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Impact of collaborative nursing care on the recovery process of mental health day hospital users: a mixed-methods study protocol

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ABSTRACT

Introduction Very few collaborative nursing care interventions have been studied and shown to be effective in the context of the paradigm shift towards recovery in mental health nursing. Understanding the changes produced in the recovery process of people with mental health problems can contribute to the design and implementation of new methodologies to offer effective and person-centred care.

Methods and analysis This is a mixed-methods study, which is structured in three phases. In phase one (baseline) and phase three (follow-up), quantitative data will be collected from patients at a mental health day hospitals based on a two-armed, parallel-design, non-randomised trial. In phase two, two groups will be established: an intervention group in which the intervention based on collaborative nursing care will be carried out through the codesign and implementation of activities through Participatory Action Research, and a control group in which the usual care dynamics will be continued. All the users of three mental health day hospitals who agree to participate in the study will be studied consecutively until the necessary sample size is reached. The outcomes used to evaluate the impact of the intervention will be the stage of the recovery process, the quality of the therapeutic relationship and the patient's level of positive mental health.

Ethics and dissemination This study has been approved by the institutional review board of the reference hospital, FIDMAG Hermanas Hospitalarias (PR-2020-10) in July 2020. All participants will be able to voluntarily withdraw from the study at any time. For this reason, users will be given a sheet with all the precise information about the study to be carried out and written consent will be requested. Preliminary and final results will be published in peer-reviewed journals and presented at national and international congresses.

Trial registration number NCT04814576.

Strengths and limitations of this study

- The mixed-methods design will allow the relationship with other important factors in the care and recovery process, such as the nurse–patient therapeutic relationship and positive mental health, to be analysed from different perspectives in order to gain knowledge about the influence of these factors in planning future interventions in this area.
- In relation to the quantitative component, the type of intervention prevents the use of a pure experimental design with randomisation of subjects. However, the possibility of using a comparison group with very similar characteristics provides robustness to the design.
- The most important under-reporting that may occur in the qualitative dimension of this study is that, during the data collection phase, some of the participants may not feel comfortable explaining their situation or feelings and, therefore, the interviews may not be as in-depth as possible. This may be more likely to occur in users with paranoid symptomatology.

INTRODUCTION

In the context of the care of users at mental health day hospitals, nurses must accompany people in their recovery process, enabling users to lead this process and establish a goal.[1] In this sense, nurses, through the therapeutic relationship and the use of a properly implemented collaborative care model, could more effectively improve important aspects in the recovery process of users such as education, changes in routines or habits and the development of information technologies.

According to the WHO,[2] the provision of mental health services should include a recovery-based approach that emphasises supporting people with mental disorders to achieve their own aspirations and goals. Thus, the WHO[3] describes recovery as a process in which a person's hope and self-determination lead to a meaningful life and a positive sense of self, whether or not the mental disorder is still present. The conceptual framework of this model is a theoretically defensible and

sound synthesis of the recovery experiences of people with mental illness.[4] Davidson[5] states that organisations that orient their services to recovery citizenship will play a key role in changing the culture of both the mental health system and society at large. This change will be in the positive direction of embracing the reality of recovery and valuing the contributions that the recovery community makes. Also, Deegan,[6] one of the great figures who have studied this process, provided recommendations for creating rehabilitation environments that facilitate the recovery process.

This model identifies five phases or stages in the process of recovery of the person with mental health problems:[7] (i) the moratorium stage or first stage consisting of denial, hopelessness, confusion and self-protective withdrawal of the person, (ii) the awareness stage or second stage in which the first moments of hope that there may be a better life and that recovery is possible, which may be an internal event or caused by an external event. This leads to the emergence of awareness that there may be a self that is capable of recovery and different from the 'sick person', (iii) the preparation stage or third stage, when the person begins to work on their own recovery by considering their values, weaknesses and strengths. This leads to learning about mental health problems, available services, recovery skills, as well as participating in groups and connecting to the network of users, (iv) the rebuilding stage or fourth stage, where there is an active pursuit of personal goals and working to achieve goals. This may involve re-evaluation of the person's goals and values. The person must take responsibility for managing his or her illness and take control of his or her own life and, finally, (v) the fifth or growth stage, which could be considered the fruit of the recovery process. The person may not be totally free of symptoms, but they will know how to live with them. They are resistant to setbacks and mishaps and believes in his/her resilience. The person has a positive self-image of themselves.[7]

In the framework of recovery-based care, the collaborative care model seems very appropriate since, through it, the user is encouraged to work in collaboration and partnership with the nurse, as well as to participate in decision making throughout the therapeutic process.[8 9] This participation improves quality of life and provides a greater sense of empowerment for the user, and is also found to improve symptom management and give the user a greater sense of control and self-determination.[10]

More specifically, in the field of mental health, there is evidence that collaborative care significantly improves levels of depression and anxiety in the short, medium and long terms, as well as the use of medications, quality of life associated with mental health and user satisfaction.[11] From the point of view of people attended in health services in both acute and rehabilitation mental health areas, collaborative care is conceived as a joint work process in which outcomes are user-centred.[11 12] For users and nurses in rehabilitation areas, this should take place in a therapeutic setting that includes open, honest and respectful communication. Where knowledge and professional and lived experience are mutually valued and shared; the ability to be active, responsive and flexible within the relationship; and the availability of adequate time and resources.[11] For collaboration to occur, it is important for nurses and users to recognise and be willing to relinquish traditional dominant and passive roles in order to identify the potential contribution of each other's knowledge and skills, and to work actively in jointly building the purpose of their relationship.[11] Similarly, for users of acute units in the context of collaborative care, it is also important to be able to develop their care plan together with the nurse as something useful for their recovery, identifying the need to establish a collaborative process, where objectives can be established through the therapeutic relationship and strategies can be developed and agreed by all.[12]

In any mental health nursing setting and regardless of the method used, it is clear that the therapeutic relationship is the central tool for delivering care.[13 14] The therapeutic relationship is an interpersonal interaction between the nurse and the patient, based on trust between them and focused on the work of therapeutic help.[15] In this regard, the evidence indicates that an adequate therapeutic relationship is associated with better health outcomes for users and also helps to maintain the focus on recovery and reduces the stress experienced by the professional.[16 17] Similarly, the literature indicates that the therapeutic relationship enhances person-centred care and shared decision making.[18]

Another factor that has been linked as an important resource for recovery from mental disorders is maintaining a good level of positive mental health.[19] Positive mental health is understood as feeling good and functioning well and vital to an individual's positive functioning and psychological well-being, especially as it relates to factors important to living a purposeful life and achieving personal goals.[20] In this sense, the literature points out that it is necessary to develop interventions aimed at promoting positive mental health in recovery, with the objective of improving positive emotions towards life and the sense of fulfilment in private and social life.[21]

However, despite the importance and evidence regarding the effectiveness of collaborative care in the recovery of people with mental health problems, no published literature has been found that specifically studies the impact on the recovery process or the therapeutic relationship between the nurse and the user from the discipline and nursing care in the context of mental health day hospitals.

In this sense, it is considered important to explore the changes that occur in the state of recovery, positive mental health and the establishment of the therapeutic relationship in users of mental health day hospitals through the implementation of collaborative nursing care. The results obtained from this research may be important both for the users of mental health day hospitals, and also to improve the clinical practice models of mental health nurses. In addition, new knowledge could be generated

regarding the relationship between the recovery process and the quality of the therapeutic relationship.

METHODS AND ANALYSIS

Aim

This study aims to:

Explore the changes produced in the recovery process of mental health day hospital users who receive collaborative nursing care through the codesign and implementation of group activities.

Evaluate the impact of a collaborative nursing care intervention through the codesign and implementation of group activities, in mental health day hospital users, in terms of the changes produced in the state of the recovery process, in the level of positive mental health and in the quality of therapeutic relationship with the nurse.

The research hypotheses to be tested in this study are:

1. Day hospital users who receive an intervention based on collaborative nursing care through the codesign and implementation of group activities will report improved changes in: (i) recovery status, (ii) level of positive mental health and (iii) quality of the therapeutic relationship at the end of the intervention, than users receiving usual care.
2. The effects of the intervention based on collaborative nursing care through the codesign and implementation of group activities on the changes in the level of recovery are mediated by the changes produced in the quality of the therapeutic relationship and the changes in the positive mental health of the users.

Design

In order to meet the main objectives, a sequential and transformative mixed-methods design is proposed[22] through three phases (figure 1). On the one hand, in phases one and three, a two-armed, parallel-design, non-randomised trial is proposed. And in phase two, the intervention will be carried out based on collaborative nursing care through the codesign and implementation of group activities using the qualitative Participatory Action Research (PAR) method.

The participatory action research

In order to carry out the intervention of codesign and implementation of activities through collaborative nursing care, PAR is a method that provides a suitable framework for implementation and evaluation, since it is a method that makes it possible to extract knowledge in a democratic, cooperative, transparent and effective way, as well as to intervene in changes in people's daily lives. It is about unveiling the complexity of problems through dialogue and collaboration, as well as acting as a tool to promote change.[23 24] The PAR process is considered open, holistic and egalitarian, that is, it equates the researcher with those being researched and requires collaboration between researcher and researched.[25] In general, the PAR consists of four stages that follow each other in a cyclical manner. The cycle begins in the first stage, where a situation or problem is analysed, and then in the second stage, the elements that facilitate its resolution and those that hinder it are identified. Once these factors have been identified, a plan of action or change

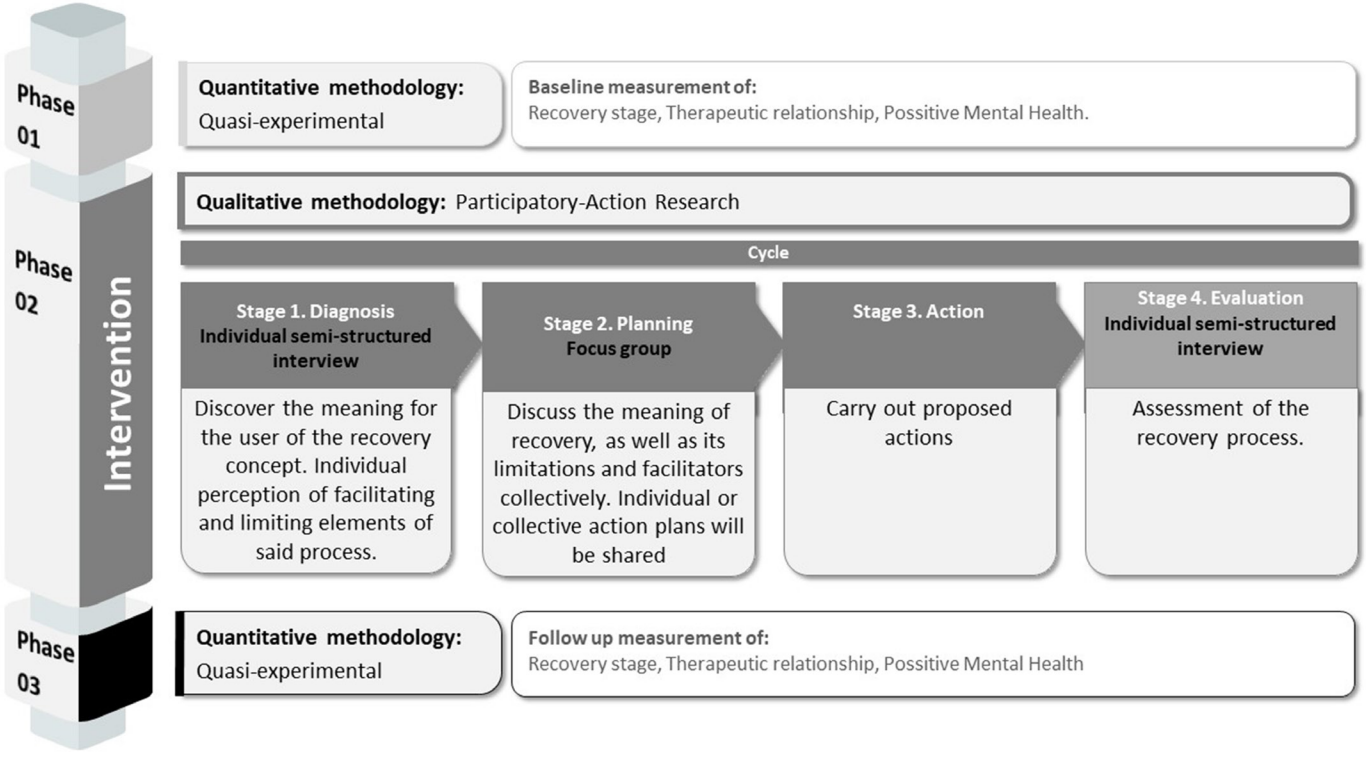

Figure 1 Study design.

is developed and implemented. Finally, the effect of this change will be evaluated, thus completing the cycle. All these stages should be evaluated in a reflective manner to improve the rationality, justification and understanding of the changes that occur in the process.[26] In other words, in this PAR process, theory and practice are combined, bringing theoretical constructs into reality and analysing them simultaneously.[25] Among the different PAR modalities, we will use the one described by Susman and Evered,[27] where a process of constant cycles of action research takes place, since it is the one that best adapts to the actual practice of care in the mental health day hospital.

Study setting and participants

The scope of the study will be three adult mental health day hospitals in the metropolitan area of Barcelona (Spain). The three centres belong to the same institution and are part of the public mental health network of Catalonia. These centres have the same management, and therefore develop the same care programme. The study population will be the users requiring treatment in the mental health day hospitals included in the study.

Criteria for selection and recruitment of participants:

- The criteria for inclusion in the study of participating users will be:
  - Users over 18 years of age of the selected day hospitals.
  - Acceptance of the study conditions and informed consent.

Hospital admission for a period of less than 1 week.

Physical or psychological conditions that do not allow collaborative nursing care through co-design of group activities.

- The exclusion criteria for participating users will be:
  - Hospital admission for a period of less than 1 week.
  - Physical or psychological conditions that do not allow collaborative nursing care through codesign of group activities.

All persons who meet the inclusion and exclusion criteria and who agree to participate in the study will be invited. Users who do not consent to participate in the study will be able to access the benefits of collaborative care, as these will be integrated into the daily practice of the unit. However, their data will not be collected. Participants will be incorporated consecutively as they are hospitalised in the three units that form part of the study. To calculate the sample size necessary to have sufficient statistical power for the quantitative part and based on the results of Lemos-Giráldez,[28] accepting an alpha risk of 0.05 and a beta risk of 0.2 in a bilateral contrast, 76 participants would be required in the first group receiving the intervention and 76 in the second group, in order to detect a difference equal to or greater than five units. It is assumed that the common SD is 11 and the correlation coefficient between the initial and final measurement is 0.6. A 20% loss-to-follow-up rate was estimated.

Procedure, techniques and analysis for the qualitative part or intervention

The intervention

Given the clinical practice conditions of the study, the intervention will be carried out in the selected hospital using the PAR method and will be implemented through a cycle of four well-defined stages,[27] which will be repeated continuously throughout the process (see TIdier checklist in online supplemental file 1).

In the context in which this study is intended to be carried out, the programme developed in day hospitals is aimed at the care of those people who need mental healthcare, but do not require a complete hospital admission. In this way, the disruption of their family, work and social processes is avoided. In them, individual and group care is provided.

Thus, for each user who joins the study, a minimum of one complete cycle of PAR will be performed before the user is discharged. The start of the cycle will begin with stage one or diagnosis, first stage of the PAR, which will be performed at the time of admission to the day hospital. The nurse, through an individual semistructured interview, will explore the meaning for the user of the concept of recovery together with the individual perception of the facilitating and limiting elements of this process. Subsequently, in the second stage or planning stage, through a discussion group with other users, the meaning of recovery, as well as its limitations and facilitators will be discussed collectively, whereby individual or collective action plans will be shared by the users in order to work and improve their level of recovery in stage three or the action stage. Once the action plan agreed on by the users and the nurse has been carried out, the cycle will conclude with stage four or evaluation, where an individual intervention in the form of a semistructured interview will be carried out again to assess the recovery process. Given that the usual dynamics of the day hospital, the nurse conducts an assessment interview, it will be at this time that the semistructured interview will be conducted. The focus groups will be integrated in the timetable established in the unit. Finally, the closing interview will be conducted at the time of discharge, when the nurse usually conducts a process closing interview.

Qualitative data collection techniques

Semi-structured interview

The conversation will be recorded with the prior consent of the participant and then a written transcript will be prepared, which requires validation by the user to avoid possible biases. The interview should take place in a room, if possible without interruptions and with an approximate duration of 40 min. The user will be given the possibility of ending the interview at any time as desired. A script will be used to conduct the interview.

Focus groups

These will also be recorded, thanks to the prior consent given by the users. A weekly group will be held at the day

hospital's facilities, during the day hospital's hours of operation. It will last approximately 45 min. There will be the possibility of leaving the group if the user wishes to do so. To carry out the group, a support script will be followed.

Researcher's diary

As a reflective tool and in order to monitor the research process, a field diary written by the principal investigator will be kept. This diary will be kept by the unit's referring nurse, who is the principal investigator of the present study.

Qualitative data analysis

The qualitative content analysis method will be used.[29] This analysis is a method that focuses on theme and context and emphasises variation, for example, similarities within and differences between parts of the text. It offers the possibility to analyse manifest and descriptive content as well as latent and interpretive content.[30] The data obtained from both the focus groups and the interviews will be transcribed verbatim. Then, once the authenticity of the transcripts has been verified by the participants (content validation), the text will be broken down into descriptive codes assigned on the basis of their purely semantic content. In a second stage, such codes will be grouped into more analytical subcategories, in such a way that the initial codes are grouped according to the meaning of the linguistic units and their combinations. This will lead to a third hierarchical stage, where, taking into account the semantic analysis of the previous subcategories, they will be categorised according to the objectives of the study. It is worth mentioning that the data analysis will be performed by two researchers, jointly in the first stage of data coding, and independently during the subsequent analytical process and again together in the comparison of their results. The analysis of these data will be carried out through the QRS Nvivo V.12 programme. It should be noted that data will be collected and analysed qualitatively until the moment when the team considers that no new meanings are found and considers that data saturation has been reached.[31 32]

Outcome measures, data collection procedure and data analysis for quantitative phases

Outcomes

Primary outcome

Changes in the users' recovery process will be evaluated with The Stages of Recovery Instrument (STORI)[7] validated in the Spanish population.[28] It is a self-report questionnaire of 50 items grouped into 5 dimensions of 10 items. Each dimension is related to one of the recovery processes (moratorium, awareness, preparation, rebuilding and growth). The items are scored from 0 'not true at all at this time' to 5 'completely true at this time', resulting in a score for each stage, ranging from 0 to 50. The participant is assigned to the stage with the highest score. The questionnaire has been validated in the Spanish population, obtaining a Cronbach's alpha of 0.86.[28]

Secondary outcomes

The quality of the therapeutic relationship between nurses and users will be evaluated with the Working Alliance Inventory-Short (WAI-S) scale. The short version of this scale contains 12 items, and each item is rated on a scale ranging from 1 (never) to 7 (always).

The scoring range of the overall WAI-S is 12–84 points. The higher the score, the higher the therapeutic relationship. This questionnaire has three dimensions: (i) bond: the bond between patient and nurse, which includes aspects such as empathy, mutual trust and acceptance; (ii) objectives: the agreement between patient and nurse on the goals of therapy (ie, mutual acceptance of what the intervention aims to achieve) and (iii) tasks or activities: the agreement between patient and nurse on the tasks or activities to be carried out. The Spanish version of the WAI-S has good reliability and validity, with a Cronbach alpha of 0.93.[33]

The level of positive mental health will be assessed with the Salud Mental Positiva (SMP) scale (Positive Mental Health), developed and validated by Lluch,[34] who studies the level of positive mental health, a concept previously developed by Jahoda.[35] The scale consists of 39 scorable items, for which the lowest value is 'always or almost always' and the highest value is 'never or almost never'. The items belong to six dimensions (personal satisfaction, prosocial attitude, self-control, autonomy, problem solving and self-actualisation and interpersonal relationship skills). The questionnaire has shown adequate internal consistency values in different populations with Cronbach's alpha values of 0.89.[36 37]

Other outcomes

Sociodemographic variables will be gathered, including age, sex, educational level, employment status and marital status.

The clinical variables consisted of the main diagnosis described by ICD10 criteria, years of evolution of the disorder, referral unit, number of previous admissions to mental health facilities.

Data collection procedure

Users who agree to participate in the study and have signed the informed consent form, both in the case of the intervention and control groups, will be given a form containing a questionnaire with sociodemographic and clinical data and the three evaluation instruments by a member of the research team who is not directly involved in the care of the users. Participants will not receive any information about their inclusion in the intervention or control group. Each user will be assigned a participant code to ensure the anonymity of the participating users. When the user is discharged, a person from the research team will collect the follow-up data in the same way by means of a new form.

Quantitative data analysis

The principal investigator will construct a database using the IBM SPSS V.25 programme ECPHDSM, the data obtained from the forms will be incorporated into the database by two members of the research team to minimise error. The analysis will focus on the numerical differences obtained through the STORI, WAI-S and SMP questionnaires before and after the intervention. In order to describe the characteristics of the participants and the scores obtained on the scales, descriptive statistics will be used, using the arithmetic mean and SD for quantitative variables and the frequency and percentage for qualitative variables. The differences between the baseline scores obtained and the follow-up assessment will be estimated, thanks to the application of parametric tests (Student's t-test in paired data) in the case of quantitative variables, first verifying the assumptions of normality and homogeneity of their variances. When the opposite is true, non-parametric tests will be used, using the Wilcoxon test for quantitative variables and χ^2 tests or Fisher's exact test for qualitative variables. In addition, to analyse the impact of changes on the dependent variable adjusted for the remainder of the secondary outcomes, multiple linear regression models will be used. A significance level of $p<0.05$ will be considered.

Validity and reliability/rigor

To ensure the validity and rigour of the study, appropriate strategies will be used for each phase of the research. In phases one and three, recruitment of an appropriate sample size together with the validity and reliability of the instruments used will guarantee validity and reliability. For phase two, reliability, authenticity and ethical criteria will be addressed. Within the framework of reliability, the credibility of the study is based on the use of triangulation of techniques and researchers. Likewise, the criterion of dependence will be obtained through the constant auditing and transfer of external reports throughout the procedure. Likewise, the dynamics of the process, which will involve a constant interaction between the realities of researchers and participants, will provide authenticity to the data obtained. The treatment of confidentiality, privacy and participant consent will guarantee the ethical rigour criteria of the project. In addition, reflexivity, understood as a process of critically reflecting on what is taking place during the research study, will be the key quality criterion on which the project will be based.

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting or dissemination plans of this research.

ETHICS AND DISSEMINATION

Authorisation has been obtained from the management of the centres and approval for the project has been granted by the Ethics Committee of the institution where the study will be carried out, FIDMAG Hermanas Hospitalarias (PR-2020-10). In relation to the current law on personal data protection and guarantee of digital rights, the authorisation of all users will be requested for the public dissemination of the data, preserving the confidentiality and anonymity of their identity at all times. This will be achieved by anonymising the names or any sign of identity by assigning a user code. All participants will be able to voluntarily withdraw from the study at any time. For this reason, users will be given a sheet with all the precise information about the study to be carried out and written consent will be requested.

Preliminary and final results will be published in peer-reviewed journals and presented at national and international congresses.

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Contributors AV-R and AM-P contributed to conceptualisation design and write the original draft. FG-G, AV-C and XV-P contributed to formal analysis. MP-L and TL-C contributed to conceptualisation, quality assessment and manuscript revision. All authors approved the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting or dissemination plans of this research.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

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The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper	Other †
	BRIEF NAME		
1.	Co-designing and implementing activities through collaborative nursing care in mental health day hospitals.	Page 1	
	WHY		
2.	The guidelines of the current lines of international mental health policies are focused on the recovery model and on the autonomy of people with mental health problems (World Health Organization, 2013). One of the primary aspects of this model is health participation, presented as a fundamental right of the user of mental health network services and not as a choice (Newman, O'Reilly, Lee, & Kennedy, 2015; Smith & Williams, 2016). It is clear that there is general agreement that collaboration is representative of the shift from the traditional paternalistic paradigm toward person-centered systems of care (Byrne et al., 2020). Under this approach, the use of a collaborative care model would appear to meet excellent conditions (Ishikawa et al., 2018; Sunderji et al., 2018). In this sense, there is no doubt that the nurse has a fundamental tool, the Therapeutic Relationship (TR) to implement care (Moreno-Poyato et al., 2016; Peplau, 1988). In the context of user care in mental health day hospitals, nurses should accompany people in their recovery process, leaving it to be led by the user, and letting the user their own goal (Agrest et al., 2018). In this sense, nurses through the TR and the use of a properly implemented collaborative care model, could more effectively improve important aspects in the recovery process of users such as education, changes in routines or habits and development of information technology.	Page 3	

	WHAT		
3 and 4	Materials and procedures: The intervention consists of the co-design and implementation of therapeutic activities by the nurse and the mental health day hospital users following a collaborative care model. For this purpose, the participatory action research (PAR) method will be used and semi-structured interviews and focus groups will be used as data collection techniques.	Pages 11-15 Figure 1	
	WHO PROVIDED		
5.	The intervention will be conducted and coordinated by a nurse with a title as a mental health specialist on the unit.	Page 15	
	HOW		
6.	Given the clinical practice conditions of the study, the intervention will be carried out in the selected hospital using the Participatory Action Research method and will be executed through a cycle of four well-defined stages (Susman & Evered, 1978) that will be repeated continuously throughout the process. Thus, for each user who joins the study, a minimum of one complete cycle will be performed before he/she is discharged. The stages of the process are: **Stage 1 or diagnosis**: this will be carried out at the time of admission to the day hospital. The nurse, through an individual semi-structured interview, will explore the meaning for the user of the concept of recovery together with the individual perception of facilitating and limiting elements of this process. **Stage 2 or planning stage**: through a focus group with other users who are at the same stage, the meaning of recovery, as well as its limitations and facilitators will be discussed collectively, thereby, action plans for individual or collective activities will be shared by the users in order to work and improve their level of recovery. **Stage 3 or action stage:** during this stage, a focus group will be used to design and implement an action plan that will be developed jointly by the nurse and the user.	Pages 11-12 Figure 1	

TIDieR checklist

	Stage 4 or evaluation: prior to the user's discharge from the day hospital and having developed stages two and three in a group setting, an individual intervention in the form of a semi-structured interview will be carried out again to assess the recovery process.		
	WHERE		
7.	The intervention will be carried out in an adult mental health day hospital in the metropolitan area of Barcelona (Spain). The individual sessions will be held in the nursing office and the group sessions will be held in the group therapy room.	Page 10	
	WHEN and HOW MUCH		
8.	The intervention will be carried out for one year, to recruit the sample that is expected to be necessary. Stages one and four foreseen in the PAR will be carried out once with each user. Stages three and four will be carried out sequentially with all users, so if the average admission of users to the unit is six weeks, they will carry out 3 cycles each.	Page 11-12 Figure 1	
	TAILORING		
9.	Given the characteristics of the method used, the only aspect established is the order of the stages. Each cycle of the PAR will be different, since the action to be developed in stage 3 will be proposed by the group of users enrolled at that time.	Page 11-12	
	MODIFICATIONS		
10.‡	No changes were made to the original plan.		
	HOW WELL		
11. and 12.‡	The possibility of abandonment for clinical or personal reasons (need for admission to acute units) or unplanned discharges that prevent the final evaluation is foreseen.	Page 10	

TIDieR checklist

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).
‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

TIDieR checklist