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Effectiveness of the creative space for mental health program in improving the quality of life of users of psychiatric services

Submission date
06/07/2021

Recruitment status
Stopped

Registration date
29/07/2021

Overall study status
Stopped

Last Edited
05/02/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The reform of the mental health care system in Serbia began more than a decade ago. In the first place, it involved a gradual transition from exclusively institutional treatment to the development of community mental health services. In the past 10 years, some progress has been made, primarily through the establishment of the Centers for mental health within the institutions and the establishment of mental health service users associations that collaborate with institutions. However, a system of community mental health services is not yet available for most people in need, nor is institutional and financial support for organizations implementing community support programs. Following the mentioned reform, the association Prostor (https://prostor.org.rs/en/prostor-en/about-us/), a non-governmental organisation from Belgrade, Serbia, has been providing community-based psychosocial support to the users of psychiatric services since 2009. The Prostor association has launched the "Creative Space for Mental Health" program, which aims to provide psychosocial support to empower and improve the quality of life of psychiatric patients through a support program aimed at recovery in the community. This study aims to test whether patients being offered the intervention in addition to treatment as usual have a better quality of life at the end of the programme as compared to patients receiving only treatment as usual.

Who can participate?
Patients aged 18 years and over with psychotic spectrum disorders

What does the study involve?
The study aims to test the effectiveness of the Creative Space for Mental Health program at improving the quality of life of psychiatric users, which patients of the Institute for Mental Health (IMH) would attend in addition to the regular treatment they receive in the Institute for Mental Health. This study will last 1 year and involves randomly allocating patients to an intervention group that receives regular treatment at IMH and program services, or a control group that receives only regular treatment at IMH. Quality of life, well-being, hope, difficulties in mental health and psychological condition are measured before joining the program and after 3 months of attending the program’s activities

What are the possible benefits and risks of participating?
The study results will be used for strengthening evidence-based practice and advocacy work which it is hoped will lead to better mental health programs and support for psychiatric patients. There is no expected risk to participants.

Where is the study run from?
Psychosocial Innovation Network (Serbia)

When is the study starting and how long is it expected to run for?
February 2021 to September 2022

Who is funding the study?
1. Caritas Serbia (Serbia)
2. Psychosocial Innovation Network (Serbia)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Effectiveness of the creative space for mental health (CSMH) program in improving the quality of life of users of psychiatric services: a randomized controlled trial

Study objectives
Usage of the creative space for mental health (CSMH) program will increase the subjective perception of quality of life, level of hope, objective indicators of social outcomes, and decrease psychiatric symptoms, and symptoms of depression, anxiety and stress.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/05/2021, Ethics Committee of the Institute for Mental Health (Milana Kašanina 3, 11000 Belgrade, Serbia; Tet. +381 (0)3238 160; ivana.gavrilovic@imh.org.rs), ref: not applicable

Study design
Two-arm exploratory randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Quality of life in psychiatric patients with psychotic spectrum disorders

Interventions
The research aims to test the effectiveness of the Creative Space for Mental Health program (Program) in improving the quality of life of psychiatric patients, which patients of the Institute for Mental Health (IMH) would attend in addition to the regular treatment they receive in the Institute for Mental Health. This two-arm exploratory RCT with blinded outcome assessment will last one year, involving 60 IMH patients randomized to an intervention group - receiving regular treatment at IMH and using Program services, or a control group - receiving only regular treatment at IMH. The measures used in the research are related to the assessment of satisfaction with the quality of life, hope, difficulties in mental health, as well as objective indicators of quality of life and psychological condition of patients, and would be collected before joining the Program, after 3 months of attending Program activities and 3 months after the Program has ended.

Participants will be recruited by psychiatrists from the Institute for Mental Health (IMH). Psychiatrists from IMH will receive a leaflet with all the basic information about the research that they can share with their patients. Patients who are presently receiving treatment at IMH will be informed about the study and asked whether they would want to be contacted by the research team for more information. Participants who show interest and readiness to participate in this project will be contacted by a research team who will explain the goal of the research as well as what participation in the research entails. Those who decide to participate will be asked to sign a consent form. After the informed consent has been signed participants will undergo an assessment of compliance with the selection criteria.
Subjects who do not meet the selection criteria will be given information about the Program, and an invitation to join the available activities. Those who meet the selection criteria will be pretested and will be randomly assigned to an intervention or control group.
Participants in the intervention group will receive more detailed information about the Program and will be referred to an initial meeting with the program manager regarding joining the Program’s activities they are interested in, and then, after three months, they will be contacted for retest purposes.
Participants in the control group will receive treatment as usual. They will be contacted again after 3 months from the initial testing for reassessment purposes and then they will be asked to participate in the Program's activities.

Experimental intervention:
The intervention group receive treatment as usual (TAU) at the Institute for Mental Health, and participate in the Program’s activities. Each participant chooses one program unit to participate in for 12 weeks.

Program - consists of four program units:

1. The educational and occupational program includes activities aimed at empowering users of psychiatric services through the development of various practical and social skills, acquiring

knowledge, encouraging self-confidence, creativity, and a sense of belonging and achievement. All activities will be organized in group form, on a weekly basis, for a duration of 90 minutes. The number of participants for each activity is from 6 to 8. Study participants will join already established groups and, therefore, the groups will include both study and non-study participants. The persons who lead this part of the program's activities must undergo training to work with vulnerable groups, primarily psychiatric patients, while required qualifications and skills will be defined depending on the type of activity. In addition, it is necessary for the activity facilitator to have supervision/consultation with the supervisor of the Prostor once a month, as well as to keep regular records of the implemented activities.

2. The psychosocial-psychotherapeutic program includes activities aimed at empowering users of psychiatric services through the development of their internal capacities, improving communication skills by recognizing and expressing thoughts and feelings, developing adaptive mechanisms for overcoming stress and life challenges, and gaining a sense of security and trust. All activities are organized in group form, and there is a possibility of individual consultation if needed. Activities are organized on a weekly basis, with a duration of 90 minutes. The number of participants for each activity is from 6 to 8. Study participants will join already established groups and, therefore, the groups will include both study and non-study participants. Qualifications for facilitators within this program unit are pre-defined and imply that the persons have the appropriate qualifications required to carry out the activity, including psychotherapy training. It is required that the person leading this part of the program activities undergo training for working with vulnerable groups. In addition, it is necessary for a facilitator to have supervision/consultation with the supervisor of the Prostor once a month, as well as to keep regular records of the implemented activities.

3. The peer support program includes activities aimed at empowering users of psychiatric services through the development of a support network that includes connecting with people who have similar experiences, sharing those experiences, learning from other people's experiences, sharing their own ways of overcoming difficulties, connecting with others, gaining a sense of belonging and togetherness. All activities are organized in group form, on a weekly basis, with a duration of 90 minutes, depending on the type of activity. The number of participants for each activity is from 6 to 8. Study participants will join already established groups and, therefore, the groups will include both study and non-study participants. Qualifications for an activity facilitator within this program unit include completed training for leading peer support groups. In addition, it is necessary for the activity facilitator to have supervision/consultation with the supervisor of the Prostor once a month, as well as to keep regular records of the implemented activities.

4. The economic and social empowerment program includes activities aimed at empowering users of psychiatric services through learning about their rights and ways to achieve the realization of these rights, acquiring skills to express and communicate their needs, and raising awareness of the community about the position of psychiatric patients in order to improve that position, acquiring skills that would lead to competitiveness in the labour market based on their own abilities and talents. Except for individual consultations with social workers, all activities are carried out in a group. Activities are organized on a weekly basis, with a duration of 90 minutes, depending on the type of activity. The number of participants for each activity is from 6 to 8. Study participants will join already established groups and, therefore, the groups will include both study and non-study participants.
Qualifications for the activity facilitators within this program unit are defined depending on the type of activity and the required qualifications and skills. It is necessary that the person leading this part of the program activities undergo training to work with users of psychiatric services or have experience in working with this population. In addition, it is necessary for the activity

facilitator to have supervision/consultation with the supervisor of the Prostor once a month, as well as to keep regular records of the implemented activities.

Control condition
The control group will receive treatment as usual (TAU), i.e., regular medical check-ups and treatment at the Institute for Mental Health. Upon completion of the research, all participants from the control group will receive more detailed information about the Program and an invitation to join the activities.

Intervention Type
Behavioural

Primary outcome(s)
Subjective perception of quality of life measured using an SQOL questionnaire at baseline, post-treatment (after 3 months) and follow up (after 6 months)

Key secondary outcome(s))
Measured at baseline, post-treatment (after 3 months) and at follow up (after 6 months):
1. Severity of symptoms of depression, anxiety and stress measured by Depression, Anxiety and Stress Scale - 21 Items (DASS-21), short version
2. Severity of psychiatric symptoms measured by the brief psychiatric rating scale
3. Level of hope measured by the Herth Hope Index (HHI)
4. Objective indicators of social outcomes assessed by the objective social outcomes index (SIX)

Completion date
01/09/2022

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
1. Age minimum of 18 years
2. Diagnosed with psychotic spectrum disorders (ICD-10 F20-F29)
3. Capacity and willingness to participate in Program's activities during the intervention period and go through psychological assessment
4. Able and willing to give informed consent
5. Native or fluent in Serbian

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Sex
All

Key exclusion criteria
Participants are excluded if:
1. They were previously diagnosed with personality disorder, organic mental disorder, or intellectual disability
2. Can’t participate in group activities
3. Were legally mandated to undergo psychiatric treatment

Date of first enrolment
01/08/2021

Date of final enrolment
01/04/2022

Locations

Countries of recruitment
Serbia

Study participating centre
Psychosocial Innovation Network
Gospodar Jevremova 48
Belgrade
Serbia
11000

Sponsor information

Organisation
Psychosocial Innovation Network

Funder(s)

Funder type
Other

Funder Name
Psychosocial Innovation Network

Funder Name
Caritas Serbia

Results and Publications

Individual participant data (IPD) sharing plan
An anonymized dataset including raw data will be made available upon request for non-commercial purposes, reproduction of the reported findings, and for academic research staff from Irena Stojadinović (stojadinovic@pin.org.rs).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes