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The effectiveness of an online e-health application compared to attention placebo or Sertraline in the treatment of Generalised Anxiety Disorder

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ABSTRACT

Background: Generalised Anxiety Disorder (GAD) is a high prevalence, chronic disorder that can be treated effectively through a number of web-based programs. However, online web programs for GAD have not been compared to standard pharmacological treatment. The present study compares an Internet Intervention (Active Website) for GAD and a selective serotonin re-uptake inhibitor (SSRI) (Sertraline), with an online attention placebo condition (Control Website).

Objective: To evaluate the effectiveness of a web-based intervention for GAD in comparison to standard antidepressant medication and an online attention placebo condition over a 10 week period, and with a follow-up at 6 and at 12 months.

Methods: The study was part of a larger scale prevention program. 152 people aged 18–30 years who met the criteria for GAD on the MINI received referrals to the treatment sub-study. The primary outcome was anxiety symptoms measured by the Generalised Anxiety Disorder 7-item Scale (GAD-7), and the secondary outcome was depression measured by the Center for Epidemiologic Studies Depression Scale (CES-D).

Results: There was very poor uptake to the trial (around 14% of those referred). However, even in this small sample, Sertraline compared to the Control Website was significant at post-test and 6 months, and the Internet Intervention was significant at post-test. Relative to the Control Website condition at post-test, for the GAD-7 and CES-D respectively, the between group effect sizes were $d = 2.43$ and $d = 0.68$ for the Active Website condition, and 3.00 and 0.20 for the Sertraline condition. The within group effect size for the Control Website from baseline to post-test was −0.04 for the GAD-7 and 0.31 for CES-D respectively.

Conclusions: The findings will need to be extended and confirmed in a larger trial. However, they do suggest that both standard pharmacological treatment and online interventions for GAD are effective in samples with a diagnosis of GAD recruited via online methods. The low rate of engagement for face-to-face treatment by those who opt first for a web program suggests that treatment preferences are important in help-seeking.

1. Introduction

Generalised Anxiety Disorder (GAD) is a high prevalence (Johansson et al., 2013), chronic disorder that can be treated through the web (Christensen et al., 2014a). Web-based interventions have high acceptability, are accessible, engaging and effective. Indeed, five meta-analyses published since 2009 (Andersson and Cuijpers, 2009; Andrews et al., 2010; Cuijpers et al., 2009; Griffiths et al., 2010b; Lewis et al., 2012) confirm the effectiveness of online interventions for anxiety. For GAD in particular, strong evidence has emerged for online cognitive behavioural therapy (iCBT) (Mewton et al., 2012; Robinson et al., 2010; Spence et al., 2011). Psychodynamic online interventions have also been found to be effective (Andersson et al., 2012). Sertraline, along with the SSRIs escitalopram and paroxetine, is a first-line pharmacologic treatment for GAD (Baldwin and Polkinghorn, 2005). Randomised, placebo controlled trials have found Sertraline efficacious for GAD in adults (Allgulander et al., 2004; Brawman-Mintzer et al., 2006), children and adolescents (Rynn et al., 2001; Walkup et al., 2008) over 9 to 12 weeks, and Sertraline

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is a standard choice for GAD treatment in clinical settings. To our knowledge, a direct comparison of online therapy to a standard pharmacological intervention has not yet been reported for GAD.

We undertook a treatment trial comparing an online program (Active Website) with SSRI/antidepressant medication (Sertraline), and a control condition (Control Website). Participants were recruited to the trial after they were excluded from the primary prevention trial, an exclusion that was based on their meeting criteria for GAD during a diagnostic interview. Participants were randomised to one of three conditions: Active Website offering iCBT, Sertraline, or a Control Website. Regardless of randomised condition, all participants were assessed and monitored by medical staff during the course of the trial.

2. Methods

2.1. Study design

The study was a randomised controlled trial of young adults recruited from the Electoral Roll, who were excluded from a prevention trial (Christensen et al., 2014b), but invited to participate in a treatment trial. The study consisted of a 10 week treatment phase and a 12 month follow-up phase, with measures administered at screening, baseline, post-test, and 6 and 12 months after post-test. Unlike the prevention trial, treatment required face-to-face assessment and monitoring. The study received ethics approval from The University of Sydney (11-2009/12091) and The Australian National University (2008/548) Human Research Ethics Committees.

2.2. Study population

Adults, aged 18–30 years with a primary anxiety diagnosis of GAD formed the study population. Inclusion criteria included a GAD diagnosis based on the Anxiety Disorders Interview Schedule for DSM-IV (ADIS-IV) criteria (Brown, DiNardo, & Barlow, 1994; Sheehan et al., 1998), informed consent, access to the internet, active email address and phone number, sufficient English, willingness to attend face-to-face assessment at an inner city medical clinic attached to a University, and willingness to take antidepressant medication and to be monitored over 12 weeks. Exclusion criteria included current undertaking of cognitive behaviour therapy (CBT) with a health professional, current treatment with a psychologist or psychiatrist, risk of self-harm, psychosis, bipolar disorder, a primary diagnosis of depression, prior treatment with Sertraline, treatment with monoamine oxidase inhibitors (MOAIs), or planned pregnancy.

2.3. Recruitment procedure

A survey was sent to 120,000 randomly selected individuals aged 18–30 who were registered on the Australian Electoral Roll and located in one of five Sydney electorates (Fig. 1). Of these, 12,400 returned questionnaires, 4205 were eligible based on a score greater than 4 on the GAD-7 (Spitzer et al., 2006), and 1687 went on to complete the MINI via phone. Informed consent for the screening survey was provided in writing. Informed consent for the telephone MINI was provided verbally. Informed consent for the intervention study was provided in writing and in person at the first face-to-face meeting. Postgraduate clinical psychology students administered the telephone MINI interviews, and were blind to the participant responses to the screening survey. Interviewers were given 4 h of training, including practice interviews, with oversight from a clinical psychologist and the research team. The 152 individuals who met the criteria for GAD on the MINI interview were offered a referral to the treatment trial at the Brain and Mind Research Institute (BMRI), University of Sydney. Participants then completed further questionnaires, the ADIS-IV, and underwent a medical consultation with a general practitioner (GP) to ascertain suitability for Sertraline. The ADIS-IV interviews were conducted by registered psychologists located at the Brain and Mind Research Institute. A total of 21 (13.9%) completed baseline and were randomised.

2.4. Baseline and randomisation

Randomisation occurred immediately after the baseline completion, using existing automated web-based software developed by the investigators. In accordance with ICH Guideline E9 (Lewis, 1999), the staff responsible for establishing randomisation procedures were not involved in the day-to-day conduct of the trial. Further, no staff members involved in the day-to-day running of the trial (i.e. not blind to group membership) were involved in conducting follow-up assessments. The research staff were not aware of group membership during the baseline assessments as randomisation occurred after this stage.

2.5. Online programs

2.5.1. Active Website

The version of the E-couch website (e-couch@anu.edu.au) used in the current study was divided into 10 modules, completed over the 10 week intervention period. The website comprises four sections including psychoeducation, cognitive behaviour therapy, relaxation and physical activity. The psychoeducation section (Modules 1 and 2) provides information on worry, stress, fear and anxiety; a description of anxious thinking; differentiation of GAD from other anxiety disorders; risk factors for GAD; comorbidity; and consequences of anxiety and available treatments. This section is based on interventions for mental health literacy that have succeeded in reducing symptoms of depression and anxiety, and improving mental health attitudes (McIntosh et al., 2004). The CBT toolkits (Modules 3–7) addressed typical anxious thoughts and included sections on dealing with the purpose and meaning of worry, the act of worrying and the content of worry. The information is derived from materials that have been found to reduce anxious cognitions in at-risk people (Kenardy et al., 2003, 2006). Progressive muscle relaxation (PMR) (Module 8) instructs participants on how to progressively tense and relax different muscle groups to induce relaxation and help to identify tension early. PMR has been trialled in a previous website program for depression in adults (Christensen et al., 2004) and adolescents (Calear et al., 2009). The mindfulness meditation module (Module 9) helps participants become aware of their breathing and body, acknowledging thoughts and external distractions but remaining focused on the present. The final module, physical activity (Module 10), tailors advice about physical activity based on the stages of change theory (Prochaska and DiClemente, 1983).

2.5.2. Control Website

HealthWatch is an online program developed for the ANU WellBeing study (Griffiths et al., 2010a). As implemented in the current study, the program provided information about various health topics each week for 10 weeks. These covered environmental health, nutrition myths, heart health, activity, medication, the effects of temperature, oral health, blood pressure and cholesterol, calcium, and back pain. Participants are also asked to respond to a number of questions about potential risk factors for anxiety. In a recent trial conducted by the Australian National University, HealthWatch was not associated with a reduction in anxiety or depressive symptoms over time, confirming its value as an attention placebo condition (Griffiths et al., 2012).

2.6. Components of trial conditions during intervention phase

All participants, regardless of condition, were provided with the same amount of exposure to the clinical team of psychologists and general practitioners (GPs). Specifically, all trial participants had scheduled appointments with a psychologist in weeks 1, 2, 5 and 10 to monitor progress and symptoms, and each participant was reviewed by a GP in