Internet Interventions 6 (2016) 80–88

Contents lists available at ScienceDirect

Internet Interventions

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

Effectiveness of an internet-delivered intervention for generalized anxiety disorder in routine care: A randomised controlled trial in a student population

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ARTICLE INFO

Article history:
Received 29 April 2016
Received in revised form 26 October 2016
Accepted 27 October 2016
Available online 29 October 2016

Keywords:
Generalized anxiety disorder
Internet-delivered interventions
Treatment
Students
CBT
Randomised control trial

ABSTRACT

Background: Cognitive behavioural therapy is one of the main and preferred treatments for generalized anxiety disorder. Numerous barriers can hinder an individual from seeking or receiving appropriate treatment; internet-delivered CBT interventions offer a relatively new means of increasing access to treatment.
Methods: A service-based effectiveness randomised waiting list control trial examined the impact of an internet-delivered CBT intervention, *Calming Anxiety*, amongst Irish university students ($N = 137$). Primary outcome was self-reported GAD and secondary outcomes included depression and work and social functioning.
Results: Analyses returned inconclusive results. Both treatment and waiting list conditions displayed significant decreases in anxiety symptoms post-treatment, but we did not observe a significant between-group effect ($p = 0.076$). Significant within-group differences from pre to post time points were observed for depression (BDI-II) and work and social functioning (WASA), and between group differences were also significant for depression ($d = 0.46$) and functioning ($d = 0.36$). Both groups demonstrated cases of remission and recovery from anxiety, however differences in the number of cases reaching clinically meaningful change between conditions were non-significant.
Conclusions: Several explanations regarding the results are presented, examining issues related to active waiting lists, study limitations and treatment expectancies.
Trial registration: Current Controlled Trials ISRCTN16303842.

1. Introduction

GAD is characterised as a chronic condition, with a DSM-V diagnosis typically requiring the persistent symptom of excessive worry occurring over a period of 6 months (American Psychiatric Association, 2013). Further symptoms consist of hypervigilance and the typical somatic responses of anxiety, where the chronicity of these symptoms often results in long-term personal suffering and feelings of a loss of control (Wittchen, 2002). European statistics place the lifetime prevalence of GAD to be between 4.3 and 5.9% and a 12-month prevalence to be between 1.2 and 1.9% (Wittchen, 2000). However, a significant amount of individuals do not seek treatment for their disorder (Wittchen et al., 2011). GAD tends to present itself with comorbidity, most often with mood and other anxiety disorders (Alonso et al., 2004; Royal College of Psychiatrists, 2011). Furthermore, negative effects can extend from the direct effects the disorder has on the individual; economic, personal and social roles can be negatively impacted upon by symptoms of GAD, which in turn can decrease quality of life (Loebach Wetherell et al., 2004; Stein and Heimberg, 2004).

1.1. Anxiety and students

Several studies have examined the link between anxiety symptomatology and university students (Royal College of Psychiatrists, 2011). Major life events, such as the transition to university life and the responsibilities that come with it can be a large source of anxiety. Furthermore, societal trends such as the increasing financial cost of university places extra burden on students, where they often have to source employment in order to fund their college lives (Royal College of Psychiatrists, 2011).

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http://dx.doi.org/10.1016/j.invent.2016.10.003

The rising incidence of mental health issues was raised by Dooley and Fitzgerald (2012) in their survey of mental health and wellbeing in an Irish sample. Utilising an Irish student-based sample, the researchers placed levels of anxiety at 36% and 30% with symptoms of stress. Although this research did not include data on GAD in students specifically.

1.2. Treating anxiety disorders

Treatment of anxiety disorders, and more specifically GAD, has largely consisted of pharmacological treatments, psychological therapies or a mixture of both (Gould et al., 1997). However, completion and cessation of a pharmacological therapy without continuing to take maintenance drugs can result in relapse (Davidson et al., 2008; Allgulander et al., 2006). Psychological therapies are often preferred, especially where they have produced similar outcomes to pharmacological treatments, along with lower relapse rates (Sturmey and Hersen, 2012).

Cognitive-behaviour therapy (CBT) is routinely chosen as the psychological treatment of choice for GAD, and has been subject to several successful trials (Cuijpers et al., 2014). CBT for GAD is composed of many elements, such as cognitive restructuring, worry exposure, mindfulness, relaxation techniques and information on the disorder (Dugas et al., 2003; Orsillo et al., 2003). CBT for GAD can be performed in either a group or one-to-one setting, where the therapist helps the patient to understand their disorder, manage it and regain quality of life. However, it has been estimated that across the anxiety disorders a large percentage do not seek treatment, or have a significant delay in receiving treatment (Kohn et al., 2004). One significant barrier is the ability to access evidence-based treatments such as CBT. Internet-delivered CBT (iCBT) interventions are a relatively new development that could help with increasing access to treatments.

1.3. iCBT for GAD

Several studies have investigated the effectiveness of iCBT for GAD and results have shown positive outcomes in regards to post-treatment and follow-up symptom relief (Titov et al., 2009, 2011; Paxling et al., 2011). Internet-delivered psychological interventions for GAD are a promising new intervention with a growing evidence base. Results from research trials are evidencing large effect sizes that can be sustained up to 2/3 years post-treatment (Titov et al., 2016). Preliminary results are encouraging, and speak to the potential of using therapist, or self-guided iCBT for GAD (Titov et al., 2016).

Richards et al. (2015a) conducted a systematic review and meta-analysis of internet-delivered psychological interventions for the treatment of GAD. Studies recruited primarily through websites and/or adverts in local newspapers; some used clinical samples referred from GPs or mental health practitioners. All studies used the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I; First et al., 1997), the Mini International Neuropsychiatric Interview Version 5.0.0 (MINI; Sheehan et al., 1998), or an interview based on the MINI (Johansson et al., 2013) to establish a formal diagnosis of GAD, over the phone or in person. Four of the eleven studies targeted a GAD sample through a GAD-specific programme; the other seven were "transdiagnostic" in nature, addressing multiple anxiety disorders or GAD and mood disorders. Most studies (9/11) used CBT-based content while two used a psychodynamic approach. Generally, content was delivered in 6–8 modules over 8–10 weeks; most interventions also included some form of support from a psychologist or therapist, typically by phone or e-mail.

There were statistically significant improvements for internet-delivered interventions compared to waiting-list controls on self-reported GAD symptoms ($d = -0.91$) and pathological worry ($d = -0.74$), both yielding what can be considered large effects (Cohen, 1988). Similar effects were found for the active treatments compared to waiting-list controls for comorbid anxiety ($d = -0.57$), depression ($d = -0.63$), distress ($d = -0.91$), disability ($d = -0.77$), and quality of life (d = 0.38). For GAD subjects, effect sizes were similar for GAD-specific ($d = -0.81$) and transdiagnostic ($d = -0.91$) interventions. Psychodynamic approaches (2 studies) had less favourable results; in fact, one study (Andersson et al., 2012) saw an unexpected improvement in the waiting list group. The authors advised caution in interpreting these results given limited and heterogenous data, and suggested what research is needed to strengthen the field.

The current study aimed to implement an iCBT (*Calming Anxiety*) for GAD. Based on previous literature in the area of online interventions for GAD (Richards et al., 2015a), it was hypothesised that the intervention would produce significant decreases in GAD symptoms at post-intervention for the treatment group compared to the control group.

2. Methods

2.1. Design

The current study utilised a service-based effectiveness, randomised controlled trial design in order to examine the delivery of an internet intervention for the treatment of individuals with GAD symptoms. The trial was registered (Current Controlled Trials ISRCTN16303842) and the protocol published (Richards et al., 2014). Participants were randomised into two groups using: the internet-delivered intervention (iCBT, *Calming Anxiety*) with clinical support and a waiting list control group. Randomisation was achieved using a computer algorithm established by a programmer and independently executed. The randomisation took place at the individual level using a 1:1 format for distribution between the groups. Participants in the waiting list control group did not receive any treatment for the 6-week duration in which the treatment group was receiving the intervention. At week 7, participants in the waiting list control group were given access to the supported intervention. The current paper describes the main outcomes from the trail. Other research data related to this trial including quality of life, satisfaction with treatment and significant events data are being analysed and will be reported elsewhere (see trial protocol for details; Richards et al., 2014).

Ethical approval for the current study was obtained from the appropriate University Ethics Committee (25/11/2013). Prior to commencing the study, all participants received information that detailed the intervention in its entirety. Informed consent was then obtained and participants were made aware that their involvement was completely voluntary and that they were free to withdraw from the study at any stage without prejudice.

2.2. Participants and sample size

Participants for the current study were recruited through the University counselling service and were all registered students. Participants were contacted via e-mail (delivered college wide) in order to advertise the current study and request their participation. This e-mail detailed how the prospective participant could obtain further information and initiate the screening process. This e-mail was sent to all students two times at an interval of two weeks during the first three weeks of the second academic semester.

Primary eligibility criteria for participation in the study was based on whether the individual's self-reported GAD symptoms were confirmed to reach an acceptable clinical threshold, defined for the study as a score of 10 or above on the GAD-7 measure. Further criteria for inclusion in the study were that participants were to be at least 18 years of age or older. Participants attending face-to-face counselling were excluded from the study. In order to target the trial as closely as possible to a GAD population, severe depression was used as a criterion for excluding possible comorbidities (BDI II scores >29). Suicidal ideation was also