

## Brief report

# A randomized clinical trial of home-based telepsychiatric outpatient care via videoconferencing: design, methodology, and implementation

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## Abstract

**Background:** Healthcare providers are continuously challenged to find innovative, cost-effective alternatives and to scale up existent services to meet the growing demand upon mental health care delivery. Due to continuous advances in technologies, telepsychiatry has become an effective tool for psychiatric care. In 2012, the Institute of Psychiatry of the University of São Paulo Medical School started a randomized clinical trial of home-based telepsychiatric outpatient care via videoconferencing. **Objective:** The objective of this article is to describe the design, methodology and implementation of a pilot project, which aimed to verify the applicability and efficiency of psychiatric attendance via Internet-based videoconferencing in a resource-constrained environment. **Methods:** The project consisted of a 12 months follow-up study with a randomized clinical trial, which compared various quality indicators between home-based telepsychiatric aftercare via videoconferencing and face-to-face aftercare. **Results:** The final sample comprised 107 outpatients (53 in the telepsychiatry group and 54 in the control group). Among 1,227 realized consultations, 489 were held by videoconferencing. Satisfaction with the aftercare by videoconferencing and the medication delivery was high among patients. Attending psychiatrists were satisfied with the assistance by videoconferencing. **Discussion:** The experiences during this pilot project have overall been very positive and psychiatric outpatient care by videoconferencing seems viable to treat patients even in a resource-constrained environment.

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**Keywords:** Telepsychiatry, telemental health, videoconferencing, outpatient care, home-based treatment.

## Introduction

Mental, neurological and substance-use (MNS) disorders constitute 13% of the global burden of disease, measured in disability-adjusted life years (DALYs), surpassing cardiovascular disease and cancer<sup>1</sup>. Thereby, depressive disorders accounted for 40,5% of DALYs caused by mental and substance use disorders<sup>2</sup>.

In a cross-national epidemiological study that compared the prevalence of DSM-IV major depressive episode between high-income and low-to-middle-income countries, Brazil took first place regarding the 12-month prevalence (10.4%), followed by Ukraine (8.4%), and the United States (8.3%)<sup>3</sup>.

Although effective interventions to reduce this burden exist, they are often not available to those in greatest need. In São Paulo, 53% of adults with an active mental disorder do not receive treatment services<sup>3</sup>. As most mental health resources are centralized in and or near big cities and in large institutions, and services are unequally distributed across Brazil, this treatment gap is, in all probability, even much worse in more remote regions of the country.

Thus, the challenge to healthcare providers is to find innovative, cost-effective alternatives and to scale up existent services to meet the growing demand upon mental health care delivery.

With 108 millions of internet users (53% of the population) in 2014, Brazil takes fifth place in the global ranking of Internet users (behind China, USA, India, and Japan)<sup>4</sup>. The use of information and communication technologies (ICT) holds enormous promise for significantly increasing the access to quality mental health care, even in settings like Brazil, where resources are restricted<sup>5</sup>.

Telepsychiatry has been defined as “the delivery of health care and the exchange of health information for purpose of providing psychiatric services across distances”<sup>6</sup> and is primarily achieved with the use of live, interactive videoconferencing. The use of videoconferencing in the field of psychiatry is over half a century old<sup>7</sup>. Due to the advances in information technologies, the sounds and images transmitted through video conferencing became equivalent to verbal information and visual cues in face-to-face assessment<sup>8</sup>. Previous studies have shown that telepsychiatry is effective for many services

(assessment, diagnosis, ongoing management/aftercare, medication review, psychotherapy, etc.) across many populations (adult, child, and geriatric) and disorders (depression, posttraumatic stress disorder, substance use, etc.), and thus, appears to be comparable to in-person care<sup>9</sup>.

However, a telepsychiatric service is not simply a technology, it also involves processes and its use is influenced by many factors. To ensure that mental health needs receive the level of priority necessary to reduce the burden associated with MNS disorders, mental health services has to be scaled up in order to increase the impact of interventions that have been successfully tested in pilot project.

The objective of this article is to describe the design, methodology and implementation of a pilot project, which aimed to verify the applicability and efficiency of psychiatric attendance via Internet-based videoconferencing in a resource-constrained environment.

## Methods

### Study design

The pilot project consisted of a 12 months follow-up study with randomized clinical trial, which compared various quality indicators between home-based telepsychiatric aftercare via videoconferencing and face-to-face aftercare. Whereas the telepsychiatry group realized monthly consultation with the attending psychiatrist through Internet-based videoconference, the control group received monthly face-to-face (F2F) consultations at the Institute of Psychiatry (IPq) of the University of São Paulo Medical School (FMUSP).

### Sampling

Interested patients received an online questionnaire via e-mail to verify their age, connectivity (broadband Internet at home), and were screened for already existing diagnostics and/or a possible presence of a depressive disorder, with the use of the Patient Health Questionnaire (PHQ-9), a self-administered screening instrument<sup>11</sup>.

Recruited patients completed at least two initial F2F consultations at the IPq, where the clinical diagnostic was confirmed, the medication initiated, and the stability of the patient ensured. Patients with a total score of less or equal than 15 in the Hamilton Depression Rating Scale (HAMD-17)<sup>12</sup> were considered as stabilized. After the second F2F appointment, patients who fulfilled the inclusion criteria (stabilized unipolar depression disorder, age 18-55 years, broadband Internet access at home) were randomized into the telepsychiatry or control group. As the randomization was realized after the initial evaluation, potential biases were balanced between the two groups. Moreover, all involved psychiatrists attended via videoconference as well as F2F. The study has been approved by the local ethics committee and written informed consent was obtained from all patients prior to inclusion.

## Safety plan

Monitoring patients through videoconferencing in a clinically unsupervised setting like the home of the patient demands an establishment of a safety plan, based on the identification of predictable cultural, clinical, organizational, structural and technical risks and barriers, such as health professional or patients resistance against the remote treatment, inappropriate substitution of personal contact due to psychopathological causes, lack of training, familiarity with technologies, or technical support.

All attending psychiatrists and patients were recruited specifically for the present project. That is to say that they all agreed to deliver treatment or to be treated by videoconferencing.

If a patient scored higher than 15 in the Hamilton Depression Rating Scale, needed additional consultations beside the monthly contacts, or showed an increased suicide risk, he or she was not included or, if already participating, excluded from the study.

As the lack of knowledge about the use of communication technologies and of confidence to manage technical problems are the main impediments patients described using telepsychiatric services<sup>13</sup>, test-consultations were conducted with each patient to verify if the equipment and Internet connection would warrant the necessary picture and audio quality in preparation for the first online consultation with the psychiatrist. Moreover, before each online contact with the psychiatrist, the study coordinator tested those technical issues again. The study coordinator accompanied all consultations by videoconferencing during the first minutes to ensure the quality of transmission and, if necessary, got in touch with the patient by telephone to solve technical problems.

## Aftercare via videoconferencing

In a first step, seven psychiatrists with several years of professional experiences in public and private health care were recruited and trained in video consultations by the study coordinator and the telemedicine staff of the FMUSP.

After being included randomly in the telepsychiatric aftercare program the patients received monthly video consultations with a psychiatrist during 12 months. All consultations took approximately 20 minutes and contained psycho-education, medication monitoring, and counseling. It has been shown that follow-up consultations providing counseling services can be defined as low-risk, as they do not include key diagnostic and clinical decisions<sup>14</sup>. Nevertheless, for patient safety reasons, another two F2F consultations, one after six and another after 12 months, were outlined. Patients have been attended by one and the same psychiatrist during the whole time, independently of the modality (face-to-face or videoconferencing).

The video consultations were realized in consulting rooms at the IPq, using three 17,3-Inch multimedia laptop computers and the institutional broadband Internet of 100 megabits per second (Mbps). If necessary, participants of the videoconference telepsychiatry group could borrow a headset and a webcam (2 Megapixels). All online consultations were performed via Skype, a free and widely used Internet videoconferencing service, which is password-protected (private accounts) and uses encryption methods to ensure privacy

and security of data transfers. A recent systematic review has shown that there do not exist any reasons for not using this software in clinical settings.

## Evaluation framework

At the baseline, after six and 12 months, various outcome variables were assessed by the psychiatrists and through online self-applied questionnaires among all participants. The primary outcome of the present study was the clinical effectiveness of psychiatric attendance via videoconferencing, measured by depression severity evolution, mental health status, relapses, and medication course. The secondary outcome was the applicability of online aftercare, measured by satisfaction with treatment, therapeutic relationship, medical compliance, and treatment adherence.

## Results

From over 2,000 interested persons who entered in contact by e-mail, 216 were invited for one or two initial F2F screening consultation at the IPq. The most common reasons for not being invited were residence in another city, state or country, other diagnostics than mood disorders, or no Internet access at home. The final sample comprised 107 outpatients (53 in the telepsychiatry group and 54 in the control group).

Within the project's aftercare, 1,227 consultations were conducted during a period of 35 months. Among them, 489 were realized by videoconferencing. Medication was delivered after every video consultation to the patients' home. In general, patients treated via videoconferencing were very satisfied with the delivery.

The general satisfaction with the treatment via videoconferencing was also high among patients, and, if they could choose, they would prefer to be treated by videoconferencing in the future.

The aftercare by videoconferencing has also received high ratings from the attending psychiatrists. Their feedback indicated that, the majority felt comfortable with providing consultations by telepsychiatry.

The evaluation of the effectiveness and applicability is ongoing and will be presented in a future article.

## Discussion

Within this paper, the design, methodology and implementation of a randomized clinical trial of home-based telepsychiatric outpatient care via videoconferencing have been presented. The experiences during this pilot project have overall been very positive and psychiatric outpatient care by videoconferencing seems a viable approach to treat patients even in a resource-constrained environment. The study is an important contribution to verify the applicability and effectiveness of treatment by videoconferencing in the management of mental illness, to improve the treatment delivery system of the Institute of Psychiatry, and to increase the access to mental health care in Brazil. Further evaluations will deliver more results about the effectiveness and applicability of this new treatment modality.

## Declarations of interest

No competing financial interests exist.

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