Internet-based treatment for panic disorder: A three-arm randomized controlled trial comparing guided (via real-time video sessions) with unguided self-help treatment and a waitlist control. PAXPD study results

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ABSTRACT

A growing body of evidence suggests that Internet-based cognitive behavioral treatments (ICBT) are effective to treat anxiety disorders. However, the effect of therapist guidance in ICBT is still under debate and guided ICBT offered in a real-time audio-video communication format has not yet been systematically investigated. This three-arm RCT compared the efficacy of guided with unguided ICBT (12 weeks intervention) and a waitlist (WL). A total of 111 individuals meeting the diagnostic criteria for panic disorder (PD) were randomly assigned to one of three conditions. Primary outcomes were the severity of self-report panic symptoms and diagnostic status. Secondary outcomes were symptoms of depression, functional impairment, catastrophic cognitions, fear of sensations and body vigilance. At post-treatment, both active conditions showed superior outcomes regarding PD and associated symptoms (guided ICBT vs. WL: $d = 1.04$–1.36; unguided ICBT vs. WL: $d = 0.70$–1.06). At post-treatment, the two active conditions did not differ significantly in self-reported symptom reduction ($d = 0.21$–0.54, all $ps > 0.05$), but the guided treatment was superior to the unguided treatment in terms of diagnostic status ($\chi^2 (1) = 13.15, p < 0.01$). Treatment gains were maintained at successive follow-ups and the guided treatment became superior to the unguided treatment at 6 months follow-up ($d = 0.72$–1.05, all $ps < 0.05$).

1. Introduction

The gap between mental health needs and available therapeutic resources is well acknowledged. Despite the potential to successfully treat mental disorders, only a small minority receive even the most basic kind of treatment and the treatment is provided with significant delays from the onset of the disorders (Wang et al., 2005). Internet-based cognitive behavioral treatments (ICBT) represent recent attempts to innovate the psychotherapeutic interventions, trying to match both the existent demands and the new attitudes of those who seek help in the digital era. Research on ICBT has grown rapidly in the past decade, providing promising results in more than 100 controlled trials evaluating ICBT for anxiety disorders, mood disorders, and other psychiatric and somatic conditions (Andersson, 2016; Hedman et al., 2012; Mewton, Smith, Rossouw, & Andrews, 2014; Richards & Richardson, 2012). With regard to ICBT for panic disorder (PD) and agoraphobia,

there are several studies supporting their efficacy and effectiveness (Bergstrom et al., 2010; Carlbring et al., 2006; Ruwaard, Lange, Schrieken, Dolan, & Emmelkamp, 2012; Wims, Titov, Andrews, & Choi, 2010), with a mean within-group effect size of 1.32, ranging between 0.79 and 1.97 (Hedman et al., 2013).

The most promising interventions designed and tested so far are guided self-help interventions. A guided ICBT intervention is a web-based self-help program combined with minimal, but regular therapist support. In guided programs, asynchronous communication (emails or text messages) is most commonly used and, on average, the patient guidance does not take more than 10 min per week (Andersson, 2015). So far, research is very limited regarding guided self-help treatments that include guidance through real-time audio-video communication (via systems such as Skype). On the other hand, there is growing evidence that the efficacy of psychotherapy delivered completely via real-time audio-video communication (videoconference) is equivalent to

face-to-face treatment for mood and anxiety disorders (Bouchard et al., 2004; Germain, Marchand, Bouchard, Drouin, & Guay, 2009; Hilty et al., 2013; Stubbings, Rees, Roberts, & Kane, 2013; Lapointe, Marchand, Langlois, Gosselin, & Watts, 2015). This type of communication closely matches face-to-face therapy and enables access to important cues such as verbal tone, facial expressions, and body language.

Through synchronous guidance, the therapists may be able to offer more individually tailored feedback and support. Furthermore, this type of contact may facilitate higher engagement, feelings of accountability and social support, and reduce the risk of misunderstandings, compared to emails and instant messaging (Abbott, Klein, & Ciechomski, 2008). All of the above could also facilitate the development of a better therapeutic alliance (Simpson & Reid, 2014), a factor that has consistently proven to be a key predictor for therapeutic change in face-to-face therapy (Horvath, Del Re, Fluckiger, & Symonds, 2011; Martin, Garske, & Davis, 2000). However, there are also disadvantages to using synchronous communication. Compared to asynchronous written exchanges, patients do not have the opportunity to revisit and reread the dialogues with their therapists (Abbott et al., 2008), sessions need to be scheduled (Andersson, 2015), the interactions depend more on the quality of the internet connection, and there might be more privacy issues. Regarding the latter aspect, in our study we used a secured Skype application, where all Skype-to-Skype voice, video, file transfers and instant messages were encrypted. For more details about this topic please refer to the published study protocol (Ciuca, Berger, Crisan, & Miclea, 2016).

So far, several meta-analyses and reviews suggest a superiority of guided versus unguided self-help treatments in terms of efficacy, adherence to treatment and dropout rates (Andersson & Titov, 2014; Palmqvist, Carlbring, & Andersson, 2007; Richards & Richardson, 2012; Spek et al., 2007). However, good outcomes have also been reported in trials on unguided ICBT, especially in the field of anxiety disorders (Berger et al., 2011; Botella et al., 2010; Dear et al., 2015; Fogliati et al., 2016; Furmark et al., 2009; Olthuis, Watt, Bailey, Hayden, & Stewart, 2016). Thus, the importance of therapist guidance is still debated (Baumeister, Reichler, Munzinger, & Lin, 2014). Furthermore, there is no study directly comparing unguided with guided ICBT in which guidance is offered through real-time audio-video communication.

In Romania, where the current study was conducted, 76.4% of the individuals with mental health disorders do not have access to any form of treatment; only about 11.5% receive psychological or psychiatric help (Florescu et al., 2009). The reduced accessibility of mental health services for a large majority of Romanian population became a catalytic factor for our research team to develop ICBT interventions for the prevention and treatment of panic disorder (PAXPD program) and other anxiety disorders. The ICBT programs are delivered on a dedicated platform called PAXonline, in two possible formats: unguided and with therapist guidance via real-time audio-video communication (Miclea, Miclea, Ciuca, & Budău, 2010). By focusing our efforts on conducting clinical trials on ICBT, we hope to stimulate the interest of Romanian policymakers and researchers from other countries new to ICBT to assess and support its potential to reduce the treatment gap in mental health care.

The primary aim of the current study was to investigate the clinical efficacy of an internet-based self-help treatment program for panic disorder (PAXPD) in Romanian adults. A secondary objective was to compare the guided self-help intervention (guided PAXPD) to the same intervention, but without therapist guidance (unguided PAXPD). We hypothesized that both active treatment conditions would be superior to the waitlist and that the guided treatment (via real-time video sessions) would be superior to the unguided format.

2. Method

2.1. Recruitment and selection of participants

The study was conducted in an academic setting, Babes-Bolyai University and University of Bern (Sciex Fellowship), as part of the doctoral thesis research of the first author. Participants, native Romanian speakers with PD, were recruited via media (TV news, internet advertisements, and social media), promotional advertising displayed in emergency rooms, and direct recommendations made by a network of general practitioners and psychotherapists. The participants started the screening process on the study website by filling out several online forms, anonymously. After providing their informed consent and demographic data (age and gender) participants completed three key questionnaires: (1) a screening for the exclusion criteria; (2) a scale for panic disorder diagnosis and severity (Panic Disorder Severity Scale – Self Report, PDSS-SR); and (3) a screening for psychiatric comorbidities (Psychiatric and Diagnostic Screening Questionnaire, PDSQ). Only participants who did not meet any exclusion criteria, who exceeded a PDSS-SR cut-off score of at least six (Furukawa et al., 2009), and have completed the entire PDSQ screening were invited to provide an email address for further contact. All eligible participants were interviewed by one of three experienced licensed clinical psychologists, based on the semi-structured interviews included in the PDSQ. In addition to panic and agoraphobia diagnoses, any other mental disorder that reached PDSQ screening cut-off point was assessed during the interview. All assessors participated in a two-day training before study commencement.

From May 2014 until March 2016, a total of 2060 individuals accessed the study website and gave their consent for the screening procedure. A total of 778 individuals fulfilled the initial screening criteria and provided a valid email address. They were contacted to schedule a clinical interview by phone or by Skype. Inclusion criteria were (a) age within the range of 18–65 years, (b) having access to a computer with internet connection, (c) being native Romanian speaker, (d) exceeding the cut-off score on the PDSS-SR, (e) meeting the diagnostic criteria for panic disorder according to the diagnostic interview made over phone or Skype, (f) not being in another psychological treatment, (g) providing a second detailed informed consent for participating in the study. We excluded individuals with comorbid severe psychiatric disorders such as bipolar disorders, psychotic disorders, and substance abuse or dependence. We also excluded participants with active suicidal plans according to clinical judgment. Medication use was permitted (except benzodiazepines), but only if the dosage was constant in the previous month and during the study. All excluded persons received information about more suitable treatment options and were offered the possibility to use the treatment program outside the study.

Out of the 778 individuals who passed the screening procedure, 406 did not answer after being contacted by email, 43 withdrew after scheduling the interview, 193 were excluded after the interview and 25 failed to return the detailed informed consent for participating in the study (see participant flow in Fig. 1). A total of 111 individuals met all inclusion and none of the exclusion criteria and were randomized to one of the three groups. There were 68% (n = 76) women and 32% (n = 35) men. The mean age was 35.19 years (SD = 10.33; range = 20-64). Of the 111 participants, 79 (71%) met the criteria for at least one other disorder in addition to panic disorder. The most common comorbid disorder in the sample was agoraphobia, 52%. The other comorbidities were: major depression (22%), generalized anxiety disorder (18%), social phobia (5%), obsessive-compulsive disorder (3%), specific phobia (2%) and bulimia (1%). At the end of the waiting period, 26 participants from the control group chose one of the treatment options and received all the necessary instructions to start the treatment. 16 participants asked for guided treatment and 10 participants asked for the unguided format (6 withdrew before starting the intervention).