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The role of "on demand" therapist guidance vs. no support in the treatment of tinnitus via the internet: A randomized controlled trial

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ABSTRACT

Objective: Internet-based cognitive behavioral self-help treatments (iCBT) have been shown to successfully reduce the distress associated with tinnitus. Despite this success, little is known about the mechanisms that make iCBT for tinnitus sufferers work. Availability of minimal therapeutic support is assumed to positively influence treatment outcome in iCBT, but the lower limit of required support is not known. In face-to-face therapy, patients' positive outcome expectations have demonstrated an advantageous effect on outcome. The first aim of our study was thus to investigate the role of 'on demand' therapeutic guidance vs. no therapeutic support on treatment outcome in an iCBT for tinnitus sufferers. Our second aim was to investigate whether positive outcome expectations can predict treatment outcome.

Methods: A total of 112 tinnitus patients were randomly assigned to one of two groups (support-on-demand or non-support). Both groups received an established iCBT treatment for tinnitus. While participants in the support group ($n = 56$) could ask a therapist for additional support, those in the other ($n = 56$) received no therapeutic guidance. Tinnitus distress was assessed pre- and post-treatment via the Tinnitus Handicap Inventory (THI) and the Mini-Tinnitus Questionnaire (Mini-TQ). Pre-treatment outcome expectations were assessed using the Patient Questionnaire on Therapy Expectation and Evaluation (PATHEV).

Results: We observed significantly less tinnitus distress in the THI (support: $t(55) = 7.51$, $p \leq .001$; non-support: $t(55) = 7.68$, $p \leq .001$) and Mini-TQ (support: $t(55) = 8.24$, $p \leq .001$; non-support: $t(55) = 8.46$, $p \leq .001$) in both groups from pre- to post-treatment, but no significant differences between the groups or interactions. The PATHEV subscale "Hope of Improvement" significantly predicted treatment outcome as measured by the THI ($\beta = 0.28$, $p = .027$).

Conclusions: The iCBT self-help program is a good treatment option for tinnitus sufferers whether or not support-on-demand is provided. Furthermore, our results show the importance of outcome expectations to the efficacy of iCBT in tinnitus patients. Future research should focus on discovering further predictors of treatment outcome.

1. Introduction

Tinnitus is referred to as the perception of sound (e.g., ringing, hissing) without any external sound stimulation (Lockwood et al., 2002). Studies indicate that between 2–9% of the population suffer from distressing tinnitus (Hasson et al., 2010; Kuttila et al., 2005; Pilgramm et al., 1999; Shargorodsky et al., 2010). Chronic tinnitus can cause several associated problems, for instance, sleeping problems, concentration difficulties, or depressive symptoms (Andersson et al., 2004; Henry et al., 2005), and thus severely affect the sufferers' quality of life and lifestyle (Kennedy et al., 2004). There is no evidence of medical treatments that cure chronic tinnitus (Baguley et al., 2013). The distress associated with tinnitus can be effectively targeted by cognitive behavioral treatment (CBT; Hesser et al., 2011; Martinez-Devesa et al., 2009; Weise et al., 2008). Unfortunately, there is a lack of clinicians offering tinnitus-specific treatment (Gander et al., 2011). Current research is therefore increasingly focused on CBT-self-help as a treatment option for tinnitus patients (Nyenhuis et al., 2013a,b), in particular on self-help programs delivered via the internet (iCBT; Andersson, 2014). Results have been promising for the reduction in tinnitus distress and associated problems (e.g., Hesser et al., 2012; Jasper et al., 2014).

For tinnitus sufferers in particular, iCBT has advantages beyond giving more patients access to treatment. Tinnitus patients often have a predominantly somatic perception of their tinnitus, indicating that traditional psychotherapy can possess lower face validity (Weise et al.,

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2008; Wickramasekera, 1989). Some patients fear being stigmatized by psychotherapy and thus refrain from seeking mental health treatment (Kendra et al., 2014). iCBT might help to overcome these problems as it is more anonymous, reduces the stigma of going to a psychotherapist, and it appears at first to be more technical and less "psychological" (Cuijpers et al., 2008; Gega et al., 2013).

While iCBT's efficacy has been proven for several disorders in several randomized controlled trials (RCTs), we do not know which factors make it work. In traditional face-to-face therapy, common factors such as the therapeutic relationship, therapist confidence, and patients' outcome expectations are assumed to have a positive impact on therapy outcome (Lambert and Ogles, 2004; Lambert, 2005). Studies on internet-delivered treatments have examined some of these, especially the role of therapeutic support and expectations (Andersson et al., 2013; Boettcher et al., 2013; Carlbring and Andersson, 2006; Palmqvist et al., 2007; Spek et al., 2007). Whereas findings regarding the role of expectations in iCBT are mixed (e.g., Boettcher et al., 2013; Kaldo et al., 2008), results show that the presence of at least minimal therapeutic support is supposed to play an important role in the efficacy of iCBT (e.g., Baumeister et al., 2014).

Several RCTs have addressed iCBT with therapeutic support in tinnitus sufferers and reported medium-to-large pre–post effect sizes (Cohen's d between 0.73 and 1.34), thus demonstrating the efficacy of treatment to reduce tinnitus distress (Andersson et al., 2002; Hesser et al., 2012; Jasper et al., 2014; Kaldo et al., 2008). Nyenhuis et al. (2013b) investigated iCBT with minimal contact and reported large effect sizes for the iCBT compared to a control group. In a non-controlled trial within a regular clinical setting, Kaldo et al. (2013) evaluated two parallel interventions in tinnitus patients, that is, iCBT with therapist support and a low-intensity version of iCBT with minimal support. They detected small-to-medium effect sizes for the reduction in tinnitus distress as well as for the alleviation of associated symptoms; they showed that low-intensity iCBT can be promising, in particular for participants with less distress or patients who cannot participate in fully guided iCBT (Kaldo et al., 2013). Although these results are encouraging, there has been no RCT comparing unguided with guided iCBT in conjunction with tinnitus, thus we cannot know whether iCBT with or that without support is more effective for tinnitus sufferers or whether they are equally effective. Previous iCBT studies investigating disorders other than tinnitus yielded mixed results on the influence of therapeutic support on treatment outcome. Whereas several studies provide evidence that therapeutic guidance has an advantageous effect on treatment outcome (Baumeister et al., 2014; Johansson and Andersson, 2012; Palmqvist et al., 2007; Spek et al., 2007; Titov and Andrews, 2008), others obtained no results favoring supported iCBT (Berger et al., 2011; Furmark et al., 2009). Considering these mixed results on therapeutic guidance, one might wonder how much therapist input is actually needed to demonstrate solid improvement after iCBT. This question is difficult to answer when relying on previous research because most of the studies provided fixed amounts of support (e.g., feedback at the end of every treatment week), instead of letting patients choose whether they actually needed support or not. We thus thought it would be worthwhile examining how much support patients would actually request if they could choose, and whether the outcome would differ compared to scheduled support or unguided interventions. One attempt in this direction was made by Berger et al. (2011) in a study on patients with social anxiety disorder. They compared a treatment group whose participants could decide whether they needed additional email and telephone support with an intervention group receiving scheduled weekly support and an unguided intervention group. No significant group differences in any outcome measures were observed, suggesting that unguided treatments are a promising option in the treatment of social anxiety disorder. It is however possible that the amount of support needed differs according to the condition, i.e., patients with social anxiety disorder or insomnia might need less guidance than depressed patients (Andersson, 2014). With regard to tinnitus, patients with significant comorbid disorders such as anxiety, depression, or even personality disorders (Andersson et al., 2004; Erlandsson and Persson, 2006; Zirke et al., 2010; Zöger et al., 2006) might require more support than those with a less disturbing tinnitus and fewer associated problems. We therefore need to take a closer look at the role of scheduled support, support-on-demand, or unguided iCBT.

Patients' outcome expectations might, as previously mentioned, play a crucial role in the efficacy of iCBT in addition to therapeutic support. In traditional face-to-face psychotherapy, we know that outcome expectations are closely related to the treatment's perceived credibility (i.e., how well the treatment is assumed to fit the individual needs; Constantino et al., 2005). Outcome expectations and perceived credibility are usually assessed together via the Credibility Expectancy Questionnaire (CEQ; Devilly and Borkovec, 2000) or the C-Scale (Borkovec and Nau, 1972). Outcome expectations and credibility are being increasingly studied in iCBT research. Studies have detected no relations between credibility/expectations as assessed by the CEQ or C-Scale and reductions in tinnitus distress (Jasper et al., 2014; Kaldo et al., 2008). Further iCBT studies on disorders other than tinnitus showed mixed results regarding the relation between credibility/expectations and outcome (Boettcher et al., 2013; Hedman et al., 2012, 2013). Use of the CEQ or C-Scale does have the drawback that credibility and outcome expectations are often interpreted as one construct, although some suggest that different forms of expectations should be regarded and investigated separately (Devilly and Borkovec, 2000; Greenberg et al., 2006; Schulte, 2008). We therefore think it could prove worthwhile to examine the relation between different forms of outcome expectations (such as hope of improvement, credibility, or fear of change) and actual treatment outcome separately.

As the aforementioned studies reveal, the role of therapeutic guidance and the impact of different forms of outcome expectations on reducing tinnitus distress through iCBT remains unclear. As different studies have proven the general efficacy of iCBT in relieving tinnitus distress, an important next step is to investigate which factors make iCBT work, or in particular which factors are associated with better treatment outcomes. This step is a necessary prerequisite for iCBT's further implementation into regular health care for tinnitus. Accordingly, our study had two major objectives, that is, (1) to examine the impact of therapeutic support in reducing tinnitus distress, and (2) to investigate which kind of patients' expectations are associated with better treatment outcome. We conducted a randomized controlled trial in which tinnitus patients were assigned to an iCBT either receiving support-on-demand or not receiving therapeutic support. Previous findings from iCBT studies for tinnitus led us to predict that the guided iCBT would lead to stronger improvements than the unsupported iCBT. Furthermore, we assumed that higher outcome expectations would be associated with greater reduction in tinnitus distress.

2. Methods

2.1. Participants

Participants were recruited by means of advertisements, articles on websites and in magazines, and via wait lists for participation in an iCBT study on tinnitus. The study's inclusion criteria were: (1) age of at least 18 years; (2) tinnitus lasting over six months; (3) at least mild tinnitus distress (defined by a total score of $\geq$18 in the Tinnitus Handicap Inventory (THI; Newman et al., 1996) or $\geq$8 in the Mini-Tinnitus Questionnaire (Mini-TQ; Hiller and Goebel, 2004)); (4) internet access; (5) good knowledge of the German language to read the text; (6) an examination by an otorhinolaryngologist prior to treatment start (assessed by self-report); (7) no psychosis or severe psychological disorder according to the Web-based Screening Questionnaire for Common Mental Disorders (WSQ; Donker et al., 2009); (8) no risk for suicide as assessed by the WSQ; (9) no previous participation in a