

Developing an instrument for assessing fidelity to the intervention in the Critical Time Intervention – Task Shifting (CTI-TS) – preliminary report

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Summary

Aim. The fidelity of an intervention can be defined as the degree to which a program is implemented following the program model, i.e. a set of well-defined procedures for such intervention. This article aims to describe the steps taken to develop an assessment tool of fidelity to the original protocol of intervention for Critical Time Intervention – Task Shifting (CTI-TS).

Methods. The development of an instrument to assess fidelity includes some key stages, such as definition of the intervention model, definition of the key components of the intervention, preparation of a preliminary scale, development of fidelity assessment sheets, development of a manual on the application of fidelity scale, training fidelity assessor and testing the preliminary scale by carrying out a pilot study.

Results. Based on the experts' opinion, 18 key components of the intervention were defined. From these components, a fidelity scale consisting of 20 items was built, divided into three sections, each evaluating one of the types of fidelity: compliance, context and competence.

Conclusion. The CTI-TS had its fidelity assessment method developed in accordance with the recommendations in the current literature. The protocol compliance is essential for the results, whether positive or not, can be credited to the intervention itself.

protocol compliance / community mental health services / intervention studies / mental disorders

INTRODUCTION

In past decades, mental health care in Latin America has undergone a huge transformation with the change of hospital-based care to community assistance. Over the years, it became clear that the treatment provided to this popu-

lation did not result in significant improvement of their functional aspects [1, 2]. Pharmacotherapy can reduce psychotic symptoms, but has little effect on social adjustment and quality of life of these patients, even if there is good adherence to treatment. So it is essential that the rehabilitation of these patients back into society goes beyond simply reducing symptoms, being fundamental to the implementation of interventions that benefit this population and their families, meeting their needs in a way that is adapted to the current economic and social reality in Brazil, contributing to the proper planning of health services [3, 4].

In agreement with this proposal, Critical Time Intervention – Task Shifting (CTI-TS) aims to complement and strengthen the current network

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of care services. The CTI-TS aims to help individuals who suffer from severe mental illness to engage and stabilize in a continuous care. This is an innovative model with predetermined duration, developed in New York, to be administered during critical periods of treatment, such as the transition between hospitalization and treatment in the community or patient integration into another health service in the community [5]. CTI-TS is designed to address a fundamental gap in the services offered by mental health clinics in Latin America. These clinics are the primary setting for outpatient treatment of individuals with severe mental disorders in the urban areas of Latin America. They offer some basic and important clinical care, such as pharmacological treatment, onsite. A major limitation of many of these clinics is that they offer minimal or no resources or training for the provision of in vivo community-based services, i.e. services delivered outside the clinic facility in homes or elsewhere in the community. In most urban areas, they are only weakly linked to primary health care and are not easily accessible to much of the population.

The literature suggests that although there are effective psychosocial interventions for individuals with severe mental disorders, these interventions are not always put into practice. The main reason for that would be the lack of knowledge about the implementation process. Also observed is the lack of structure and support, and the lack of a defined model for these interventions [6, 7].

So for an intervention to be successful, it is essential that it has not only theoretical and structured guidelines but also a well-defined plan of implementation in order not to compromise the outcomes for the service and for the target population. Consequently, the outcomes of the implementation are prerequisites for the subsequent clinical outcomes [8]. However, it is crucial to distinguish implementation effectiveness and intervention effectiveness, since lack of effectiveness of the intervention could be either due to the fact that the intervention was not really effective or it was a good intervention that was implemented incorrectly.

The fidelity of an intervention can be defined as the degree to which a program is implemented following the program model, i.e.

the set of well-defined procedures for such intervention. The intervention model must specify the type and amount of service that the participants should receive, the way in which this service will be performed and the necessary administrative structure for its implementation [8, 9]. The fidelity instruments quantify the extent to which elements of the model have been implemented properly. Protocol fidelity measures have been required more and more often in mental health. Both in terms of securing scientific publications, such as obtaining financing from agencies such as the National Institute of Mental Health (NIMH), and also to compare the results obtained [10, 11, 12]. The fidelity measures look at adherence to the original protocol, the quantity of activities performed and the quality of these activities [8].

This article aims to describe the steps taken to develop the assessment tool of fidelity to the original protocol of intervention for Critical Time Intervention – Task Shifting (CTI-TS).

METHODS

The implementation of an intervention can be described as a set of specific activities planned to implement a program with known dimensions. The implementation involves efforts to incorporate the intervention in a community practice, service agency, professional association or health system. Therefore, two types of activities and their results can be identified: implementation activities and intervention activities [13]. Thus, the process of implementing an intervention should have its quality assessed in order to ensure that the intervention outcomes will not be impaired.

In developing a new instrument it should be decided how many dimensions will be considered and the amount of items that each dimension will be composed of. Some authors suggest that the number of items in each dimension should be the same, but sometimes this is not feasible. The decision regarding the size of the instrument needs to strike a balance between practical issues for application and the need to cover all elements of the model. An instrument which is too long may cause difficulties during its application, while an instrument which

is too short may not be sufficiently comprehensive. The development of an instrument to assess fidelity includes seven key stages [9]:

1. Definition of the intervention model

The first step is to define where the intervention differs from the usual care offered to the target population. Community treatment offered by the public health system (SUS) in psychosocial care centers (CAPS) was considered the standard treatment.

2. Definition of the key components of the intervention

The next step in the development of a scale to assess fidelity is to list properties that are essential to the intervention and are in contrast with the standard treatment offered. These properties are defined by collecting information from the authors of the intervention and reviewing the literature on the topic.

3. Preparation of a preliminary scale

The development of the CTI-TS fidelity scale considered all the material gathered through the authors' reports, bibliography and key components to draft the instrument. Moreover, fidelity scales of evidence-based interventions recorded in the National Registry of Evidence-based Programs and Practices were used as examples [14].

The scale items should consider fidelity to the protocol regardless of the outcomes of the intervention. While some external factors can influence the success of an intervention, the level of fidelity can be assessed based only on those characteristics which are under the control of professionals, not other factors. For example, it would not be appropriate to include an item that assesses the cooperation of the local political administration with a given intervention, or an item that assesses the unemployment rate in the area of vocational program implementation [15].

As important as the preparation of questions is the development of a range of possible answers to each item, which should not be so brief as to

lose sensitivity nor so detailed that it impairs the objectivity of the instrument. It is recommended to use 5 to 7-point scales for answers. The order of items should also be carefully established –the scale must begin with more general issues, increasing the complexity progressively. It is recommended that items are divided into different dimensions according to the topic covered and that they do not have different weights to calculate the final score [9].

4. Development of fidelity assessment sheets

Forms are designed to help the fidelity rater to collect and record data during their work. These forms facilitate the conversion of information obtained into percentages which are then rated on a scale of fidelity.

5. Development of a manual application of a fidelity scale

Creating a manual allows the standardization of data collection and thus increases inter-rater agreement. It should contain a clear description of each item of the instrument and the anchors for the score. It should also contain an introductory section about the intervention being evaluated and describe what the objects of assessment for each item will be (e.g. medical records, proper forms, interviews, observation of field work, etc.) [16].

6. Training the fidelity assessor

The person responsible for fidelity assessment of an intervention should be familiar with the intervention itself, with the fidelity scale to be used and the auxiliary assessment sheets. The training will have the manual for the application of the scale as a base. It is also advisable that the evaluator has prior knowledge about mental health and should be independent, i.e., not part of the intervention team, in order to avoid bias in the evaluation, since they would have no preconceived notions about the best way to carry out the intervention [10, 16].

7. Test the preliminary scale, the use of assessment sheets and the procedures included in the manual by carrying out a pilot study

The fidelity scale and assessment sheets developed should be tested in a pilot, after proper training of raters in the method [17].

RESULTS

Critical Time Intervention – Task Shifting (CTI-TS) is an intervention that proposes the transfer of functions, providing support for a better life for the patient in the community and promoting social integration. Regarding the system itself, it strengthens the connections between mental health services and primary health care. The CTI-TS has a limited duration of up to nine months and can be implemented at a critical moment, for example, when patients are discharged from hospital or when the first attendance is offered to them in a mental health service. During this period, CTI-TS workers establish relationships that will outline the continued use of services. The CTI-TS is conducted by community mental health workers (CMHWs) and peer support workers (PSWs) supervised by mental health professionals. These workers offer community activities and support to engage patients, families, primary care practitioners, peers and other community members in the recovery process. The CMHWs and PSWs will work synergistically using their experience and distinct capacities.

The CTI-TS is implemented in three consecutive phases: initiation, try-out and transfer of care. Each of these phases is implemented over a period of three months. In the first phase, initiation, the patient and the CTI-TS workers formulate a treatment plan focused on areas identified as crucial to strengthening stability and facilitating engagement in community life. The main task of this phase is to link the subject with appropriate community resources. In the second phase, try-out, support systems that have been established in the first phase are tested. At this stage, these systems are already in place, so the CTI-TS workers and the patient can verify in vivo the functioning of this system and at which points it needs adjustments. The final phase, transfer of care, is devoted to making any necessary fine-tunings in

the individual's network of supports. Long-term, community-based linkages that were previously established should at this point be functioning smoothly. In this phase, the client, CTI-TS workers, and other key service providers should meet to specifically review transfer-of-care issues and long-term goals. The same should occur among the main individuals providing informal support. CTI-TS workers will be withdrawing from the scene gradually, until leaving the patient in the community, using the support systems implemented along the intervention.

In this context, 18 key components of this intervention were defined (Table 1 – *next page*) and from these the CTI-TS fidelity scale was built. The scale consists of 20 items, divided into three sections, each evaluating one of the types of fidelity: compliance, context and competence. Compliance refers to the extent to which the practitioner uses the core intervention components prescribed by the evidence-based program or practice and avoids those proscribed by the program or practice. Context refers to the prerequisites that must be in place for a program or practice to operate (e.g., staffing qualifications or numbers, practitioner-consumer ratio, supervisor-practitioner ratio, location of service provision, prior completion of training). Given the key interpolative role of coaching between staff selection and training on the one hand and staff performance assessments on the other hand, research is needed that evaluates the relative contributions of selection, training, and coaching and (especially) interaction effects among the three factors. Competence refers to the level of skill shown by the therapist in using core intervention components as prescribed while delivering the treatment to a consumer (e.g., appropriate responses to contextual factors and consumer variables, recognizing the key aspects of presenting problems, understanding the consumer's individual life situation, sensitivity).

Each scale item is scored using a Likert scale of five points, ranged from 1 = not implemented to 5 = implemented optimally. For each item there is a corresponding evaluation form that helps the evaluator to collect and record data while working. These forms guide the conversion of data into percentages in an easy and practical way so that correct values are then scored on a scale of fidelity, avoiding misclassification.

Table 1: 18 key components of the CTI-TS intervention

18 key components of the CTI-TS intervention	
Limited number of cases per each CTI-TS agent	Strengthening community ties through mediation and negotiation
Presence of two types of agents – peer support worker and community mental health worker	Relationship between agents and CTI – TS patients based on social solidarity
Standardized training for CTI-TS agents	Ready availability of CTI-TS agents for patients
Duration limited to 9 months	Focus on 1–3 pre-established areas
Gradual decrease of service intensity	Presence of basic structural features
Harm reduction approach, behavior change	Create connection between family, primary care services and mental health services
Fast establishment of links with the community	Maintaining close contact with patients more likely to abandon treatment
Regular supervision meetings with all staff to review the case of each patient	Presence of three distinct phases
Avoid becoming the main source of care for patients	Assessment of patient needs in the community

The rater should receive standardized training based on manual application of the scale to avoid errors of judgment. This training includes the presentation of the intervention with regard to appropriate implementation, the target population, the phases and specific training for fidelity assessment.

Each period of assessment for CTI-TS considers the past 3 months. Each evaluation of fidelity lasts about 3 days, 2 days for observation of a regular meeting of supervision, brief interview with the supervisor and collection of data recorded on specific intervention forms. The third day is reserved for observing the field work of CTI-TS workers and brief interviews with these professionals.

DISCUSSION

Individuals suffering from mental disorders require complementary interventions and support to successfully engage in a continued long-term care. The Critical Time Intervention Task-Shifting (CTI-TS) was developed from these concerns, aiming to complement and strengthen the network of existing care services. The CTI-TS is intended to help individuals who suffer from severe mental illness to engage and stabilize in a continuing care. This is an innovative model developed in New York, to be administered during a critical and limited period⁵.

Ensuring the fidelity of an intervention allows it to be disseminated widely, maintaining its integrity to the principles and techniques originally proposed. This allows checking whether the professionals involved have received proper training, and whether the frequency and intensity of the intervention procedures meet the minimum criteria determined by the model. With the results obtained from an intervention faithful to the original model, its effectiveness can be determined as well as its “dose-response” function, that is, how much improvement was observed and the number of contacts between professionals and patients [18, 19].

The assessment of fidelity in psychosocial interventions not only focuses on the conduct of professionals, but also addresses the structural aspects of the program such as the qualification of the professionals involved, the ratio number of patients to professionals, the location of the services offered, the material to be used by professionals, and the integration between the usual care and intervention proposal. Therefore, the development of a manual for a psychosocial intervention is a complex task that involves many aspects and indicating which elements of the model should be evaluated [9].

Assessing the fidelity of an intervention is useful both for reasons related to research and as a practical matter. Regarding research, the measure of fidelity ensures the internal validity of the study confirming that the manipulation of the

independent variable occurred as planned. This allows differentiating the intervention from usual care (control group). Assessing the fidelity of an intervention is especially important in multicenter studies in which some results may be more prevalent in some sites than others. The fact that some programs distance themselves from the original model may explain this, hence the importance of assessing fidelity in different centers where an intervention is being implemented [20]. More than simply documenting how the original model was followed, fidelity also provides information to carry out necessary changes during the course of the intervention so that the procedures do not distance themselves from the protocol and excellence in the implementation process is achieved [12].

Evaluation of fidelity is also fundamental in longer-term studies to ensure that adherence to the protocol does not decrease over time, especially when changes occur in the organization of the professionals involved [21].

The fidelity measure is also important to facilitate communication in the literature. Systematic reviews aim to analyze the extent to which results of certain studies are generalizable, i.e., their external validity. When an intervention is implemented with certain variations in procedures at different centers, it is difficult to include such studies in a single revision. Ideally, a review should include studies that were implemented with minimal variations of the protocol, i.e. studies that were evaluated by the same instrument for measuring fidelity and obtained a minimum level of agreement with the original protocol. Fidelity scoring scales can also be used as an independent variable in a meta-analysis¹⁰.

Some studies have associated fidelity to the protocol to the results of the intervention. McGrew et al²² found significant correlation between the fidelity of an intervention and a reduction in using hospital services. Latimer [23] evaluated a sample of 34 centers implementing ACT (Assertive Community Treatment), and concluded that centers which have implemented the intervention with greater fidelity to the original protocol obtained better results at the end of the study than those with low fidelity. Such associations can help in identifying critical elements – predictors of patient outcomes. This

is related to the predictive validity of the assessment of fidelity [10].

Regarding the practical uses of the assessment of fidelity, an example could be the introduction of an intervention to a population that has no previous experience with the model. The fidelity instrument can be used as a quick reference to the essential points of the protocol and as a starting point for estimating the costs of its implementation. It can also be used to communicate key elements of the intervention to the professionals who will participate in the implementation as well as to patients and their families²⁴.

Managers can use funding of certain interventions of fidelity measures for monitoring the quality of implementation in different centers, for example, comparing different regions (urban vs. rural), comparing individual centers and by comparing the overall mean maintaining fidelity in the course of implementation time. Such comparisons are useful in identifying regional problems that may reflect different cultural, economic and social contexts. By identifying a region with difficulty in implementation, the problem can be corrected in time. The monitoring of fidelity may be useful not only to managers, but also to individual centers for self-evaluation over time [9].

In the case of CTI-TS, it is indicated that fidelity assessment is not carried out before the start of the first 6 months of the intervention, because this is enough time for the professionals involved to get used to the procedures and conduct preliminary adjustments in the implementation process. Moreover, it is appropriate that the number of cases per agent is already complete at the time of the assessment of fidelity, and already there are patients allocated at different phases of the intervention. This has the advantage of covering the greatest number of items in the final score scale, since some items are phase specific. So this score is more reliable of intervention fidelity.

It is recommended that fidelity assessment is held every three months to minimize recall biases in interviews of professionals and allow any deviation in the implementation to be recognized and corrected in time to prevent the loss of effectiveness, but without burdening the implementation with frequent valuations.

The literature suggests that the most accurate assessment of fidelity involves the analysis of different sources such as medical records, appropriate forms of intervention, interviewing the professionals involved, observation fieldwork, self-administered questionnaires, participation in supervisory meetings, among others^{9,10}. This has advantages and disadvantages: the increased accuracy obtained by evaluating multiple sources is accompanied by rising costs. On the other hand, a simple review of medical records and forms may not be sufficient to capture the essence of the work. The presence of disagreement between sources can be useful in the identification and resolution of problems in the implementation of a model [25].

After the development of the scale, its feasibility should be tested in practice in a pilot study, during which both aspects of the content and the psychometric properties of the instrument should be assessed. Content analysis can identify problems in terminology, description and item scores, assess the adequacy of the scale of responses, observe if there are important topics identified in practice that were not included in the scale, as well as increasing the expertise of the performance evaluator. Psychometric analysis determines the reliability and validity of an instrument [17]. This is a limitation of the present article, since the psychometric properties of the fidelity scale have not been tested so far, as the pilot study in Brazil has not yet started.

The implementation of a psychosocial intervention involves several steps, such as the adaptation of the proposal to the local context, the development of a manual to be used as a guide, the description of the personal and structural components necessary to carry out the intervention and the development of a method to assess the fidelity in relation to the theoretical model [13].

The CTI-TS had its fidelity assessment method developed in accordance with the recommendations in the current literature. Future studies will evaluate the psychometric properties, feasibility and implementation cost. Fidelity to the protocol is essential for the results, whether positive or not, can be credited to the intervention itself [9, 10, 13]. Furthermore, in the case of an intervention that will be used in various locations, it is essential that all involved centers develop the

intervention in a reliable manner so the results can be comparable.

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