

A trial of the Self-Help Online program for Ukrainian refugees

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| Submission date 22/06/2022 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 28/06/2022 | Overall study status Completed | <input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 31/10/2024 | Condition category Other | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

The study wants to test if the self-help online program helps adult people to cope with high-stress situations. The program focused on Ukrainian citizens, but do not exclude the people with other citizenship who were living in Ukraine. The program is not open to people living outside Ukraine and European Union. This program aims to help people to improve their psychological well-being and reduce stress. The results of the study will help to understand if a self-help online program can be a solution to help a large number of people across borders cope with high-stress situations.

Who can participate?

Adults (18+ years) residing in Ukraine or adults who resided in Ukraine before February 24 2022 and had to move to one of the countries in the European Union.

What does the study involve?

If you agree to participate in this study, you will be offered a chance to attend a full online self-help program for free. The full program will take you about 1.5 hours of study time on the educational platform and about 30 minutes to learn recent information about opportunities provided to Ukrainians by different countries. The computer randomly decides who will be offered participation in the full online program and who will get only the information about opportunities provided to Ukrainians by different countries.

Everyone in the study will be asked to take two brief surveys: one survey at the beginning and one survey at the end. We will use the information collected from the surveys and learning activities on the platform to analyze the effectiveness of this course for research purposes. Your participation in this study will end with an endline survey. We might contact you after the endline survey to better evaluate the results of the course and your experience.

What are the possible benefits and risks of participating?

If you are selected to complete the course, it can help you to improve your psychological well-being and reduce stress. All participants of the program will receive information about opportunities provided to Ukrainians by different countries. All participants of the program will get a certificate of completion of the program after the final survey. All participants who completed the endline survey will participate in a random draw to get 1 of 250 gift cards of 10

Euro (~320 hryvnia) value.

We will use content and materials that do not pose any risk to your mental, physical health, or socioeconomic risks.

Where is the study run from?

University of Kassel International Center for Higher Education Research (Germany)

When is the study starting and how long is it expected to run for?

May 2022 to December 2022

Who is funding the study?

University of Kassel International Center for Higher Education Research (Germany)

Who is the main contact?

Dr. Igor Asanov, igor.asanov@uni-kassel.de

Contact information

Type(s)

Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

4 4002 97

Study information

Scientific Title

The psychological online self-help program: a randomized controlled trial

Acronym

SHO

Study objectives

Hypothesis 1: Participants who receive the self-help online course show a lower level of stress compared to the control group participants.

Hypothesis 2: Participants who receive the online self-help course show a higher level of psychological well-being compared to the control group participants.

Hypothesis 3: Participants who receive the online self-help course show better results on the life-related outcome, variables compared to the control group participants.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 25/05/2022, Kassel University Central Ethics Committee (Geschäftsstelle der zentralen Ethikkommission der Universität Kassel Mönchebergstr. 19 34125 Kassel, Germany; no telephone number provided; ethikkommission@uni-kassel.de), ref: zEK-33

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

High levels of stress in refugees

Interventions

We use simple individual-level randomization. The randomization takes place automatically via the online platform.

Participants who are assigned to the treatment group receive the complete course materials: 90-minute self-help course and extensive information material about the support offered to Ukrainians in Ukraine and other countries.

Participants in the control group only have access to the information material.

Intervention Type

Behavioural

Primary outcome(s)

Kessler-6 distress will be measured online through self-assessment. It will be measured at the baseline before the intervention and 3 weeks after the beginning of the intervention.

Key secondary outcome(s)

1. The WHO-5 Well-Being Index. It will be measured at the baseline before the intervention and 3 weeks after the beginning of the intervention.
2. The Mental Health Inventory-5. It will be measured at the baseline before the intervention and 3 weeks after the beginning of the intervention.

3. Actions in order to improve the current situation - whether the participant has registered with the local authorities, hours spent looking for accommodation, a job, educational opportunities, and learning a foreign language. It will be measured at the baseline before the intervention and 3 weeks after the beginning of the intervention.

Completion date

31/12/2022

Eligibility

Key inclusion criteria

Participation in the project is open to adults (18+ years) residing in Ukraine or adults who resided in Ukraine before February 24 2022 and had to move to one of the countries in the European Union.

Participant type(s)

Other

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

645

Key exclusion criteria

1. Age under 18 years

Date of first enrolment

22/06/2022

Date of final enrolment

06/07/2022

Locations

Countries of recruitment

Austria

Belgium

Bulgaria

Croatia
Cyprus
Czech Republic
Denmark
Estonia
Finland
France
Germany
Greece
Hungary
Ireland
Italy
Latvia
Lithuania
Luxembourg
Malta
Moldova
Netherlands
Poland
Portugal
Romania
Slovakia
Slovenia
Spain
Sweden
Ukraine

Study participating centre
INCHER-University of Kassel
Mönchebergstraße 17
Kassel
Germany
34125

Sponsor information

Organisation
University of Kassel

ROR
<https://ror.org/04zc7p361>

Funder(s)

Funder type
University/education

Funder Name
Universität Kassel

Alternative Name(s)
University of Kassel

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan

We plan to make the anonymized data available on open access repositories after the publication. No further information available at time of registration.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| Results article | | 24/10/2024 | 31/10/2024 | Yes | No |
| Interim results article | | 04/11/2023 | 18/12/2023 | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Statistical Analysis Plan | | 18/07/2022 | 20/07/2022 | No | No |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |