Pilot study of the DIALOG + intervention: Evaluating the feasibility of implementing a therapeutic intervention for people with mental health problems in Argentina

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1. **INTRODUCTION**

In Argentina, 1 in 3 people have a mental health problem after 20 years [1]. In the Autonomous City of Buenos Aires (CABA), neuropsychiatric disorders are an important cause of disability, the prevalence being due to mental, neurological and due to substance use of 34% [2]. Despite its high prevalence, there is a treatment gap between 75% and 80%, with few people receiving mental health care at the right time [3]. These disorders are usually chronic, requiring clinical and community interventions to improve the patient's recovery and quality of life.

Currently, Argentina is in a process of national reform from the implementation of the Mental Health Law No. 26,657, whose foundation is the foundation is the perspective of Community Mental Health and integration of people with mental illness for full validity of their rights, in accordance with the principle of “non-discrimination” [4]. To this reform is added the participation of the program areas with the Centers for Health and Community Action (CeSAC) of the CABA, which are specialized centers in mental health and are articulated with the primary care centers (CAP) . The program areas have teams of health professionals, consisting of a psychiatrist, psychologist, family doctor, nurse, social worker, occupational therapist, language therapist and nursing technicians [5].

There is evidence that a positive relationship between provider-user is a predictor of improvement in the short and long term in patients receiving psychiatric care [6]. In this sense, as part of the community mental health care model, routine meetings are recommended to evaluate user 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]. Therefore, 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 on quality of life, concepts of patient-centered communication, technological information and components of solution-focused therapy, through an application for Tablet or Smartphone.

DIALOG + allows an assessment, 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, such as greater needs covered, less 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, which uses the existing resources of health services and seems to empower patients to improve their mental health and social status as it focuses on the resources and potential of themselves, their families and community [10].

It is estimated that DIALOG + could be effective in low and middle income countries, where resources are often scarce to care for people with severe mental disorders. A good strategy is its implementation in the CeSAC, since it will take advantage of the work they have been doing with this type of patients, and if it shows good results, it could be expanded nationally.

**2 OBJECTIVES OF THE STUDY**

**2.1 Main Objective**

Evaluate the implementation of the DIALOG + intervention to support community mental health care and identify improvements in the quality of life of users 6 months after initiating the intervention

**2.2 Secondary Objectives**

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

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

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

4) Collect user experience in the intervention, exploring the benefits for their daily lives.

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

**3 MEASUREMENTS OF RESULTS AND OTHER VARIABLES OF THE STUDY**

This section details the main and secondary results of the study, the variables that will be collected throughout it, the instruments that will be used to measure them, and the time they will be collected. In addition to the individual evaluations of 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 participating users, based on the Manchester Short Assessment of Quality of Life (MANSA) score, 6 months after the intervention began.

**3.2 Secondary Results**

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

2) Improvement in the objective social situation of the participating users, based on the score of the Objective Social Outcomes Index (SIX) scale, 6 months after initiating 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 with 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 users with severe mental disorder, through semi-structured interviews with 10 participating users, at the end of the intervention period.

**4 STUDY DESIGN**

**4.1 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 Location of Study**

The study will be carried out in two program areas of the City of Buenos Aires: CeSAC N ° 11 and CeSAC N ° 3, and in two community centers in the towns of Pilar (GBA North) and Monte Grande (GBA South).

**4.3 Study Participants**

Service Users of community mental health centres with severe mental illness and health providers of these establishments. In these centres, users receive specialized mental health care with a community-based model. Upon entering the community mental health centre, 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 they will receive 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 organize themselves to work in a coordinated manner and thus monitor users jointly, 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 the 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 carried out in two program areas of the City of Buenos Aires: CeSAC N ° 11 and CeSAC N ° 3, and in two community centers in the towns of Pilar (GBA North) and Monte Grande (GBA South).

**5.2 Participation Inclusion Criteria**

* All study participants must meet the following criteria during the recruitment process:
* Inclusion criteria for users:
* Users with primary diagnosis of severe mental disorder (ICD 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 one 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.
* Currently work in one of the participating community mental health centers.
* Not have plans to leave the community mental health center during the study implementation period.

**5.3 Participant Exclusion Criteria**

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 have clinical contact with users.
* Have little regular contact with users, for example, more than one month between each contact.
* Have less than one year of clinical experience

**6 STUDY INTERVENTION: DIALOG +**

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 is focused on the user and that it promotes a positive change effectively.

The intervention is based on 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 participating users, and create new sessions for every encounter he has with them. In the first session, the health provider uses the tablet, explaining to the user what the intervention is and giving him the opportunity to familiarize himself with the procedure.

Each session begins with the user evaluating their satisfaction with eight domains of their life (mental health, physical health, employment status, housing, recreational / leisure activities, relationship with the couple and family, friendships, personal safety) and with three aspects of their treatment (medication, practical help, meetings with health providers). Each domain is scored on a scale ranging from 1 ("totally dissatisfied") to 7 ("totally satisfied"). These scores are recorded and can then be reviewed and compared with previous scores. Healthcare providers are instructed to provide positive feedback in case of improvements in the score or high scores in the 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 more detail. Once the domains are selected, a 4-step methodology focused on the solution is used. The four steps are: (1) to understand, is to know why the user is dissatisfied in that domain, and what aspects, despite dissatisfaction, are still going well in the domain; (2) look forward, it is to help the user identify which is the ideal scenario and what are the smallest steps that can be taken to reach said scenario); (3) consider options, is to explore and identify what the user, the health care 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 remembering the actions to follow, they 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 care providers will be recruited at the community health centers where they work. Each of them will be presented with the study and their interest in participating will be explored. If you agree to participate, you will be asked to sign an informed consent.

Healthcare providers, with the help of the research team, will review the burden 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. 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 whether 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 their mobility expenses will be reimbursed to meet with the research team.

Participants who are eligible will complete the rest of the baseline evaluation with the research team member. The baseline evaluation 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 user's social situation (SIX), and a questionnaire on their contact with services of health (CSRI). Once the questionnaire is finished, the user will be thanked for their time and their mobility expense will be reimbursed to meet with the research team.

**7.2 Training and Supervision of Health Providers**

Health care providers participating in the study will receive a single training session (about 3 hours), provided by the UK principal investigator. This session will explain the use of the application, and the methodology of the intervention.

Once the study has begun, the providers will participate in a 4-week supervisory session, in which doubts will be cleared 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 suppliers, 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 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 at baseline, at month 1, 2, 3 and then at 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.

**7.4 Follow-up at 6 months**

After 6 months of 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 evaluation, 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 both positive and negative aspects of the intervention, gather 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 evaluations of the study (baseline evaluation and follow-up) 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, compared to 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 responsible for textually transcribing the audio of the interviews. 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 code book based on the main themes identified in the interviews. All interviews will be analyzed using the Atlas.Ti software (ATLAS.ti Scientific Software Development GmbH, 2012).

**9 ETHICS AND PROTECTION OF HUMAN SUBJECTS**

**9.1 Ethical Approval of the Study**

The research protocol, instruments and informed consents will be submitted for review and approval by the Independent Ethics Committee (CIE) of the Faculty of Medicine of the University of Buenos Aires, and by the Ethics Committee of Queen Mary University of London before starting field work.

**9.2 Ethical and Regulatory Aspects**

This project contemplates the use of subjects, so this trial should be carried out in accordance with Good Clinical Practices (BPC). Before starting the project, the protocol, informed consent and other test documents must be approved by an Independent Ethics Committee (CIE). This committee must be formed in accordance with the relevant regulatory requirements. When appropriate, the CIE must also approve the amendments to the protocol prior to its execution in the center, unless early execution is justified to eliminate an immediate danger. The CIE must issue its approval in writing and the document must clearly identify the essay, the documents reviewed (including informed consent) and the date of the review. The trial may only be implemented as described in the protocol (or the amendment), sign the informed consents and use the documents related to the trial after all necessary approvals have been obtained and it is acceptable for the investigator to begin with essay.

This investigation will be carried out under the current regulatory norms: National Law 25326 of Protection of Personal Data of the Argentine Republic, Resolution 1480/2011 of the Ministry of Health of the Argentine Republic, National Law 26529 of Patient Rights in their Relationship with Professionals and Health Institutions, and Law 3301/09 of the Autonomous City of Buenos Aires on the Protection of Subjects' Rights in Health Research. The documents and international regulations to which this research conforms is as follows: the Belmont Report, the Nuremberg Code Code, CIOMS / 2012 standards, Declaration of Hesinki.

Individual registration of the data will be done on an electronic basis. The researcher must provide data on the subjects or the results of analysis obtained following the appropriate instructions, in accordance with the BPC. The researcher must keep and keep records and data during the course of the test in accordance with all relevant legal and regulatory requirements. Each data must be supported by a source document that is at the center of the investigation. All records or documents used as a source of information (called "subject source data") must be kept so that authorized representatives of the sponsor or any regulatory body can examine them.

It is necessary to complete a Registry of each subject that granted their informed consent. Do not collect personal data such as name, initials or any personal information of the subjects that is not necessary to perform the test. It is not allowed to identify the subjects by name or initials in the Registry or in any other document of the essay. The only acceptable information about the subjects that may appear is the unique identification number of the subject. The researcher should keep a list of contact information for each subject so that he can quickly communicate with everyone if necessary.

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**9.3 Informed Consent Process**

Before performing any procedure related to the trial, it is necessary to provide a written description of the protocol to each possible subject, explain in detail the protocol and what its 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 users, this will include the baseline evaluation, the follow-up evaluation and the exit interview.

Recruitment research team members 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 they will also be informed that there are certain limits to confidentiality in situations where there is a serious risk to the participant or others. Under these circumstances, even without the participant's consent, 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 consequences 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 until the moment of withdrawal of consent can be used or not. The research team will comply with the participant's decision in this regard.

The informed consent procedure will be carried out in a private environment of the health facility where the recruitment takes place.

The document that the subject must sign to grant his informed consent must be written in the language and terms that the subject can understand. The subject or legal representative of the subject must grant their written consent to participate in the trial. The consent form signed and dated by the subject must remain with the investigator as part of the trial records and the subject must keep a copy of the signed and dated consent forms.

**9.4 Information Confidentiality**

Participants who agree to participate in the study will receive an identification code that will be used throughout their participation. A list of codes and identification information will be stored on a password protected computer, to which only the research team will have access. Likewise, during the interviews, 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.

Informed questionnaires and consents will be stored separately in locked cabinets in the office of the research team.

**9.5 Potential Risks for participants**

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

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 could arouse emotions such as sadness. The research team responsible for the recruitment and application of these questionnaires will be trained to handle these types of situations.

Also, during the application of the questionnaires, the research team may encounter users who are 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 at 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 secure storage. of all the information collected.

**9.6 Potential Benefits for participants**

DIALOG + is an intervention that complements the care provided by health providers, focusing the attention provided on the needs of the 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 in Argentina.