

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

<b>Submission date</b> 22/06/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/06/2022	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 31/10/2024	<b>Condition category</b> 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](mailto:igor.asanov@uni-kassel.de)

### **Study website**

<https://www.sho4ukraine.com/informationinenglish.html>

## **Contact information**

### **Type(s)**

Principal Investigator

### **Contact name**

Dr Igor Asanov

### **ORCID ID**

<http://orcid.org/0000-0002-8091-4130>

### **Contact details**

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## **Additional identifiers**

### **EudraCT/CTIS number**

Nil known

### **IRAS number**

### **ClinicalTrials.gov number**

Nil known

### **Secondary identifying numbers**

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Internet/virtual

## Study type(s)

Quality of life

## Participant information sheet

<https://prometheus.org.ua/kassel-university-info-page/>

## 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 measure**

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.

### **Secondary outcome measures**

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.

### **Overall study start date**

25/05/2022

### **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

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

Up to 30000

**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

**Sponsor details**  
International Center for Higher Education Research  
Mönchebergstraße 19  
Kassel  
Germany  
34125  
+49-561-804-2961  
buenstorf@uni-kassel.de

**Sponsor type**  
University/education

**Website**

<http://www.uni-kassel.de/uni/>

**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

**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**

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?
<a href="#">Statistical Analysis Plan</a>		18/07/2022	20/07/2022	No	No
<a href="#">Interim results article</a>		04/11/2023	18/12/2023	Yes	No
<a href="#">Results article</a>		24/10/2024	31/10/2024	Yes	No

