1. INTRODUCTION

In Peru, neuropsychiatric disorders are the leading cause of disease burden [1], and only in Lima and Callao do they have a life prevalence of 26% [2]. Despite its high prevalence, there is a treatment gap between 75% and 85% [3]. Also, in terms of severity, a local study found that only 21% of people with severe mental disorders received mental health care during the last year [3]. These disorders are usually chronic, requiring clinical and community interventions to improve the patient's recovery and quality of life.

Currently, Peru is in a process of National Mental Health Reform, which follows a model of community-based care [4]. This reform has created a series of new structures within the health system to care for people with mental disorders. One of them is the Community Mental Health Centers (CSMC), which are centers specialized in mental health and which are articulated in the first level of care. CSMCs have teams of health professionals, consisting of a psychiatrist, psychologist, family doctor, nurse, social worker, occupational therapist, language therapist and nursing technicians. There are currently about 120 CSMC in the country, and it is projected that by the year 2021, 281 will have been implemented nationwide [5].

There is evidence that a positive relationship between provider-user is a predictor of short-term and long-term improvement in patients receiving psychiatric care [6]. In this sense, as part of the community mental health care model, routine meetings are recommended to evaluate the users' problems, decide on the treatment they will follow and monitor their progress. One of the main challenges for the implementation of these routine meetings is that they are therapeutically effective in themselves [7]. For this reason, a group of European researchers has developed DIALOG +, which is an intervention that seeks to improve provider-patient communication and thus the results of mental health treatment [8]. This intervention is based on research into quality of life, concepts of patient-centered communication, technological information and components of therapy focused on solutions, by means of an application for Tablet or Smartphone.

DIALOG + allows a valuation, planning, therapeutic intervention and evaluation of the patient in a single procedure, and requires a brief training. This intervention has been tested through clinical trials, showing positive results in patients with psychosis, as greater needs covered, fewer psychopathological symptoms and better results in their objective social situation [9, 10], in addition to presenting good results in the associated costs to treatment [8]. It is a low-cost intervention that uses the existing resources of health services and seems to empower patients to improve their mental health condition and social situation as it focuses on the resources and potentials of themselves, their families and the community. [10]

It is estimated that DIALOG + could be effective in low and middle income countries, where resources are often scarce to serve people with severe mental disorders. A good strategy is its implementation in the CSMC, since it will take advantage of the work that is being done with this type of patients, and if it showed good results, it could be expanded to other CSMC, at a national level.

2 OBJECTIVES OF THE STUDY2.1 Main Objective Evaluate the implementation of the DIALOG + intervention to support community mental health care and identify improvements in the quality of life of the users within 6 months of starting the intervention.

2.2 Secondary Objectives

1) Analyze the changes in the psychiatric symptoms of the participating users 6 months after starting the intervention.

2) Analyze the changes in the objective social situation of the participating users 6 months after starting the intervention.

3) Explore with the users and health providers the barriers and facilitators for the implementation of the intervention.

4) Collect the experience of the users in the intervention, exploring the benefits for their daily life.

5) To gather the experience of the providers in the intervention, exploring the benefits for their attention to the users with severe mental disorder.

3 MEASUREMENT OF RESULTS AND OTHER STUDY VARIABLES

This section details the main and secondary results of the study, the variables that will be collected along it, the instruments that will be used to measure them, and the time they will be collected. In addition to the individual evaluations to the participants, through questionnaires, to obtain the main and secondary results, information will also be collected with health providers and participants to evaluate the implementation of the intervention.

3.1 Main Result

Improvement in the quality of life of the participating users, based on the score of the Manchester Short Assessment of Quality of Life (MANSA) scale, 6 months after starting the intervention.3.2 Secondary Results

1) Improvement in the psychiatric symptoms of the participating users, based on the score of the Brief Psychiatric Rating Scale (BPRS) 6 months after starting the intervention.

2) Improvement in the objective social situation of the participating users, based on the score of the Objective Social Outcomes Index (SIX), 6 months after starting the intervention.

3) Identification of barriers and facilitators for the implementation of the intervention, through semi-structured interviews with 10 users and all participating providers, at the end of the intervention period.

4) Positive and negative experiences of the users in the intervention and the benefits for their daily life, through semi structured interviews to 10 participating users, at the end of the intervention period

.5) Positive and negative experiences of the providers in the intervention and the benefits for their attention to the users with severe mental disorder, by means of semi structured interviews to 10 participating users, at the end of the intervention period.

4 STUDY DESIGN4.1 Study Design

A mixed methodology pilot study will be carried out, in which quantitative and qualitative data will be collected, concurrently, that is, in parallel [11].

4.2 Fields of Study

The intervention will be implemented in four community mental health centers in Metropolitan Lima.

4.3 Study Participants

Users of community mental health centers with severe mental disorder and health providers of said facilities.

In these centers, users receive specialized mental health care with a community-based model. Upon entering the community mental health center, they are evaluated by an interdisciplinary team (psychiatrist, psychologist and nurse) who prepare an Individualized Care Plan together with the user to determine how the treatment will be. This plan is constantly updated according to the objectives and needs of the users.

The providers of these establishments have been trained to provide community-based care. The activities they perform are both inside and outside the health facility, including outpatient care, workshops, home visits, among others. Likewise, they are organized to work in a coordinated manner and thus jointly monitor users, and articulate their work with other levels of care, depending on the needs of their users (eg health centers of the first level of care, hospitals).The intervention will be carried out with 40 users of community mental health centers and at least 5 health providers, with no more than 10 users each.

5 PARTICIPANTS

5.1 Description of the Health Establishments of the Study

The study will be developed in four community mental health centers in Metropolitan Lima: CSMC "Carabayllo", CSMC "San Gabriel Alto", CSMC of Pueblo Libre "Honorio Delgado" and CSMC "La Victoria". These centers are located in Lima Norte (1), Lima Sur (1) and Lima Centro (2). Two of these centers were recently created, while the other two are older than four years.

5.2 Inclusion Criteria of Participants

All study participants must meet the following criteria during the recruitment process:

Inclusion criteria for users:

• Users with primary diagnosis of severe mental disorder (CIE F20-F29, F31 and F32),

• To be 18 years old or more• Be able to provide informed consent.

• Score of 5 or less on the Manchester Short Assessment of Quality of Life (MANSA) scale.

• Receive care from any of the health providers participating in the study.

Inclusion criteria for health providers:

• Health professional who provides clinical care to users (eg psychiatrist, psychologist, nurse)

• Have a month or more of experience working with users with severe mental disorders.

• Work currently in one of the participating community mental health centers.

• Not having plans to leave the community mental health center during the study implementation period.

5.3 Criteria for Exclusion of Participants

Any individual who meets the following criteria during the recruitment process will be excluded from participating in the study:

Exclusion criteria for users:

• Diagnosis of dementia or organic psychosis.

• Primary diagnosis of substance use disorder.

• Severe learning problems or severe cognitive disability.

Exclusion criteria for health providers:

• Not having clinical contact with users.

• Have little regular contact with users, for example, more than a month between each contact.

6 STUDY INTERVENTION:

DIALOG + is a simple intervention to evaluate the user's satisfaction with their life and the treatment they are receiving, address the concerns they have, and facilitate communication between the user and the health provider in mental health care. The intervention seeks to ensure that the communication between the user and the provider focuses on the user and promotes a positive change effectively.

The intervention is supported by the use of an application for tablets, which details all the steps to follow in each session with the user. In the application, the health provider can add the assigned participant users, and create new sessions for each encounter that they have with them. In the first session, the health provider uses the tablet, explaining to the user what the intervention consists of and giving them the opportunity to familiarize themselves with the procedure.

Each session begins with the user evaluating his satisfaction with eight domains of his life (mental health, physical health, work situation, housing, recreational activities / leisure, relationship with the couple and family, friendships, personal security) and with three aspects of his treatment (medication, practical help, meetings with health providers). Each domain is scored on a scale ranging from 1 ("totally unsatisfied") to 7 ("totally satisfied"). These scores are recorded and can then be reviewed and compared with previous scores. Health providers are instructed to provide positive feedback in case of improvements in scoring or high scores in domains.The scores are followed by a question about whether the user wants additional help with a domain. With the help of the health provider, the user chooses some domains to discuss them in greater detail. Once the domains have been selected, a 4-step methodology focused on the solution is used. The four steps are: (1) understand, is to know why the user is dissatisfied in that domain, and what aspects, despite the dissatisfaction, still go well in the domain; (2) look forward, is to help the user identify the ideal scenario and what are the smallest steps that can be taken to reach that scenario); (3) consider options, is to explore and identify what the user, the health provider and others can do to achieve the desired change; and (4) agree tasks, is to reach an agreement on what action (s) should be taken, and by whom. After agreeing on the actions to follow, these are registered in the application, and will be shown at the beginning of the next session to follow up.

7 STUDY PROCEDURES AND EVALUATIONS

7.1 Recruitment

Health providers will be recruited in the community health centers where they work. The study will be presented to each of them and their interest in participating will be explored. If you agree to participate, you will be asked to sign an informed consent.

The health providers, with the help of the research team, will review the load of users they serve in order to identify potential participants who meet the inclusion criteria. It is estimated to recruit between 5 to 10 users for each health provider.

The potential participating users will be contacted by the research team to present the study and explore their interest in participating. Those users who agree to participate, will be asked to sign an informed consent and complete the MANSA questionnaire to assess if they are eligible. Only users with a score equal to or less than 5 will be eligible to continue in the study.

Those participants who are not eligible will be thanked for their time and will be reimbursed for their mobility expenses to meet with the research team.

Participants who are eligible will complete the rest of the baseline assessment with the member of the research team. The baseline assessment will consist, in addition to the MANSA questionnaire, of 4 more instruments: a sociodemographic questionnaire, a questionnaire on the severity of psychiatric symptoms (BPRS), a questionnaire on the social situation of the user (SIX), and a questionnaire on their contact with services of health (CSRI). Once the questionnaire is completed, the user will be thanked for their time and will be reimbursed for their mobility expenses to meet with the research team.

7.2 Training and Supervision of Health Providers

Health providers participating in the study will receive a single training session (about 3 hours), provided by the UK's principal investigator. In this session, the use of the application and the methodology of the intervention will be explained.

Once the study has begun, the providers will participate in a supervisory session at 4 weeks, in which doubts will be answered and the contents provided in the training will be reinforced. After that, supervision sessions will be held once every two months, with additional sessions at the request of the providers, if necessary.

Additionally, during the first weeks the research team will visit the providers to provide support and answer questions, if necessary

7.3 Intervention

The DIALOG + intervention will be used in the consultations between the health provider and the user for a total of 6 months, at the beginning on a monthly basis, and then less frequently. In this sense, the intervention will be used in the baseline, at month 1, 2, 3 and then in month 6.

Each provider will be assigned a number of participants, and they will be instructed to only apply the DIALOG + intervention with them, this in order to prevent different health providers from applying the intervention with the same participating user, increasing the expected frequency of application of the intervention.

intervention.

7.4 Follow-up at 6 months

After 6 months receiving the DIALOG + intervention, users will participate in a follow-up evaluation, where a member of the research team will invite them to answer the same questionnaires used in the baseline assessment, with the exception of the sociodemographic questionnaire.

7.5 Exit interviews

In addition to monitoring users, the research team will conduct semi-structured interviews with all health providers and a sample of users (25%, 10 in total). These interviews will seek to explore the positive and negative aspects of the intervention, collect the opinions of the participants and their suggestions to improve the intervention and its implementation. The audio of the interviews will be recorded and transcribed literally

8 ANALYSIS

Descriptive statistics will be used to report the sociodemographic information of the participants. To assess the impact of the intervention, the means and standard deviations of the two study evaluations (baseline and follow-up evaluation) will be calculated and compared. The main result of the study will be the comparison of scores of the MANSA questionnaire in the 6-month follow-up, in comparison with the baseline evaluation. The study data will be analyzed using Stata for Windows (Stata Corp, College Station, TX).

To analyze the qualitative information obtained in the exit interviews, a person external to the research team will be in charge of transcribing the audio of the interviews textually. All information that identifies the interviewee will be removed from the transcript, including references to users or health providers.

The analysis process will begin with the creation of a codebook based on the main themes identified in the interviews. All interviews will be analyzed using Atlas.Ti software (ATLAS.ti Scientific Software Development GmbH, 2012).

9 ETHICS AND PROTECTION OF HUMAN SUBJECTS

9.1 Approval Ethics of the Study

The research protocol, the instruments and the informed consents will be presented for review and approval by the Institutional Ethics Committee (CIE) of the Universidad Peruana Cayetano Heredia, registered in OHRP (IORG0000671), IRB # 1 (IRB00001014) and Federal Wide Assurance (FWA00000525), and by the Ethics Committee of Queen Mary University of London before starting field work.

9.2 Process of Informed Consent

The potential participants will receive a detailed explanation about the study and what their participation will consist of. In the case of health providers, this will include training, the use of DIALOG + intervention during consultations with users and exit interviews. In the case of the users, this will include the basal evaluation, the follow-up evaluation and the exit interview.

The members of the research team responsible for recruitment will be properly trained in how to provide the necessary information to potential participants to obtain informed consent and how to answer their questions.

Participants will be assured of the confidential nature of all information provided, but will also be informed that there are certain limits to confidentiality in situations where there is a serious risk to the participant or to others. Under these circumstances, even without the consent of the participant, certain information could be shared with the health center to guarantee its integrity or that of other people at risk.

All participants will also be informed that their participation is strictly voluntary, and that the choice not to participate will not have any consequence or affect them in any way. Study participants will not be financially rewarded for their participation in the research, but transportation costs for meetings with the research team will be reimbursed.

The participant may withdraw their consent at any time during the study. If this occurs, the participant will be consulted if the information collected up to the moment of withdrawal of consent can be used or not. The research team will comply with the decision of the participant in this regard.

The informed consent procedure will be carried out in a private environment of the health establishment where recruitment is carried out

9.3 Confidentiality of Information

Participants who agree to participate in the study will receive an identification code that will be used throughout their participation. A list of the codes and identification information will be stored in a password protected computer, to which only the research team will have access. In the same way, during the interviews the participants will have the possibility of using a pseudonym if they prefer, in order to avoid mentioning their real names and being registered in the transcripts. On the other hand, the recordings of the interviews will be stored on a password protected computer that will only be accessible to the research team.

The questionnaires and informed consents will be kept, separately, in locked cabinets in the research team office.

9.4 Potential risks for participants

The potential risks for the participants in this study are minimal, although some circumstances are anticipated in which they could manifest themselves.

During the application of the baseline and follow-up questionnaire, some questions may be uncomfortable for some participants. For example, for some, the nature of the questions might arouse emotions such as sadness. The research team in charge of the recruitment and application of these questionnaires will be trained to handle this type of situation.

Also, during the application of the questionnaires, the research team may encounter users at risk of suicide or who have been victims of violence. In these cases, it will be sought that the user receives prompt attention from the health providers available in the community mental health center. This in order to guarantee the safety and well-being of the user.

Some participants may worry about the confidentiality of their data. All study participants will receive an explanation, included in the informed consent form, about the procedures that will be taken into account to ensure the confidentiality of their data, including the use of codes instead of names and safe storage. of all the information collected.

9.1 Potential benefits for participants

DIALOG + is an intervention that complements the care provided by health providers, focusing on the attention provided to the needs of users. In this sense, the intervention is expected to have a positive impact on user-provider communication. Likewise, the DIALOG + intervention has proven effective in improving the quality of life and reducing psychiatric symptoms in patients with psychosis, so it is expected that these benefits will also be reflected in the users participating in the study.

Finally, the evidence generated through this research will serve as a first input and evidence so that in the future it can be adapted and implemented on a larger scale in more community mental health centers of Peru.