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Improving outcomes for survivors of human trafficking

Submission date
14/02/2020

Recruitment status
No longer recruiting

Registration date
24/02/2020

Overall study status
Completed

Last Edited
16/09/2021

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Survivors of human trafficking report a range of health problems, especially psychological distress. 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 mental health recovery is lacking.

In the UK, survivors of trafficking are entitled to government-funded support that aims to help them recover from abuse and rebuild their lives. Support is provided in England and Wales by a network of 12 non-governmental organisation (NGOs) that provide specialist post-trafficking support. Support follows an "advocacy" model, although the specific service model and the intensity of support varies between organisations. 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. The effectiveness of advocacy interventions in reducing psychological distress among survivors of trafficking remains unknown: outcomes have not been evaluated for this population either in the UK or elsewhere. The evaluation of advocacy-based interventions is therefore a priority need in informing the design of future services and to guide commissioning and investment. Additionally, there are no data examining how service level variations of or specific components of care appear most beneficial for which trafficked people.

The aim of this study is to evaluate the effectiveness of advocacy interventions in improving the mental health of people who have been referred into NGO services for government-funded post-trafficking support in England and Wales. Additional objectives of this study are: to evaluate whether aspects of the advocacy intervention experience thought to improve outcomes modify the effect of the advocacy intervention on mental health and well-being, to assess the service use and costs associated with advocacy interventions for trafficked people who have been referred into NGO services; and to explore service user and staff perspectives on how advocacy interventions improve outcomes, for whom, and under which circumstances.

Who can participate?
Adult survivors of human trafficking who have entered into the UK National Referral Mechanism and received fewer than 14 days' residential advocacy support or 28 days' outreach advocacy support from any NGO through the UK National Referral Mechanism.

What does the study involve?
The cohort study involves completing three questionnaires. The first questionnaire should be completed as soon as possible after participants have started receiving support. The second questionnaire should be completed three months the onset of support; the third questionnaire should be completed six months after the onset of support. Questions are asked about current health and wellbeing; the same questionnaire is administered at each time point. Participants are asked to consent to the research team accessing routinely collected case file information about support needs and the type, frequency, and duration and support received. We will ask about 30 cohort study participants to also take part in a qualitative interview about their experience of receiving advocacy support. Fifteen members of staff will also be asked to participate in a qualitative interview about their experiences of providing advocacy support.

What are the possible benefits and risks of participating?
The researchers do not anticipate that participants will directly benefit from participating in the study. It does however represent an opportunity to inform the provision of services in the future that may benefit others. Risks include potential distress; although participants will not be asked about what happened to them during the time they were trafficked, some of the questions may bring up upsetting memories or feelings.

Where is the study run from?
King's College London (UK)

When is the study starting and how long is it expected to run for?
March 2020 to December 2023

Who is funding the study?
NIHR Public Health Research (UK)

Who is the main contact?
Dr Sian Oram
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
V2/14/02/2020, NIHR127593

Study information

Scientific Title
Improving outcomes for survivors of human trafficking - evaluating the effectiveness of advocacy interventions in improving mental health and wellbeing among trafficked people: a prospective uncontrolled cohort study.

Acronym
PROTECT-II

Study objectives
1. Receipt of advocacy support is associated with improved mental health
2. Change in mental health is associated with the amount of advocacy support received
3. Change in mental health is associated with NGO service characteristics

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/01/2020, PNM Research Ethics Subcommittee King's College London (Research Ethics Office, Franklin Wilkins Building, 5.9 Waterloo Bridge Wing, Waterloo Road, London, SE1 9NH, UK; +44 (0)20 7848 4020; rec@kcl.ac.uk), ref: HR-19/20-14424

Study design
Exploratory prospective uncontrolled cohort study and realist evaluation

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Mental health

Interventions
Current intervention as of 01/12/2020:
The study evaluates the effectiveness and cost-effectiveness of advocacy interventions in improving mental health and wellbeing among trafficked people.

Advocacy interventions are provided as standard care to survivors of trafficking in England and Wales who consent to be referred into the UK National Referral Mechanism. Support is funded by the U.K. government and provided by a network of non-governmental organisations (NGOs). The specific service model and the intensity of support varies between these NGOs. Advocacy interventions are strengths-based, survivor-centred interventions based on empowerment models. They are individualised and non-manualised. Advocacy interventions typically involve helping people to set their own goals, giving them information about their rights, helping them to use health and other types of services, helping them to meet people and form new friendships, helping people to develop their skills and to get jobs, and being understanding and encouraging and respectful. Some survivors will receive support on a residential basis in shared houses or self-contained units, while others will receive support on an outreach basis.

The study does not have 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 difficult to identify for recruitment.

This study will assess whether the mental health of survivors of trafficking improves following referral to advocacy support. Measures will be taken at baseline (e.g. i.e. at or soon after onset of advocacy), at 3 months follow up, and at 6 months follow up.

It is anticipated that most participants will receive at least 6 months of advocacy support. Data will be collected on the duration, frequency, and mode of support.

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 an 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. 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. NGO researchers will take informed consent and administer the T1 and T2 questionnaires. A KCL researcher will administer T2 questionnaires to participants who leave the recruiting organisation and will administer T3 questionnaires. 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.

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. Clients intending to participate in the study will be asked to agree a date for the qualitative interview. Informed consent will be taken and interviews will follow a topic guide and will be audio-recorded on an encrypted digital recorder.

Remote, synchronous, qualitative semi-structured interviews will be conducted with 15-20 staff using Microsoft Teams software. Participants will be asked to use only their work laptops/work mobile devices for the interview purposes. All participants will be sent the instructions about how to use Microsoft Team software to their work emails in advance of the interview. Potential participants will be contacted by email with a study invitation and copy of the participant information sheet. 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. People intending to participate in the study will be invited to complete an online consent form, hosted on the Qualtrics platform.

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Previous intervention:
The study evaluates the effectiveness and cost-effectiveness of advocacy interventions in improving mental health and wellbeing among trafficked people.

Advocacy interventions are provided as standard care to survivors of trafficking in England and Wales who consent to be referred into the UK National Referral Mechanism. Support is funded by the U.K. government and provided by a network of non-governmental organisations (NGOs). The specific service model and the intensity of support varies between these NGOs. Advocacy interventions are strengths-based, survivor-centred interventions based on empowerment models. They are individualised and non-manualised. Advocacy interventions typically involve helping people to set their own goals, giving them information about their rights, helping them to use health and other types of services, helping them to meet people and form new friendships, helping people to develop their skills and to get jobs, and being understanding and encouraging and respectful. Some survivors will receive support on a residential basis in shared houses or self-contained units, while others will receive support on an outreach basis.

The study does not have 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 difficult to identify for recruitment.

This study will assess whether the mental health of survivors of trafficking improves following referral to advocacy support. Measures will be taken at baseline (e.g. i.e. at or soon after onset of advocacy), at 3 months follow up, and at 6 months follow up.

It is anticipated that most participants will receive at least 6 months of advocacy support. Data will be collected on the duration, frequency, and mode of support.

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 an 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. 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. NGO researchers will take informed consent and

administer the T1 and T2 questionnaires. A KCL researcher will administer T2 questionnaires to participants who leave the recruiting organisation and will administer T3 questionnaires. 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.

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. Clients intending to participate in the study will be asked to agree a date for the qualitative interview. Informed consent will be taken and interviews will follow a topic guide and will be audio-recorded on an encrypted digital recorder.

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. Staff intending to participate in the study will be asked to agree a date for the qualitative interview. Informed consent will be taken and interviews will follow a topic guide and will be audio-recorded on an encrypted digital recorder.

Intervention Type
Behavioural

Primary outcome measure
Clinical Outcomes in Routine Evaluation-Outcome Measure (CORE-OM) which measures global psychological distress, captured at T1 (baseline), T2 (3 months follow up) and T3 (6 months follow up). Primary outcome is CORE-OM score at T2 versus T1.

Secondary outcome measures
Collected at T1, T2, and T3:
1. Use of health and social care services will be measured using an adapted version of the Adult Service Use Schedule (AD-SUS)
2. Health-related quality of life will be measured using the EQ-5D-5L and SF-12 and the

Recovering Quality of Life-10 (ReQoL-10)
3. Social resources and support will be measured using an adapted version of the Social Support Network Scale (SSN)
4. Unmet needs will be measured using an adapted version of the Post-Migration Living Difficulties Checklist (PMLDC)
5. Perceived safety and risk of harm will be measured using an adapted version of the Intimate Partner Violence Threat Appraisal and Fear Scale
6. Autonomy will be measured using a six-item measure adapted from the Burchardt Inequality of Autonomy scale (Centre for Analysis of Social Exclusion, University of Oxford)

Overall study start date
01/11/2019

Completion date
31/12/2023

Eligibility

Key inclusion criteria
Cohort study:
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. English language proficiency is not a selection criterion.

Qualitative study:
1. Survivors: For survivors to be eligible for inclusion, they must meet the inclusion criteria for the above cohort study and must additionally consent to participate in the qualitative study. English language proficiency is not a selection criterion
2. Staff: Staff working at participating NGOs (e.g. managers, caseworkers, volunteers). To be eligible for inclusion, staff must work (on a paid or voluntary basis) at one of the participating NGOs

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
Cohort study: 450 survivors of human trafficking/ Qualitative study: 15 staff members of participating NGOs, 30 survivors of human trafficking drawn from cohort study participants.

Key exclusion criteria
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.

Date of first enrolment
01/02/2022

Date of final enrolment
01/02/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College London
Institute of Psychiatry, Psychology & Neuroscience, Department of Health Service and Population Research
David Goldberg Centre
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Sponsor information

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Sponsor type
University/education

Website
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ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
Public Health Research Programme

Alternative Name(s)
NIHR Public Health Research Programme, PHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. Manuscripts will be submitted for consideration by high impact peer-reviewed scientific journals. At a minimum, papers will include (1) protocol paper; (2) cohort study findings paper, reporting effectiveness and cost-effectiveness results; (3) qualitative study findings paper, reporting on service user expectations and experiences of advocacy support; (4) programme theory paper, reporting on findings of realist evaluation and presenting refined programme theory
2. Survivor commentaries, independently authored by members of the Research Advisory Committee, for publication alongside scientific articles
3. Presentations at major academic and practitioner conferences

4. Articulated programme theory and practice guidance for service managers and commissioners, setting out evidence on how advocacy support improves outcomes, for whom, and under what circumstances
5. Quarterly newsletters to participating NGOs
6. Leaflet summarising findings for study participants, co-produced with members of the Research Advisory Committee
7. Briefing papers, presentations for policymakers and parliamentarians, including the Home Office's Modern Slavery Unit, the All-Party Parliamentary Group on Modern Slavery, Public Health England, and NHS England
8. Written responses to government and parliamentary consultations, enquiries and reviews where these arise. The Public Accounts Committees and Home Affairs Select Committees have held enquiries into responses to human trafficking and modern slavery in recent years, and the Home Office have consulted on its modern slavery and victim support strategies
9. YouTube videos hosted by The Salvation Army TV and King's College London Spotlight Series describing key findings for the general public and other social media including Twitter

Intention to publish date
01/09/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the ongoing and high risk of harm to participants in the event of de-anonymisation and identification.

IPD sharing plan summary
Not expected to be made available