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Effectiveness of a recovery workshop implemented in a psychiatric hospitalization unit

Submission date
29/06/2022

Recruitment status
No longer recruiting

Registration date
05/07/2022

Overall study status
Completed

Last Edited
16/10/2024

Condition category
Mental and Behavioural Disorders

[_] 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
Currently, following the guidelines of the United Nations and the World Health Organization, public mental health policies seek to promote self-determination and respect for one's own preferences in mental health recovery processes. This change was initiated by the Anglo-Saxon countries, it has been followed by Northern Europe and, more recently, it is beginning to take place in Italy and Spain.
Despite this change in the strategic plans, no intervention program aimed at meeting these objectives has yet been implemented in Spain. Recently, based on a participatory process carried out in Catalonia (Spain), a series of materials were created to implement a workshop that allows people to be taught how to prepare their own personalized Recovery Plan and to self-manage their own wellbeing. This study aims to test the effectiveness of this workshop. The main objective is to evaluate the effectiveness of a recovery workshop implemented in a subacute psychiatric hospitalization unit in Catalonia to improve personal recovery, empowerment, hope and perceived social support.

Who can participate?
Patients aged 18 to 65 years with a mental disorder who are users of a subacute psychiatric hospitalization unit in Catalonia

What does the study involve?
Experimental group participants attend a 6-session workshop that teaches the concept of personal recovery, the importance of self-determination, and how to make their own recovery plan, including a wellness toolbox, a maintenance toolkit, and a crisis plan. Control group participants attend the usual activities of the same community mental health services but do not participate in the workshop.

What are the possible benefits and risks of participating?
For the participants of the experimental group (6-session recovery workshop) there is a direct benefit for participating in this study, which is independent of the effectiveness of the workshop to improve the evaluated variables. All of them have the opportunity to develop their own recovery plan. This includes being able to decide what their recovery goals are, who are the support people in their personal environment, what resources (professionals and non-

professionals) they want to include in their plan, who are their reference professionals in mental health services, and what should be done in case they have a relapse (do they prefer a hospitalization, or do they prefer to receive treatment at their own home?). For participants in the control group there are no direct benefits of participating in this study. There is an indirect benefit for all study participants. This evaluation is done as a pilot project that will allow deciding if the recovery workshop is incorporated into the hospital mental health services portfolio in Catalonia. There are no risks of participating.

Where is the study run from?
The study is a collaboration between the Catalonia Mental Health Services Administration, the University of Barcelona and ActivaMent Catalunya Associació (an association of users and survivors). It is implemented in the subacute psychiatric hospitalization unit of the Parc Sanitari Sant Joan de Déu (Spain)

When is the study starting and how long is it expected to run for?
June 2022 to June 2024

Who is funding the study?
Ministry of Science and Innovation (Spain)

Who is the main contact?
Dr Juana Gómez Benito, juanagomez@ub.edu

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
PID2019-109887GB-I00

Study information

Scientific Title
Effectiveness of a recovery workshop implemented in a subacute psychiatric hospitalization unit: a 6-week non-randomized controlled trial

Study objectives
The hypotheses that guide this study are:
1. The participants in the Recovery Workshop will show significant higher level of personal recovery compared to the people in the control group.
2. The participants in the Recovery Workshop will present a significantly higher level of empowerment compared to the control group.
3. The participants in the Recovery Workshop will show a significantly higher level of perceived social support compared to the control group.
4. The participants in the Recovery Workshop will have a significantly higher level of hope for recovery compared to the control group.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 29/11/2021, Bioethics Committee of the University of Barcelona (C/Baldiri i Reixac 2, Barcelona, 08028, Spain; +34 934 035 463; cbub@ub.edu), ref: IRB00003099

Study design
Single-centre interventional non-randomized controlled trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
See trial outputs table

Health condition(s) or problem(s) studied
Promotion of personal recovery in users of a subacute psychiatric hospitalization unit

Interventions
The intervention consists of a six-session recovery workshop, in which participants learn to develop their own personalized recovery plan, including a wellness toolbox, a maintenance toolkit (to prevent relapse), and a crisis plan.

The evaluation design is pre-post intervention, with a control group. The people in the control group attend the same community mental health services but do not participate in the workshop, but in the usual activities of the service.

The evaluation is done with a battery of psychometric instruments that includes the Recovery Assessment Scale – Domains and Stages (Hancock et al., 2015), Empowerment Scale (Rogers et al., 1997), Recovery Process Inventory (Jerrell et al., 2006), Dispositional Hope Scale (Galiana et al., 2014), and Multidimensional Scale of Perceived Social Support (Zimet et al., 1988).

The study is single-centre. The Psychiatric Hospitalization Unit of the Parc Sanitari Sant Joan de Déu (Catalonia) will participate in the trial. Attendance of the recovery workshop is voluntary.

Intervention Type
Behavioural

Primary outcome measure
Personal recovery measured using the Recovery Assessment Scale – Domains and Stages and the Recovery Process Inventory at baseline (2 days before starting the 6-session recovery workshop) and 2 days after the end of the workshop

Secondary outcome measures
Measured at baseline (2 days before starting the 6-session recovery workshop) and 2 days after the end of the workshop:
1. Empowerment measured using the Empowerment Scale
2. Hope measured using the Dispositional Hope Scale
3. Perceived social support measured using the Multidimensional Scales of Perceived Social Support

Overall study start date
01/06/2020

Completion date
24/06/2024

Eligibility

Key inclusion criteria
1. Adults (older than 18 years old and under 65 years old)
2. Users of a subacute psychiatric hospitalization unit
3. Interest and commitment to participate in a six-session workshop

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
100 (50 Experimental Group and 50 Control Group)

Total final enrolment
111

Key exclusion criteria
1. Relevant cognitive impairment and comprehension difficulties
2. Severe or decompensated somatic disease

Date of first enrolment
30/06/2022

Date of final enrolment
06/05/2024

Locations

Countries of recruitment
Spain

Study participating centre
Parc Sanitari Sant Joan de Déu
C/ del Dr. Antoni Pujadas, 42.
Sant Joan de Déu
Spain
08830

Sponsor information

Organisation
University of Barcelona

Sponsor details

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Sponsor type
University/education

Website
https://www.ub.edu/web/portal/en

ROR
https://ror.org/021018s57

Funder(s)

Funder type
Government

Funder Name
Ministerio de Ciencia e Innovación (MCIN/AEI/10.13039/501100011033)

Alternative Name(s)
CienciaGob, Ministerio de Ciencia e Innovación de España, Ministry of Science and Innovation, Spanish Ministry of Science and Innovation, Ministry of Science and Innovation of Spain, Spain, Ministry for Science and Innovation, Ministeri de Ciència i Innovació, MCIN, MICINN

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/03/2025

Individual participant data (IPD) sharing plan

Raw data, including individual participant data, will be shared at the repository CORA Portal de la Recerca de Catalunya (https://portalrecerca.csuc.cat/).

The data files that will be shared are: (a) the database of the study, containing anonymized participants' responses (.csv format); and (b) the coding book that accompanies the database (. pdf format). The database (a) will be accompanied by a coding book in which there will be documentation on correspondence between questionnaire items and variable names in the database, the definition of new variables generated after data collection (e.g., recoded variables), and type of variable (e.g., nominal, ordinal). The database structure will conform to standards in the field (e.g., it will contain as many rows as participants and as many columns as variables in the study).

Standard vocabulary will be used to assign names, categories, keywords, etc. to files and variables. All files will conform to standard software formats (.csv and .pdf) since they are widespread use and allows data consultation by other users.

These two data files will be assigned to a Creative Commons license "Attribution-No Commercial 4.0 International (CC BY-NC 4.0)". This information will be specified at the repository, where terms of use will be described. Data citation will be provided, and proper credit will be requested.

Data will be uploaded to the repository CORA-Repositori de Dades de Recerca (https://dataverse.csuc.cat/) 2 years after the end of the trial to ensure the necessary time to exploit the data, given the timing for the analysis and review of the data by scientific journals. A long-term data sharing and preservation plan will be used to store and make publicly accessible the data beyond the life of the project. Specifically, the data files will remain accessible for at least 10 years after the data are made available publicly at the CORA repository.

According to the CORA repository, for each of the two data files the following metadata will be created: dataset persistent ID (DOI number), publication date, title, author, contact information, description (i.e., a summary describing the purpose, nature and scope of the dataset), subject (i. e., domain-specific subject categories that are topically relevant to the dataset), keywords (i.e., key terms that describe important aspects of the dataset), topic classification (i.e., classification field using standard language, Thesaurus UB), related publication (i.e., publications that use the data), language, grant information, depositor, deposit date, date of collection, kind of data (i.e., type of data included in the file), and software. Data file versions will be registered at the repository using two-digit numbers (e.g., 1.0 to identify the first published version, 1.1 to identify the first modification, 1.2 to identify the second modification, and so on).

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Control group		05/07/2022	No	Yes
Participant information sheet	Experimental group		05/07/2022	No	Yes
Protocol file			05/07/2022	No	No