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

Submission date	Recruitment status	[_] Prospectively registered
22/06/2022	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
28/06/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
31/10/2024	Other	

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

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Additional identifiers

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

Primary study design
Interventional

Study design
Interventional randomized controlled trial

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