Internet Interventions 4 (2016) 92–98

Contents lists available at ScienceDirect

Internet Interventions

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

Internet-based CBT for social phobia and panic disorder in a specialised anxiety clinic in routine care: Results of a pilot randomised controlled trial

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ARTICLE INFO

Article history:
Received 29 June 2015
Received in revised form 29 January 2016
Accepted 1 March 2016
Available online 9 March 2016

Keywords:
Internet
Computer
Internet-based
Cognitive behavioural therapy
CBT
iCBT
cCBT
RCT
Randomised controlled trial
Anxiety
Social phobia
Panic disorder
Specialised care
Secondary care
Self-help

ABSTRACT

Ample studies have demonstrated that internet-based cognitive behavioural therapy (iCBT) for anxiety disorders is effective and acceptable in controlled settings. Studies assessing the clinical effectiveness of iCBT for anxiety disorders among routine care populations are, however, not as numerous. The purpose of this study was to assess the effectiveness of iCBT among anxiety patients, who were on a waiting list for intensive outpatient treatment, in a specialised routine care clinic.[1]

A randomised controlled pilot trial was conducted. Recruited patients were on a waiting list and had a primary diagnosis of either social phobia or panic disorder. Participants were randomised into either receiving iCBT with minimal therapist contact (received access to the programme FearFighter® (FF) and received support from a clinician via telephone) or no treatment (stayed on the waiting list). The primary outcome was self-reported symptomatic change of anxiety on Beck Anxiety Inventory (BAI). The secondary outcomes were comorbid depression measured on Beck Depression Inventory (BDI-II) and quality of life measured with the EuroQol one-item visual-analogue scale (EQ-vas). All results were analysed by intention-to-treat analyses using a mixed-effects approach. $N = 158$ patients were assessed for eligibility of which $N = 67$ met all eligibility inclusion criteria, signed informed consent forms, and were randomised. Post-treatment assessment was completed by $N = 47$ (70%). In the intervention group, $N = 11$ (31%) completed all modules of FF. No significant differences of change of symptomatic levels were found between the intervention and control group for anxiety (BAI: mean diff. = 2.42; 95% CI −1.03 to 5.86; $p = 0.17$; $d = 0.06$) or for depression (BDI-II: mean diff. 1.87; 95% CI −2.25 to 6.00; $p = 0.37$; $d = 0.02$). A large and significant effect was found in self-reported quality of life in favour of the experimental group (EQ-vas: mean diff. −20.88; 95% CI −30.64 to −11.11; $p < 0.001$; $d = 0.81$).

This study was not able to document statistically significant clinical effect of iCBT with minimal therapist contact compared to a waiting list control group in a specialised anxiety clinic in routine care. However, a large and significant effect was seen on self-reported quality of life. Although these results offer an interesting perspective on iCBT in specialised care, they should be interpreted with caution, due to the limitations of the study. A large scale fully powered RCT is recommended.

1. Introduction

Panic disorder and social phobia are common, debilitating disorders characterised respectively by an excessive anxiety response when experiencing either normal bodily symptoms such as small palpitations or when confronted with social situations (American Psychiatric Association, 2000). A large epidemiological survey estimated a 12-month prevalence rate of 2.7% for adult panic disorder (with or without agoraphobia) and 6.8% for adult social phobia (Kessler et al., 2005). Onset is typically between the ages of 13–15 for social phobia and 24–40 for panic disorder. If untreated these disorders often become chronic (Bruce et al., 2005). They are associated with negative consequences such as impaired career trajectories, absenteeism from work, reduced work performance, impaired romantic relationships, impaired quality of life, elevated medical utilisation and high societal costs (Katon,

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http://dx.doi.org/10.1016/j.invent.2016.03.001

1996; Wittchen et al., 2000; Batelaan et al., 2007; Olatunji et al., 2007; Konnopka et al., 2009).

There is now substantial evidence to support internet-based cognitive behavioural therapy with minimal support (iCBT) as being effective for panic disorder and social phobia compared to non-intervening (Spek et al., 2007; Barak et al., 2008; Andrews et al., 2010; Andersson et al., 2014) with large effect sizes (e.g. Carlbring et al., 2006; Berger et al., 2009).

iCBT even seems to offer treatment results comparable to those of traditional face-to-face therapy. For example, in a randomised study by Hedman et al. (Hedman et al., 2011) no difference was found between iCBT and group face-to-face CBT for social phobia on the Liebowitz Social Anxiety Scale (non-inferiority randomised design, where the lower-bound of the 95% CI of the mean difference fell within 10 LSASS points). Similarly, Kiropoulos et al. (Kiropoulos et al., 2008), found support for iCBT to be equally effective as face-to-face CBT for panic disorder in a randomised study (post-treatment assessment for Panic Disorder Severity Scale: iCBT ($N = 45$): $M = 9.92$ $SD = 5.88$; CBT ($N = 35$): $M = 9.24$ $SD = 5.65$; ANOVA analysis on group effect $p = .88$). And in a meta-analysis of studies comparing iCBT with face-to-face CBT for depression and anxiety disorders, Cuijpers et al. (Cuijpers et al., 2010) did not find support for iCBT to yield smaller effect sizes than traditional face-to-face CBT.

However, most studies have been conducted under controlled conditions and have primarily included self-referred patients. To our knowledge, only a few studies had been conducted on patients in routine care settings. Cavanagh et al. (Cavanagh et al., 2006) conducted a naturalistic, open, non-controlled study of adult anxiety and/or depression using the programme Beating the Blues. $N = 219$ was included of which, $N = 84$ (38%) dropped out, and $N = 104$ (47%) completed post-treatment outcome measures. A significant change was found using intention-to-treat analyses on the Clinical Outcomes in Routine Evaluation-Outcome Measure ($p < 0.001$; $d = 0.5$) and on the Work and Social Adjustment scale ($p < 0.001$; $d = 0.26$). Similarly, in a specialised CBT clinic Learmonth et al. (Learmonth et al., 2008) conducted a naturalistic, open, non-controlled study on adult anxiety and/or depression using the programme Beating the Blues as well. $N = 555$ participants were included, and almost three quarters ($N = 394 \approx 71\%$) concluded all modules in the programme. A significant improvement was seen ($p < 0.001$) on Beck Depression Inventory ($d = 0.72$) and on Beck Anxiety Inventory ($d = 0.5$) using intention-to-treat analyses. Even though these studies were uncontrolled, a positive effect was indicated for the use of iCBT in routine care.

Since more research on this topic was needed and due to long waiting lists for anxiety treatment, it was decided to conduct a pilot RCT on iCBT for these disorders using a waiting list population in an outpatient clinic for anxiety disorders[2] in a Danish specialised care setting. No studies had been conducted on iCBT in routine care in Denmark up to this point.

The intervention chosen was the programme FearFighter® (FF). This online self-help programme is specifically designed for panic disorders and phobias and is completed over 9 steps. Two previous randomised controlled trials (RCT) had investigated the effectiveness of FF on adult populations with positive results being indicated. The first RCT was conducted by its original developer Isaac Marks et al. (Marks et al., 2004) on a population ($N = 93$) of mainly self-referred patients who answered notices in general practitioner (GP) offices or self-help groups. FF with minimal guidance was compared to face-to-face therapy and relaxation in a three-arm trial in a 2:2:1 ratio. On the Fear Questionnaire Global Phobia scale a significant difference was found between FF and relaxation (mean diff. −1.2; 95% CI −2.4 to −0.1; $p < 0.001$) but no significant difference was found between FF and face-to-face therapy (mean diff. −0.2; 95% CI −1.2 to 0.8), which indicated FF to be effective. The second RCT was conducted by Schneider et al. (Schneider et al., 2005) on a population ($N = 68$) referred to a self-help clinic. This RCT compared FF to a minimal form of iCBT referred to as 'anxiety management' in a 2:1 ratio. Both groups received minimal guidance in equal doses. In both groups a significant improvement was seen (FF: $d = 0.5$–5.1; MA: $d = 0.5$–5.1; $p < 0.01$), but no significant between-group effect was seen ($p > 0.3$). There was, however, a tendency in favour of FF compared to anxiety management after 14 weeks. Given the relatively small sample size ($N = 68$), the active control condition, and the significant within group results in both groups, the authors conclude that this might also indicate FF to be an effective treatment.

2. Methods

2.1. Trial design

For the present study, the trial was designed as a pilot two-arm randomised controlled trial. The experimental group was given access to FearFighter® (FF) (ST Solutions Ltd., Birmingham, England) with minimal therapist contact. The control group was placed on a waiting list for face-to-face CBT as part of normal routine practice and received no psychological treatment.

2.2. Patients and recruitment

Inclusion criteria were: a primary DSM-IV diagnosis of panic disorder with or without agoraphobia or social phobia, mastery of the Danish language (written and spoken) and access to a computer with a broadband Internet connection. Exclusion criteria were: developmental disorders or other cognitive disabilities or Axis II disorders other than cluster C (avoidant, dependent, obsessive–compulsive), suicidal plans, bipolar disorder or depressive psychotic features.

Patients referred to the clinic first underwent a diagnostic assessment as part of routine practice to establish diagnosis. They were diagnosed by use of (a) the Anxiety Disorders Interview Schedule (Brown et al., 1994) a reliable, structured interview for anxiety disorders and related conditions, (b) Structured Clinical Interview for DSM-IV Axis II Personality Disorders (First et al., 1997) to establish possible axis II disorders, and (c) an anamnestic interview which is a comprehensive interview of the patient and is standard care practice throughout the Central Region of Denmark. Such an interview includes the patient's social background and context; history of the disorder e.g. time of onset and circumstances surrounding that; and other relevant diseases and disorders e.g. neurological disorders. All interviews were conducted by trained, experienced clinicians (five clinical psychologists and one psychotherapist). After this diagnostic assessment, eligible patients were asked to participate in the study. Provided that they still wanted it, the patients were informed that they would still be able to receive the treatment they were promised even if the iCBT programme helped them.

Prior to participation all patients signed informed consent documents; additionally, they received both spoken and written information, which explained their rights. The trial was approved by the Danish Research Ethics Committee (ref. nr. M-20110143).

Within the permitted timeframe of the study (9 months for the clinical trial running from September 2011 through July 2012), a total of N = 158 patients were referred to the clinic. N = 75 patients met the inclusion criteria and were invited to participate in the study.

2.3. Intervention

In the intervention group, patients used the therapist-assisted, self-help Internet intervention FearFighter® (FF). FF is an iCBT treatment and self-management programme for panic disorder and phobic disorders (Marks et al., 2004). It includes weekly screening of symptoms by

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