



Side effects in Internet-based interventions for Social Anxiety Disorder



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ABSTRACT

Internet-based interventions are effective in the treatment of various mental disorders and have already been integrated in routine health care in some countries. Empirical data on potential negative effects of these interventions is lacking. This study investigated side effects in an Internet-based treatment for Social Anxiety Disorder (SAD).

A total of 133 individuals diagnosed with SAD took part in an 11-week guided treatment. Side effects were assessed as open formatted questions after week 2 and at post-treatment after week 11. Answers were independently rated by two coders. In addition, rates of deterioration and non-response were calculated for primary social anxiety and secondary outcome measures (depression and quality of life).

In total, 19 participants (14%) described unwanted negative events that they related to treatment. The emergence of new symptoms was the most commonly experienced side effect, followed by the deterioration of social anxiety symptoms and negative well-being. The large majority of the described side effects had a temporary but no enduring negative effect on participants' well-being. At post-treatment, none of the participants reported deterioration on social anxiety measures and 0–7% deteriorated on secondary outcome measures. Non-response was frequent with 32–50% for social anxiety measures and 57–90% for secondary outcomes at post-assessment.

Results suggest that a small proportion of participants in Internet-based interventions experiences negative effects during treatment. Information about potential side effects should be integrated in patient education in the practice of Internet-based treatments.

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1. Introduction

In the last decade, Internet-based interventions have been developed for a variety of mental and physical health problems (Andersson et al., 2013). Several meta-analyses have summarized the evidence supporting the overall efficacy of Internet-based interventions in the reduction of psychopathological symptoms (e.g. Andrews et al., 2010; Cuijpers et al., 2009; Macea et al., 2010; Muresan et al., 2012; Spek et al., 2007). As a result, Internet-based interventions were integrated into routine mental health care in some countries, for example in Sweden and in the Netherlands (e.g. Hedman et al., 2013). Overall good effects do not, however, capture the proportion of patients who do and who do not benefit from an intervention. Average good effects can include any number of patients who do not respond to treatment, who

deteriorate or who experience side effects. No study so far has focused on negative effects in Internet-based interventions (Emmelkamp et al., 2014). In light of the increasing use of Internet-based interventions, research on potential risks of these innovative treatments is highly warranted. The present study focuses on negative effects in Internet-based treatments for Social Anxiety Disorder (SAD). So far, two different Internet-based treatment approaches have been evaluated for SAD with differing success. Trials on guided Internet-based cognitive-behavioural treatments (ICBT) have consistently yielded good effects in reducing symptoms of SAD (for an overview see Ref. (Boettcher et al., 2013b)). In contrast, attempts to apply innovative attention training programmes to the Internet-based setting have produced mixed results (Boettcher et al., 2012; Boettcher et al., 2013d; Carlbring et al., 2012; Neubauer et al., 2013). Whilst ICBT programmes consistently resulted in large effects for social anxiety measures, attention training programmes only yielded small to moderate effect sizes. However, effect sizes are only one indicator of treatment efficacy. So far, nothing is known about potential risks associated with these interventions and empirical data on the frequency of

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deterioration or other unwanted events is still missing. The present report will therefore evaluate unwanted events in ICBT as well as in attention training programmes for patients with SAD.

Linden (2012) defined unwanted events as all events of negative quality that occur parallel to treatment. Unwanted events can be related to treatment or not. In events that are related to treatment, one can distinguish between side effects, which occur in relation to correct state-of-the-art treatment, and the effects of malpractice (malpractice reaction). Whereas malpractice reactions result from incorrect or inappropriately applied treatments and are the direct fault of a therapist, side effects are treatment-inherent and can occur when the treatment is adequate and appropriately delivered (Linden, 2012). Hoffmann et al. (2008) provided an overview of potential side effects in psychotherapy. These include the deterioration or chronification of targeted symptoms, the manifestation of new symptoms, suicidality, decreased self-esteem and self-efficacy due to the failure to achieve (unrealistic) treatment aims, the manifestation of the sick role, dependency on the therapist, negative and enduring personality changes, stigmatisation, and marriage/relationship problems.

Deterioration and non-response (no clinical change through treatment) are the most frequently researched side effects of psychotherapy. In their review of face-to-face psychotherapy research, Lambert and Ogles (2004) estimated that 5–10% of the patients in psychotherapy deteriorate. Unfortunately, only very few studies directly provide empirical insight into rates of non-response and deterioration. Kraus et al. (2011) reported on 6960 patients treated in regular outpatient care for a mean of 16 sessions. In panic/anxiety, 25% of the patients deteriorated significantly and 34% showed no clinical change (Kraus et al., 2011). Results from a cognitive-behavioural university-based outpatient clinic are more encouraging. Jacobi et al. (2011) reported that 0.8–3% of the 1776 patients experienced reliable deterioration, and 27–49% showed no significant clinical change. Some additional evidence on negative effects on a group level has been reported in meta-analyses. Two early meta-analyses on psychotherapeutic treatments showed that 9–11% of the calculated effect sizes were negative (Shapiro and Shapiro, 1982; Smith and Glass, 1977). With regard to Internet-based interventions, only one meta-analysis reported the proportion of negative effects. Barak et al. (2008) found that 75 out of 746 calculated effect sizes were zero or negative (10.1%).

Empirical studies on the nature and frequency of side effects other than non-response and deterioration are extremely rare. One study was conducted with psychotherapists who reported on their own training psychoanalysis/psychotherapy. Twenty-one percent experienced side effects (Buckley et al., 1981). Examples of side effects were “deleterious to my marriage”, “allowing destructive acting out”, and “fostering too much withdrawal from the outside world” (Buckley et al., 1981, p.304). One recent study on former psychotherapy patients (CBT, psychoanalysis and other therapies) showed that 3–23% reported prolonged periods of depression after treatment termination (Nestoriuc and Rief, 2012). Other frequent side effects in this study were: negative changes of the personality (2–15%), deteriorated coping with negative events of the past (0.5–16%), strained relationship to family members and more marital conflicts (1–11%), as well as fear of stigmatisation (1–4%) and problems with insurance companies due to having been in therapy (8–13%) (Nestoriuc and Rief, 2012).

Side effects are experienced by only a minority of patients in psychotherapy. Patient variables that might be associated with a higher risk of negative treatment outcome include high initial symptom severity, high comorbidity, low social support, low motivation, low outcome expectations, and inadequate treatment process expectations (Bohart and Greaves Wade, 2013; Mohr, 1995). Therapist characteristics that showed an association with poor therapeutic outcome included lack of empathy, hostility, and anger (Beutler et al., 2004; Mohr, 1995). It is yet unclear how these therapist characteristics may affect negative outcomes in Internet-based interventions. Web-based treatments differ in regard to the amount and intensity of therapist contact. Unguided

Internet-based attention training programmes do not include any therapist–patient interaction at all. In ICBT, therapists usually provide weekly feedback and encouragement via e-mail and answer direct questions of the patients. Paxling et al. (2012) studied specific therapist behaviours in the e-mail correspondence with patients in ICBT for Generalized Anxiety Disorder. The authors found that specific therapist behaviours, e.g. the demonstration of ‘deadline flexibility’, were negatively related to treatment adherence and outcome. At the same time, the influence of the overall working alliance between patient and therapist seems less pronounced in Internet-based treatments compared to face-to-face treatments (Andersson et al., 2012) even though alliance ratings are positive and comparable to those in traditional therapies (Preschl et al., 2011).

It is so far unknown how the differences between face-to-face and Internet-based therapies might influence the occurrence of negative effects. Whilst research on side effects in face-to-face therapy is scarce, it is non-existent in Internet-based interventions. The frequency and nature of side effects in Internet-based treatments are unknown.

The aim of the current study was twofold. First, we wanted to investigate what kind of unwanted events occur in Internet-based interventions for SAD and how frequent they are in attention training and guided ICBT for SAD. We aimed at analysing their relatedness to treatment, their impact on patients' well-being as well as their association with treatment outcome. We also explored potential predictors of unwanted events. Second, we aimed at providing an estimate of rates of deterioration and non-response on standardised outcome measures in Internet-based attention training and ICBT.

2. Methods

2.1. Participants and procedure

Participants were recruited for a randomised controlled trial on the combination of attention bias modification (ABM) training and ICBT (registration number at clinicaltrials.gov: NCT01570400) (Boettcher et al., 2013c). The study compared two groups: one group received attention training in addition to ICBT and the other group received a control training programme in addition to ICBT. A detailed description of the selection of participants, randomisation procedures, and interventions is provided elsewhere (Boettcher et al., 2013a). Participants were recruited via the Internet and via advertisement in regional and national newspapers. After registering with their e-mail address, participants obtained detailed information on the study and were asked to return written informed consent by mail.

The selection of the participants followed two steps. First, participants were asked to fill out the outcome questionnaires which included the Liebowitz Social Anxiety Scale – self report (LSAS-SR; Baker et al., 2002) and additional questions regarding current and past treatment. In the second step, participants who scored above the cut-off of 30 on the LSAS-SR were invited to take part in a telephone-administered diagnostic interview. Two advanced MSc clinical psychology students conducted the social anxiety and depression section of the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I, First and Gibbon, 2004). All interviewers had received training in using the SCID-I. We applied the following inclusion criteria: (a) being at least 18 years old, (b) having access to the Internet, (c) meeting diagnostic criteria for a primary diagnosis of SAD according to the DSM-IV (d) no suicidal ideation (e) not participating in any other psychological treatment for the duration of the study, and (f) if on prescribed medication for anxiety/depression, dosage had to be constant for 3 months prior to the start of the treatment.

A total of 133 participants met all inclusion criteria and were randomised to one of two groups (see flowchart in Fig. 1). After randomisation, participants received access to a website where the respective tasks of the attention training/control training were presented and where the ICBT manual was accessible from weeks

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