PROTOCOL

1. **Title:** Improving outcomes for survivors of human trafficking

2. **Trial registration:** Intended registry: ISRCTN

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5. **Roles and Responsibilities**

    a. Protocol contributors:

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    c. Role of the study sponsor and funders:

        The study sponsor and funders have no role in study design; collection, management, analysis, and interpretation of data; writing of the report; or the decision to submit the report for publication.

    d. Study Steering Committee:

        The Study Steering Committee (SSC) meets a minimum of twice per year and comprises Dr Nicola Wright (Chair), University of Nottingham; Dr Eva Bonin, LSE, Ms. Justine Currell, Unseen UK; Ms Minh Dang, Survivor Alliance; Ms. Tatiana Gren-Jardan, Justice and Care; Dr Rebecca Jones, UCL; Prof Cornelius Katona, Helen Bamber Foundation; Prof Cathy Zimmerman, London School of Hygiene & Tropical Medicine.

6. Background and rationale

Human trafficking is defined as the "recruitment, transportation, transfer, harbouring or receipt of persons by means of threat or use of force or other forms of coercion, of abduction, of fraud, of deception, of the abuse of power, or of a position of vulnerability or of the giving or receiving of payments or benefits to achieve the consent of a person having control over another person, for the purpose of exploitation" (1). It is estimated to affect 136,000 women, men, and children in the United Kingdom (2).

Survivors of trafficking report a range of health problems, especially psychological distress. Previous research has found 78% of women and 40% of men in contact with post-trafficking support services in England screened positive on validated and specific measures of depression, anxiety or post-traumatic stress disorder (3). Elsewhere, research with women survivors of trafficking who had returned to Moldova found that 54% met diagnostic criteria for DSM-IV mental disorder using the Structured Clinical Interview for DSM-IV (SCID) (4).

Failure to provide effective mental health support for trafficked people increases the risk of persisting mental ill health and, in consequence, poor social outcomes, which carry costs for both individuals and society. Yet, evidence on what helps people's recovery is absent (5, 6). .A systematic review of published and unpublished experimental, quasi-experimental, and pre-experimental studies reporting on the effectiveness of post-exit intervention programs for trafficked people identified only six eligible studies (7). The majority of these studies were appraised as having been poorly designed and executed, none had a sample size larger than 55 and the review failed to reach any conclusions with regards to what constitutes an effective intervention for this population.

In the UK, survivors of human trafficking are entitled to government-funded support that aims to help them recover from abuse and rebuild their lives. Data show a year on year increase in the number of trafficked people being referred into support, with 1,856 people referred for support in 2017/18, 1,554 in 2016/17, 1,400 in 2015/16, and 1,097 in 2014/15 (8). Support is currently provided by a network of 12 non-governmental organisation (NGOs) that provide specialist post-trafficking support as part of a Victim Care Contract (VCC) managed by The Salvation Army. The provision of this support represents a significant financial commitment from the government at an average of £18m per year (9).

VCC support follows an "advocacy" model, although the specific service model and the intensity of support varies between organisations (10, 11). Advocacy interventions are defined as strengths-based, survivor-centred services based on empowerment models, in which caseworkers help service users to make sense of their situations, achieve self-identified goals, link them to community services, and provide ongoing support and informal counselling (12). Caseworkers generally do not have a background or training in psychological therapies and do not provide counselling or other specified forms of therapy.

Two small (n=28 and n=36) uncontrolled studies examined the impact of advocacy interventions with refugees in the USA. These studies found participants reported reduced psychological distress following intervention (13, 14). One controlled study found reduced depression scores in both intervention and control groups, but reported likely contamination in their control group, with informal support having been provided to controls during data collection (15). A Cochrane review of 13 randomised controlled trials of advocacy interventions for victims of domestic violence concluded that intensive advocacy improved everyday life and reduced experiences of physical violence (12).

The generalisability of these findings to trafficked people is not clear. However, findings that risk of mental disorder is higher for survivors of human trafficking who have increased social needs and lower levels of social support (3, 4, 16) suggests a need for interventions that that address current stressors and improve social support. The evaluation of advocacy-based interventions is therefore a priority need in informing the design of future services and to guide commissioning and investment. However, outcomes have not been evaluated (either in the UK

or elsewhere): the effectiveness of advocacy interventions in reducing psychological distress among survivors of trafficking remains unknown.

7. Aims & objectives

The current study aims to assess the effectiveness of advocacy-based casework support in improving the mental health of trafficked people. We hypothesize that advocacy-based casework support for trafficked people is beneficial and dose-dependent. There are no data examining how service level variations or specific components of care affect mental health outcomes for trafficked people. We therefore additionally propose research to explore which service configurations and components of support appear most beneficial for which trafficked people. This research will be among the first rigorous intervention evaluation studies to assess the effectiveness of a post-trafficking intervention and will contribute to public mental health initiatives by providing evidence for a understudied group at high risk of mental health problems (17).

Specific objectives of this study are to:

1. Evaluate the effectiveness of advocacy interventions in improving the mental health of people who have been referred into NGO services for post-trafficking support through the UK NRM.
2. Evaluate whether aspects of the advocacy intervention experience thought to improve outcomes modify the effect of the advocacy intervention on mental health and wellbeing; in particular, to test whether
    a. the effect changes as the amount of support received increases
    b. the effect varies according to structural or service characteristics of NGOs;
3. Assess the service use and costs associated with advocacy interventions for trafficked people who have been referred into NGO services

8. (a) Study design

Exploratory prospective uncontrolled cohort study and realist evaluation with assessments at baseline (T1) (i.e. at or soon after onset of advocacy support), at 3 months follow up (T2) and at 6-months follow-up (T3). The primary outcome is reduced psychological distress (measured using the CORE-OM) at 3 months follow up (T2) compared with baseline (T1).

(b) Rationale for not including a control group

It is not feasible to recruit a control group for the following reasons: (1) All trafficked people who enter the National Referral Mechanism (NRM) are entitled to government-funded NGO support. Support is provided by a national network of NGOs; there is enough capacity, so NGOs do not operate waiting lists that could serve as a source of controls; (2) Trafficked people who enter the NRM but elect not to receive NGO support are extremely difficult to identify for recruitment. The PI's previous research showed that it is not feasible to recruit from settings such as the NHS and Local Authorities (4).

This study will therefore assess whether mental health among survivors of trafficking improve over the period during which advocacy support is provided, with measures taken at or soon after onset of advocacy intervention, at 3 months follow up, and at after a further 6 months follow up. To support the interpretation of any detected change as a causal intervention effect in the absence of a control group dose-response relationships between change over time and

factors describing the intervention experience will be assessed. Such factors are the "dose of support" which will quantify by frequency and duration of support and "intervention characteristics" (while all NGOs provide advocacy-based support, the structural characteristics of services and the relative emphasis placed on components of support provided vary - reports of the National Audit Office and Public Accounts Committee, and conversations with NGOs, indicate considerable variability between services (9, 18).). Participant characteristics that predict outcomes will also be identified and dose-response analyses will be adjusted for their potential confounding effect.

9. Study setting

A total of six of the 12 NGOs providing government-funded advocacy interventions to survivors of trafficking in England have been purposively selected for variation in structural characteristics and service model. Participating organisations are as follows:

1. Ashiana
2. BAWSO
3. Hestia
4. Medaille Trust
5. Migrant Help UK
6. Salvation Army Accommodation Services

10. Eligibility criteria

Study 1 – Cohort Study

Inclusion criteria

To be eligible for inclusion in the study, participants must meet all inclusion criteria:

1. Be aged 18 years or older;
2. Have entered into the UK National Referral Mechanism;
3. Have consented to receive advocacy support from a participating non-governmental organisation (NGO);
4. At date of baseline interview, have received fewer than 14 days' residential advocacy support or 28 days' outreach advocacy support from any NGO through the UK National Referral Mechanism;
5. No longer be being exploited by their traffickers.

If the participant has undergone an age determination procedure (i.e. is age-disputed), the participant's age as confirmed by the local authority should be used.

Exclusion criteria

People will be excluded from the study if they:

1. Do not have the capacity to provide consent to participate in the studies, including because of learning disability, psychotic illnesses or severe drug or alcohol problems.

Eligibility will be assessed by trained NGO staff members referred hereafter as "NGO Researchers".

Study 2 - Qualitative study

Inclusion criteria

Survivors- To be eligible for inclusion, survivors must meet the inclusion criteria for the above cohort study and additionally have consented to participate in the qualitative study. English language proficiency is not a selection criterion.

Staff - To be eligible for inclusion, staff must work (on a paid or voluntary basis) at one of the participating NGOs to be eligible for inclusion

Exclusion criteria

Individuals will be excluded from the study if they:

1. Do not have the capacity to provide consent to participate in the studies, including because of learning disability, psychotic illnesses or severe drug or alcohol problems.

Eligibility will be assessed by a trained KCL researcher.

11. Intervention

The intervention being evaluated is advocacy support as provided by NGOs during the study period. Advocacy interventions are multi-faceted and non-manualised, and the specific support provided varies according to service model (i.e. between NGOs) and to individual need (i.e. between participants). The intervention is delivered by NGO caseworkers.

The core components of advocacy interventions for this population, as identified by NGOs during work to develop initial programme theory, typically include:

1. Providing information about rights and support options
2. Offering encouragement, empathy, and respect;
3. Providing informal counselling and setting goals;
4. Increasing access to community resources and to housing and welfare support;
5. Increasing social support;
6. Building skills, including training, education, and life skills, and assistance to access employment.

In order to access the intervention, trafficking survivors must consent to be referred into the National Referral Mechanism (the "NRM" - a centralised system for identifying and referring trafficked people into government-funded support services). Individuals may not self-refer into the NRM but must be referred by a First Responder organisation.

Individuals who have been referred into the NRM undergo a two-stage decision-making process regarding their claim to have been trafficked. Decisions are made by a centralised Single Competent Authority and not by NGOs. An initial "reasonable grounds" decision is usually made within five days of referral into the NRM. This is a low threshold test which determines the person's status as a "potential victim of trafficking"; individuals in receipt of a positive reasonable grounds decision are then eligible to receive NGO support funded through the UK Victim Care Contract. Individuals will ordinarily have received a positive reasonable

grounds decision prior to entry into NGO support, though this is not always the case. Individuals who have entered NGO support prior to receiving a reasonable grounds decision who then receive a negative decision are exited from support services.

A second "conclusive grounds" decision regarding an individual's claim to have been trafficked will then be made. The target for decision-making is 45 days, though in practice the decision-making period is often longer. An individual who receives a negative conclusive grounds decision is determined not to be a victim of trafficking, and is exited from support services. Individuals who receive a positive conclusive grounds decision can continue to receive NGO support services; the default support period in England and Wales is 45 days. Individuals can, however, apply to extend their access to support services by up to 6 months (renewable) via the Recovery Needs Assessment process.

Prior to intake, an Initial Assessment will be completed in order to determine eligibility, risk, and urgent needs. Individuals who lack mental capacity, who have severe drug and alcohol problems, or who are acutely mentally unwell are not supported by the NGO services. After arrival at NGO services, a Detailed Needs Based Assessment is undertaken, followed by an Individual Support Plan. The intervention is considered to commence at the initiation of the individual support planning process. The support plan is individualised but organised according to the following categories:

1. Secure and appropriate accommodation
2. Provision of subsistence payments
3. Access to emergency health services
4. Advocacy for specialist services
5. Assistance with criminal proceedings
6. Access to education for dependent school age children
7. Access to compensation

These categories align to the entitlements of survivors of trafficking under the Council of Europe Convention on Action Against Trafficking in Human Beings (ECAT) rather than to advocacy activity categories described by the initial programme theory.

Other concomitant care and interventions are permitted during the trial (e.g. psychological interventions); data on receipt of other health and social care services are collected (see section 12, outcomes).

12. Outcomes

Study 1 – Cohort Study

Outcomes align with the initial programme theory for the advocacy intervention developed in collaboration with NGOs and informed by relevant literature. Commonly-used, well-validated measures have been chosen where these exist for the outcome of interest and items are relevant to the experiences of trafficking survivors.

Primary outcome

The primary outcome is psychological distress at T2 versus T1. Psychological distress will be measured by the Clinical Outcomes in Routine Evaluation- Outcome Measure (CORE-OM), a 34-item questionnaire which measures global psychological distress. The questionnaire was

designed to assess efficacy and effectiveness across multiple disciplines offering psychological therapies (19). It has good internal and test-retest reliability (0.75-0.95), large differences between clinical and non-clinical samples, and good sensitivity to change (19). Validation work in general population samples shows the CORE-ORM is highly correlated (r=0.77) with the Clinical Interview Schedule-Revised (CISR), supporting convergent validity (20). It has good acceptability in domestic violence research (21, 22) and has been used in research with survivors of human trafficking (23).

Secondary outcomes

Secondary outcomes are CORE-OM score at T3, and health-related quality of life, social support, unmet needs, perceived safety and risk of harm, autonomy, and use of health and social care services at T2 and T3.

1. **Health-related quality of life** will be measured using the EQ-5D-5L and SF-12 (25, 26) and the Recovering Quality of Life-10 (ReQoL-10) (27), a new 10-item Patient Reported Outcome Measure (PROM) that has been developed to assess the quality of life for users of mental health services.
2. **Use of health and social care services** will be measured using an adapted version of the Adult Service Use Schedule (AD-SUS) (24). The AD-SUS is a structured instrument which collects data on participants' use of health and social care services for the three-months preceding interview (at baseline) or since the previous interview (at any follow-up point).
3. **Unmet needs** will be measured using an adapted version of the Post-Migration Living Difficulties Checklist (PMLDC) (29), a checklist to assess current life stressors of asylum-seekers. Each item is rated on a 6-point scale from 'no problem' to 'very serious problem', with a composite score determined. This study will use a 22-item version adapted for use in the UK. After completion of the scale, participants are asked whether they have experienced any "other" problems that have not been covered in the scale. Responses to these questions are not scored and will be used to inform future iterations of the instrument for use with this population. The questionnaire will be administered in the same way at each time point, i.e. at T2 and T3, individuals will not be asked about the status of problems disclosed under "other" problems at earlier time points.
4. **Social resources and support** will be measured using an adapted version of the Social Support Network scale (SSN) is a 12- item questionnaire covering three domains: acceptance and support, access to tangible help in emergencies, and access to and knowledge of resources (28). One question has been amended; whereas the original questionnaire asks "I would know where to tell a friend to get help if they were being harmed or beaten by a partner", the adapted scale asks "I would know where to tell a friend to get help if they were being exploited or controlled"
5. **Perceived safety and risk of harm** will be measured using an adapted version of the Intimate Partner Violence Threat Appraisal and Fear Scale uses a four-point Likert scale to measure the perceived likelihood of actual or threatened harm (30). Seven of the original 17 harm items were identified as likely to be relevant to trafficking survivors and have been selected for use in this study.
6. **Autonomy** will be measured using a six-item measure developed and piloted by the Centre for Analysis of Social Exclusion, University of Oxford (31), measuring three components of autonomy: active decision-making, coercion, and perceived range and quality of options.

Validated translations for the above instruments are not available across all of the language groups expected to be represented in the study sample. Although a limited number of translations are available for some of the above instruments (e.g. the CORE-OM, the EQ-5D-5L) their quality is not considered to be high. Questions will therefore be translated by interpreters during interviews.

Additional baseline measures

Measures to be collected at baseline also include participant level socio-demographic and trafficking related factors that may modify the intervention effects or predict outcomes and so may act as confounders of the dose response relationships investigated by research questions 2 and 3. Measures that will be additionally collected at T2 and T3 are indicated by an asterisk. These are:

1. Gender
2. Age
3. Nationality
4. Immigration status*
5. Housing status*
6. Type of exploitation
7. Duration of exploitation
8. Time since exploitation

Process variables

NGOs routinely record participant-level data on the type, frequency, and duration of advocacy support, including number of sessions. These data will be extracted from client records and used to construct a measure of dose.

Study 2 – Qualitative Study

Data will be collected using qualitative semi-structured interviews. Interviews will follow topic guides; indicative topic guides are appended as supporting documentation. The topic guides will be finalised for piloting following review and feedback by participating organisations, the study steering committee, and the survivor research advisory group. The topic guides will be piloted with three survivor and three staff participants and then reviewed.

Interviews with survivors will explore, for example, which aspects of support made a difference to them, why, and how, and which were less helpful (mechanisms); and perceived changes in safety, risk, autonomy, social connectedness, unmet needs, and mental health and wellbeing attributable to advocacy support (outcomes) or to other circumstances; and what barriers and enablers they identify in the context of assistance for the service and for themselves in achieving improved safety, risk, autonomy, social connectedness, unmet needs, and mental health and wellbeing (context). Where survivors had less successful outcomes or experiences, interviews will explore opinions about what might have helped. Professional interpretation will be provided as required.

Interviews with staff will explore, for example views about the type of support provided, the ways in which programme components are implemented, the way change is facilitated, current organisational practice and culture, local and national context of trafficking support provision, enabling and constraining factors (contextual factors); what does and does not help survivors and why (mechanisms); and perceived changes in the mental health and wellbeing of service users (outcomes).

13. Participant timeline

The baseline questionnaire (T1) will take place after commencement of individual support planning (i.e. start of intervention) and within two weeks of intake into NGO support services (for clients receiving residential advocacy support) or within 4 weeks of intake (for clients receiving outreach advocacy support).

Follow-up comprises completion of questionnaires at 3 months' follow-up (T2) and at 6 months' follow-up (T3). A 28 day window, defined as 7 days before and 21 days after the due date, will be available to complete the T2 and T3 follow up interviews. Participants who do not complete T2 and T3 interviews with the defined window will be considered to have missed that data collection point. Participants who do not complete T2 interviews will remain eligible to participate at T3.

The data collection timetable is as follows

Research data type	Form name	T1 (Baseline)	T2 Follow Up (+90 days)	T3 Follow Up (+180 days)	Ongoing	End of Study
Baseline characteristics	1. Registration Form	X				
Baseline characteristics	2. Eligibility	X				
Baseline characteristics	3. Trafficking-Related Characteristics	X				
Baseline characteristics	5. Immigration and Housing Status	X	X	X		
Primary outcome	6. CORE-OM	X	X	X		
Secondary outcome	7. EQ-5D-5L	X	X	X		
Secondary outcome	8. SF-12	X	X	X		
Secondary outcome	9. ReQoL-10	X	X	X		
Secondary outcome	11. Adapted AD-SUS	X	X	X		
Secondary outcome	12. Adapted PMLDC	X	X	X		
Secondary outcome	13. Adapted SSN	X	X	X		
Secondary outcome	14. Adapted IPV Threat Appraisal and Fear Scale	X	X	X		
Secondary outcome	15. Autonomy	X	X	X		
Process variables	16. Advocacy Support Attendance Log				X	
CONSORT data	4. Status Form		X	X		
CONSORT data	17. Withdrawal Form				X	
-	18. PI Sign Off					X

14. Sample size

<u>Study 1 – Cohort Study</u>

The study will aim to recruit 450 participants. This will allow a loss to follow up of 25% between T1 (baseline) and T2 (3 months follow up) and a further loss to follow up of 25% between T2 and T3 (6 months follow-up) to ensure we achieve our required sample size of 250 participants. Recruiting 5 participants per NGO per month over an 18-month recruitment period will be sufficient to achieve the desired sample size.

This sample size will be sufficient to detect small standardised differences between at or soon after onset of advocacy (T1) and after receiving advocacy support for 3 months and 6 months (d=0.18 and d=0.20 for T2 and T3 respectively) with 90% power using a two-tailed paired samples t-test at the 5% significance level. These are smaller than effect sizes detected in studies of psychological interventions using the CORE-OM as an outcome measure (32) and in trials of interventions for women who have experienced domestic violence (33-35). The sample size will enable the detection of a pre-post difference score as small as 3.2 and 3.6 at T2 and T3, respectively. This is comparable to pre-post difference scores on the CORE-OM detected by trials of an advocacy intervention for female victims of domestic violence (22). It is also smaller than the reliable change index for the CORE-OM (≥5), i.e. there is sufficient power to detect a statistically significant difference in CORE-OM score (36). Calculations are based on a standard deviation estimate for the CORE-OM (SD=18) taken from baseline data for a sample of trafficked women referred for psychological therapy (23).

Study 2- Qualitative study

The study will aim to recruit up to 30 service users who participated in the cohort study (approximately 6 per participating organisation) and 15 staff (approximately 3 per participating organisation). We will recruit a purposive sample aiming to ensure representation from each of the five participating organisations and to maximize variation in characteristics likely to be relevant to outcomes identified in our preliminary theory of change (e.g. social connectedness, unmet needs, mental health and wellbeing). Based on previous research we expect these characteristics will include gender, type of trafficking, and secure versus insecure immigration status. We will similarly recruit a purposive sample of staff, selecting for variation in level, years of experience, and role.

15. Recruitment

Study 1 – Cohort Study

Participants will be recruited over an 18-month period: 1st March 2020-31st August 2021. In the first month, recruitment will be restricted to a single organisation. From 1st April 2020, recruitment will roll out to the remaining sites.

The intake criteria of participating organisations are such that all clients should be eligible for participation in the study, i.e. they should meet all of the inclusion criteria and none of the exclusion criteria. Nonetheless, caseworkers will complete an eligibility screen prior to giving written and verbal information about the study to their clients during Initial Support Planning. All incoming clients will be screened for eligibility and, with the exception of clients who are screened as ineligible, all will be provided with information about the study. The written information to be provided comprises the participant information sheet and consent form. Translated copies of participant information sheets and consent forms will be available for clients who are not able to read English.

Clients will be asked to indicate whether they wish to be contacted by the NGO researcher to discuss potential participation or whether they wish to contact the NGO researcher themselves; their preference will be recorded on the eligibility screening sheet.

NGO researchers will contact clients who indicate that their preference is to be contacted directly after a minimum of 24 hours. These professionals will confirm eligibility to participate and explain the study aims and procedures; the nature of informed consent; potential risks; and any queries/concerns service users may have regarding their participation in the study. Where NGO researchers are caseworkers, they may provide information about the study to their own clients during Initial Support Planning, but they may not re-contact clients to determine eligibility and intention to participate in the study, take informed consent, or administer research interviews.

Clients who decline to enter the study will be asked if their basic socio-demographic characteristics can be collected anonymously to determine whether there are differences between participants and non-participants. Clients intending to participate in the study will be asked to agree a date for the T1 interview.

Study 2 - Qualitative study

Survivors - A purposive sample of potential participants will be identified by the research team based on characteristics of interest following participation in the T1 interview. Cohort study participants are informed on the participant information sheet that they may be contacted and asked to participate in an additional qualitative study. Participant information sheets for the qualitative study will be posted to selected participants and prospective participants asked to contact the KCL researcher by telephone, email, or return of post if they would like to discuss participation in the study. A stamped addressed envelope and response card will be enclosed with the information sheet. If no response has been received after a minimum 5 working days, prospective participants will be contacted by telephone by the KCL researcher to ask if they would like more information about the study. The researcher will leave a voicemail message if no answer is received. A second attempt to contact the potential participant will be made after a minimum of a further 5 working days. If no response is received after the second follow-up attempt, it will be assumed that the survivor does not want to participate in the study.

Staff - A purposive sample of potential participants will be identified at each site by the research team based on characteristics of interest (level, years of experience, and role) in collaboration with the lead NGO contact and/or NGO researcher. Potential participants will be contacted by email or by post with a copy of the participant information sheet and invited to participate. Prospective participants will be asked to contact the KCL researcher by telephone or email if they would like to discuss participation in the study. If no response has been received after a minimum 5 working days, prospective participants will be re-contacted by the KCL researcher by telephone or by email to ask if they would like more information about the study. A second follow up attempt will be made by telephone or by email after a minimum of a further 5 working days. If no response is received after the second follow-up attempt, it will be assumed that the staff member does not want to participate in the study.

16. Assignment of intervention

The intervention is provided as standard care to survivors of trafficking who have consented to be referred into and receive support through the UK National Referral Mechanism. All participants will receive the intervention.

17. Blinding

There is no blinding of participants, providers, outcome assessors, or analysts.

18. Data collection methods

18a Personnel

To minimise participant burden and facilitate engagement:

- NGO caseworkers will screen incoming clients for eligibility and provide a verbal summary and written information (participant information sheet and consent form) about the study.
- NGO researchers will, after a minimum of 24 hours, confirm eligibility to participate and study information and schedule T1 interview for those intending to participate.
- NGO researchers will take informed consent and administer the T1 questionnaire and T2 questionnaire.

The PI/post-doctoral researcher will visit participating organisations to provide training to NGO researchers to ensure quality and consistency of administration; additional training will be provided as required, for example if new caseworkers are recruited or if problems of questionnaire administration or completion are identified. Fortnightly calls will be made to sites by a post-doctoral researcher to monitor recruitment and completion of questionnaires and enquire about any difficulties with recruitment or administration of questionnaires.

To minimise burden on participating organisations:

- The KCL researcher will administer T3 questionnaires
- The KCL researcher will administer T2 questionnaires to participants who leave the recruiting organisation, e.g. because they voluntarily withdraw from NRM support, because NRM support is withdrawn following a negative reasonable or conclusive grounds decision, or because they are moved to a new NRM support service.
- The KCL researcher will conduct interviews with survivors and staff for the qualitative study.
- Data entry for the cohort study will be completed at KCL under the supervision of the post-doctoral researcher.

To facilitate participation by clients who do are not proficient in English:

- Independent and professionally qualified interpreters will be available to interpret during the provision of information about the study, informed consent processes, and questionnaire administration.

18b Mode

Interviews may be scheduled to take place either face-to-face or by telephone; the mode of interview will be recorded.

18c Interpretation

Only independent, professionally-qualified interpreters may be used. Where an interview takes place with the assistance of an interpreter, this should be recorded on the questionnaire pack, along with the language, mode (i.e. face-to-face or telephone interpretation) and the initials of the interpreter. Interpreters must sign or provide verbal assent to a confidentiality agreement prior to the interview.

18d Reimbursement of expenses:

If clients have incurred expenses in attending the interview (e.g. travel or childcare expenses) these should be reimbursed in cash prior to the informed consent process. Clients must initial an expenses receipt form after receiving expenses payments.

18e Informed consent

The researcher will explain the information contained within the participant information sheet and answer the participant's questions about the research before completing the consent form.

18f Vouchers

All participants will be given multi-use (e.g. Love2Shop/One4All) vouchers to thank them for their time. The value of the voucher varies by time point: £10 at T1 and T2, and £20 at T3. Vouchers should be given to participants immediately after informed consent; participants should sign/initial a voucher receipt form upon receiving their voucher.

18g Questionnaire administration

Study 1 – Cohort Study

PROTECT-II uses a researcher-administered (i.e. rather than a self-administered) questionnaire. Scales should be administered in the order they appear in the pack, and questions asked in the order they appear in the individual scales.

If an interview is terminated prior to completion (i.e. because of participant preference, participant distress etc.), the researcher should complete the remainder of the questionnaire indicating that questions have not been asked (i.e. using the "not asked" missing data code).

Study 2 – Qualitative Study

Interviews will follow a topic guide and will be audio-recorded on an encrypted digital recorder.

18h Assignment of participant identification number:

Participant Identification Numbers (PINs) are assigned to cohort study participants via the MACRO database after the T1 interview has been completed/terminated. After completing the interview, the NGO researcher should log into the MACRO database and complete the participant Registration Form. Completion of this form automatically generates a PIN. The PIN should be written in ink at the top of all sheets in the questionnaire pack and the questionnaire pack then securely stored as detailed below.

18i Retention

People recruited to the research may (a) drop out of the support programme; (b) drop out of

the research; (c) both. We will seek to retain participants in the research if they drop out of the support programme. As per section 16a, the KCL researcher will administer T2 and T3 questionnaires to participants who leave the recruiting organisation.

We will use several strategies to reduce drop out from the research based on the experience of the applicants and collaborators in conducting evaluations of complex interventions. These include:

- Asking participants to complete a contact details information sheet at baseline, including a contact telephone number and (if applicable) email address, plus a contact telephone number for a person they trust. The participant information sheet explains that we request the details of a trusted contact in case we are unable to get in touch with them at follow-up.
- Upon completion of T2, provision of a business card with the details of the Study Manager plus a stamped addressed envelope in case of change in contact details.
- Upon receipt of information following T2, the Study Manager will telephone the participant to introduce themselves, thank them for participating to date, and to let them know they will be in touch with them in three months' time to complete the final questionnaire. This additionally provides an opportunity to recheck contact details.
- Providing flexible follow-up appointments (see section 13 for details of data collection windows);
- Providing expenses to cover travel to appointments if required;
- Sending text message reminders at interview 1 week and 1 day prior to follow-up appointments;
- Maintaining contact between data collection points (e.g. thank you cards, newsletters);
- Providing multi-use shopping vouchers thank participants for their time.

When seeking to schedule an interview by telephone, voice messages may be left referring to their interest in a research study, but for confidentiality and safety reasons will not make mention of either human trafficking or mental health. After two failed telephone contact attempts, the researcher will send a text message. A further two follow-up calls and a further text message can be sent, after which the researcher will begin to work through the locator contacts given by participants at the point of recruitment into the study.

18j Withdrawal

Participants may withdraw from the research at any time. A Withdrawal Form should be completed in the MACRO database for participants who have chosen to withdraw from the research or who have been lost to follow up. Participants may additionally choose to withdraw their data from analysis by contacting the Principal Investigator.

19. Data management

19a Data entry

<u>Study 1 – Cohort Study</u>

Data will be entered by trained researchers at KCL into a MACRO database. Where relevant, minimum and maximum values are programmed to promote data quality.

Data checks will be conducted by the study manager during data entry to identify potential errors and missing data that may indicate incorrect administration or recording. Further training will be provided in the event of problems being identified. Quarterly database extracts will be provided to identify data entry errors.

Study 2 – Qualitative Study

Audio recordings of the qualitative interviews will be taken on encrypted digital recorders and transcribed by a professional transcription agency following signature of a confidentiality agreement.

19b Data security and storage

Personal data will be protected in line with the requirements of the General Data Protection Regulation (GDPR).

All hard-copy data are to be stored in key-locked filing cabinets at the staff offices of the NGO prior to transfer to a key-locked filing cabinet at KCL. Consent forms and questionnaires are to be stored separately at both the staff offices of the NGO and of the university site. No names should be written on the questionnaire.

Access to the KCL site is highly restricted: key-locked cabinets are stored in key-locked offices, the doors to which are locked when research team members are not present. Access to office buildings and corridors is restricted to identity card holders by means of swipe card readers. Although the exact security arrangements of participating NGOs may vary between sites, access is also highly restricted due to the need to protect trafficked people from potential risk of harm and staff offices are locked when staff are not present.

Hard copy data may be transferred between the NGO and the university manually or using a signed for and tracked mail service. Manual transfers are scheduled for when the study PI or manager is visiting the site. The data should be signed out by the PI/post-doctoral researcher and counter-signed by a representative of the NGO. The data should be transferred into a padlocked bag and taken directly to the university site, where they must be signed in and securely stored.

If data are removed from the filing cabinet by a member of the research team (e.g. for data entry into the MACRO database) they must be signed out and signed back in upon return. Data must be returned to the filing cabinet if the researcher is leaving the office even if temporarily.

The departmental postal address for the location within the College at which research data will be stored during and after the study is as follows: PO31 David Goldberg Centre, IOPPN, De Crespigny Park, London, SE5 8AF.

Research data entered into the electronic MACRO database will be stored on the secure university network/server.

Project data (i.e. data routinely collected by the NGO) will be extracted by The Salvation Army for participants who have provided their consent. Extracts will be securely transferred from The Salvation Army to the research team using the KCL Secure File Transfer service and

downloaded to the secure internal university network/server. Data contained within the extract will be entered into the MACRO database and checked before deletion.

Audio recordings of the qualitative interviews will be taken on encrypted digital recorders. Recordings will be transferred onto the secure internal university network with password-protected permissions. Audio files will then be removed from the recording device. Audio files will then be securely transferred to a professional transcription agency following signature of a confidentiality agreement. Transcripts will be downloaded to the secure internal university network and checked against the audio file: after checking, the audio file will be deleted from the university network/server. Transcripts will be anonymised during this checking process.

As per funder guidance, research data will be stored for 10 years after project completion.

19c Data access

Access to participants' personal data will be restricted to the study team (including NGO researchers, for the purposes of data collection and transfer, and Clinical Trials Unit staff), interpreters, transcribers, and auditors. The only exception to that is if a participant discloses something that leads the research team to believe that the participant or another person is at serious risk of harm. In this scenario, the researcher will explain to the participant that they need to break confidentiality to respond to the identified risk. This is detailed on the participant information sheet.

A confidentiality agreement will be in place with transcribers and interpreters.

20. Statistical methods

20a Statistical methods for analysing primary and secondary outcomes

To assess whether receipt of advocacy support is associated with improved mental health a paired samples t-test (or nonparametric equivalent) to assess mean change over the study period (6 months) will be conducted.

20b Methods for additional analyses

To assess whether change over times varies with intervention characteristics (amount of advocacy support received by study participant RQ2 or NGO service characteristics) change scores will be constructed over the intervention period.

The "dose of the support received" will be quantified (e.g. duration in terms of session length, frequency, and the period over which sessions are received; structural and service characteristics NGOs) and change scores will be regressed on this dose. Possible confounders of the dose-response relationship will be identified by testing whether any baseline participant characteristics (e.g. gender, immigration status) predict change over time. Any such potential confounders will then be adjusted for in a second step which regresses the change changes on the dose variable and the putative confounders.

These analyses (which do not include a control group) are based on the assumption that a control group would not exhibit any change over the intervention period. In order to assess the

impact of departures from this assumption on the evaluation of the advocacy support intervention sensitivity analyses will be conducted. Literature evidence will be used to generate a possible distribution of mean outcome change in a hypothetical control group of eligible trafficked woman waiting to start the support program (37); and will then include such sensitivity parameters in our analyses models to study their impact on the estimation of the pre-post effect.

20c Methods for handling missing data

In the case of missing data in the CORE-OM outcomes, putative baseline confounders, or process variables, multiple imputation (MI) will be used to ensure that the analyses remain valid under an appropriate missing at random assumption. This will enable us to (multiply) impute realistic outcome patterns including allowing for process variables such as discontinuation of advocacy support to drive loss-to follow-up.

21. Economic evaluation

An exploratory analysis of service use, costs and effects before and after intervention will be undertaken with the results presented using a cost consequences framework, which is recommended for the evaluation of complex interventions that have multiple effects (38). This work will be used to support the generation of recommendations for future research and the development and testing of economic measures appropriate for this population. Specific objectives will include the following:

1. Calculate the cost of the advocacy interventions taking a micro-costing (bottom-up) approach (38).
2. Develop and test an appropriately adapted version of the AD-SUS to collect data on the use of all health and social care services (taking the NHS/personal social services perspective preferred by NICE) and use this data to estimate the cost per participant through the application of nationally applicable unit costs (39).
3. Assess whether receipt of advocacy support is associated with changes in service use and costs (i.e. before and after intervention).
4. Test the acceptability and relevance of preference-based measures of health-related
5. quality of life (HRQoL) for the current population, including the EQ-5D-5L (EuroQol 5 dimensions, 5 levels), the SF-6D (Short Form 6 dimensions), and the ReQoL-10, which are all capable of generating quality adjusted life years (QALYs) suitable for future economic evaluations (25, 27, 40).
6. In line with the proposed clinical analyses noted above, explore whether receipt of advocacy support is associated with improvements in HRQoL and QALYs and whether change over time varies with participant characteristics at baseline or with the structural or service characteristics of NGOs.

22. Qualitative analysis

Analysis of qualitative data collected in study 2 will support the testing of initial programme theory using empirical data and the refinement of programme theory. This will involve moving iteratively between case analysis, refinement of programme theory, and further data collection to test emerging theory about how advocacy interventions improve outcomes, for whom, and under what circumstances. The coding of qualitative data will be inductive, deductive, and

retroductive (i.e. informed by theory, emerging from the data, and making inferences about mechanisms based on interpretations of the data).

In the first stage of analysis, we will develop a detailed narrative for each of the three study sites. We will combine data on intervention receipt from study 1, and qualitative data from study 2 to describe service model and structures, staffing, and intervention provision (including session frequency, duration, and type). In the second stage, and to test proposed context mechanism outcome (CMO) configurations in relation to intervention components, we will conduct within-case analyses to look for evidence threads that suggest different ways in which the proposed mechanisms operated in practice and associated the contexts and outcomes, while seeking to identify alternative mechanisms and explanations. We will then seek to identify and understand interactions between specific mechanisms, the contexts in which they were triggered, and the associated outcomes. These analyses will also investigate whether the activation of mechanisms from one component depends on the outcomes of another component. In the final stage of analysis, we will conduct cross-case comparisons and synthesis, comparing CMO models emerging from the sites, and refining programme theory. This analysis will identify contextual factors that are common across all sites and re-examine the associated mechanisms and outcomes, which will produce evidence on the ways in which advocacy interventions influence the mental health and wellbeing of trafficked people.

Findings from this study – an understanding of what works for whom and under what circumstances and refined programme theory - will be used to provide practical guidance on orienting services into configurations that seem to improve the mental health and wellbeing of survivors of trafficking.

23. Monitoring

A DMEC is not required.

24. Harms

Collection of information regarding adverse events is limited to death. In the event of participant death, a Withdrawal Form must be completed by the Study Manager and information sought from the recruiting NGO regarding date and cause of death.

With regards to harms that may arise during interviews, we will follow the WHO Ethical and Safety Guidelines on Interviewing Trafficked Women (47) and standard operating procedures adapted from our previous research with trafficked people that set out measures to be taken to minimise risk to researchers, distress and risk to participants, and steps to be taken if risks of serious harm to the participant or others are identified.

25. Auditing

The PI has overall responsibility for the study and will allow audit by providing the study sponsor direct access to source data and other documents as required.

26. Research ethics approval

The study gained approval from the King's College London (KCL) Research Ethics Committee (HR-19/20-14424) and from the Salvation Army Research Ethics Committee and will be

conducted in full compliance with the current version of the Declaration of Helsinki, relevant regulations, and MRC Good Clinical Practice (GCP) guidelines.

All researchers involved in data collection will undertake and/or update GCP training on obtaining informed consent when conducting research plus training on obtaining informed consent when conducting research with vulnerable populations.

27. Consent

The General Medical Council (GMC) guidance on obtaining consent from adults and young people for research purposes will be followed (41). Prior to the recruitment process, NGO and KCL researchers will undertake Good Clinical Practice (GCP) training on obtaining informed consent when conducting research, supplemented by training on obtaining informed consent when conducting research with vulnerable populations.

During the recruitment stage, potential study participants will be offered clear information in their own language, verbally and in writing (i.e. Participant Information Sheet), about the purpose, subject and nature of the study and what would be required of them if they consented to participate. Professionally translated copies of the Participant Information Sheet (PIS) and Consent Form will be provided to NGOs. Information on potential benefits and risks of participating will be detailed in the Participant Information Sheet (PIS). The PIS will additionally set out why they have been asked to participate in the study, what participation will involve, that participation is voluntary and will not affect the service they receive, and that consent to participate can be withdrawn at any time without having to provide a reason. In describing what participation involves, the PIS will state that all participants will be asked complete questionnaires at three time points.

Potential participants will be given a minimum of 24 hours to consider their participation in the study before consent is sought, and it will be emphasised that participation is voluntary. During the formal consent process, each participant will be informed that their responses will be anonymous and confidential (e.g., no names would be used on questionnaires, and questionnaires will not be seen by anyone outside the study), and that the study is not related to any immigration or policing procedures. Participants will be advised that they do not have to answer any questions, if they do not wish to, that they may take a break or terminate the interview at any time, and that declining to participate will not in any way affect the services they are receiving. Participants who decline to participate in the study will be asked if their basic socio-demographic characteristics (gender, age, and country of origin) can be collected anonymously to determine whether there are differences between participants and non-participants.

Only people who meet all inclusion criteria and no exclusion criteria and can provide informed consent will be recruited. Individuals who are interested to participate will be asked by NGO researchers to provide written consent. Prior to the administration of questionnaires, participants will be reminded that participation is voluntary and will not affect the service they receive, that they do not have to answer questions if they do not wish to, and that they can take a break or terminate the questionnaire at any time. Questionnaires will be administered only by trained individuals and in private.

28. Confidentiality and anonymity

The information provided by participants will be confidential and pseudo-anonymised. In some situations, however, it may be necessary to disclose personal information without a patient's consent if it is in the public interest (i.e. where a failure to do so may expose the patient or others at risk of death or serious harm). The limits of confidentiality are explained on the participant information sheet and will be discussed with all participants as part of the informed consent process.

All participants will be assigned a unique PIN. PINs will be used at all times when managing the research data. Any data collected that includes identifiable details about study participants will be stored separately from the research data. To reduce the risk of attribute disclosure, cell counts less than or equal to 5 will be suppressed.

29. Declaration of interests

The Principal Investigator declares no conflict of interest.

30. Dissemination policy

The protocol will be submitted for publication on an open access basis. The study results will be submitted for publication on an open access basis. A lay summary of the study findings will be produced and disseminated to study participants who indicated on their consent forms that they wished to receive a copy of study findings. Briefing notes will summarise study findings for recruiting organisations and policymakers.

ICMJE authorship guidelines will be followed.

Public access to the participant-level dataset is not planned.

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