Journal of Affective Disorders 174 (2015) 485–492

Contents lists available at ScienceDirect

Journal of Affective Disorders

journal homepage: www.elsevier.com/locate/jad

Research report

A web-based preventive intervention program for bipolar disorder: Outcome of a 12-months randomized controlled trial ☆

Caryl W. Barnes [a,b,*], Dusan Hadzi-Pavlovic [a,b], Kay Wilhelm [a,b], Philip B. Mitchell [a,b]

[a] School of Psychiatry, University of New South Wales, Sydney, NSW, Australia
[b] Black Dog Institute, Sydney, NSW, Australia

ARTICLE INFO

Article history:
Received 16 June 2014
Received in revised form
18 November 2014
Accepted 19 November 2014
Available online 26 November 2014

Keywords:
Bipolar disorder
RCT
Relapse prevention
Psychoeducation
Internet

ABSTRACT

Background: The Internet is used to deliver information on many psychiatric disorders such as bipolar disorder. This paper reports on the results of a 12-months randomised controlled trial, which examined the efficacy of an Internet-based preventive program for bipolar disorder, adjunctive to usual pharmacological management.
Methods: Participants were recruited by completing an online screening questionnaire accessed through the Black Dog Institute and Sentiens websites based in Australia. The treatment was predominantly psycho-educational with cognitive behavioral therapy optional elements. The attention control treatment comprised directing subjects to a variety of websites focused on 'healthy living'. Time to recurrence was determined using Kaplan–Meier survival analysis. The main outcome measures were recurrence as defined by: (i) depressive and/or hypomanic symptomatology and functional capacity (using Beck Depression Inventory, Internal State Scale and Sheehan Disability Scale) and (ii) hospitalization.
Results: Two-hundred-and-thirty-three subjects were randomized to the active or control treatment groups. There were no significant differences between the active and control treatment groups on any of the definitions of recurrence.
Limitations: Reliance on an online self-report tool to confirm diagnosis and hospitalization rates may have potentially allowed for inclusion of individuals with other diagnoses such as borderline personality disorder. The 'attention control' treatment may have included more 'active' components than intended.
Conclusions: This is the first report examining the efficacy of a randomized controlled web-based psychological intervention in a large sample of subjects with bipolar disorder. The potential reasons for failing to demonstrate a significant difference compared to the active control are discussed.

1. Introduction

Bipolar disorder is a chronic episodic condition characterized by frequent recurrences in many patients. It affects up to 4% of the adult population (Kessler et al., 1994,2005; Angst, 1998;Mitchell et al., 2013) and is highly disabling (Murray and Lopez, 1996; Murray et al., 2012). In recent years the field has become increasingly aware of the limitations of pharmacological treatment with the majority of people with bipolar disorder continuing to experience recurring episodes as well as inter-episodic sub-syndromal symptoms (Coryell et al., 1993; Gitlin et al., 1995; Judd et al., 2005). Furthermore, epidemiological studies report that many bipolar disorder patients are not receiving adequate medication for their condition (Mitchell et al., 2013) often due to poor adherence.

A large body of evidence now exists demonstrating the efficacy of several forms of psychological intervention adjunctive to medications in patients with bipolar disorder (Miklowitz, 2008). The Internet provides one possible path for disseminating these targeted and standardized interventions, due to its accessibility, versatility and capacity to assist individuals who do not seek help, and provides a feasible means for increasing the rate of those with bipolar disorder receiving evidence-based psychological interventions.

In addition to our prior description of this current web-based study (Barnes et al., 2007), there have also been published descriptions of three other similar interventions for bipolar disorder (Todd et al., 2012; Lauder et al., 2013; Smith et al., 2011; Poole et al., 2012). Two small studies have been published, first a quantitative outcome report to date of an Internet-based intervention for bipolar disorder was a pilot study of a web-based psychoeducational intervention, which used the quality of life instrument WHOQOL-BREF as the primary outcome measure

☆**Trial Registration:** Australian New Zealand Clinical Trials Registry (ANZCTR); Identifier-ACTRN12608000492358

* Corresponding author at: School of Psychiatry, University of New South Wales, Black Dog Institute Building, Prince of Wales Hospital, Hospital Rd, Randwick, NSW 2031, Australia. Tel.: +61 2 9382 4518; fax: +61 2 9382 8207.
E-mail address: Caryl.Barnes@blackdog.org.au (C.W. Barnes).

http://dx.doi.org/10.1016/j.jad.2014.11.038
0165-0327/

(Smith et al., 2011). Although no significant difference was found between intervention and control (treatment as usual) groups on the total WHOQOL-BREF score, a marginal statistical ($p=.05$) improvement was found in the psychological quality of life subsection of this measure, but this did not persist after correction for multiple testing. The authors concluded that the program had a modest positive impact on the quality of life of individuals with bipolar disorder. The trial was relatively underpowered ($n=50$) and was only administered for a short duration (4 months). However, with over two-thirds in the intervention group completing more than 75% of the program, it would appear that online delivery of such psychosocial interventions might be acceptable to this population. The second by Proudfoot et al., which examined the comparative effectiveness of an 8-weeks online psychoeducation program for people newly diagnosed with bipolar disorder. Participants were randomized to either complete program alone, with a peer-supporter or to a control 'attentional program'. This study found increased perception of control, decreased perception of stigma as well as significant decrease in depression and anxiety across all groups, with a small clinical difference in depressive symptoms and functional between supported and unsupported groups. (Proudfoot et al., 2012).

This current paper reports on Phase I of a randomized controlled trial of an Internet-based psychoeducational program adjunctive to usual treatment for individuals with bipolar disorder. The sample was followed up over 12 months to determine the extent to which recurrence was averted (this Phase II follow-up is not included in this current report). The aim of this trial was to investigate the efficacy of an Internet-based intervention in reducing rates of recurrence in patients with bipolar disorder. An overview of this current trial and development of the treatment program included description of earlier pilot study validating online Bipolar Disorder Screening Questionnaire (BDSQ) have been described elsewhere (Barnes et al., 2007).

2. Methods

The study was approved by the Human Research Ethics Committee of the University of New South Wales, Sydney, Australia. Informed consent was obtained on-line from all subjects prior to participation in the trial.

3. Study design

This 12-months randomized controlled trial derived from of a research partnership between the University of New South Wales and Black Dog Institute in Sydney with a commercial e-health provider (Sentiens Pty Ltd) in Perth, Western Australia.

For *inclusion*, participants needed to be at least 18 years of age and meet DSM-IV criteria for Bipolar I or II disorder. To examine the generalizability of this intervention to 'real world' bipolar disorder samples accessing the Internet, we pragmatically allowed for inclusion of those with current DSM-IV depressive or hypomanic episodes in addition to those with euthymia (defined as not fulfilling current DSM-IV mood episode criteria; see below for the approach for determining recurrence in those who were in an episode at baseline). For the same reason, subjects with current or past alcohol or drug abuse and those who met criteria for a current DSM-IV anxiety disorder were not excluded. All participants were required to be taking medication for bipolar disorder, previously had a clinical diagnosis of bipolar disorder confirmed by a mental health professional, and to be under the continuing care of a clinician. Subjects were also required to have had at least one prior episode (depressive or hypo/manic) in the preceding 2 years (to ensure a sufficient degree of active recurrent illness to demonstrate a difference between the active and control treatments). Furthermore, all participants needed to have a current email address, access to a computer and the Internet, and to have an adequate understanding of English.

Subjects were *excluded* if they were not currently taking psychotropic medication, were not under the care of a mental health physician during the trial, if they indicated that the diagnosis of bipolar disorder was a self-diagnosis (without medical confirmation), and if they did not meet the above inclusion criteria.

All demographic and clinical data was collected on-line; there was no face-to-face contact between research staff and subjects. The diagnosis of DSM-IV bipolar disorder was determined by an algorithm using DSM-IV depressive and hypo/manic symptoms which were elicited by specifically developed online survey, the Bipolar Disorder Screening Questionnaire (BDSQ). This used questions similar to those used in the SCID (adapted as required for the utility of on-line usage) and was validated in an earlier pilot study which compared results BDSQ against clinician rated diagnosis with robust inter-rater reliability (Barnes et al., 2007). The comorbid presence of a range of anxiety and alcohol/substance abuse or dependence disorders was determined by subjects agreeing to a glossary-type description of each of these conditions, rather than specifying the presence of detailed operationalized DSM-IV criteria.

Participants who met study inclusion criteria after completing the baseline questionnaires were sent an emailed invitation to enroll in the trial. Enrollment involved returning to a webpage via a link in the email to complete an online enrollment form. After submitting this enrollment form, participants were automatically randomized to either the study or control group. Randomization was performed using time sequencing software with each individual being allocated a unique eight digit number which then became their personal registration number for the study. An automatic password was also generated; this and the registration number were automatically emailed back to the participant with logon details on how to access their program. Although it was not possible to blind participants once they had commenced the study, subjects did not know to which program they had been randomized until logging onto their first session.

4. Study and control interventions

The study intervention – the Internet-based psychoeducational 'Recovery Road for Bipolar Disorder' program (now called 'HealthSteps for Bipolar Disorder') was adapted for use in the current study, and an 'attention control' program – 'Virtual Highway for Bipolar Disorder' – developed using the same web platform. The research partnership with Sentiens enabled all participants to have free access to the 'active' program or control to which they were randomized for 12 months. Control participants were then offered access to the 'active' program and 'Recovery Road' program after completion of the randomized controlled phase of the trial.

The study and control Internet based programs both consisted of 20 sessions delivered automatically and sequentially over fixed intervals during the 12-months period. The first 8 sessions were released weekly, sessions 9 and 10 at 2-weeks interval, and sessions11–20 monthly. This scheduling was used by all of Sentiens other online programs and as a result could not be altered for this study. During each session the *study group* was given educational text-based material about bipolar disorder structured around five areas: 'Dealing with Symptoms'; 'Medication Issues'; 'Psychological Approaches'; 'Lifestyle and Relationships'; and 'Staying Safe', with the content for each area differing between sessions. It was estimated that completion of all outcome measures (which were done at start of each of 20 sessions) and in-built