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Feasibility study of a digital suicidal ideation intervention for Syrian asylum seekers and refugees in the UK

Submission date 30/01/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 02/02/2024	**Overall study status** Completed	
Last Edited 13/04/2026	**Condition category** Signs and Symptoms	

Plain English summary of protocol

Background and study aims
The study aims to increase access to treatment for suicidal ideation for Syrian asylum seekers and refugees in the UK. The study's objectives include assessments of the feasibility of meeting recruitment goals and completing outcome measures, the suitability of the culturally adapted intervention in terms of adherence rates and the facilitators and barriers to engagement, and the acceptability of the culturally adapted intervention in terms of its cultural relevance; cultural appropriateness, and whether participants were satisfied with their experience.

Who can participate?
Syrian asylum seekers or refugees in the United Kingdom aged 18 years old and over

What does the study involve?
Through social media, participants will be recruited via NGOs, charities and cultural brokers. Potential participants will be provided a participant information sheet describing the purpose and methods of the study. After providing informed consent, they will be screened for eligibility and randomly assigned to the culturally adapted intervention to reduce suicidal ideation or control – a 6-week waiting list. Baseline measures will be taken for eligible participants, and they will then begin the 6-session digital intervention to reduce suicidal ideation (SI). The 6 sessions include: thinking about suicide; dealing with thoughts and feelings; thinking about the future; thinking about the self; thinking about others; and repetition and relapse. Adherence rates for all participants will be measured in terms of the number of sessions completed and the time they took to complete. 12 participants will be selected for a subsequent online interview to assess the suitability and acceptability of the intervention as described above.

What are the possible benefits and risks of participating?
The study will involve recruiting and providing an online intervention to Syrian asylum seekers and refugees with suicidal thoughts. As such, the safety protocol has an important balance between minimizing the risk of adverse events and ensuring that the intervention is provided to populations most likely to use it. One of the key benefits of a short low-intensity digital intervention is its ability to reduce the burden of help-seeking for suicidal ideation at scale.

However, despite its ability for international reach, it is still important to have a local safety protocol. Thus, to avoid risks, the study will only include Syrian asylum seekers and refugees in the UK who do not have severe suicidal thoughts. Any risks of harm participants might pose to themselves or others will be reported to the principal investigator, Prof. Kamaldeep Bhui, and depending on his judgement it will be referred to the relevant authorities.

Where is the study run from?
University of Oxford

When is the study starting and how long is it expected to run for?
October 2022 to December 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Mr Oliver Beuthin, oliver.beuthin@linacre.ox.ac.uk

Contact information

Type(s)
Principal investigator

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Prof Kamaldeep Bhui

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Feasibility and acceptability of a culturally adapted digital intervention to reduce suicidal ideation for Syrian asylum seekers and refugees in the United Kingdom: A mixed methods study

Study objectives
The aim of the study is to improve the understanding and treatment of suicidal ideation among Syrian asylum seekers and refugees in the UK. In particular, this involves assessing the feasibility and acceptability of a culturally adapted digital intervention and culturally appropriate recruitment strategies.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 22/11/2023, Medical Sciences Interdivisional Research Ethics Committee (MS IDREC) (University of Oxford, Research Services, Boundary Brook House, Churchill Drive, Headington, Oxford, OX3 7GB, United Kingdom; +44 (0)1865 616575; ethics@medsci.ox.ac.uk), ref: R89074 /RE001

Study design
Single-group uncontrolled mixed-methods feasibility study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Reduction of suicidal ideation among Syrian asylum seekers and refugees in the United Kingdom.

Interventions
This is a single-group, non-controlled, mixed methods feasibility study of a culturally adapted digital intervention to reduce suicidal ideation for Syrian asylum seekers and refugees in the United Kingdom.

Participants will receive the 6-week self-help digital culturally adapted intervention via Qualtrics which consists of the following 6 sessions:

1. Thinking about suicide: This module aims to enable participants to identify the automatic thoughts that give rise to suicidal thoughts to gain some control over their thoughts. Specific attention is given to the dichotomous and overgeneralizing nature of the thoughts.
2. Dealing with thoughts and feelings: Participants will learn that they can be resilient in the face of seemingly unbearable feelings. Focus will be given to learning how to tolerate and regulate intense emotions in situations of crisis.
3. Thinking about the future: Participants will evaluate their ideas about the future and ask whether they are realistic. Consequently, participants will develop a more realistic view of the future and set new goals.
4. Thinking about the self: Common mistakes in thinking about the self are discussed and challenged. Participants are also taught how to manage suicidality as a long-term vulnerability. Particular attention is given to learning to seek help.
5. Thinking about others: Mistakes in thinking about others will be discussed. Participants will also be provided with information about the effects of suicide on relatives and friends.
6. Repetition and relapse: Several mistakes in thinking and acquired skills are repeated. Attention will also be given to relapse and how to avoid it.

The primary outcomes of the study include the acceptability and suitability of the intervention to Syrian asylum seekers and refugees in the United Kingdom with SI. The acceptability of the intervention to participants will also be assessed during post-intervention interviews in terms of cultural relevance (i.e. familiarity of the therapeutic content to one's cultural background and lived experiences with the migratory process); cultural appropriateness (i.e. appropriateness of the therapeutic content in terms of the Syrian cultural context), and whether participants were satisfied with their experience. Interviews will be held one week after completing the 6-week intervention.

Suitability of the intervention will be analyzed quantitatively in terms of recruitment and adherence rates. Recruitment rates will be assessed in terms of the percent of those contacted who met the eligibility criteria and the percent of those eligible that enrolled which should be 70% at each stage. Adherence rates will be assessed in terms of the number of sessions attended which should be at least 70%, and time spent completing them. Suitability of the intervention will also be assessed qualitatively in terms of the barriers and facilitators of engagements by way of the case tracking form and post-intervention interviews.

Secondary outcomes include the feasibility of recruitment goals and measurement instruments. Recruitment goals will be tracked in accordance with Stewart and colleagues' (2020) guidelines for diverse populations. This will include using an electronic case tracking form (eCTF) to track the sources of potential participants (NGOs, charities, social media), the number of participants recruited within the set time period (30 in 6 months), sample characteristics (age, gender, ethnicity, religion), and reasons for loss at each stage (consent, eligibility, enrolment, etc.).

The feasibility of measurement instruments will be assessed in terms of the number of people who completed questionnaires, the amount of information missing which should not exceed 10%, and the time it took to complete them. This will include measuring suicidal ideation for intervention participants at baseline (T1), after 3 weeks (T2), and post-treatment (6 weeks after baseline: T3). Depression, anxiety, and post-traumatic stress disorder will also be measured at baseline and post-treatment. If possible, all participants who begin the intervention will

complete the follow-up assessment at week 6 irrespective of whether they complete the intervention or not. All the data will be recorded on the eCTF. The outcomes measures used in the study include:

Suicidal ideation will be measured using the suicidal ideation subscale of the Columbia-Suicide Severity Rating Scale (CSSRS) which is a 6-item tool used to assess suicidal ideation (Posner et al., 2010) which has shown good internal consistency (α =0.966) for an Arabic-speaking population (Zakhour et al., 2021). The CSSRS was chosen due to its compatibility with Syrian's conceptualization of suicidal ideation as a wish for death. An answer of yes to any of the 6 questions indicates a presence of suicidal ideation and a score of 4 and above indicates serious suicidal ideation.

Anxiety and depression will be measured with the Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983; Spinhoven et al., 1997). The Arabic version has shown acceptable internal consistency for both the anxiety (α = 0.73) and depression scale (α = 0.77) (Al Aseri et al., 2015). HADS consists of 14 items which are scored on 4-point Likert scale between 0 and 3. The total score range is between 0 and 21, with scores between 0 to 7 indicating normal anxiety /depression, scores between 8 to 10 indicating borderline abnormal anxiety/depression, and scores above 11 indicating abnormal anxiety/depression.

PTSD will be measured with the Arab versions of the PTSD Checklist for DSM-5 (PCL-5) (Ibrahim et al., 2018) which has shown high (α = 0.85) internal consistency (Ibrahim et al., 2018). The scale consists of 20 self-report items. Each item includes five points with scores ranging between 0 (not at all) and 4 (extremely). A total score of 31-35 or higher suggests that a patient may benefit from PTSD treatment.

Intervention Type
Behavioural

Primary outcome(s)
1. The acceptability of the intervention to participants measured using data recorded during post-intervention interviews one week after completing the 6-week intervention
2. The suitability of the intervention will be analyzed using data recorded on an electronic case tracking form (eCTF) at the end of the study:
2.1. Recruitment rate, assessed using the percentage of those contacted who met the eligibility criteria and the percentage of those eligible who enrolled
2.2. Adherence rate, assessed in terms of the number of sessions attended and time spent completing them
2.3. The suitability of the intervention, assessed qualitatively using the barriers and facilitators of engagements and during post-intervention interviews

Key secondary outcome(s))
1. Recruitment goals measured using an electronic case tracking form (eCTF), the number of participants recruited within the set period (30 in 6 months), sample characteristics (age, gender, ethnicity, religion), and reasons for loss at each stage (consent, eligibility, enrolment, etc.).
2. The feasibility of measurement instruments measured using the number of people who completed questionnaires, the amount of missing information, and the time it took to complete them
3. Suicidal ideation for intervention participants the suicidal ideation subscale of the Columbia-Suicide Severity Rating Scale (CSSRS) at baseline (T1), after 3 weeks (T2), and post-treatment (6 weeks after baseline: T3)

4. Anxiety and depression measured with the Hospital Anxiety and Depression Scale (HADS) at baseline and post-treatment
5. Post-traumatic stress disorder measured using the Arab versions of the PTSD Checklist for DSM-5 (PCL-5) at baseline and post-treatment

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. Aged 18 years old and over
2. Syrian asylum seeker/refugee in the United Kingdom
3. At least a score of 1 on the Columbia Suicide Severity Rating Scale (CSSRS)
4. Access to a PC or mobile phone with internet
5. Willing to provide their e-mail address and that of their GP surgery

Participant type(s)
Service user

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
15

Key exclusion criteria
1. Participants with a score of 4 or above on the CSSRS, indicating serious suicidal ideation

Date of first enrolment
02/02/2024

Date of final enrolment
31/07/2024

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Department of Psychiatry, University of Oxford
Warneford Hospital, Warneford Ln, Headington
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Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
Following university policy, all non-identifiable data will be stored for at least three years after publication in OneDrive for Business available through the University of Oxford. The DPhil student will transfer all data from university servers to the custodianship of the PI who will be responsible for data deletion. The data will be available upon request from Oliver Beuthin at oliver.beuthin@linacre.ox.ac.uk.

Post-intervention interviews in the form of anonymized translated transcripts and anonymized participant tracking forms that record recruitment sources, eligibility, outcome measure results, adherence, and reasons for non-participation will be available upon request. Written informed consent will be obtained from all participants before they participate in the intervention and post-intervention interview. All data will be anonymized using a unique participant number and

any identifiable data including audio recordings will be deleted as soon as they are transcribed. The study as outlined in the protocol has received ethics approval from an internal ethics committee at the University of Oxford and will have access to the data for purposes of auditing. Any significant changes to the protocol require prior approval from the ethics committee. The study is under no legal restrictions other than to comply with UK common law.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		02/09/2024	03/09/2024	Yes	No