



## Research paper

## Is a SIMPLE smartphone application capable of improving biological rhythms in bipolar disorder?



Diego Hidalgo-Mazzei<sup>a,b</sup>, María Reinares<sup>a</sup>, Ainoa Mateu<sup>c</sup>, Mario F. Juruena<sup>b,d</sup>, Allan H. Young<sup>b</sup>, Víctor Pérez-Sola<sup>e,f</sup>, Eduard Vieta<sup>a,\*</sup>, Francesc Colom<sup>f</sup>

<sup>a</sup> Bipolar Disorder Program, Department of Psychiatry and Psychology, Institute of Neuroscience, Hospital Clinic, University of Barcelona, IDIBAPS, CIBERSAM, Barcelona, Catalonia, Spain

<sup>b</sup> Department of Psychological Medicine, Institute of Psychiatry, Psychology and Neuroscience, King's College London and South London and Maudsley NHS Foundation Trust, Denmark Hill, Camberwell, London, United Kingdom

<sup>c</sup> Centre for Psychiatry, Division of Brain Sciences, Department of Medicine, Imperial College London, London, United Kingdom

<sup>d</sup> Stress and Affective Disorder Programme, Department of Neuroscience and Behaviour, University of Sao Paulo, Brazil

<sup>e</sup> Institute of Neurosciences and Addictions, Hospital del Mar, Barcelona, Catalonia, Spain

<sup>f</sup> Mental Health Group, IMIM-Hospital del Mar, CIBERSAM, Barcelona, Catalonia, Spain

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## ABSTRACT

**Background:** Biological rhythms (BR) disturbance has been suggested as a potential mediator of mood episodes in Bipolar Disorder (BD). The Biological Rhythms Interview of Assessment in Neuropsychiatry (BRIAN) was designed as an assessment tool to evaluate BR domains comprehensively. In the context of a trial evaluating a smartphone application delivering personalized psychoeducational contents for BD (SIMPLE 1.0), the main aim of this study is to evaluate the potential impact of SIMPLE 1.0 in BR regulation using the BRIAN scale.

**Methods:** 51 remitted BD patients were asked to use the application for 3 months. Paired *t*-test analyses were employed to compare baseline and follow-up BRIAN's total and domains scores. The sample was divided into completers and non-completers of the study to evaluate differences between groups regarding BRIAN scores using ANCOVA analyses.

**Results:** The BRIAN's mean total score of the whole sample significantly decreased from baseline to post-intervention (35.89 (SD 6.64) vs. 31.18 (SD 6.33),  $t = 4.29$ ,  $p = 0.001$ ). At post-intervention, there was a significant difference between groups regarding the total BRIAN mean score (29.47 (SD 6.21) completers vs. 35.92 (SD 3.90) non-completers,  $t = 2.50$ ,  $p = 0.02$ ). This difference was maintained after conducting a one-way ANCOVA controlling for pre-intervention BRIAN scores,  $F(1, 46) = 10.545$ ,  $p = 0.002$ .

**Limitations:** A limited sample, pre-post measures, and a short study timeframe could have affected the results. Additional factors affecting BR, such as medication, could not be ruled out.

**Conclusion:** Our results suggest that there are potential positive effects of a psychoeducational smartphone application as an adjunctive to treatment as usual on BD patients' BR.

## 1. Introduction

Bipolar disorder (BD) is a chronic recurrent condition affecting approximately 2% of the world population (Grande et al., 2016; Merikangas et al., 2011). Alongside the acute episodes, the illness encompasses a significant negative impact on the quality of life, cognition

and life expectancy of those affected (Angst et al., 2002; Kessing et al., 2015; Martínez-Arán et al., 2004; Michalak et al., 2005).

Biological rhythms disturbance has been suggested as a potential mediator not only of the mood episodes but also of the impairment and reduced quality of life in BD patients (Ashman et al., 1999; Giglio et al., 2010; Murray and Harvey, 2010; Rosa et al., 2013; Shen et al., 2008).

**Abbreviations:** ANCOVA, Analysis of Covariance; BD, Bipolar disorder; BRIAN, Biological Rhythms Interview of Assessment in Neuropsychiatry; BT, Biological Rhythms; HDRS, Hamilton depression rating scale; IPSRT, Interpersonal and social rhythm therapy; MG, Morisky Green test; NES, Not elsewhere specified; SD, Standard deviation; SIMPLE, Signs and Symptoms Self-monitoring and Psychoeducation in Bipolar Patients with a Smart-phone Application Project; SRT, Social Rhythms therapies; YMRS, Young mania rating scale; TAU, Treatment as usual

\* Correspondence to: Bipolar Disorders Program, Neurosciences Institute, Hospital Clínic de Barcelona, IDIBAPS, CIBERSAM, Universitat de Barcelona, Villarroel 170, 08036 Barcelona, Catalonia, Spain.

E-mail address: [evieta@clinic.ub.es](mailto:evieta@clinic.ub.es) (E. Vieta).

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Previous studies reported that biological rhythm disturbance was proportional to the intensity of depressive symptoms in BD, and both variables contributed to a poorer psychosocial functioning (Pinho et al., 2016). Variations of the biological rhythms are widely recognized as one of the most common warning signs in BD, being part of the diagnostic criteria for mood episodes (American Psychiatric Association, 2013; Harvey et al., 2009). However, until recently, there has been a lack of well validated instruments available to correctly assess this issue. The Biological Rhythms Interview of Assessment in Neuropsychiatry (BRIAN) was designed as an assessment tool to ascertain most of the biological rhythms' domains (i.e. sleep/wake cycles, social activity and diet intake). It has been validated in different countries and languages, and extensively employed with the aim of evaluating biological rhythms in BD (Giglio et al., 2009; Moro et al., 2014; Rosa et al., 2013).

Accordingly, the disturbance of biological rhythms has been addressed by evidence-based psychotherapeutic interventions in the field of BD. Improving habits regularity is, very likely, one key factor in order to understand the proven efficacy of psychoeducation in BD (Cardoso et al., 2015; Colom and Vieta, 2006). Not by chance, each and every psychological intervention tested in the field of BD includes lifestyle one way or another. Particularly, Interpersonal and Social Rhythm Therapy (IPSRT) and other Social Rhythms therapies (SRTs) have targeted biological rhythms with some encouraging results (Frank, 2007; Frank et al., 2005; Haynes et al., 2016).

Unfortunately, there are several barriers hampering psychological treatments' broad implementation and availability (Colom, 2011; Reinares et al., 2014; Stafford and Colom, 2013). It is assumed that the vast majority of bipolar patients worldwide do not have access to a proper psychotherapeutic treatment.

Internet-based resources may improve the accessibility and affordability of psychological treatments for the whole affected population. Interestingly, people diagnosed with BD often use internet to gather information about their condition (Bauer et al., 2016). Hence, there is an increasing number of initiatives aimed to adapt psychotherapeutic treatments to Internet platforms (Hidalgo-Mazzei et al., 2015a). Most of them, attempted to provide psychoeducational contents and programs over web-based platforms, showing high levels of feasibility but mixed results regarding its efficacy (Hidalgo-Mazzei et al., 2016).

On the other hand, the rising use of smartphones has further enhanced the potential to ubiquitously and unobtrusively track behaviour and mood (Gershon et al., 2016; Glenn and Monteith, 2014). This is especially relevant since, in recent years, a great percentage of socializing activities have shifted from "traditional in-person" to online social networks, nowadays mostly centered on smartphones (Morahan-Martin and Schumacher, 2003; Sarwar and Rahim Soomro, 2013).

Despite these advancements, very few of the current smartphone applications (i.e. app) developed for BD routinely assess sleep and most of them cover a small percentage of psychoeducational contents, revealing an overall poor evidence-based quality (Nicholas et al., 2015). The SIMPLE project main aim is to provide mood monitoring and personalized psychoeducation contents through a smartphone app. The psychoeducational contents cover all the modules of evidence-based psychoeducational programs. Furthermore, content related to sleep/wake cycles was especially emphasized both in the app monitoring and psychoeducational messages (Hidalgo-Mazzei et al., 2015b). The central purpose of the SIMPLE app, as an adjunctive to treatment as usual, is to promote BD patients' self-management and empowerment in order to modify behaviours and prevent relapses alongside quality of life improvement. The feasibility and satisfaction of the first version of the SIMPLE 1.0, relying solely on the use of the app and subjective information, was evaluated in a 3-month feasibility trial which has shown 74% retention rates (Hidalgo-Mazzei et al., 2016).

In the context of this trial, the main aim of this study is to evaluate the impact of the SIMPLE app on biological rhythms regulation.

## 2. Methodology

### 2.1. The intervention SIMPLE 1.0

Overall, the SIMPLE 1.0 app consists of a daily short 5-item screening test, where the user has to reply by means of a visual friendly slider to his/her state regarding current mood, energy, irritability, night-sleep duration and medication intake. This daily assessment is completed once a week with a more comprehensive YES or NO test, considering all DSM-5 criteria for manic and depressive episodes including –and paying special attention to– suicidal thoughts. Based on this collected information, a daily pop-up notification prompts the user to read a short psychoeducational message. The time to fulfil the daily tests and to receive psychoeducational messages could be configured by the user as well as the day of the week to do the weekly test. Psychoeducational messages are based on an evidence-based group psychoeducation program (Colom and Vieta, 2006) and other client-aimed materials produced by the Bipolar Disorder Group at Hospital Clínic of Barcelona. These educational messages provide the user with a brief information or advice of how to deal with specific situations to avoid a relapse. Each message is extracted from a library of more than 500 messages categorized according to different clinical situations. The application's algorithm selects which category should be targeted based on the users' answers (e.g. if adherence problems are identified, the educational message will focus on this issue). One of those categories is specifically aimed to tackle circadian rhythms and sleep disturbances.

### 2.2. Procedure, participants and measures

The feasibility study evaluating the first version of the app was conducted from March 2015 to June 2015 as part of the broader SIMPLE project. The sample (N = 51) consisted of a consecutive sample of remitted BD patients to whom it was requested to use the application. 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).

Sociodemographic data and results of clinical assessments were collected during the study. The following clinical measures were administered in face-to-face interviews at baseline and after 3 months of the app use: the Spanish validated versions of the Young Mania Rating Score (YMRS) (Colom et al., 2002; Young et al., 1978) and 17-item Hamilton Depression Rating Score (HDRS) (Hamilton, 1960; Ramos-Brieva and Cordero-Villafila, 1988), 4-item Morisky-Green test (MG) (Morisky et al., 1986) and the BRIAN –validated Spanish version– (Giglio et al., 2009; Rosa et al., 2013). The BRIAN is a 21-item evaluation considering five main areas of daily rhythms (i.e. sleep, activities, social rhythms, eating patterns and predominant circadian rhythms). Each item is scored using an ordinal 4-points scale according to the frequency of daily habits disturbance, ranging from 1 for never to 4 for often. The total BRIAN score is the sum of all individual items scores. Thus higher scores suggest a greater degree of rhythms disturbance (Giglio et al., 2009).

Additionally, the use of the application as well as the input of subjective data were analysed from the data stored at the cloud server during the duration of the study. Detailed baseline characteristics of the sample, the app design process and the results of the feasibility study are described in detail elsewhere (Hidalgo-Mazzei et al., 2016, 2015b).

### 2.3. Statistical analyses

An assessment of normality was previously performed to determine the distribution of the variables implicated in the analyses. Accordingly, paired *t*-test analyses were employed to compare baseline and follow-up BRIAN's domains and total scores. We further divided the group in completers and non-completers according to whether they had used the

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