005, Home Office.

41. Saied-Tessier, A., Estimating the costs of child sexual abuse in the UK. 2014.

42. Ellsberg, M., et al., Prevention of violence against women and girls: what does the evidence say? Lancet, 2015. 385(9977): p. 1555-66.

43. O'Driscoll, C. and E. Flanagan, Sexual problems and post-traumatic stress disorder following sexual trauma: A meta-analytic review. Psychol Psychother, 2016. 89(3): p. 351-67.

44. WHO, Responding to intimate partner violence and sexual violence against women: WHO clinical and policy guidelines. 2013, World Health Organization: Geneva.

45. Gillies, D., et al., Psychological therapies for children and adolescents exposed to trauma. Cochrane Database Syst Rev, 2016. 10: p. CD012371.

46. MacMillan, H.L., et al., Interventions to prevent child maltreatment and associated impairment. Lancet, 2009. 373(9659): p. 250-66.

47. Rasmussen, B., Children's advocacy centers (Barnahus) in Sweden. . Child Indicators Research, 2011. 4: p. 301-321.

48. Brown, K., Bayley, J., & Baxter, A. , Evaluation of the Sexual Assault Referral Centre (SARC) based at George Eliot Hospital, Nuneaton. 2014, Coventry University: Coventry

49. Messham, L., Peers, L., & Alison, L., Feedback for Sheffield children's hospital sexual assault referral centre: Are we getting it right? Journal of the Royal Medical Society, 2015. 23: p. 63-72.

50. Robinson, A., & Hudson, K. , Different yet complementary: Two approaches to supporting victims of sexual violence in the UK. . Criminology and Criminal Justice, 2011. 11(515-533).

51. Hester, M., Regan, L., Coulter, M., Chantler, K., Gangoli, G., Davenport, R., & Green, L., Exploring the service and support needs of male, lesbian, gay, bi-sexual and transgendered and black and other minority ethnic victims of domestic and sexual violence. 2012: Bristol.

52. NHS England, Commissioning Framework for Adult and Paediatric Sexual Assault Referral Centres (SARC) Services. . 2015.

53. Mudaly, N., & Goddard, C. (2009). The Ethics of Involving Children Who Have Been Abused in Child Abuse Research. International Journal of Children's Rights, 17(2), 261-281. doi: 10.1163/157181808X38992

54. Ramsay, J., et al., Advocacy interventions to reduce or eliminate violence and promote the physical and psychosocial well-being of women who experience intimate partner abuse (Review). Cochrane Database of Systematic Reviews, 2009(3).

55. O'Doherty, L., et al., Screening women for intimate partner violence in healthcare settings. Cochrane Database of Systematic Reviews, 2015(7): p. Art. No.: CD007007.

56. Cochrane Collaboration, Review Manager (RevMan). 2011, The Nordic Cochrane Centre: Copenhagen.

57. GRADE Working Group, Grading quality of evidence and strength of recommendations. BMJ, 2004. 328(7454): p. 1490.

58. Thomas J., H.A., Methods for the thematic synthesis of qualitative research in systematic reviews. BMC Medical Research Methodology 2008. 8(45).

59. Barnett-Page, E. and J. Thomas, Methods for the synthesis of qualitative research: a critical review. BMC Med Res Methodol, 2009. 9: p. 59.

60. Brown, S.J., Brady, G., Franklin, A., Bradley, L., Kerrigan, N., & Sealey, C. , Child Sexual Abuse and Exploitation: Understanding Risk and Vulnerability. . 2016, Early Intervention Foundation: London.

61. Rivas, C., et al., Advocacy interventions to reduce or eliminate violence and promote the physical and psychosocial well-being of women who experience intimate partner abuse. Cochrane Database Syst Rev, 2015(12): p. CD005043.

62. O'Doherty, L.J., et al., Screening women for intimate partner violence in healthcare settings: abridged Cochrane systematic review and meta-analysis. BMJ, 2014. 348: p. g2913.

63. Griffiths, S.E., et al., Are digital interventions for smoking cessation in pregnancy effective? A systematic review protocol. Syst Rev, 2016. 5(1): p. 207.

64. COSAI, Benchmarking & evaluation tool to assess sexual assault services. 2012.

65. Finch, T.L., et al., From theory to 'measurement' in complex interventions: methodological lessons from the development of an e-health normalisation instrument. BMC Med Res Methodol, 2012. 12: p. 69.

66. May, C., A rational model for assessing and evaluating complex interventions in health care. BMC Health Serv Res, 2006. 6: p. 86.

67. McEvoy, R., et al., A qualitative systematic review of studies using the normalization process theory to research implementation processes. Implement Sci, 2014. 9: p. 2.

68. Reason, P. and H.E. Bradbury, The Sage handbook of action research. Participative Inquiry and Practice. 2nd ed. 2008, London: Sage.

69. Pawson, R. and N. Tilley, Realistic Evaluation. 1997, London: SAGE Publications Ltd.

70. Hegarty, K., et al., Women's evaluation of abuse and violence care in general practice: a cluster randomised controlled trial (weave). BMC Public Health, 2010. 10(1): p. 2.

71. Ford-Gilboe, M., et al., A tailored online safety and health intervention for women experiencing intimate partner violence: the iCAN Plan 4 Safety randomized controlled trial protocol. BMC Public Health, 2017. 17(1): p. 273.

72. Blanchard, E.B., et al., Psychometric properties of the PTSD Checklist (PCL). Behav Res Ther, 1996. 34(8): p. 669-73.

73. Monson, C.M., et al., Change in posttraumatic stress disorder symptoms: do clinicians and patients agree? Psychol Assess, 2008. 20(2): p. 131-8.

74. Radloff LS. The CES-D scale: a self-report depression scale for research in the general population. Applied Psychological Measurement. 1977;1:385-401..

75. Morgan JF, Reid F, Lacey JH. The SCOFF questionnaire: assessment of a new screening tool for eating disorders BMJ 1999; 319:1467

76. Skevington, S.M., M. Lotfy, and K.A. O'Connell, The World Health Organization's WHOQOL-BREF quality of life assessment: psychometric properties and results of the international field trial. A report from the WHOQOL group. Qual Life Res, 2004. 13(2): p. 299-310.

77. Babor T.F., et al., The Alcohol Use Disorders Identification Test. 2001, WHO.

78. Maxwell, L., et al., Estimating the effect of intimate partner violence on women's use of contraception: a systematic review and meta-analysis. PLoS One, 2015. 10(2): p. e0118234.

79. Grace, K.T. and J.C. Anderson, Reproductive Coercion: A Systematic Review. Trauma Violence Abuse, 2016.

80. Hegarty et al.The Utility of Intimate Partner Violence Screening Questions (Afraid/Controlled/Threatened/Slapped - ACTS) among Antenatal Women in a Victorian Hospital, Australia: a cross sectional study (In preparation)

81. Probst, D., et al., Assessment of Sexual Assault in Clinical Practice: Available Screening Tools for Use with Different Adult Populations. HJournal of Aggression, Maltreatment and Trauma, 2011. 20(2): p. 199-226.

82. Fargas Malet, M., McSherry, D., Larkin, E., & Robinson, C. (2010). Research with children: methodological issues and innovative techniques. Journal of Early Childhood Research, 8(2), 175-192. https://doi.org/10.1177/1476718X09345412

83. Christensen, P., & Prout, A. (2002). Working in ethical symmetry in social research with children. Childhood, 9(4), 477-97. doi: 10.1177/090756820200900400

84. Curtis, L., Personal Social Services Research Unit (PSSRU) University of Kent, Unit Costs of Health and Social Care 2011. 2011.

85. Ophuis, R.H., et al., Cost-effectiveness of interventions for treating anxiety disorders: A systematic review. J Affect Disord, 2017. 210: p. 1-13.

86. Mihalopoulos, C., et al., Is implementation of the 2013 Australian treatment guidelines for posttraumatic stress disorder cost-effective compared to current practice? A cost-utility analysis using QALYs and DALYs. Aust N Z J Psychiatry, 2015. 49(4): p. 360-76.

87. van Hout, B.A., et al., Costs, effects and C/E-ratios alongside a clinical trial. Health Econ, 1994. 3(5): p. 309-19.

88. Briggs, A.H., et al., Model parameter estimation and uncertainty: a report of the ISPOR-SMDM Modeling Good Research Practices Task Force--6. Value Health, 2012. 15(6): p. 835-42.

89. Drummond, M.F., Sculpher, M.J., Claxton, K., Stoddart, G.L., Torrance, G.W., Methods for the Economic Evaluation of Health Care Programmes 2015, Oxford Medical Publications: Oxford.

90. Blue Sky Centre George Eliot Hospital NHS, Annual Report 2013-14 Coventry and Warwickshire's Sexual Assault Referral Centre. 2014.

91. Gunn, J., et al., A trajectory-based approach to understand the factors associated with persistent depressive symptoms in primary care. J Affect Disord, 2013. 148(2-3): p. 338-46.

92. Murray, M., Narrative Psychology, in Qualitative Psychology: A practical guide to research methods, J.A. Smith, Editor. 2003, Sage: London.

93. Anderson, S., et al., Violence prevention and municipal licensing of indoor sex work venues in the Greater Vancouver Area: narratives of migrant sex workers, managers and business owners. Cult Health Sex, 2015. 17(7): p. 825-41.

94. Kim, T., et al., Somos Hermanas Del Mismo Dolor (We Are Sisters of the Same Pain): Intimate Partner Sexual Violence Narratives Among Mexican Immigrant Women in the United States. Violence Against Women, 2016.

95. Foster, J.M. and W.B. Hagedorn, Through the eyes of the wounded: a narrative analysis of children's sexual abuse experiences and recovery process. J Child Sex Abus, 2014. 23(5): p. 538-57.

96. Becker, G., Disrupted lives: how people create meaning in a chaotic world. 1997, Berkeley, CA: University of California Press.

97. Wallace, L.M., K.E. Brown, and S. Hilton, Planning for, implementing and assessing the impact of health promotion and behaviour change interventions: a way forward for health psychologists. Health Psychol Rev, 2014. 8(1): p. 8-33.

98. Horvath, H., et al., Preterm birth: the role of knowledge transfer and exchange. Health Res Policy Syst, 2017. 15(1): p. 78.

99. WHO, Ethical and safety recommendations for intervention research on violence against women. Building on lessons from the WHO publication Putting women first:ethical and safety recommendations for research on domestic violence against women. 2016, WHO.

100. Valpied, J., et al., "Sometimes cathartic. Sometimes quite raw": Benefit and harm in an intimate partner violence trial Aggression and Violent Behaviour, 2014. 19(6).

101. Devries, K., et al., Intimate partner violence and incident depressive symptoms and suicide attempts: a systematic review of longitudinal studies. PLoS Med, 2013. 10(5): p. e1001439.

102. National Patient Safety Agency, Data Monitoring Committees in clinical trials: guidance for research committees. 2010.

103. INVOLVE. 2017; Available from: http://www.invo.org.uk/resource-for-researchers-case-studies/.

104. Hegarty K, Bush R, Sheehan M. The composite abuse scale: further development and assessment of reliability and validity of a multidimensional partner abuse measure in clinical settings. Violence Vict 2005;20:529–47

105. UNCRC. (1989). The United Nations Convention on the Rights of the Child. Retrieved from:https://downloads.unicef.org.uk/wpcontent/uploads/2010/05/UNCRC_united_nations_convention_on_the_rights_of_the_child.pdf

106. Øverlien, C., & Holt, S. (2017). Including Children and Adolescents in Domestic Violence Research: When myths and misconceptions compromise participation. In S. Holt, C. Øverlien, & J. Devaney (Eds.),

Responding to Domestic Violence - Emerging Challenges for Policy, Practice and Research in Europe (pp. 97-112). Philadelphia: Jessica Kingsley Publishers.

107. Prout, A., & James, A. (1990). A New Paradigm for the Sociology of Childhood? Provenance, Promise and Problems. In A. James & A. Prout (Eds.), Constructing and Reconstructing Childhood: Contemporary Issues in the Sociological Study of Childhood (pp. 7-33). London: Falmer Press.

108. Powell, M. A., & Smith, A. B. (2009). Children's Participation Rights in Research. Childhood, 16(1), 124-142.

109. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. Fifth Edition. Washington, DC: American Psychiatric Association; 2013.

110. Berman, A. H., Bergman, H., Palmstierna, T., & Schlyter, F. (2005). Evaluation of the Drug Use Disorders Identification Test (DUDIT) in Criminal Justice and Detoxification Settings and in a Swedish Population Sample. European Addiction Research, 11(1), 22-31.

111. Al-Janabi H, Flynn T, Coast J. (2012) Development of a self-report measure of capability wellbeing for adults: the ICECAP-A. Quality of Life Research 21: 167-176 (DOI: 10.1007/s11136-011-9927-2).

112. EuroQol Research Foundation EQ5D Accessed online: 01/04/2019: https://euroqol.org/eq-5d-instruments/

113. McManus S, Hassiotis A, Jenkins R, Dennis M, Aznar C, Appleby L. (2014) Suicidal thoughts, suicide attempts, and self-harm. Adult Psychiatric Morbidity Survey 2014 CHAPTER 12 Accessed online: 12/05/2020 : https://digital.nhs.uk/data-and-information/publications/statistical/adult-psychiatric-morbidity-survey/adult-psychiatric-morbidity-survey-survey-of-mental-health-and-wellbeing-england-2014