ISRCTN19217696 https://doi.org/10.1186/ISRCTN19217696

Effectiveness of a guided mental health chatbot for youth living in Jordan in communities exposed to adversity

Submission date
17/10/2022

Recruitment status
No longer recruiting

Registration date
02/11/2022

Overall study status
Completed

Last Edited
07/02/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Mental disorders are a leading cause of disability worldwide, with an estimated 264 million people affected by depression alone. Up to half of mental disorders start during adolescence, often with long-lasting and serious consequences for health and productivity. There is a need for evidence-based psychological interventions targeting young adults that can be used in settings which are resource pressured.

The study objective is to conduct a feasibility randomized controlled trial to determine whether all aspects of the study methodology can be feasibly implemented. The study will test a guided self-help e-mental health intervention called “Scalable Technology for Adolescents and youth to Reduce Stress (STARS)”. This study will inform a larger randomized controlled trial on the effectiveness of STARS in reducing symptoms of depression and anxiety. STARS is a self-help programme delivered through a chatbot over the Internet using smartphones, tablets or computers, and with additional support from a trained non-specialist care provider.

Who can participate?
Young adults living in Jordan (i.e., Jordanian nationals, Syrian displaced people, and other populations residing in Jordan) aged 18-21 years who are experiencing moderate levels of psychological distress, and with access to a device for intervention delivery. Participants will be recruited through social media, community centres, and primary health care centres.
Persons outside of Jordan, under 18 years of age or over 21 years of age, and persons at imminent risk of suicide will be excluded from the study and provided with information on appropriate services.

What does the study involve?
To test whether we can feasibly deliver the STARS intervention aimed at reducing symptoms of depression and anxiety, two groups will be compared. Participants in the intervention group will receive basic information on psychological distress and a list of resources for support, as well as the STARS programme with additional weekly e-helper support delivered over the phone, while those in the control group will only receive the basic information.

In order to assess symptoms of depression and anxiety, wellbeing and functioning, participants in this study will complete several questionnaires at two time points: At the beginning of the study and after 8 weeks.

What are the possible benefits and risks of participating?
STARS is based on evidence-based techniques and may reduce psychological distress, but it is not certain. There is broad evidence for the use of digital interventions, and it is unlikely there will adverse effects due to the intervention.

Where is the study run from?
The study is conducted by the University of New South Wales (Sydney, Australia), World Health Organization (Geneva, Switzerland), and Institute of Family Health (Amman, Jordan).

When is the study starting and how long is it expected to run for?
September 2021 to March 2023

Who is funding the study?
Enhancing Learning and Research for Humanitarian Assistance – Research for Health in Humanitarian Crises (Elrha - r2hc) (UK)
Save the Children Wales (UK)

Who is the main contact?
Professor Richard Bryant, r.bryant@unsw.edu.au

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ERC ID: 0003729

Study information

Scientific Title
Effectiveness of the STARS guided mental health chatbot for youth living in Jordan in communities exposed to adversity - Feasibility study

Acronym
STARS

Study objectives
The STARS intervention can be feasibly delivered to young adults in Jordan.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/07/2022, Ethics Review Committee at World Health Organization (Avenue Appia 20, 1211 Geneva, Switzerland; no telephone number provided; ercsec@who.int), ERC ID: 0003729

Study design
Single-blind 2-arm feasibility randomized controlled trial

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Common mental disorders; Depression; Anxiety

Interventions
STARS
STARS is a brief, 10-session intervention developed to address emotional distress experienced by adolescents and youth. The 10 sessions are each around 20-25 minutes of content delivered in a conversational style by a chatbot. In addition, participants will also receive weekly calls by an e-helper (trained and supervised non-specialist) who will support and motivate participants in completing the intervention.
STARS follows a cognitive behavioural therapy (CBT) framework to deliver all psychological content to address the broad mental health needs reported by adolescents and youth. CBT is an approach recommended by WHO for treatment of mental disorders in adolescents. A transdiagnostic approach is used that covers ten sessions: (1) introduction (intervention overview, privacy, and confidentiality); (2) emotions (psychoeducation about emotions); (3) relax (emotion regulation techniques, such as slow breathing); (4-5) what we do (behavioural activation); (6-7) managing problems (problem management techniques); (8-9) self-talk (thought challenging); and (10) what next (consolidating learnings and planning for the future). In addition, the intervention also encourages the user to practice and apply the skills in their own life, which is supported by activities such as recorded stress management audios.

Enhanced usual care
The enhanced usual care (EUC) intervention includes basic information about depression and anxiety, as well as signposting to evidence-based care available in Jordan. The information will be based on a session from STARS. Thereafter, participants will receive a list indicating organizations offering mental health and psychosocial support in Jordan.

The basic information and signposting to evidence-based care will be provided to participants in both group (STARS intervention group and control group).

Randomization will be carried out in Qualtrics on a 1:1 ratio.

The intervention will take 5 weeks. The follow-up assessment will take place 8 weeks after baseline.

Intervention Type
Behavioural

Primary outcome measure

Feasibility of the STARS intervention, including:
1. Recruitment rate recorded as the number of eligible participants who consent to participate in the study
2. Drop-out rates recorded as the number of randomized participants who do not complete the intervention or the post-assessment
3. Number of adverse events and serious adverse events
4. Evaluation of (secondary) outcome measures and estimation of differences across the two groups
The above will be supported by qualitative process evaluation interviews to further understand aspects related to implementation.

Secondary outcome measures
Measured at screening/baseline and week 8 unless noted:
1. Psychological distress (Hopkins Symptom Checklist; HSCL-25)
2. Psychological distress (Kessler Psychological Distress scale; K10)
3. Functioning (WHO Disability Assessment Schedule; WHODAS 2.0)
4. Subjective wellbeing (WHO Well-Being Index; WHO-5)
5. Self-identified problems (Psychological Outcomes Profiles; PSYCHLOPS)
6. Agency (agency subscale of the State Hope Scale; SHS-A)
7. User-satisfaction questionnaire (Client Satisfaction Questionnaire; CSQ-I) [only at post-assessment (8 weeks after baseline)]

Overall study start date
01/09/2021

Completion date
27/03/2023

Eligibility

Key inclusion criteria
1. Any person living in Jordan who can read English or Arabic
2. Is between the ages of 18 and 21 years
3. Is experiencing moderate levels of psychological distress as determined by a score of 20 or above on the Kessler distress scale, 10-item version (K10)
4. Has access to a device for intervention delivery or is willing to use one at a participating centre

Participant type(s)
Other

Age group
Other

Sex
Both

Target number of participants
60

Total final enrolment

60

Key exclusion criteria
1. Persons under 18 years of age or over 21 years of age
2. People at imminent risk of suicide (as defined by the mhGAP intervention guide)

Date of first enrolment
02/11/2022

Date of final enrolment
26/01/2023

Locations

Countries of recruitment
Jordan

Study participating centre
Institute for Family Health, Noor Al Hussein Foundation
PO Box 955
Amman
Jordan
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Sponsor information

Organisation
World Health Organization

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Sponsor type
Other

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https://www.who.int/teams/mental-health-and-substance-use/overview

ROR
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Funder(s)

Funder type
Charity

Funder Name
Enhancing Learning and Research for Humanitarian Assistance

Alternative Name(s)
Enhancing Learning & Research for Humanitarian Assistance, ELRHA

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The (de-identified) datasets generated during the current study will be available upon request from Professor Richard Bryant (r.bryant@unsw.edu.au).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		05/02/2025	07/02/2025	Yes	No