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Mental health assessment of adult people living in different parts of Ukraine and in the Ukrainian diaspora (Canton Zurich)

Submission date
11/01/2024

Recruitment status
No longer recruiting

Registration date
15/01/2024

Overall study status
Ongoing

Last Edited
31/01/2025

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
While the long-term, population-level mental health impact of Russia's invasion of Ukraine on February 24, 2022, cannot yet be fully predicted, high demand for mental health and psychosocial support is anticipated in a post-war context. Since no public mental health surveillance exists in Ukraine, or in the Ukrainian diaspora, our aim is to assess and monitor mental health and health care needs of people living across Ukraine and in the diaspora (Canton Zurich), thus facilitating adapted and responsive mental health care planning and provision.
The aim of this study is the Mental Health Assessment of the Population project implement agile, digital surveillance of public mental health in adult people living in different parts of Ukraine and in the Ukrainian diaspora (Canton Zurich).

Who can participate?
Eligible participants for this study include adults (age ≥18 years) who are residents of Ukraine, as well as adults from Ukraine with refugee status S, currently residing in the Canton of Zurich. Additionally, adults (age ≥18 years) residing in the Canton of Zurich are invited to participate. To be eligible, individuals must provide informed consent and possess the ability to complete the surveys, available in both Ukrainian and German, either online or through a phone interview.

What does the study involve?
Mental Health Assessment of the Population (MAP) study conducts by a team of Swiss and Ukrainian researchers and focuses on mental health surveillance of adult people living in different parts of Ukraine and displaced Ukrainian citizens living in Canton Zurich. Baseline assessments will be conducted in February 2024. Follow-up assessments will take place every three months after baseline for at least two years.
The digital monitoring system will be designed to be cost effective, have a low participation burden, be responsive to changing information needs of Ukrainian stakeholders. Participants will be selected based on random sampling. Data will be collected through a secure digital study platform (REDCap). The results will be displayed in almost real-time on an online platform. Therefore, well before results are available in conventional scientific communication channels, the public, scientists, humanitarian organizations and policymakers can monitor the prevalence

of PTSD, depression, anxiety, and alcohol use disorder among the general population, their trajectories over time, and by subgroup.

What are the possible benefits and risks of participating?
MAP will create a robust, longitudinal mental health surveillance that will provide policy- and decision-makers with essential, high-quality data to make informed and timely decisions on mental health care and support in Ukraine. Establishing a mental health surveillance at the country level will provide vital information for the government to assess healthcare needs, formulate policies and programmes for psychological support, focusing efforts on areas which require most attention.
Data security: As with any online study, there is a small risk of threats to the security of stored personal and sensitive data. We will minimize this risk by relying on UZH infrastructure (Science IT), which provides high levels of data security, by anonymization of stored data and separate storage of information about participants identification. We will rely on our long-term experience with Science IT with the Swiss MS Registry, a particularly sensitive project, and studies at our institute. We will be in regular exchange with the cyber security officer of UZH.
Psychological distress: it is possible that confrontation with personal psychiatric symptoms or reflection on traumatic events may cause psychological distress in participants. We will minimize this risk by relying on established questionnaires for the identification symptoms only, by keeping the length of the survey to the minimum necessary and by providing information on access to hotlines, acute psychiatric support.

Where is the study run from?
University of Zurich (Switzerland)

When is the study starting and how long is it expected to run for?
November 2023 to January 2026

Who is funding the study?
1. Canton Zurich (Entwicklungszusammenarbeit) (Switzerland)
2. University of Zurich (Switzerland)

Who is the main contact?
Prof. Dr. med. et PhD Milo Puhan, miloalan.puhan@uzh.ch

Study website
https://map-studies.ch/

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Mental Health Assessment of the Population

Acronym
MAP

Study objectives
The overall aim of this study is to implement agile, digital surveillance of public mental health in adult people living in different parts of Ukraine and in the Ukrainian diaspora (Canton Zurich).
The specific objectives are:
1. To determine the prevalence of symptoms of PTSD, depression, anxiety, and alcohol abuse at

the beginning of the surveillance, and at follow-up intervals of every three months until two years. Short-term and long-term temporal development in the Ukrainian general population (in Ukraine and in the Canton of Zurich) and subgroups defined by age, region, and level of war-related exposure will also be monitored.
2. To assess how mental health impacts general health and health care seeking behaviour.
3. To assess needs, preferences, barriers, and facilitators for mental health care services of the Ukrainian general population and subgroups.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 13/02/2024, Cantonal Ethics Committee Zurich (Stampfenbachstrasse 121, Zurich, CH-8090, Switzerland; +41 43 259 79 70; info.kek@kek.zh.ch), ref: 2023-02247

2. Approved 14/11/2023, Commission on Bioethics of Sumy State University (Sanatorna 1, Sumy, 40018, Ukraine; +380542660950; info@med.sumdu.edu.ua), ref: 60-0274

Study design
Prospective population-based digital cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Community

Study type(s)
Quality of life, Screening

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
Prevalence and incidence of post-traumatic stress disorder, depression, anxiety, and alcohol use disorder

Interventions
Upon enrolment, participants, who are residents of Ukraine will complete the baseline assessment through a secure digital study platform (REDCap). To access REDCap for the baseline and follow-up assessments, participants will receive an e-mail (automated, including reminders) containing a link to the respective assessment. For the Ukrainians with refugee status S residing in the Canton of Zurich and general population of the Canton of Zurich, the initial contact will be established by postal mail. Participants will not need a specific app, but simply a web browser on their computer, tablet or smartphone. Follow-up assessments will take place every three months for at least 2 years.

Intervention Type
Other

Primary outcome measure
Measured at baseline and then every 12 weeks for 2 years:
1. PSTD measured using Posttraumatic Stress Disorder Checklist (PCL-5)
2. Depression measured using Patient Health Questionnaire (PHQ)-9
3. Anxiety measured using generalized anxiety disorder 7 (GAD-7)
4. Alcohol use disorder measured using Alcohol Use Disorders Identification Test (AUDIT)

Secondary outcome measures
Current secondary outcome measures as of 08/07/2024:
Measured at baseline and then every 12 weeks for 2 years:
1. General health (as measured by the Feeling Thermometer from the European Quality of Life 5 Dimensions (EQ-5D) questionnaire, as well as five questions of the EQ-5D, describing the participant's health: mobility, self-care, usual activities, pain/discomfort, anxiety/depression), experiences of somatic distress syndrome (PHQ-15)
2. To measure social isolation and social integration we used questions taken from the Swiss Health Survey (2022)
3. Needs, preferences, barriers, and facilitators for mental health services will be assessed by closed-ended questions (based on pre-defined dropdown options)

Previous secondary outcome measures:
Measured at baseline and then every 12 weeks for 2 years:
1. General health (as measured by the Feeling Thermometer from the European Quality of Life 5 Dimensions (EQ-5D) questionnaire, as well as five questions of the EQ-5D, describing the participant's health: mobility, self-care, usual activities, pain/discomfort, anxiety/depression), experiences of somatic distress syndrome (PHQ-15), and one question about suicidal thoughts)
2. To measure social isolation and social integration we used questions taken from the Swiss Health Survey (2022)
3. Needs, preferences, barriers, and facilitators for mental health services will be assessed by closed-ended questions (based on pre-defined dropdown options)

Overall study start date
14/11/2023

Completion date
31/01/2026

Eligibility

Key inclusion criteria
1. Adults (age ≥18 years) who are residents of Ukraine.
2. Adults (age ≥18 years) from Ukraine with refugee status S residing in the Canton of Zurich.
3. Adults (age ≥18 years) residing in the Canton of Zurich.
4. Providing informed consent.
5. Being able to complete the surveys (available in Ukrainian and German) online or by phone interview.

Participant type(s)
Population

Age group
Adult

Lower age limit
18 Years

Upper age limit
120 Years

Sex
Both

Target number of participants
A target sample size of the population living in Ukraine is 5,220 persons; A target sample size of the Ukrainian population living in Zurich is 1,220 persons; A target sample size of the general population of the Canton of Zurich is 1,740 persons

Total final enrolment
8180

Key exclusion criteria
Persons who cannot be reached on multiple attempts.

Date of first enrolment
25/03/2024

Date of final enrolment
15/08/2024

Locations

Countries of recruitment
Switzerland

Ukraine

Study participating centre
Epidemiology, Biostatistics und Prevention Institute (University of Zurich)
Hirschengraben 84
Zurich
Switzerland
8001

Study participating centre
Center for Social Research (Sumy State University)
Rymskogo-Korsakova 2

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University of Zurich

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Sponsor type
University/education

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http://www.uzh.ch/index_en.html

ROR
https://ror.org/02crff812

Funder(s)

Funder type
Not defined

Funder Name
Kanton Zürich

Alternative Name(s)
Canton Zurich

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location

Switzerland

Funder Name
Universität Zürich

Alternative Name(s)
University of Zurich, Switzerland, University of Zurich, UZH

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Switzerland

Results and Publications

Publication and dissemination plan
Results of the study will be published in a high-impact peer-reviewed scientific journals.

Intention to publish date
15/02/2025

Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the current study will be available upon request from Prof. Dr. med. et phil. Milo A. Puhan, Director Epidemiology, Biostatistics and Prevention Institute (EBPI) University of Zurich, email: miloalan.puhan@uzh.ch

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		13/01/2025	31/01/2025	Yes	No