



Research paper

Psychoeducation in bipolar disorder with a SIMPLe smartphone application: Feasibility, acceptability and satisfaction



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ARTICLE INFO

Article history:

Received 1 March 2016

Received in revised form

11 April 2016

Accepted 16 April 2016

Available online 20 April 2016

Keywords:

Bipolar disorder

Psychoeducation

Smartphone

Application

SIMPLe

ABSTRACT

Background: During the last fifteen years, the possibility of delivering psychoeducation programs through Internet-based platforms have been explored. Studies evaluating those programs have shown good to acceptable retention rates. In this context, we developed a smartphone application (SIMPLe) collecting information about mood symptoms and offering personalized psychoeducation messages. The main aims of this study were to evaluate the feasibility, acceptability and satisfaction of the smartphone application.

Methods: The study was conducted from March to August 2015. Participation in the study was proposed to a consecutive sample of adult patients attending an outpatient mental health clinic. Sociodemographic data, clinical and functional assessments alongside smartphone ownership and uses were collected at baseline and at 3 months' follow-up. A 5 item Likert-scale satisfaction questionnaire was also employed. **Results:** 51 participants were initially enrolled in the study, 36 (74%) remained actively using the application after 3 months. The whole sample interacted with the application a mean of 77 days (SD=26.2). During these days they completed 88% of the daily tests. Over 86% of the participants agreed that the experience using the application was satisfactory.

Limitations: The diversity of smartphones operating systems led to a moderate, although representative, sample number. Additionally, the subjective data reporting, narrow time frame of use and stability of the patients could have affected the results.

Conclusions: The results confirm that this particular intervention is feasible and represent a satisfactory and acceptable instrument for the self-management of bipolar disorder as an add-on to the usual treatment but future clinical trials must still probe its efficacy.

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1. Introduction

The estimated prevalence of bipolar disorder (BD) in the general population is estimated to be around 2%, although this could have been underestimated due to undiagnosed cases (Fagioli

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<http://dx.doi.org/10.1016/j.jad.2016.04.042>

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et al., 2013). Besides the well-known behavior changes during pathological mood episodes, BD has a serious impact on psychosocial functioning, cognition, quality of life and survival of those affected (Catalá-López et al., 2013). Some pharmacological treatments and adjunctive psychological interventions have shown to improve the long-term outcome of the disorder (Grunze et al., 2013; Reinares et al., 2014).

Among psychological interventions, psychoeducational programs proved to be a cost-effective approach to help patients improve adherence, regularity of habits and recognize early signs

and symptoms in order to prevent episodes (Colom et al., 2009; Scott et al., 2009). However, although there is an increasing demand from patients and their relatives to receive this kind of treatments, its availability is still limited due to the costs and resources involved (Miklowitz and Scott, 2009). The implementation of psychoeducation programs require trained specialists and specialized units (Colom, 2011). Unfortunately, this combination is available only at very few centers around the globe. Moreover, from the patients' side, it requires attendance to weekly sessions during a period of about 6 months. This may limit its implementation in large countries and rural areas with long geographical distances between the patient and the care center. Besides the aforementioned challenges, tailoring these interventions to individual clinical characteristics and schedules in a cost-effective way are difficult aims yet to be addressed. For these reasons, there is an increasing need to find new efficient methods to deliver and extend psychoeducation programs to a wider population of patients with BD.

During the last fifteen years, several projects have explored the possibility of delivering psychoeducation programs through Internet-based platforms such as web-sites and mobile devices (Cosgrove et al., 2013; Depp et al., 2014; Meiser et al., 2013). These platforms offer the patients the possibility to access the program according to their schedules even if they live in remote areas, something which represents a very attractive complement to the standard treatment (Holländare et al., 2015; Palmier-Claus et al., 2013; Parmanto et al., 2013). Studies evaluating these programs have shown good to acceptable retention rates of about 50–80%; however, due to the extreme heterogeneity in outcome measures and methodologies used, it is still not possible to draw sound conclusions about their long-term efficacy (Hidalgo-Mazzei et al., 2015a).

On the other hand, the wide availability, constant miniaturization and increasing computing power of mobile devices make it possible to obtain a reliable and continuous collection of relevant users' information at a low-cost. Smartphones, through the increasing embedded sensors and daily usage patterns, can collect a vast amount of objective information to identify behavioral symptoms patterns as well as physiological signs, which have the potential to provide novel insights about mental illnesses (Munk-Jørgensen et al., 2014). Moreover, this still underutilized kind of data have recently shown to be a feasible potential biomarker of illness activity in BD (Faurholt-Jepsen et al., 2015, 2014).

Based on an increasing number of studies, it seems that smartphones technology is perceived by the patients as a comfortable, time-unconstrained, user-friendly and non-invasive method in the self-management of their mental health (Bush et al., 2013). Furthermore, it makes possible to register and monitor relevant signs and symptoms in real-time (Faurholt-Jepsen et al., 2015). In addition, it can provide continuous self-managed psychoeducational contents, which can be tailored to the specific needs of each individual based on their smartphone data (Benzeev et al., 2013; Torous et al., 2015).

As an initial phase of the SIMPLe project (Hidalgo-Mazzei et al., 2015a), we initially set out to develop a smartphone application (SIMPLe 1.0) collecting information about potential bipolar symptomatology (i.e. subjective information), with the additional advantage of offering personalized psychoeducation messages and alerts delivered to the patient. The application is intended to be an additional tool to the usual treatment. Before testing its efficacy and due to the novelty of the intervention, it is mandatory to carry out a rigorous feasibility study in a real-world clinical setting in order to ensure the acceptability, satisfaction and safety of these interventions and increase the chances of reaching some degree of engagement in the long term (Bowen et al., 2009; Wenzel et al., 2014).

Accordingly, the main aims of this feasibility study were to evaluate, during 3 months, acceptability, safety and satisfaction of the SIMPLe smartphone application designed to monitor symptoms in BD, offering customized embedded psychoeducation contents and empowering self-management. Secondary objectives were to explore whether sociodemographic and clinical variables of the sample could predict or enhance the usage of this application. Additionally, patients' suggestions and comments regarding the application were collected during the study in order to improve further versions.

2. Materials and methods

2.1. Participants, procedure and measures

The study was conducted from March to August 2015. Participation in the study was proposed to a consecutive sample of adult patients attending the outpatient mental health clinic of the Bipolar Disorders Program in the Hospital Clínic of Barcelona. The eligibility criteria included a diagnosis of a BD type I, II or not elsewhere specified (NES) based on DSM-5 criteria. The study was approved by the Ethics Committee of the Hospital Clínic of Barcelona and registered at clinicaltrials.gov (Identifier: NCT02258711).

If the patient met eligibility criteria, their usual psychiatrist or psychologist explained briefly the aims of the study, the intervention and enquired if they were interested. If this was the case, an independent researcher extended a brochure with all the information and requirements regarding the study. At this point the patient could choose whether to participate or not, based on their will or if they have a compatible smartphone (i.e. Smartphone with Google™'s Android Operating System version ≥ 4.0). In case of denial, the reason, gender and age of the patient were also registered. If the patient agreed to participate, an informed consent was handed out and, upon acceptance, signed by the participants. Since the ultimate goal of the intervention was relapse prevention, to be included participants had to be euthymic, determined by a current Hamilton Depression Scale (HDRS; (Bobes et al., 2003; Hamilton, 1960)) score below 8, and a Young Mania Rating Scale (YMRS; (Colom et al., 2002; Young et al., 1978)) score below 6 (Tohen et al., 2009). Patients currently participating in group psychoeducation or with an intelligence quotient score below 90, were excluded from the study. Sociodemographic data and standardized clinical and functional assessments were registered at baseline and after three months. These included: manic symptoms using the YMRS, depressive symptoms using the HDRS as well as Functional Assessment Short Test (FAST) (Rosa et al., 2007) and treatment adherence using the Morisky-Green 8-item test (Morisky et al., 1986). In addition, information about smartphone most common uses and ownership time were collected. No rewards or incentives were offered to the patients for their participation or completion.

After study inclusion, a random identification six-digit username and password were provided to each participant. This username was linked to their electronic health records (EHR) identifier in a completely independent encrypted database. According to the research protocol, de-identification process was activated if there was an emergency detected by the application (i.e. suicide ideation) and treating psychiatrist was alerted, in order to contact the patient.

At the end of the first interview, the researcher helped the patient to install the application in their own smartphones, log into the system and a brief explication on the application was provided. Since the application was designed to be user-friendly and self-explanatory, no further information or training was

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