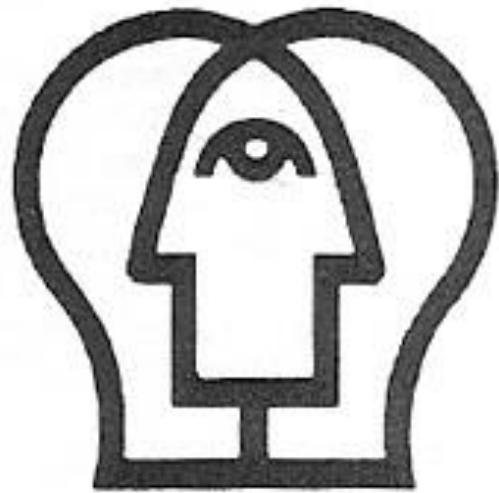


**Adverse effects of psychotherapy:
Outcomes of a combined Internet
treatment for Social Anxiety Disorder.**

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MASTER'S THESIS, 30 CREDITS, 2013

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ADVERSE EFFECTS OF PSYCHOTHERAPY: OUTCOMES OF A COMBINED INTERNET TREATMENT FOR SOCIAL ANXIETY DISORDER.

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Social Anxiety Disorder (SAD) is a mental disorder with high prevalence but low treatment accessibility. A way to facilitate care to these patients is through Internet based treatment. As is the case of most psychological treatments, much has been studied about positive effects but there is a gap regarding adverse effects. This study seeks to fill this gap in the case of an Internet delivered treatment. From a total of 127 participants who took part in a treatment that combined attention biased modification (ABM) and Internet based cognitive behavior therapy (iCBT), 21 (16.5%) presented adverse effects. Most of the adverse effects were detected after participants had received iCBT (13.4%), and these were mostly related to deterioration of symptoms (5.5%), negative wellbeing (3.9%) and emergence of new symptoms (1.6%). Perceived side effects after attention training were less common (4.7%). A thematic analysis showed also that the techniques used in treatment, the lack of time to complete treatment and becoming aware with the impairments of the disorder and its consequences could influence the emergence of adverse effects.

When suffering from a headache, one option to cure it is by taking an analgesic that contains paracetamol. Doing this is choosing a treatment even knowing that it can encompass the possibility of drowsiness (De Craen, Di Giulio, Lampe-Schoenvaeckers, Kessels, & Kleijnen, 1996). What makes this possible is the possibility to be informed about the side-effects of the medicine in advance. The same cannot be applied to psychological treatment. In the case of an anxiety disorder, for example, it's known that behavior therapy is an effective treatment (The Swedish National Board of Health and Welfare, 2010) but not that exposure, which is a part of the treatment, can cause discomfort and increased anxiety (Arch, Dimidjian, & Chessick, 2012).

Psychology today is a well-established science, and psychotherapy is the recommended treatment in the case of different psychological disorders (The Swedish National Board of Health and Welfare, 2010) and in some cases even being preferred over drug treatment (Clark et al., 2003; Nutt & Sharpe, 2008). This would not be possible without research that shows psychotherapy effectiveness, making it an empirically supported treatment (Powers, Sigmarsson, & Emmelkamp, 2008; Seekles et al., 2013). The question is, could a treatment cause harm even when providing improvement to the patient?

Adverse effects research is of high importance as it can contribute to the development of treatments that are as less harmful as possible (Barlow, 2010). Awareness of the adverse

effects in psychotherapy would help the comparison of different treatment alternatives, which would help patients to make more conscious treatment choices (Jonsson, 2012; Lilienfeld, 2007). Furthermore, it would lead to improvements in psychotherapy techniques (Mohr, 1995) and, decrease the differences in the research of psychological and drug treatment as the absence of side-effects associated with psychotherapy is one of the current reasons that causes it to be considered safer (Nutt & Sharpe, 2008).

The American Psychological Association (APA) has proposed criteria for evaluating treatment guidelines where it recommends that, it should be clear which outcomes the recommended treatments produce. Such guidelines are even more specific when it indicates that outcomes comprehend both positive and negative effects and that in the case of negative effects “they should be explicitly documented and considered in the formulation of any guideline” (APA, 2002, p. 1057). Still, ten years later, there is not enough research to fulfill this criterion. On this basis, a study of side-effects in psychotherapy, such as the one presented here, is a matter of clinical and academic importance.

Side-effects in psychotherapy are not much explored (Barlow, 2010). The history of psychology, as in other sciences, is about hits and misses, but, when researching about psychotherapy effects the hits are better documented than the misses.

Berk and Parker (2009) lifted up the need of looking more carefully at the negative effects of psychotherapy and showed how different types of psychotherapies have achieved unwanted results. Until now, most of the studies that comprise psychotherapy negative effects were directed to find the efficacy of psychotherapy and the adverse effects were on the back burner. This is the case of a review of meta-analysis of the effectiveness of cognitive behavior therapy (Hoffmann, Asnaani, Vonk, Sawyer, & Fang, 2008) which showed not just the positive effects but also gave an overview of the potential side-effects of the treatment. Only a handful of studies have directly focused into negative outcomes, Mohr (1995), for example, examined patient, therapist and therapy variables in his literature review of negative outcomes. Heins et al. (2010) in turn, looked for possible detrimental effects of cognitive behavioral therapy for chronic fatigue syndrome.

In the case of Internet-based treatments, several meta-analysis evidences the positive outcomes (e.g. Andrews, Cuijpers, Craske, McEvoy, & Titov, 2010; Cuijpers et al., 2009; Macea, Gajos, Calil, & Fregni, 2010; Muresan, Montgomery, & Damid, 2012; Spek et al., 2007), but Internet treatments can also present risks, as well as misinterpretation of instructions and incorrect execution of the exercises (Carlbring, Andersson, & Kaldø, 2011).

Social Anxiety Disorder

From all anxiety disorders, the most common is Social Phobia (Stein & Stein, 2008), renamed in the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-V) to Social Anxiety Disorder (SAD) (Grohol, 2013). It is one of the mental disorders that cause great loss in quality of life (Alonso et al., 2004; Saarni et al., 2007). The onset is often during adolescence and it has lifetime prevalence estimated in 6.6% in Europe (Fehm, Pelissolo, Furmark, & Wittchen, 2005).

One of the characteristics of SAD is the fear of social encounters, in other words, the person who suffers of SAD feels discomfort and avoid situations where they are supposed to relate to other people. In these kinds of situations a feeling of being exanimated and, most of the time disqualified by the others, prevails. This feeling can be accompanied by trembling, blushing, avoidance of eye contact and in some cases panic attack. As a consequence the individual can shun situations that require speaking in public, talking to authority figures or socialize with new groups and new people (APA, 2000; Stein & Stein, 2008).

According to DSM-IV, the individual that has SAD recognizes that the fear is excessive and unreasonable but is unable to change the behavior that follows this feeling, which entails significantly limited quality of life (APA, 2000). In DSM-V the diagnosis can only be settled if the anxiety is out of proportion to the actual situation and this judgment must be done by a clinician (Grohol, 2013).

Despite of the high prevalence (Fehm et al., 2005; Kessler et al., 2005) and the diversity of effective treatments (Heimberg, 2001), the fear and embarrassment associated with seeking help causes a great number of patients to not seek therapy (Andersson et al., 2006; Gross et al., 2005; Stein & Stein, 2008). A way to reach this population can be through Internet based treatments that have shown positive outcomes (Andersson et al., 2006; Carlbring et al., 2007) and facilitates accessibility (Reger & Gahm, 2009) as the patient doesn't need to step into a situation that requires social contact, or that will at least require less contact.

Internet-Based Cognitive Behavior Therapy

Internet-based cognitive behavior therapy (iCBT) is an empirically supported treatment that shows positive outcomes in the treatment of different disorders, including SAD (Andersson, 2009). Patients with anxiety disorders that received iCBT showed better outcomes than waiting-list and placebo controls (Berger, Hohl, & Caspar, 2009). According to Reger and Gahm (2009), Internet treatment benefits were equaled or even overcame the face-to-face treatment. Furthermore, results achieved by Internet based treatment have shown long term effects (Andersson et al., 2006; Carlbring, Nordgren, Furmark, & Andersson, 2009).

An issue that is raised in the literature about Internet based treatment is the importance of therapeutic guidance (e.g. Andersson et al., 2006; Carlbring et al., 2007; Titov, Andrews, Choi, Schwenck, & Mahoney, 2008a). Most of the Internet based treatments are framed with a minimal contact approach, also called guided treatment, which means that patients are assisted and supported via e-mail when using an Internet adapted self-help guide (Berger et al., 2009).

Several models have been conducted to test guided Internet treatment for SAD. Andersson et al. (2006) achieved positive outcomes when using a model with therapist feedback by e-mail and in vivo exposures in a randomized controlled trial. However, it was unclear if positive effects were a result of the exposure itself or of the guided Internet treatment. Carlbring, Furmark, Steczko, Ekselius and Andersson (2006) in turn, tested a purely Internet based program and achieved significant improvements on measures of social anxiety, fear, avoidance, depression and general anxiety. Overall, positive results have showed the efficacy of minimal contact Internet therapy (Berger et

al., 2009; Titov, Andrews, Schwencke, Drobny, & Einstein, 2008c; Titov, Andrews, & Schwencke, 2008b) and even long term effects (Carlbring et al., 2009).

When comparing guided and unguided self-help Internet treatments, Berger et al. (2011) found that the level of therapeutic support does not affect the results, which were significant in both treatments. On the other hand, Titov et al. (2008a) found better outcomes in the case of guided Internet based treatment. That is also the case of Anderson (2010) who concluded that iCBT works best when support is provided. In addition results from a meta-analysis by Spek et al. (2007) suggested that self-help programs are more effective when they include therapeutic support.

The use of unguided Internet based treatment produced significant positive results when enhanced by adding weekly telephone reminders (Titov, Andrews, Choi, Scwencke, & Johnston, 2009b) and a clinician-moderated online discussion forum (Titov et al., 2009a).

As indicated above, Internet based treatment, both with more or less therapeutic contact, is an effective option for treating SAD. However, nothing is mentioned about the adverse effects of treatment. Andersson et al., (2006) and Carlbring, et al. (2007) mentioned treatment adherence as a problem in Internet treatments which leaves space to question if adverse effects would interfere in participants' completing or not treatment. The relation between the amount of time offered to complete treatment and the number of exercises/information in each module was named as a reason for discontinuing treatment (Andersson et al., 2006; Carlbring et al., 2006)

Attention Bias Modification

Despite the effectiveness of cognitive behavioral therapy (CBT) in treating SAD, one feature of the disorder was not encompassed in the treatment, namely, that social anxious patients use to show a biased attention to social threatening stimulus (Rapee, & Heimberg, 1997), which is one important aspect of the maintenance of the disorder (Clark & MacManus, 2002). With an attempt to comprise this feature of the disorder, a technic, based on computer-delivered training that intends to modify attention bias to social threat, was used in SAD treatment (e.g. Amir, 2009; Bar-Haim, 2010; Boettcher, Berger, & Renneberg, 2012; Carlbring et al., 2012).

According to Amir et al. (2009) the attention training is basically “a computerized procedure that involves repeatedly redirecting participants' attention away from socially relevant threat cues in order to induce selective processing of neutral (nonthreat) stimuli” (p. 961).

Researches using attention biased modification (ABM) shows very mixed results. Some studies have shown promising effects and support attention training as an efficient treatment of SAD when testing it in laboratory (Amir et al., 2009; Bar-Haim, 2010; Schmidt, Richey, Buckner, & Timpano, 2009). Other authors tested Internet delivered ABM in clinical samples (Boettcher et al., 2012; Carlbring et al., 2012; Neubauer et al., 2013) but the outcomes were not so successful as there were non-significant results between treatment and placebo group (Carlbring et al., 2012) or training and control groups (Boettcher et al., 2012). Furthermore, Emmelkamp (2012) calls into doubt the clinical value of AMB as it have showed mostly negative results and studies that found positive results could not be replicated.

Boettcher et al. (2012) offered an iCBT treatment to all participants of the research at the end of the training and what they found was that those participants who had undergone ABM training showed a considerable improvement, the same did not happen with the control group. Because of these results the authors suggested further research in combining ABM and iCBT.

Taking in consideration the aim of this study, it is important to stress that investigations about adverse effects are not part of the researches mentioned above.

Aim

The present study attempts to begin remedying the gap existent in psychotherapy adverse effects research. The aim is not to underestimate the quality and the effectiveness of psychotherapeutic treatment but to present the frequency and the types of adverse effects when treating SAD with an Internet based treatment that combines ABM and iCBT. The present study aims also to explore which variables can be responsible for the emergence of adverse effects.

What it's meant by adverse effects in this study, is the description used by Linden (2012) as "effects that are unwanted because of their negative quality and because they are not intended by the treatment" (p.2). Thus, this includes even effects that are necessary to achieve the wellbeing of the patient but produce discomfort and affect the patient in a negative way.

Method

Participants

The participants of the present study were part of SOFIE13, the thirteenth study of a social anxiety disorder treatment via Internet in combination with exposure. The project aims to produce more effective treatments for SAD and to obtain better knowledge about what can influence the effects of the treatment. A randomized controlled double-blind trial was conducted to compare iCBT combined with ABM training and iCBT combined with control training.

The initial sample consisted of 133 adults that fulfilled the diagnosis of SAD according to DSM-IV (APA, 2000) and met all the inclusion criteria to be part of the study (Boettcher et al., 2013). Participants were recruited via Internet, advertisements in Swedish newspapers and announcements at Umeå, Linköping and Uppsala Universities. Participants with acute substance-use disorders, psychotic symptoms, bipolar disorders, and those who showed suicidal risk were excluded from the study. It was also part of the inclusion criteria to not participate in other psychological treatment during the period of the study. In the case of those participants already under medication for anxiety/depression, the participant should have had a constant dosage for 3 months prior to the start of the Internet treatment.

The average age of participants were 33.4 years old (SD=10.39). More detailed information about the demographic characteristics of the initial sample is displayed in Table 1.

Table 1: Demographic characteristics of participants on initial sample

	Attention training group (n=66)		Control group (n=67)		Total (N=133)	
	n	%	n	%	N	%
Gender						
Male	21	32	27	40	48	36
Female	45	68	40	60	85	64
Marital status						
Married/in a relationship	42	64	35	52	77	58
Single	24	36	32	48	56	42
Level of education						
Low level of education	3	5	1	1	4	3
Medium level of education	16	24	19	28	35	26
High level of education	47	71	47	70	94	71
Other treatment						
Former psychotherapy	36	55	31	46	67	50
No (former) medication	38	58	42	63	80	60
Former medication	19	29	17	25	36	27
On stable medication	9	14	8	12	17	13

Procedure

The participants were randomized to one attention training group (n=66) that received two weeks of ABM followed by 9 weeks of guided iCBT and one control group (n=67) that received two weeks of control training followed by 9 weeks of iCBT.

Six participants were excluded from the analysis because they did not complete the attention bias assessment after having received ABM treatment; this resulted in a final sample of 127 participants.

During the attention training participants were trained to modify their attention from a threatened stimulus to a neutral one. First, two words with different emotional values or two portrait images expressing different feelings of the same person were showed simultaneously, one on the top and one on the bottom of the computer screen for 1000ms for the first 96 trials and 500ms for the other 96 trials. Stimulus pairs were divided equally in neutral-negative, positive-negative and neutral-positive. Then the stimulus was replaced by a probe, always where the more negative stimulus was located before, thus, establishing a connection between the more negative cue and the probe.

The control group received a neutral version of ABM, i.e. without directing the attention to negative, positive or neutral faces or words. In this case the number of times that the probe replaced more negative and more positive stimulus was equally distributed.

In both cases, the participants were instructed to respond as quickly and accurately as possible to the probe by pressing the correspondent button on the keyboard. The

duration of ABM and control group training was two weeks. Both groups then received a nine week Internet-based cognitive behavior treatment.

The iCBT treatment was based upon previous evaluated self-help manuals for SAD adapted for Internet use (Andersson et al., 2006; Carlbring et al., 2007) and composed of nine modules. The amount time to complete each module was one week.

The first module included a description of SAD and facts about CBT. In the second, third and fourth module a cognitive model for SAD was presented and cognitive restructuring introduced. Modules five to seven introduced exposure and self-focused attention exercises. Finally, modules eight and nine focused in social skills and relapse prevention. Participants had no direct contact with therapist but they were asked to discuss the homework assignments weekly with an Internet therapist via e-mail.

After having received the ABM treatment, participants answered to an open questionnaire named "Side effects of treatment"; the same was done after iCBT treatment. The questionnaire was composed of thirteen questions and gave the participants a chance to indicate three or more side effects that he/she experienced during treatment (see Appendix 1). In the case of affirmative answer participants were requested to describe the adverse-effect in their own words as well as when, how often and for how long the adverse effect occurred.

The questionnaire also assessed how negatively adverse effects affected participants; both at the time that the adverse effect occurred and at the present time (when they were answering the questionnaire). Negative impact was measured on a Likert scale ranging from 0=no impact at all to 3=severely negatively impact.

Linden's checklist

Linden (2012) has proposed a classification aimed to facilitate the work when searching for side-effects in psychotherapy. He assumes that there are combinations of factors that contribute to the emergence of side-effects and he distinguishes them from non-response, deterioration of illness and malpractice reaction. Based on this, he has created a checklist that aims to guide the work when searching for side-effects.

According to Linden (2012) even though any unwanted effect (UE) has to be taken to account not every UE can be considered an adverse effect. What turns an UE into an adverse-effect is its correspondence to the treatment which he divided in treatment emergent reactions and adverse treatment reactions (ATR). This last one includes only the negative reactions caused by correct treatment, reactions that although being negative are necessary to reach treatment's goal.

In the present study some adaptations were done to the checklist proposed by Linden (2012). Linden's (2012) classification is divided in 17 categories but in the present study 13 categories were used. Categories associated with the relation between patient and therapist and one category related to prolongation of the treatment were excluded. These changes were necessary first, because, in the case of Internet based treatment participants had a pre-determined time to finish each module and the treatment could not be prolonged. Second, because the relation between patient and therapist were minimal, and with the only purpose of giving support and feedback. Furthermore, the context of development of adverse effects was not taken into consideration.

Analysis

The answers were tabled and categorized by two independent raters, the author of this thesis and a clinical psychologist specialized in Internet based interventions who was also part of the Sophie 13's team and the supervisor of this thesis. The categorization was based upon UE-ATR (Linden, 2012) and its inter-rater reliability was calculated using Cohen's Kappa (Cohen, 1960).

Intra-Class-Correlation (ICC) is a measure used to assess the reliability of judgments made by different observers (Shrout & Fleiss, 1979). According to Shrout and Fleiss (1979) "if all the data in the final study are to be combined for analysis, the judge's effects will contribute to the variability of the ratings (p. 425)."

The degree of relation to treatment was also judged by the two raters on a 5-point Likert scale (1= unrelated, 2=probably unrelated, 3=possibly related, 4=probably related, 5=related). A two-way mixed, agreement, average-measures Intra-Class-Correlation (Hallgren, 2012) was used to calculate the inter-rater reliability for this measure.

Furthermore, all the answers were analysed using a thematic analysis (Braun & Clark, 2006). The aim was to understand better what could be behind the emergence of adverse effects. Answers which referred to the same adverse effect class were assembled together and every similarity found was examined. This made possible to see what the different answers had in common and if the detected themes were part of the same categories or spread across different ones.

Ethics

In order to participate in the study, participants signed and submitted a form where they gave their consent to participate in the study and that the researches could handle their personal information.

Results

Classification

From the 127 participants who completed the combined Internet treatment, 21 (16.5%)¹ reported having perceived the presence of some kind of adverse effect. Of these, 6 (4.7%) detected adverse effects after having received attention training and 17 (13.4%) after having received iCBT. Interestingly one of the participants that presented adverse effects related to treatment was part of control group.

Of those participants who received ABM, 3 (2.4%) were excluded from the analysis, because the adverse effects they presented were rated as been "not related" or "probably not related" to treatment. Taking this in consideration a total of 19 (14.9%) participants presented adverse effects that were related to treatment. The frequency of adverse effects in the different categories is depicted in Table 2.

The participants that received ABM treatment reported three types of adverse effects with the same frequency, namely, deterioration of symptoms, stigmatization, and

¹ Two participants have reported side effects both after receiving ABM and iCBT, which results in a total of 23 detected side effects being 20 related to treatment.

emergence of new symptoms. Deterioration of symptoms perceived during attention training is described as feeling more discomfort in social situations than it was felt before treatment.

Stigmatization is described as a fear that friends will get to know about the disorder. When describing stigmatization the participant mentioned the necessity to interrupt the training when the presence of a colleague was noticed. Participants even mentioned that this kind of interruption interfered in training results.

Participants that presented emergence of new symptoms after receiving ABM describe it as physical symptoms like having a headache and feeling sick.

As addressed above, three described adverse effects were not included in the analysis as they were not considered to be related to treatment. All of them could not be specified in the classification proposed for this study and was classified as “others”. That was the case of understanding a recurrent bad dream, symptoms of eating-disorder and stumbling on a threshold.

Table 2: Classification of adverse effects' frequency (N=20) perceived after receiving attention biased modification (ABM) and after receiving Internet based cognitive behavior therapy (iCBT).

Classification	After ABM (n=3)		After iCBT(n=17)	
	<i>n</i>	%	<i>n</i>	%
Lack of clear treatment result	0	0,0	1	0,8
Non-compliance of the patient	0	0,0	1	0,8
Emergence of new symptoms	1	0,8	2	1,6
Deterioration of symptoms	1	0,8	7	5,5
Negative well-being	0	0,0	5	3,9
Strains in family relations	0	0,0	0	0,0
Changes in family relations	0	0,0	0	0,0
Strains in work situation	0	0,0	0	0,0
Changes in work situation	0	0,0	1	0,8
Sick leave of the patient	0	0,0	0	0,0
Problems in the extend social net	0	0,0	0	0,0
Any change in life circumstances of the patient	0	0,0	0	0,0
Stigmatization	1	0,8	0	0,0
Other	0	0,0	0	0,0

The most frequent adverse effects detected after iCBT treatment were deterioration of symptoms and negative wellbeing. In the former case, the participants mainly described increased anxiety which was associated with being more conscious about the automatic thoughts and SAD symptoms. Deterioration of symptoms was also described as becoming more nervous than usual in the presence of authorities and strangers. Negative wellbeing, in turn, was described by participants as feeling stressed and frustrated.

Emergence of new symptoms when detected after iCBT treatment was reported as becoming more observant of behaviors that previously were unnoticed. An example is becoming more aware of how many people start to shake in social situations. Difficulty sleeping is also described as a new symptom that emerged during treatment.

Lack of treatments results, not compliance by the patient and changes in work situation were less frequent, whereas sick leave of the patient, problems in the extend social network, strains and changes in family situation, strains in work situations, and changes in life circumstances of the patient were not reported.

The Kappa coefficient of inter-rater reliability indicated substantial agreement both after ABM procedure ($\kappa=0.786$) and after iCBT treatment ($\kappa =0.619$) (Landis, & Koch, 1977).

Relation to treatment and severity of adverse effects

The resulting of ICC was in the excellent range for the rating after ABM training (ICC=0.98) and in good range for the rating after iCBT treatment (ICC=0.83) (Cicchetti, 1994). Three of the adverse effects presented in the study were rated as not related to treatment and not considered in the final analysis. However, most of the side effects were rated as “related to treatment”, both to ABM ($Md=5$, $M=4.33$, $SD=1.15$) and to iCBT treatments ($Md=5$, $M=4.53$, $SD=0.62$).

Participants that received ABM treatment had mostly rated the severity of side effects as negative ($Md=2$, $M=1.67$, $SD=0.57$) at the time they happened but described no negative effects over time ($Md=0$, $M=0.67$, $SD=1.15$). After receiving iCBT participants experienced moderate negative effects ($Md=1$, $M=1.59$, $SD=1.12$) which also decreased over time ($Md=1$, $M=0.76$, $SD=0.90$).

Behind the categories

A qualitative thematic analysis (Braun & Clark, 2006) was conducted and three key themes were found to influence the emergence of adverse effects: therapy techniques, awareness of the disorders symptoms and lack of time. Being more aware of the disorders’ characteristics was only related to negative well-being, but even the other themes were associated with this category. The themes about the role of therapy techniques and lack of time were spread over different categories but were mostly concentrated in deterioration of symptoms and negative wellbeing.

The role of therapy techniques on the emergence of adverse effects.

The analysis of the participants’ answers suggests that techniques used in CBT have importance for the emergence of adverse effects. Participants did not specify in which module or which kind of exercise was the responsible for inciting adverse effects, however, they made clear that interpreting situations, identifying thoughts and recording

them could lead to increased anxiety, stress and sadness. This can be illustrated with the quote below:

“I became more conscious about my thoughts and how I behave, which is good, as I can counteract it easier. At the same time, having this consciousness created some kind of expectation and adverse effect. I became more conscious about situations and because of this I experienced situations that I didn’t have problem with before as difficult, because I now reflect more and analyze more the situation. I think suddenly that is difficult to have eye contact with teachers and talk to them. I think too much when I have eye contact. Thus, eye contact and talk to authorities are two things that became more difficult for me after treatment.”

Participants described how they became focused on the anxiety, more self-conscious and preoccupied in how they should register their thoughts. Thinking in a metacognitive level increased the anxiety and sometimes even the fear characteristic of SAD. It provided a new way that participants saw themselves and the disorder. One participant named that having to explain in therapy the thoughts he had when talking to other people made him even more nervous in social situations.

Awareness of the disorder’s consequences and impairments.

Participants described a feeling of sorrow of becoming aware of the consequences that the disorder had in their lives. It was portrayed as loss of opportunities in the past, consciousness about the own shortcomings or the comprehension of the amplitude of SAD and the difficulties that were enclosed in it. One participant for example answered: “To realize that my social phobia is more extensive than I thought and it is harder to change than I have hoped for, made me a little depressed.”

Becoming aware of the disorder’s consequences and impairments provoked different feelings. In some cases adverse effects caused by this closer contact with the disorder became so difficult to handle that lead to a pause in treatment. In another situation it could be seen as painful but worthwhile as it was the way to a new life without social anxiety.

Stress: a matter of time.

Some participants found it stressful completing the exercises on time and indicated that nine weeks were not sufficient to get enough treatment. The lack of time is also pointed out as responsible for feeling bad conscience, stress and to not getting results from the treatment. “I experienced stress when I realized that I would not have time for enough treatment in nine weeks.”

Discussion

The purpose of this study was to explore the frequency and types of adverse effects when treating social anxiety disorder with a combination of attention bias modification (ABM) and Internet based cognitive behavioral therapy (iCBT). Lindens’ classification (Linden, 2012) gave an insight of the “big picture” allowing a closer contact with adverse effects that could emerge from both treatments and their frequency. The

thematic analysis gave an expanded vision of the details in the participants answers and enabled a better comprehension of the “behind the scenes” of adverse effects.

Nearby 15% of the participants presented adverse effects that were associated to treatment and those were mostly experienced as mildly negative and not enduring. According to Linden (2012) these results are considered less problematic if compared to treatments that produce rare but severe adverse effects.

The number of adverse effects found in the different phases of treatment can be related to treatment efficacy. Most of the participants that experienced adverse effects did it after iCBT treatment and only a few participants experienced adverse effects after having received ABM treatment. Consistently, Berger et al. (2009), Carlbring et al. (2006), Titov et al. (2008c), and Titov et al. (2008b) showed positive effects with guided iCBT while ABM showed no significant effects when tested as Internet delivered treatment (Boettcher et al., 2012; Carlbring et al., 2012; Neubauer et al. 2013).

The association between the emergence of unwanted effects and treatment efficacy is also consistent with Boettcher, Hasselrot, Sund, Andersson and Carlbring (in press). Their research about outcomes of a combination of ABM and iCBT is the base for the present study and the results showed that participants that received attention training had similar results than participants of the control group regarding changes in social anxiety. On the other hand participants from both attention and control groups improved substantially ($d_{within}=1.39-1.41$) from pre (prior to the treatment) to post-assessment (after iCBT treatment) suggesting that iCBT treatment was effective independent of attention training.

In this study, the most frequent adverse effects were deterioration of symptoms and negative well-being. The thematic analysis indicated that in these cases, techniques used in therapy such as cognitive restructuring was largely associated with increase of anxiety and emergency of depression. Techniques used in CBT are responsible for many of the positive effects of treatment but only few studies about the different CBT techniques focuses on issues of safety or negative consequences specifically. Such studies are geared toward exposition (Foa, Zoellner, Feeny, Hembree & Alvarez-Conrad, 2002; Olatunji, Deacon, & Abramowitz, 2009) and relaxation (Edinger & Jacobsen, 1982; Lazarus & Mayne, 1990; Rickard, McCoy & Collier, 1989). Hence, more research is necessary with focus on how therapy techniques influences the emergence of adverse effects, in the case of SAD more attention should be given to cognitive restructuring.

The results of the thematic analysis indicated also that awareness with the disorder' impairments and consequences were related to negative wellbeing. During the first modules of the treatment, as part of psychoeducation, patients receive information about the disorder, how it develops, how it is maintained and how treatment will work. One possible explanation is that, getting a patient to know more about his disorder can lead to musings that contributes to negative wellbeing. However, contrary to this, Andersson, Carlbring, and Furmark (2012) have showed that, on average, the increase of knowledge about social phobia was associated with a decrease of social fears.

According to the present study, emergence of new symptoms was the third most experienced adverse effect. The symptom described after receiving ABM was having headaches. A hypothesis is that the required attention on the computer screen can trigger this symptom as has been shown in the use of video-games (Neut, Fily, Cuvellier, & Vallée, 2012). The participants that received iCBT in turn indicated problems with sleeping but the answers did not lead to more information and how iCBT treatment could be associated with difficulty in sleeping needs to be investigated. As many participants described increased anxiety and depression as an adverse effect, it can be thought that these symptoms were the cause of sleeping problems. Soldatos (1994) found a strong relationship between insomnia and both depression and anxiety but could not specify the cause-effect relation between them. A moderate correlation between insomnia and anxiety was also found by Koffel and Watson (2009).

One of the categories of side effects proposed by Linden (2012) is the lack of clear treatment results which was also detected by Parker, Fletcher, Berk and Paterson (2013). Just one participant experienced adverse effects that concerned to this category and related it to not having time enough to complete treatment. It is important to note that lack of clear treatment results or non-response to treatment can exist even without participants having listed it as an adverse effect (e.g. Kraus, Castonguay, Boswell, Bordberg, & Hayes, 2011). Future research should investigate the correlation between non response to treatment and adverse effects.

Just one participant in the present study described terminating treatment as an adverse effect. Adherence to treatment is described as a problem in Internet based treatments (Carlbring et al., 2007) and its relation with adverse effects should be investigated.

According to Andersson et al. (2006) and Carlbring et al. (2006), lack of time is mentioned as a reason for participants discontinuing or not finishing treatment. In the present study participants pointed that lack of time was involved in experienced stress and bad conscience. This information complements Andersson et al. (2006) and Carlbring et al. (2006) and leads to a new hypothesis, that possibly lack of time per se is not the reason for participants leaving treatment but the adverse effects that are provoked by not having time enough to complete the modules.

Two participants mentioned the need of help during treatment, one to accomplish the exercises, and the other to deal with the sense of discouragement when finishing the treatment without results. This is an interesting topic as it concerns guided internet delivered therapy. The question is, if participants had the opportunity to contact a therapist weekly, why did they not use this contact to get the help needed? The contact with therapist in guided iCBT treatments are underexplored but Berger et al. (2011) study showed that 33% of the participants that were offered the possibility to step up to telephone or mail contact used it, those that asked for support found it important and those that didn't still found it unnecessary in the end of the treatment. Future studies should consider maintaining the category proposed by Linden (2012) that identifies adverse effects related to strains in patient-therapist relationship, maybe in the case of Internet based treatment not focusing on relationship but in quality of contact. More research about how participants experience and what they expect from the therapeutic e-mail contact in Internet-based treatments would also put some light into this question.

The results of the present study suggests that stigmatization was not direct related to treatment but to the way treatment was executed which, in turn, contributed to the fact that the participant felt that his disorder could be revealed to others. This highlights the importance to take in consideration how and where participants execute the training as it can influence on treatments results. Consistently, one assumption for no finding significant effect of ABM when it's Internet delivered (Boettche et al., 2012; Carlbring et al., 2012; Neubauer et al., 2013) is that maybe the environment of laboratory might be more adequate as it does not offer any kind of distractions (Carlbring et al., 2012). Boettcher et al. (2012) also mentioned the possibility of interruptions interfering in attention training results.

As suggested by the analysis, most of the side effects were not directly associated with the fact that treatment was Internet delivered as such effects could be found even in face-to-face psychotherapy that uses the same model. Further research investigating adverse effects of face to face treatment of SAD would clarify this point.

In sum, the results of this study reinforce the importance of looking for side-effects in psychotherapeutic treatments (Barlow, 2010; Nutt, & Sharpe, 2008) and confirm that treatments that are effective are at the same time, more prone to endure adverse effects (Linden, 2012). The practical use of these findings implies in both preventive and proactive interventions. Preventive as it encourages research in finding ways to delivery iCBT and ABM in ways that would affect the patient as less negatively as possible decreasing emergence of side effects. Secondly, it would be more proactive by making patients conscious of the possibility of adverse effects so they can evaluate the cost-benefits of psychotherapy as well as by giving patients strategies to deal with eventual side effects.

Strengths and limitations

The present study used Linden's (2012) categories list to classify side effects which were accessed with participants filling in an open questionnaire. The results showed which kind of adverse effects can be generated when social anxiety patients receive Internet based treatment. However, during the analysis the feeling was that more information and a clarification of some answers could have enriched the results. Dimidjian and Hollon (2010) suggest qualitative research as an effective way to identify and generate hypothesis in the study of psychotherapy side effects.

The use of a thematic analysis lifted up information that was beyond Linden's classification, creating new hypotheses about the causes of adverse effects, nevertheless open interviews would contribute for a better collection of data for this kind of study and should be used in further studies. It is important to note that the questionnaire can have limitations on the investigation of the existence of adverse effects, for instance, participants could not ask for clarification about what was meant by side effect/unwanted effect, which can have left space for misinterpretation. Another possible limitation is that participants who were very satisfied with positive effects have a risk of disregarding adverse effects.

Negative outcomes can be caused by the illness per se (Linden, 2012), in this case the development of the disorder can work as a mediator variable but this was not accessed in this study. Further studies should take in consideration the severity of the disorder and how it correlates with the presence of adverse effects.

In the study of Boettcher et al. (in press), 5.3% of the participants were excluded from the analyses because they had initiated psychological or medical treatment during the course of the study. Berger et al. (2011) reported more than 7.4% of dropouts for different reasons, from interest for other kind of treatment to lack of motivation or pause for vacation. Similarly, Andersson et al. (2012) described a dropout rate of 14%. The question is if adverse effects that emerge during the treatment could be associated with the dropout rates. In the present study just participants that finished treatment answered the adverse effects questionnaire. Further research is necessary to understand the connection between adherence to treatment and adverse effects.

As the participants of the present study were recruited in Swedish Universities it is evident that more research is needed prior to making generalizations. In special when taken in consideration that Internet treatment is meant to attend all the population diagnosed with social anxiety disorder.

Conclusion

The results of this study show that adverse effects are part of Internet based treatment for SAD. The presence of adverse effects is associated with treatment effect, in other words, treatments that produce positive effects produces also adverse effects. This stresses the importance of further investigation of adverse effects in other Internet-based treatments and even in face to face psychotherapy. Research about adverse effects in psychotherapy can lead to the creation of a standard classification of adverse effects which can be very helpful both for the work of clinicians and researches.

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APPENDIX 1: Side effects of treatment questionnaire

Side effects of treatment

We ask the questions below with the intention to know if the treatment caused some side effects. We will hereinafter call these side effects “unwanted events”. The aim here is to find out and report if Internet delivered CBT can cause some short or prolonged side effects. You have the possibility to specify three unwanted events or unwanted effects. If you happened to have more than three unwanted events or unwanted effects, describe those three that have had most negative effect in your wellbeing and use the free space in the end for describing others unwanted events or unwanted effects.

1. Have you during the treatment experienced some kind of unwanted event that you consider to be due to the treatment or have got some unwanted effect because of the treatment?

Yes

No

2. Describe the unwanted event or unwanted side effect. Inform even when during the treatment, such events/effects occurred, how often they have occurred and for how long each event/effect endured.

3. How negatively do you consider that these unwanted events or unwanted effects influence your wellbeing at the time they happened?

It didn't influence me at all

Influenced me a little negatively

Influenced me moderated negatively

Influenced me very negatively

4. How negatively do you consider that these unwanted events or unwanted effects influence your wellbeing today?

It didn't influence me at all

Influenced me a little negatively

Influenced me moderated negatively

Influenced me very negatively

5. Have you during the treatment experienced some additional unwanted event that you consider to be due to the treatment or have got some unwanted effect because of the treatment?

Yes

No

6. Describe the unwanted event or unwanted side effect. Inform even when during the treatment such events/effects occurred, how often they have occurred and for how long each event/effect endured.

7. How negatively do you consider that these unwanted events or unwanted effects influence your wellbeing at the time they happened?

It didn't influence me at all

Influenced me a little negatively

Influenced me moderated negatively

Influenced me very negatively

8. How negatively do you consider that these unwanted events or unwanted effects influence your wellbeing today?
It didn't influence me at all
Influenced me a little negatively
Influenced me moderated negatively
Influenced me very negatively
9. Have you during the treatment experienced some additional unwanted event that you consider to be due to the treatment or have got some unwanted effect because of the treatment?

Yes

No
10. Describe the unwanted event or unwanted side effect. Inform even when during the treatment such events/effects occurred, how often they have occurred and for how long each event/effect endured.
11. How negative do you consider that these unwanted events or unwanted effects influence your wellbeing at the time they happened?
It didn't influence me at all
Influenced me a little negatively
Influenced me moderated negatively
Influenced me very negatively
12. How negatively do you consider that these unwanted events or unwanted effects influence your wellbeing today?
It didn't influence me at all
Influenced me a little negatively
Influenced me moderated negatively
Influenced me very negatively
13. If you during the treatment experienced some additional unwanted event that you consider to be due to the treatment or have got some unwanted effect because of the treatment, describe this/these here. Inform when during the treatment this events/effects occurred, how often they have occurred, for how long each event/effect endured, how negative they influence your wellbeing at that time and how negative they influence your wellbeing now.