

A learning health system for innovative, community-based mental health care delivery in Ukraine: an international, multi-stakeholder effort

Submission date 30/06/2025	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/07/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 02/07/2025	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Ukraine's mental health system remains shaped by its Soviet legacy, characterized by institutionalized, long-term psychiatric care. Historical misuse of psychiatry for political purposes has further fuelled public mistrust. In response, the Ukrainian government initiated reforms in 2017 aimed at modernizing mental health care. These include shifting towards community-based mental health care models, Mental Health Centers (MHCs), that emphasise empowerment, human rights, and destigmatization. International efforts, such as the Mental Health for Ukraine (MH4U) project are central to this transition. MH4U embodies the approaches outlined in the "concept of the development of mental health care in Ukraine for the period until 2030", which aims to create a comprehensive and effective mental care. The MH4U supported MHCs aim to provide low-threshold, outpatient mental health services integrated into the community. Despite these promising developments, evidence on the accessibility, acceptance, effectiveness, and user experience of MHCs in Ukraine remains limited.

This study aims to evaluate the process and effectiveness of mental health services provided by the eight MH4U-supported MHCs and to support their ongoing development toward a more accessible and effective community-based model of care. The objectives include assessing each MHC individually, comparing patient outcomes to the general population, identifying process-related differences across centers, and establishing a learning health environment to inform continuous improvement and guide national mental health reform.

Who can participate?

Eligible participants for this study include patients (age ≥ 18 years), who are currently receiving treatment at the MHCs, providers/health professionals currently working at the MHCs and providers/health professionals, social- and community workers as well as health authorities who are working in the community of these MHCs and are part of the community-based mental

health service through cooperations/partnerships with the MHCs. To be eligible, individuals must provide informed consent and possess the ability to complete the surveys and to take part in interviews and focus groups.

What does the study involve?

EMHC (Evaluation of Mental health Care Center) study is conducted by a team of Swiss and Ukrainian researchers and focuses on the process and effectiveness evaluation of eight MHCs established by MH4U in Ukraine. The evaluation involves patients, who currently receive treatment at the MHCs, providers/healthcare professionals, social- and community workers, and local decision-makers working at the MHCs as well as working in the catchment areas of the MHCs across three oblasts (regions) in Ukraine. The evaluation will be conducted in two phases, evaluating three MHCs in Chernivtsi and Rivne in phase one and five MHCs in Lviv in phase two. We will evaluate the MHCs according to the RE-AIM-Framework focusing on five core dimensions: reach, effectiveness, adoption, implementation, and maintenance, using a mixed-methods approach. The mixed-methods approach includes quantitative data assessments that will be gathered through standardized questionnaires and secondary data analysis (center record of the MHCs) and qualitative interviews and focus groups. Quantitative assessment of effectiveness (patient-reported outcomes measurements) will be conducted at baseline, 3-months follow-up and 6 months follow-up. Quantitative data will be collected through a secure digital study platform (REDCap). A follow-up assessment for the qualitative data as well as the secondary data is planned following the completion of phases 1 and 2 of the evaluation, anticipated to occur within 1 to 2 years.

What are possible benefits and risks of participating?

This study provides critical insights to improve mental health services in Ukraine by systematically evaluating the process and effectiveness of eight community-based MHCs established under the MH4U project. By assessing core dimensions such as accessibility, acceptance, adoption, effectiveness, implementation, and continuity of care, the study addresses the current lack of empirical evidence on the performance and user experience of these new service models. The findings will support evidence-based decision-making, guide the refinement and scale-up of community-based mental health services, and ensure that ongoing reforms result in meaningful improvements in mental health outcomes and service delivery. Moreover, the study will foster a learning health system (LHS) by involving key stakeholders in the evaluation process and promoting knowledge exchange for continuous improvement of mental health care across different regions in Ukraine.

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 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 the treatment journey may cause psychological distress in participants (patients). We will minimize this risk by relying on established questionnaires, by keeping the length of the survey to the minimum necessary and by not asking too deep questions regarding their disease history and treatment journey.

Where is the study run from?

University of Zurich (Switzerland)

When is the study starting and how long is it expected to run for?
July 2025 to November 2027

Who is funding the study?
University of Zurich (Switzerland)
Swiss Agency for Development and Cooperation (SDC)
Swiss National Science Foundation

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

IZURZ3_224797

Study information

Scientific Title

EMHC - Evaluation of community-based Mental Health Centers in Ukraine: A multi-center observational study using mixed methods

Acronym

Study objectives

Community-based Mental Health Centers (MHCs) aim to raise awareness, reduce stigma, and provide low-threshold access to mental health services within a community-integrated outpatient care setting. Despite promising developments, there is limited evidence on the accessibility, acceptance, adoption, effectiveness, implementation and user experience of these MHCs in Ukraine.

Evaluating the process and effectiveness of community-based MHCs and model of care is therefore crucial to understand their impact, guide further implementation, and ensure that ongoing reforms translate into meaningful improvements in mental health outcomes and service delivery. So far, eight MHCs have been established supported by the Mental Health for Ukraine Project (MH4U) in Ukraine: five in Lviv Oblast, one in Rivne Oblast and two in Chernivtsi Oblast.

The overall aim of this study is to evaluate the process and effectiveness of the mental health service provided by eight MH4U supported MHCs and to support their further development towards an accessible and effective community-based care model for people with mental health conditions in Ukraine.

Five core dimensions of the healthcare service will be evaluated:

1. Reach of the healthcare service
2. Effectiveness of the healthcare service
3. Acceptance of the healthcare service by patients and providers
4. Implementation of the healthcare service
5. Sustainability of the healthcare service (maintenance)

The objectives of the study are:

1. To understand how community-based MHCs in Ukraine contribute to accessible and effective mental health care delivery within their community.
2. To evaluate the current state and development of mental health care processes across MHCs, identifying site-specific strengths, gaps, and variations in service delivery.
3. To explore individual and contextual factors that influence experiences of patients and providers/health professionals with MHCs, including barriers and facilitators to care access, engagement, and collaboration with the community.
4. To assess how MHCs are integrated into their local communities, including how referral pathways, partnerships, and service coordination function in practice.
5. To generate evidence that supports the ongoing development, adoption and potential scale-up of the MHC model of care.
6. To foster a learning health environment by informing key stakeholders based on the evaluation results to facilitate improvement in mental health care delivery in Ukraine.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 06/11/2024, Commission on Bioethics of Sumy State University (Sanatorna 1, Sumy, 40018, Ukraine; +380 542660950; info@med.sumdu.edu.ua), ref: 60-236

Study design

Multicenter observational longitudinal study design using mixed methods

Primary study design

Observational

Secondary study design

Longitudinal study

Study setting(s)

Community, Medical and other records, Workplace

Study type(s)

Other

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

Evaluation of Mental Health Centers (new model of care) in Ukraine according to the RE- AIM- Framework including the dimensions reach, effectiveness, adoption, implementation, maintenance); improvement of community-based mental health services for adults for (relapse-) prevention, diagnostic and treatment of mental health conditions.

Interventions

We will conduct a mixed method approach guided by the RE-AIM framework assessing the five dimensions reach, effectiveness, adoption, implementation, and maintenance. The results of the quantitative assessment of the patients (demographics and self-reported outcome measurements) will be compared with the general population as control group based on the results of the Ukrainian population-based cohort study “Mental Health Assessment of the Population” (MAP). The evaluation of the currently established eight MHCs takes place in two phases. In the first phase we will evaluate two centers in Chernivtsi (Polyclinic 1,2) and one center in Rivne (Varash Hospital). In the second phase we will evaluate five centers in Lviv (Polyclinics 1,2,4,5 and 6).

After each evaluation phase, data analysis will be performed to inform key stakeholders in Ukraine. After data collection and analysis of the evaluation phases are completed, workshops with key stakeholders including providers/health professionals working at the MHC and in the community, social- and community workers and health authorities will be planned to inform stakeholders about the results and to identify key actionable result.

The evaluation will include quantitative and qualitative data assessments across the five RE-AIM- dimensions (reach, effectiveness, adoption, implementation, and maintenance). Details of outcome measures will be explained in the primary and secondary outcome sections. Quantitative data will include demographic assessment and the use of validated, established questionnaires, in addition to routinely collected data from center records of the MHCs (secondary data analysis). Qualitative data will be gathered through interviews and focus groups with patients, providers/health professionals, and other key stakeholders (e.g., community health workers, local health authorities).

Quantitative data assessment:

Patients: Upon enrollment, participants will complete the baseline and follow-up assessments through a secure digital study platform (REDCap). Before enrollment, patients will be (pre-) screened and contacted by the registrar at each MHC during their regular planned visit. Eligible Patients will receive a flyer containing information about the study. The flyer also provides a QR-Code directing the patients to a registration form in REDCap. We will further assess the eligibility based on the submitted registration data by the patients. Further eligible patients will receive a REDCap link to provide informed consent and complete the quantitative basic assessment questionnaire assessing information about demographics and treatment status at the MHC as well as self-reported outcome measurements. The basic demographic assessment and the self-reported outcome assessments are both aligned with our control cohort group (MAP-Study). Two follow-up assessments for the outcome measurements are planned, at 3-months (follow-up 1) and at 6 months (follow-up 2) to evaluate effectiveness of the MHC services. The follow-up assessment will be also distributed via REDCap.

Providers/health professionals working at the MHCs: All providers working at MHCs will be contacted to invite them to participate in the study. The providers/health professionals will receive information about the study (study summary). After that, providers will receive an invitation via E-Mail/viber with a personalized link directing the providers to informed consent as well as basic demographic assessment in REDCap. Providers/health professionals at the MHC will contain written informed consent for the quantitative assessment. Providers receive a link for the further quantitative assessments via REDCap.

Secondary data analysis: Annual center records, collected routinely at the end of the calendar year at each MHC, will be obtained in January 2026 for the year 2025 to examine patient demographics, clinical characteristics, and retention. Because the center record data will be available for the full year, we will collect the total number of patients treated at each MHC after study start for the year 2024 to perform exact sample size calculation (current sample size calculation is based on estimations).

Qualitative data assessment:

Patients: A sample of the same participants (patients) that already has participated in the quantitative assessment and that has agreed to be contacted for an interview during the quantitative assessment, will be contacted after 2 weeks of baseline-assessment to recruit for the qualitative assessment and to schedule qualitative interviews not earlier than 6 weeks from the baseline assessment (minimum of 6 weeks between baseline assessment and interviews). Prior to the interviews, informed consent will be obtained orally. Interviews will be performed by telephone with (a semi-structured) developed interview guide by the research team from Sumy State University. The interview guides have been piloted at the MHC Polyclinic 1 in Lviv with 12 patients in terms of feasibility and revised based on the pilot results.

Providers/health professionals working at the MHC: All providers working at the MHC will be invited to participate in the qualitative interviews. Informed consent will be obtained orally at the time point of qualitative data collection. Interviews will be performed online with (a semi-structured) developed interview guide by the research team from the Sumy State University. The interview guides have been piloted at the MHC Polyclinic 1 in Lviv with 5 providers working at the MHC in terms of feasibility and revised based on the pilot results. For the directors (chief of MHC), additional questions were incorporated in the qualitative interview guide to explore operational processes, resource allocation, and site-specific implementation barriers and enablers.

Providers/health professionals working in the community (cooperation/ partners of MHCs): Providers working in the community and are collaborating with the MHC (to ensure community-based mental health care approach) will be contacted based on a list provided by MH4U. We will conduct two focus groups: One focus group with health professionals (GPs, Neurologists and Rehabilitation Specialists) and one focus group with community-, and social workers and health authorities. Given the size and more centers in Lviv, 4 focus groups (2 each) will be conducted to ensure representation and manageability of discussion. Focus group discussion will be guided by a developed focus group guide and will take place in person led by the research team of the Sumy State University. Informed consent will be obtained orally at the time point of qualitative data collection.

Intervention Type

Other

Primary outcome measure

1. Reach will be assessed by capturing patient data about the total number, characteristics, and referral sources of patients receiving care at MHCs based on the center record data (secondary analysis). Center records and baseline assessment questionnaire will explore demographic and clinical characteristics of patients compared to those who are not receiving care in the center, using data from the control group (MAP study) as a reference. Patient interviews will be conducted to identify factors that hinder or support access to services. A follow-up assessment is planned to follow the completion of phases 1 and 2 of the evaluation, anticipated to occur within 1 to 2 years.
2. Effectiveness will be assessed through quantitative assessment of patient measuring patient symptoms and severity of specific mental health conditions using self-reported outcome measurements: PTSD by the Posttraumatic Stress Disorder Checklist (PCL-5), depression by the Patient Health Questionnaire 9 (PHQ- 9), anxiety by the Generalized Anxiety Disorder 7 (GAD-7), alcohol use disorder by the Alcohol Use Disorders Identification Test (AUDIT). Health-related quality of life will be measured using EQ-5D and therapeutic alliance by Working alliance inventory – short revised (WAI-SR). These assessments take place at baseline, follow-up 1 (after 3 months) and follow-up 2 (after 6 months).
3. Adoption will be evaluated at the MHC- and the community-level. Center records will capture the number, proportion and characteristics of MHCs and their affiliated providers/health professionals. For providers/health professionals working at the MHC, self-reported validated questionnaires will be completed: The Team Development Measure (TDM), the Mental Illness Clinicians' Attitudes Scale (MICA-4), the Copenhagen Psychosocial Questionnaire (COPSOQ-111), General Health Questionnaire (GHQ-12), Perceived Stress Scale (PSS-10), and Burnout Assessment Tool (BAT). At the community-level we will perform two focus groups: one focus group with community healthcare providers (GPs, neurologists, rehabilitation specialists) and another focus group with the health authorities and social-/community workers. A follow-up assessment is planned following the completion of phases 1 and 2 of the evaluation, anticipated to occur within 1 to 2 years.
4. Implementation will be assessed through quantitative assessment at the provider/health professional-level working at the MHC: the Organizational Readiness for Implementing Change (ORIC) scale. Furthermore through qualitative interviews with the providers at the MHCs and focus groups with the providers working in the community. Fidelity will be explored qualitatively by examining how core components of the model are interpreted and operationalized across sites. Interviews with the directors of the MHCs will capture operational process, resource allocation, and center specific barriers and enablers to implementation. A follow-up assessment is planned following the completion of phases 1 and 2 of the evaluation, anticipated to occur

within 1 to 2 years.

5. Maintenance will be assessed at the patient level, long-term outcomes will be captured ≥ 6 months after patients' first contact, using the same standardized patient-reported outcome measures administered at baseline: PCL-5, PHQ-9, GAD-7, and AUDIT, EQ-5D and WAI-SR. Center records will be used to explore long-term attrition and subgroup-specific patterns of retention and outcomes. (Please see also number 2, effectiveness).

Secondary outcome measures

Qualitative data and context-specific insights generated in workshops with key stakeholders after each phase of the evaluation was completed to inform about the results of the evaluation and to facilitate improvement in mental health care delivery.

Overall study start date

06/11/2024

Completion date

30/11/2027

Eligibility

Key inclusion criteria

1. Providers/health professionals working at the MHCs: We include all providers (all roles and functions) working at the MHC.
2. Provider/health professionals working in the communities where the MHCs are located: Existing cooperation/partnership with MHCs.
3. Patients:
 - 3.1. Adults (age ≥ 18 years) who are resident of Ukraine
 - 3.2. Receiving current treatment at the MHC
 - 3.3. A minimum of ≥ 2 treatment sessions received at the MHC for the quantitative assessment; a minimum of 6 weeks of treatment received for the qualitative assessment (interviews)
 - 3.4. Providing informed consent
 - 3.5. Being able to complete assessments (no acute mental health condition including, but not limited to psychosis, alcohol intoxication, dementia)

Participant type(s)

Patient, Health professional

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Qualitative interviews (providers/health professionals at the MHC and patients): We perform interviews until we have reached content saturation (no new themes or codes are emerging from additional interviews; approx.: 12-16 interviews); focus groups (providers/health

professionals in the community): We include 6-9 participants in each focus group (2-4 focus groups are planned per oblast/community); quantitative assessment providers at the MHC: We include all providers working at the MHC (approx. 3-7 per MHC); quantitative assessment patients: We have performed a sample size calculation based on the estimated number of patients treated at the MHCs per year for each MHC. We will recruit and enroll approx. 400 patients for all eight MHCs (50 patients per MHC). An exact sample size calculation will be also performed after we have received the exact total number of patients treated per MHC for the full year 2024 based on center records data of the MHCs as part of the data assessment. Given the speed of recruitment of the patients (approx. 10-15 patients per month per MHC) we will start with the recruitment and assessment and will update the target number for patients per center once we have received the data from the center records of the MHC.

Key exclusion criteria

Patients: Patients who cannot be reached on multiple attempts

Date of first enrolment

07/07/2025

Date of final enrolment

15/03/2026

Locations

Countries of recruitment

Ukraine

Study participating centre

Sumy State University

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Sponsor information

Organisation

University of Zurich

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Sponsor type

University/education

Website

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ROR

<https://ror.org/02crff812>

Funder(s)

Funder type

University/education

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

Funder Name

Swiss Agency for Development and Cooperation (SDC)

Funder Name

Schweizerischer Nationalfonds zur Förderung der Wissenschaftlichen Forschung

Alternative Name(s)

Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, SNF, SNSF, FNS

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Switzerland

Results and Publications

Publication and dissemination plan

Results of the study will be published in high-impact peer-reviewed scientific journals.

Intention to publish date

01/03/2026

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