ISRCTN10152961 https://doi.org/10.1186/ISRCTN10152961

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

Submission date
15/05/2023

Recruitment status
No longer recruiting

Registration date
18/05/2023

Overall study status
Completed

Last Edited
17/02/2025

Condition category
Mental and Behavioural Disorders

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

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 will test a guided self-help e-mental health intervention called “Scalable Technology for Adolescents and youth to Reduce Stress (STARS)”. The objective is to investigate the effectiveness of STARS in reducing symptoms of depression and anxiety among young adults (18-21 years) living in Jordan. STARS is 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 individuals 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 STARS is effective in 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 intervention 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 three time points: At the beginning of the study, after 8 weeks and again 3 months later.

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?
March 2023 to June 2024.

Who is funding the study?
Elrha – Research for Health in Humanitarian Crises (r2hc)

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

Contact information

Type(s)
Principal investigator

Contact name
Prof Richard Bryant

ORCID ID
https://orcid.org/0000-0002-9607-819X

Contact details
University of New South Wales
School of Psychology
Sydney
Australia
2052
+61-2-93853640
r.bryant@unsw.edu.au

Type(s)
Public

Contact name
Dr Kenneth Carswell

ORCID ID
https://orcid.org/0000-0001-5344-5802

Contact details
World Health Organization (WHO)
Department of Mental Health and Substance Abuse
Geneva
Switzerland
1211
+41-22-791-5024
carswellk@who.int

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
ERC ID: 0003729

Study information

Scientific Title
Scalable technology for adolescents and youth to reduce stress (STARS) - Randomised controlled trial

Acronym
STARS

Study objectives
Participants in the STARS intervention group will have reduced anxiety and depression scores (HSCL-25 subscale scores) relative to participants in the control group at three-month follow-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/03/2023, Ethics Review Committee at World Health Organization (Avenue Appia 20, 1211 Geneva, Switzerland; no telephone number provided; ercsec@who.int), ref: 0003729

Study design
Single-blind two-arm randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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 youth. A transdiagnostic approach is used that covers ten sessions: (1) Let's get started (intervention overview, privacy, and confidentiality); (2) Emotions are not our enemies (psychoeducation about emotions); (3-4) Breathe to relax (emotion regulation techniques, such as slow breathing); (5-6) What we do can change how we feel (behavioural activation); (7) Managing problems (problem management techniques); (8-9) Talking kindly to yourself (thought challenging); and (10) Put your skills together (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, along with 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 (and automated) in Qualtrics.
The intervention period is 8 weeks.

Intervention Type
Behavioural

Primary outcome(s)
Measured at all timepoints (at the beginning of the study, after 8 weeks and again 3 months later):
1. Symptoms of anxiety (Hopkins Symptom Checklist anxiety subscale; HSCL-25)
2. Symptoms of depression (HSCL-25 depression subscale)

Key secondary outcome(s))
Current secondary outcome measures as of 17/08/2023:
Measured at all timepoints (at the beginning of the study, after 8 weeks and again 3 months later) unless noted:
1. Psychological distress (Kessler Psychological Distress scale; K10) [at screening, 8 weeks after baseline and again 3 months later]
2. Symptoms of depression (Patient Health Questionnaire; PHQ-2) [only during the STARS intervention, i.e., in every second chatbot session]
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. Mental health care use (2 items)
8. User-satisfaction questionnaire (Client Satisfaction Questionnaire; CSQ-I) [only at post-assessment (8 weeks after baseline)]

Previous secondary outcome measures:
Measured at all timepoints (at the beginning of the study, after 8 weeks and again 3 months later) unless noted:
1. Psychological distress (Kessler Psychological Distress scale; K10)
2. Symptoms of depression (Patient Health Questionnaire; PHQ-2)
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. Mental health care use (2 items)
8. User-satisfaction questionnaire (Client Satisfaction Questionnaire; CSQ-I) [only at post-assessment (8 weeks after baseline)]

Completion date
27/06/2024

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

Healthy volunteers allowed
No

Age group
Other

Lower age limit
18 years

Upper age limit
21 years

Sex
All

Total final enrolment
344

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
06/07/2023

Date of final enrolment
31/01/2024

Locations

Countries of recruitment
Jordan

Study participating centre
Institute for Family Health (Noor Al Hussein Foundation)
PO Box 955, Amman, 11910, Jordan
Amman
Jordan
11910

Sponsor information

Organisation
World Health Organization

ROR
https://ror.org/01f80g185

Organisation
UNSW Sydney

ROR
https://ror.org/03r8z3t63

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

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?
Protocol article		08/11/2024	20/11/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes