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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.

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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; Kuttilla 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 ≥ 18 in the Tinnitus Handicap Inventory (THI; Newman et al., 1996) or ≥ 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

similar study; (10) no ongoing psychotherapy for tinnitus; (11) tinnitus as the primary problem (e.g., tinnitus not as a consequence of Menière's disease).

Participants were informed about the study design and the treatment prior to the beginning of the study. All gave their written informed consent. The ethics committee at our site approved the study protocol, and it was registered at www.clinicaltrials.gov (NCT01927991).

2.2. Procedure

Two web pages were set up for the study. One website contained general information about the study and was freely available on the internet. The other website was the treatment portal which included a messaging system; it could only be accessed with a personal study code and password (Andersson, 2014). Tinnitus sufferers interested in participating in our study could answer the Mini-TQ on the information page as a first screening. Patients with at least mild tinnitus distress (≥ 8 in the Mini-TQ) automatically received a link to our study's registration form. After registering, participants could fill in the entire study questionnaire online, which served as the pre-treatment assessment. The questionnaire included questions about demographics, tinnitus characteristics, and study-specific measures including the Tinnitus Handicap Inventory (THI). Participants were also asked about their preferred treatment ("If you were to choose, which treatment (support- or non-support-group) would you prefer?"). The decision on study

inclusion was done according to our inclusion and exclusion criteria. In case a cut-off criterion existed, e.g., participants suffered from severe depression or were suicidal (as assessed by the WSQ), they were telephoned in order to conduct further diagnostics. If necessary, the excluded individuals were offered advice and information on how to seek further help. After inclusion, participants were randomly allocated to one of two groups: iCBT with support-on-demand, or iCBT without support (non-support group). Both groups received the same treatment, however, the amount of therapeutic support that was offered varied between groups. The baseline characteristics of participants in both groups did not differ (see Table 1). Randomization was performed by an independent psychologist using an online service which applies a pseudorandom number algorithm (www.randomization.com). Randomization was conducted in two blocks according to the date of registration. Treatment started accordingly at two different points in time (either in October 2012 or in May 2013) and lasted 10 weeks. Participants were randomly assigned to either the support-on-demand or the non-support group at each time point. Post-assessment, which was carried out immediately after treatment, consisted mainly of the same measures as the pre-assessment and included questions on satisfaction with the treatment. An additional telephone interview was conducted one week after the end of treatment. To enhance their compliance throughout the intervention, participants were informed about this interview in advance via email (Andersson et al., 2009). Participants in both groups received the same information about the

Table 1
Sample characteristics.

Characteristics	Support (n = 56)	Non-support (n = 56)	Group differences
Age in years, <i>M</i> (<i>SD</i>)	51.09 (11.02)	54.14 (12.63)	$t(110) = -1.36, p = .176$
Number females, <i>n</i> (%)	21 (37.5)	21 (37.5)	$\chi^2(1) = 0.0, p = 1.00$
Citizenship, <i>n</i> (%)			$\chi^2(2) = 2.16, p = .340$
German	53 (94.6)	49 (87.5)	
German & Other	–	1 (1.8)	
Other	3 (5.4)	6 (10.7)	
Highest educational level, <i>n</i> (%)			$\chi^2(2) = 0.44, p = .978$
No degree	–	–	
Secondary school	23 (41.1)	22 (39.3)	
A-level	11 (19.6)	11 (19.6)	
Academic degree	22 (39.3)	23 (41.1)	
Employment, <i>n</i> (%)			$\chi^2(3) = 3.38, p = .336$
Employed	38 (67.9)	36 (64.3)	
Unemployed	1 (1.8)	4 (7.1)	
Retired	7 (12.5)	10 (17.9)	
Other	10 (17.9)	6 (10.7)	
Married, <i>n</i> (%)	39 (69.6)	38 (67.9)	$\chi^2(1) = 0.42, p = .838$
Tinnitus loudness, <i>n</i> (%)			$\chi^2(2) = 0.58, p = .747$
Slight	1 (1.8)	2 (3.6)	
Moderate	29 (51.8)	31 (55.4)	
Severe	26 (46.4)	23 (41.1)	
Tinnitus duration in years, <i>M</i> (<i>SD</i>)	9.54 (9.23)	12.51 (12.86)	$t(99.77) = -1.41, p = .162$
Hearing impairment, <i>n</i> (%)			$\chi^2(3) = 1.44, p = .697$
None	11 (19.6)	15 (26.8)	
Slight	26 (46.4)	22 (39.3)	
Moderate	14 (25.0)	12 (21.4)	
Severe	5 (8.9)	7 (12.5)	
Tinnitus distress, <i>M</i> (<i>SD</i>)			
THI	62.14 (17.41)	57.32 (16.32)	$t(110) = 1.51, p = .133$
Mini-TQ	18.00 (3.96)	16.68 (3.82)	$t(110) = 1.80, p = .075$
Depressed sympt. (PHQ-9), <i>M</i> (<i>SD</i>)	10.36 (5.13)	9.52 (4.03)	$t(110) = 0.96, p = .338$
Expectation (PATHEV), <i>M</i> (<i>SD</i>)			
Hope of improvement	15.27 (2.68)	15.04 (2.65)	$t(110) = 0.46, p = .646$
Suitability	14.98 (2.69)	14.57 (2.17)	$t(105.24) = 0.89, p = .375$
Fear of change	4.14 (1.35)	3.91 (1.13)	$t(110) = 0.98, p = .327$
Group preference, <i>n</i> (%)			$\chi^2(2) = 0.16, p = .921$
Support	29 (51.8)	29 (51.8)	
Non-support	4 (7.1)	3 (5.4)	
No preference	23 (41.1)	24 (42.9)	

Note: THI = Tinnitus Handicap Inventory; Mini-TQ = Mini-Tinnitus Questionnaire; PHQ-9 = Patient Health Questionnaire; PATHEV = Patient Questionnaire on Therapy Expectation and Therapy Evaluation; Hope of Improvement = subscale of the PATHEV; Suitability = subscale of the PATHEV; Fear of Change = subscale of the PATHEV.

post-treatment interview. Follow-up measures were assessed 12 months after treatment. Patients were contacted via email and asked to fill in the questionnaire online, which was the same as the post-treatment questionnaire. Participants who had failed to fill in the online questionnaire after four weeks (during which they were sent two reminders) received the questionnaire and a prepaid envelope via regular mail and were asked to mail it back to us.

2.3. Measures

2.3.1. Primary outcome measures

The Mini-Tinnitus Questionnaire (Mini-TQ; Hiller and Goebel, 2004) and the German version of the Tinnitus Handicap Inventory (THI; Kleinjung et al., 2007; Newman et al., 1996) were used to assess tinnitus distress and severity. Containing 12 items, the Mini-TQ is a shortened version of the well-established Tinnitus-Questionnaire (TQ; Goebel and Hiller, 1992) that proved to be equally powerful as the TQ in detecting improvements during treatment (Hiller and Goebel, 2004). Its test–retest reliability is .89, and its internal consistency for inpatients is Cronbach's $\alpha = .87$, for outpatients it is Cronbach's $\alpha = .90$ (Hiller and Goebel, 2004), in the present study it was Cronbach's $\alpha = .79$. The authors recommend different cut-off scores when classifying tinnitus severity: scores between 1 and 7 indicate clinically relevant tinnitus distress; scores between 8 and 12 are considered as moderate distress; scores between 13 and 18 suggest severe tinnitus distress; and a score above 19 indicates most severe distress.

The THI contains 25 items and is an internationally well-accepted and often used measure in treatment studies on tinnitus (Hesser et al., 2012; Kaldo et al., 2008). It possesses good psychometric properties, having an internal consistency of Cronbach's $\alpha = .93$ (Newman et al., 1996) and a correlation of $r = .70$ with the TQ (Kleinjung et al., 2007). The internal consistency in the present study was Cronbach's $\alpha = .89$. Just as with the Mini-TQ, different levels of tinnitus severity can be classified: scores between 0 and 16 suggest no handicap; those between 18 and 36 indicate mild tinnitus severity; scores between 38 and 56 suggest moderate tinnitus severity; and a score between 58 and 100 is considered as severe tinnitus.

2.3.2. Secondary outcome measures

The German version of the depression scale of the Patient Health Questionnaire (PHQ-9) was used to assess symptoms of depression (Löwe et al., 2002). Each of its nine questions covers one diagnostic criterion of depression according to DSM-IV. With Cronbach's $\alpha = .88$, in the current sample it was Cronbach's $\alpha = .82$, and a correlation with the Hospital Anxiety and Depression Scale (Zigmond and Snaith, 1983) of $r = .74$, the PHQ-9 shows good psychometric properties and is an internationally standard measure when evaluating depressive symptoms in medical settings (Gilbody et al., 2007).

To assess the participants' outcome expectations regarding the treatment, we administered the Patient Questionnaire on Therapy Expectation and Evaluation (PATHEV; Schulte, 2005). The PATHEV consists of three subscales with internal consistencies of $\alpha = .73$ ("Fear of Change"), $\alpha = .81$ ("Suitability"), and $\alpha = .89$ ("Hope of Improvement") in the original study. In the present sample, alpha was $\alpha = .62$ ("Fear of Change"), $\alpha = .67$ ("Suitability"), and $\alpha = .82$ ("Hope of Improvement"). The scale "Hope of Improvement" assesses how much the patients believe that the treatment can help them with their problems (e.g., "I believe my problems can finally be solved."). "Fear of Change" addresses the extent to which participants fear negative effects from the therapy (e.g., "From time to time I worry about all the things that will change once my problems have vanished."). The subscale "Suitability" measures how confident patients are that they have found the right treatment (e.g., "I've found the right therapy.>").

Satisfaction with treatment was assessed with a measure developed at our site which has not yet been published. It consists of 13 items

(e.g., "The self-help met my expectations."), which are answered on a 6-point Likert-scale ranging from "I totally disagree" to "I totally agree". The items load on one factor with loadings between .70 and .93 in the current sample. Internal consistency in the present study was $\alpha = .94$.

2.4. Treatment

Both treatments were based on a manual first used by Andersson et al. (2002) and later updated by Kaldo and Andersson (2004) and Kaldo et al. (2008). It has been translated and modified for use in Germany (for details on the German adaptation see Jasper et al., 2014). The treatment lasted 10 weeks and consisted of 12 mandatory and 6 optional modules which could be downloaded as PDF files via the treatment portal. Treatment modules were assigned individually to each participant and were provided online every week according to each participant's individual treatment plan. Compared to the iCBT previously used (Andersson et al., 2002; Jasper et al., 2014), we added an automated messaging system to the treatment since there is evidence that it furthers treatment completion (Titov et al., 2013). To be able to download the PDF files for the upcoming week, participants had to answer a question about their treatment process by selecting one of three answers (the three answer categories were: (1) "I have evaluated the modules and would like to download the material for the next training week."; (2) "I have not yet evaluated the modules. However, I would still like to download the material for the next training week."; (3) "I have not yet evaluated the modules and would like to download old training materials."). Depending on their answer, participants received an automated email in which they were either complimented for working on the treatment or motivated to do so in the next week. The general content (i.e., complimenting or motivating participants) of the emails was the same every week, but we tried to change the way in which the emails were written to avoid boring patients because that could have made them stop reading the messages. The emails were the same for both treatment groups. The amount of provided therapeutic support differed between the two groups (support-on-demand vs. no support) and is described below.

2.4.1. Support-on-demand

Half of the participants were randomly assigned to the "support-on-demand" condition and hence, to a personal "therapist". The therapist's role was to help participants with the self-help material whenever questions occurred. This contrasts with the normal way support is provided, which usually includes scheduled support within 24 h after submitting the homework (Andersson, 2014). Furthermore, it was the therapist's task to motivate, encourage, and inspire participants to work on the material. Participants could contact their individually-assigned therapist via email to ask for support whenever needed. However, after five weeks of treatment, participants who had not logged into the treatment portal for two and a half weeks were contacted via their private email address and asked whether they were having problems and needed help. The therapists were three advanced psychology students supervised by a licensed therapist with experience in tinnitus treatment.

2.4.2. Non-support

The other half of the participants was allocated to the non-support condition and was also randomly assigned to an individual contact person. In contrast to the personal "therapist" in the support-on-demand group, we call this person an "individual contact person" because he or she could mainly be contacted in case of technical problems. At the beginning of treatment, participants were instructed to work on the treatment themselves and to 'become their own therapist'. Ethical considerations, however, required us to provide therapeutic support in case of a significant deterioration in any of the symptoms or if problems with the training occurred that would have hindered

participants' continuation with the training. We informed participants that they could get in touch with the contact person in such pressing cases. If participants in the non-support condition addressed the contact person, requests were generally answered in a neutral, non-motivating, and non-praising yet friendly manner. In case of questions related to a module's contents, the contact person did not answer the question specifically but rather suggested re-reading the information provided in the module. The contact person gave direct advice only when a) a severe worsening of symptoms was suspected; b) participants asked how to continue after an absence due to illness or holiday, or c) participants wrote that they wanted to end the training. In these cases, participants received precise recommendations on how to proceed.

2.5. Statistical analyses

Prior to recruitment, the sample size was calculated with G*Power (Faul et al., 2007). To reveal a small time x group interaction effect ($f = 0.1, \alpha = 0.05, \beta = 0.8$) the estimated total sample size was $n = 98$. With an expected dropout rate of about 10%, we decided to recruit about 108 patients.

Statistical analyses were performed with the program IBM SPSS 21.0. Baseline characteristics were analyzed using *t*-tests and χ^2 -tests. Since 12.5% of participants did not answer the post-questionnaire, we used a multiple imputation method offered by IBM SPSS 21.0 to estimate missing values on the THI, the Mini-TQ, and the PHQ-9 at post-assessment. By default, this multiple imputation method uses the Markov Chain Monte Carlo (MCMC) method to replace missing data (Asendorpf et al., 2014). To test for differences within and between groups in the aforementioned three measures from pre- to post-treatment, analysis of variances (ANOVA) for repeated measures with the factors time (pre- and post-treatment) and group (support-on-demand and non-support) was carried out followed by paired *t*-tests with a Bonferroni corrected significance level ($\alpha = .008$). Intra-group and inter-group effect sizes (Hedges' *g*) were also calculated. Statistically significant changes are not equivalent to clinically relevant changes

since they do not provide information about the efficacy of psychotherapy (Jacobson and Truax, 1991). Therefore we calculated clinically significant change for each participant for the THI and Mini-TQ according to the Reliable Change Index (RCI), as defined by Jacobson and Truax (1991). Reliable Change (RC) is calculated by taking into account a patients' pretest (x_1) and posttest (x_2) score as well as the standard error of difference between these two scores (S_{diff}): $RC = (x_2 - x_1) / S_{diff}$. According to the authors, a reliable change of ≥ 1.96 indicates clinically significant improvement, whereas a reliable change of ≤ -1.96 indicates a reliable deterioration (Jacobson and Truax, 1991). In our study, a participant was regarded as clinically significantly improved when attaining an RCI of 1.96 on both measures, that is the THI and the Mini-TQ. Clinically significant change was calculated for completers only.

For follow-up-data at 12 months we analyzed completer data due to a high loss of data from post- to follow-up-assessment. As with the pre- to post-data, we also conducted an ANOVA for repeated measures to test for differences within groups over the three time points (pre, post, follow-up) and between the groups. Again, paired *t*-tests with Bonferroni corrected significance levels ($\alpha = .006$) were calculated afterwards.

The impact of outcome expectations on treatment outcome was investigated via a linear regression model using the completer data. The change score (pre-treatment – post-treatment) on the THI was entered as the dependent variable in the model. For the data entry, the hierarchical entry method was used as the predictors to select were known from previous research. In a first step, demographic variables (sex, age, tinnitus duration in months, tinnitus loudness according to the Klockhoff and Lindblom rating; Klockhoff and Lindblom, 1967) were entered as predictors in the model. In a second step, the three subscales of the PATHEV (“Hope of Improvement”, “Suitability”, and “Fear of Change”) were entered in the model. Since participants answered the PATHEV before being randomized to either of the two treatment groups and there were no significant differences on the dependent variable between groups, we did not run the regression for the two groups separately. In addition, with the seven

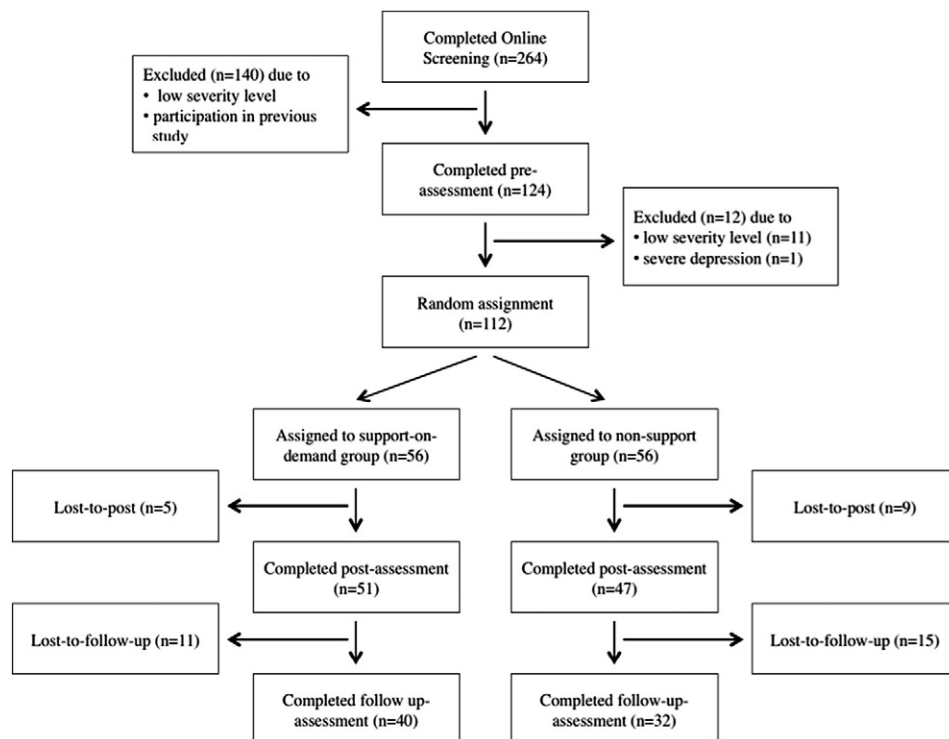


Fig. 1. Flow of participants through the study.

predictors entered in the model, the two groups' sample sizes would have been too small (Field, 2013).

During the whole study, we tried to follow the “Guidelines for Executing and Reporting Internet Intervention Research” (Proudfoot et al., 2011).

3. Results

3.1. Flow of participants and baseline characteristics

As displayed in Fig. 1, of the 264 participants who completed the initial screening, 112 participants met all inclusion criteria and were randomly allocated to one of the two treatment groups.

At the post-assessment, 5 participants in the support-on-demand group and 9 in the non-support group failed to fill in the post-questionnaire, resulting in missing data of 12.5% in total. At follow-up, another 11 support-group patients and another 15 in the non-support group did not fill in the questionnaire, representing a total loss of participants from pre-assessment to follow-up amounting to roughly 36%.

In addition to the missing data, we defined a dropout criterion to specify those participants who did not complete the treatment (but had filled in the post-questionnaire). Participants were regarded as treatment dropouts when they did not log onto the treatment portal anymore during the second half of the treatment time. The rationale for this criterion was based on the fact that to download the majority of the modules, one had to have visited the treatment portal at least once during the second half of the treatment time. With this definition, 9 participants in the support-on-demand group and 11 of those in the non-support group were classified as dropouts, and the difference between groups was not statistically significant ($\chi^2(1) = 0.24, p = .622$).

Table 1 displays the demographics, tinnitus-specific characteristics, outcome measures, and group preference at baseline for each group. As the *t*-tests and χ^2 -tests show, there were no significant pretreatment differences between the groups in any of the variables. Participants suffered on average from severe tinnitus distress as assessed by the THI and the Mini-TQ. The range of severity at baseline as measured by the Mini-TQ was between 8 and 24, that is, moderate to most severe distress. On the THI the range was 26 to 98, meaning that patients suffered from mild to severe distress.

3.2. Analysis of treatment efficacy and differences between groups from pre- to post-treatment

3.2.1. Primary outcome

Multivariate analyses revealed a significant time effect for overall improvement as measured by the THI and the Mini-TQ ($p \leq .001$). However, contrary to our hypothesis, neither the group effect nor interaction effect for time and group reached significance. Post-hoc tests

showed that participants from the support-on-demand and the non-support group improved on the THI and the Mini-TQ (see Table 2). These results show that both groups experienced reduced tinnitus-related distress through the study.

3.2.2. Secondary outcome

The time effect for the PHQ-9 was significant in the ANOVA ($p \leq .001$). Again, we observed neither a significant group effect nor a significant interaction. Additional post-hoc tests revealed that only participants in the support-on-demand group improved significantly on the PHQ-9 (see Table 2), but the lack of interaction suggests that this between-group difference is unreliable.

3.2.3. Effect sizes and clinically significant change

On tinnitus-specific measures (THI, Mini-TQ), both the support-on-demand and the non-support group displayed large within-group effect sizes (Hedges' *g* between 0.99 and 1.40). The support-on-demand group's effect size on the PHQ-9 was within a small range ($g = 0.47$; Table 2).

Twenty-seven participants (48.2%) in the support-on-demand and 25 participants (44.6%) in the non-support group revealed clinically significant change according to our criterion of having an RCI of at least 1.96 on the THI and the Mini-TQ. The difference between groups was not significant ($\chi^2(2) = 1.31, p = .52$). Furthermore, both groups' mean scores on the THI and Mini-TQ at the start of treatment were in the range indicating severe tinnitus distress. After the end of treatment, means of both groups improved to the range indicating moderate tinnitus distress on both measures. Two participants showed clinically significant deterioration on the Mini-TQ and two on the THI. No participant presented clinically significant deterioration on both of the measures.

3.3. Analysis of treatment efficacy and differences between groups from pre- to post-treatment to follow-up

3.3.1. Primary outcome

The ANOVA for repeated measures testing for differences between pre-, post-, and follow-up-assessments between the two treatment groups on the THI and Mini-TQ revealed a significant time effect in the multivariate analyses ($p \leq .001$). Contrary to our hypothesis, however, neither the interaction nor group effect revealed any significant results, thus no significant differences between groups existed. According to Mauchly's Test of Sphericity, the assumption of sphericity was violated for the univariate analyses. Degrees of freedom were therefore corrected according to Greenhouse–Geisser. Univariate analyses showed that the differences are significant for the THI and Mini-TQ (see Table 3). Additional post-hoc *t*-tests investigating within-groups differences revealed that differences between the pre- and post-assessments as well as those between pre-assessment and follow-up were

Table 2
Treatment outcome at post-assessment: Means, F- and t-statistics, and effect sizes.

	Pre M (SD)	Post M (SD)	Within groups			Between groups		
			Time effect	Pre-Post	ES (95% CI)	Group effect	Interaction	ES (95% CI)
THI			F(1, 110) = 118.00**			F(1, 110) = 1.04	F(1, 110) = 1.27	0.05 (−0.32, 0.42)
Support	62.14 (17.41)	41.33 (19.17)		t(55) = 7.51**	1.13 (0.73, 1.53)			
Non-support	57.32 (16.32)	40.36 (17.71)		t(55) = 7.68**	0.99 (0.60, 1.38)			
Mini-TQ			F(1, 110) = 159.59**			F(1, 110) = 2.74	F(1, 110) = 0.24	0.19 (−0.19, 0.56)
Support	18.00 (3.96)	11.75 (4.86)		t(55) = 8.24**	1.40 (0.99, 1.81)			
Non-support	16.68 (3.82)	10.86 (4.68)		t(55) = 8.46**	1.35 (0.94, 1.76)			
PHQ-9			F(1, 110) = 15.07**			F(1, 110) = 0.11	F(1, 110) = 1.76	0.07 (−0.44, 0.30)
Support	10.36 (5.13)	8.02 (4.82)		t(55) = 3.52**	0.47 (0.09, 0.84)			
Non-support	9.52 (4.03)	8.38 (5.11)		t(55) = 1.54	0.25 (−0.13, 0.62)			

Note. *n* = 56 in each group; ** = $p < .001$; ES = effect size (Hedges' *g*); CI = Confidence Interval; THI = Tinnitus Handicap Inventory; Mini-TQ = Mini-Tinnitus Questionnaire; PHQ-9 = Patient Health Questionnaire.

Table 3
Treatment outcome at post-assessment and follow-up: Means, F- and t-statistics.

	Pre		Post		FU		Within groups			Between groups		
	M (SD)	M (SD)	M (SD)	M (SD)	M (SD)	M (SD)	Time effect ^a	Pre-Post	Pre-FU	Post-FU	Group effect ^a	Interaction
THI												
Support	60.85 (17.32)	38.80 (20.36)	37.05 (20.48)				F(1.63, 69.37) = 85.74**	t(39) = 6.39**	t(39) = 7.57**	t(39) = 0.88	F(1.63, 69.37) = 0.58	F(1, 70) = 0.06
Non-Support	58.50 (16.65)	35.88 (19.30)	33.25 (22.90)					t(31) = 8.30**	t(31) = 7.40**	t(31) = 1.17		
Mini-TQ												
Support	17.68 (3.94)	11.58 (5.04)	9.98 (5.27)				F(1.80, 69.20) = 101.01**	t(39) = 6.93**	t(39) = 8.76**	t(39) = 2.56	F(1.80, 69.20) = 1.49	F(1, 70) = 0.42
Non-Support	16.59 (4.06)	9.84 (4.87)	9.28 (6.00)					t(31) = 8.57**	t(31) = 8.37**	t(31) = 0.82		
PHQ-9												
Support	9.85 (4.70)	6.80 (4.17)	6.35 (4.48)				F(1.81, 69.19) = 32.39**	t(39) = 4.25**	t(39) = 5.03**	t(39) = 0.85	F(1.81, 69.19) = 0.53	F(1, 70) = 1.76
Non-Support	9.06 (4.35)	6.78 (4.67)	5.17 (4.72)					t(31) = 3.22*	t(31) = 5.22**	t(31) = 2.89		

Note. n = 40 in the support group; n = 32 in the non-support group ** = p < .001; * = p < .05; FU = follow-up; THI = Tinnitus Handicap Inventory; Mini-TQ = Mini-Tinnitus Questionnaire; PHQ-9 = Patient Health Questionnaire; ^a degrees of freedom have been corrected according to Greenhouse-Geisser.

significant in both groups (see Table 3). No significant differences between the post-assessment and follow-up were observed, demonstrating that improvements in both measures were stable from the post- to follow-up-assessment.

3.3.2. Secondary outcome

The time effect for the PHQ-9 was significant in the ANOVA. Again, the group effect and interaction revealed no significant differences, thus no significant differences between groups existed. Post-hoc t-tests addressing within-groups differences showed that differences in both groups from the pre- to post-assessment and from the pre- to follow-up-assessment were significant on the PHQ-9. No significant differences between the post- and follow-up assessments were apparent, indicating that improvements in the PHQ-9 were stable from the post- to follow-up assessment.

3.4. Expectation as a predictor of treatment outcome

We hypothesized that patients' positive outcome expectations would be associated with greater reductions in tinnitus distress. Of the demographics entered in the regression model, only tinnitus loudness was a significant predictor of treatment outcome ($\beta = 0.21, p = .046$), meaning that louder tinnitus at treatment start predicted improvement. Of the three PATHEV subscales, "Hope of Improvement" predicted treatment outcome significantly ($\beta = 0.28, p = .027$, see Table 4) at post-treatment, indicating that being more optimistic of improvement at the start of treatment leads to greater treatment efficacy and thus to significantly lower levels of tinnitus distress at the end of treatment. Contrary to our hypothesis, neither the treatment's perceived suitability nor fear of change predicted treatment outcome.

3.5. Further analyses

3.5.1. Treatment preference and satisfaction with treatment

We analyzed which of the two groups was the preferred treatment option at pre-assessment and how satisfied participants were with the treatment at post-assessment. Prior to treatment, 51.8% of participants preferred the support-on-demand group over the non-support group (6.2%), whereas 42.0% expressed no preferences. At the post-assessment there was no significant group difference in satisfaction with treatment as assessed by the self-developed measure ($t(86) = 0.22; p = .822$).

3.5.2. Number of messages from patients

Below we describe calculations of the messages the patients sent. Calculated were all the messages sent by patients, both those containing therapeutic requests and messages requesting technical support, or about arranging an appointment for the post-treatment interview. The support-group participants sent 224 messages throughout the treatment, or 4 messages ($SD = 0.53$) per patient throughout treatment ($MD = 3$, range 0–22). Eight participants in the support-on-demand group (14%) never sent a message. The non-support group participants also sent messages asking for technical support and containing questions about treatment contents despite having been advised not to. The non-support group participants sent 109 messages, equaling an average of 1.95 ($SD = 0.26$) messages per patient throughout treatment ($MD = 1$, range 0–8). Fifteen of the non-support group participants (26.8%) never sent a message. The number of messages sent differed significantly between groups ($t(80.34) = 3.46; p \leq .001$); the number of those who never sent a message did not differ between groups ($\chi^2(1) = 2.13; p = .144$). Initial tinnitus distress as assessed by the THI and number of messages sent did not correlate significantly ($r = .113; p = .234$), nor did we observe any association between the number of messages sent and treatment outcome as assessed by the difference score (pre – post) in the THI ($r = .138; p = .175$).

Table 4
Expectation as a predictor of outcome.

Step	Predictor	B	SE	β	p	R ²	Change in R ²	F	p
1	Sex	3.14	3.87	0.08	.419	.05	.05	1.31	.274
	Age	0.16	0.19	0.09	.417				
	Tinnitus duration	−0.01	0.02	−0.04	.727				
	Tinnitus loudness	5.94	3.71	0.17	.113				
2	Sex	3.68	3.69	0.10	.321	.18	.13	4.59	.005
	Age	0.04	0.19	0.02	.845				
	Tinnitus duration	−0.001	0.01	−0.01	.953				
	Tinnitus loudness	7.14	3.53	0.21	.046				
	PATHEV—Hope of Improvement	1.91	0.85	0.28	.027				
	PATHEV—Suitability	1.13	0.94	0.15	.233				
	PATHEV—Fear of Change	2.05	1.48	0.14	.169				

Note. $n = 98$; dependent variable = change score from pre- to post-assessment on the Tinnitus Handicap Inventory; SE = standard error; PATHEV = Patient Questionnaire on Therapy Expectation and Evaluation.

3.5.3. Time spent by therapist

We calculated the time the therapist spent on each participant throughout the treatment (irrespective of group allocation). In the first step, just the therapeutic time (answering messages, training or supervision on how to answer messages) spent per patient was calculated separately for each group. In the support-on-demand group, therapists spent on average 36.18 min ($SD = 83.68$) on each participant over the entire treatment duration, on average 3 min and 36 s of support per patient every week. As we noted wide divergence in the amounts of support demanded throughout the treatment by participants in the support-on-demand group (range 0 to 541 min), we investigated whether the support demanded was related to initial tinnitus severity, but detected no significant correlation ($r = .023$; $p = .806$).

Concerning the non-support group, therapists spent on average 6.62 min ($SD = 9.59$) answering emails over the entire treatment period, equaling 42 s per patient per week on average. The average time spent supporting each participant differed significantly between the two groups ($t(56.45) = 2.63$; $p = .011$), that is, more time per patient was spent in the support group. Therapeutic time was not related to treatment outcome as determined by the difference score on the THI ($r = -.068$; $p = .507$).

In the second step, time spent per patient with the purpose of providing technical support was calculated for each group separately. In the support-on-demand group, therapists spent on average 2.93 min ($SD = 6.00$) per patient providing technical support during the entire treatment. In the non-support group, 2.70 min ($SD = 5.65$) were spent. The difference between groups was not significant ($t(110) = .211$; $p = .833$). In addition, there was no correlation between time spent on technical support and treatment outcome on the THI ($r = 0.09$; $p = .396$).

4. Discussion

Our study shows that iCBT is effective in reducing tinnitus-related distress in patients suffering from tinnitus. However, contrary to our hypothesis, we could not demonstrate that the on-demand guidance provided by iCBT led to greater improvements than the unguided iCBT. Positive treatment expectations in the form of hope of improvement did however predict better outcome regarding tinnitus distress.

Our finding that both the support-on-demand and the non-support groups revealed similar improvements is somewhat surprising. However, previous studies on the role of therapeutic support in iCBT also reported mixed results. For example Berger et al. (2011) found that guided self-help for social anxiety disorder was not superior to unguided iCBT, whereas Baumeister et al. (2014) provided evidence that internet-based interventions including therapeutic guidance yielded better results than interventions without guidance. Similarly, some

argue that at least minimal therapist contact is one of the most important aspects of successful outcomes in iCBT (Andersson et al., 2013). Several reasons for both groups' good improvements are conceivable. First, the treatment program had a fixed endpoint that was 10 weeks after the start of treatment, meaning that the program was available online only up to a specific deadline. According to Andersson et al. (2009), a fixed deadline is an important aspect in treatment efficacy that might even reduce the need for therapeutic support. Second, as Andersson et al. (2009) recommended, we included a post-treatment interview to enhance overall treatment compliance. They argued that if progress in treatment is expected and evaluated in a post-treatment interview, compliance might increase. Although we did not explicitly ask participants to describe their treatment's progress, but rather their satisfaction with treatment, they knew that we were expecting feedback from them about the treatment in the post-treatment interview. This fact also may have kept the non-support group participants motivated to work on the treatment and hence led to their good treatment outcome. Third, we included automated emails in the treatment with the aim of motivating participants to work on the treatment. Although the therapists did not send these emails personally and patients were not addressed personally, participants received at least some feedback every week, a factor known to facilitate treatment completion (Titov et al., 2013). Fourth, all participants knew from the beginning that treatment was being carried out by psychologists who could be contacted in urgent cases. This knowledge may also have had a positive impact on treatment outcome.

Another interesting aspect regarding our results is the low amount of support that was actually requested by the support-on-demand group. In contrast to previous studies that administered the same self-help program in tinnitus-sufferers (e.g., Jasper et al., 2014), the therapeutic support was not scheduled to take place on a specific date. This implied that participants could ask whenever and for as much support as they wanted, but they were not obliged to ask for support or to send any feedback. Jasper et al. (2014) reported an average therapist's time-spent-per-patient-per-week of 13.76 min. This stands in contrast to the support-on-demand group's 3.36 min per week and patient. Despite this difference in therapist time, the numbers of clinically significant improvement (support-on-demand group: 48%; non-support group: 44%) are comparable to those in Jasper et al.'s study (41%). This indicates that self-help in tinnitus sufferers can be effective even when little therapist support is provided, revealing the potential of offering iCBT with minimal therapeutic contact.

In our study, positive expectations in the form of hope of improvement were a predictor of treatment success. For future internet-delivered treatments, this means that it could be advantageous to raise patients' expectations regarding treatment outcome prior to the start of treatment in order to enable greater improvement. But how are positive outcome expectations like hope of improvement induced?

In conjunction with pharmacological treatment, some suggest that providing information on the expected drug effect positively influences beliefs about outcome (Bingel, 2013). With iCBT, this might mean that providing information on the efficacy of the treatment being offered, for example by presenting study results or satisfaction ratings from patients who have already completed therapy, could enhance improvement. Furthermore, it might be important to inform patients about the clinicians conducting the treatment to boost positive expectations regarding treatment outcome and thus to enhance treatment efficacy. Participants might experience greater hope of improvement if they are made aware that well-trained CBT-professionals with substantial experience in the field will be treating them. This might apply to tinnitus sufferers especially, as they often have long histories of (unsuccessful) treatment attempts (Pilgramm et al., 1999) and might thus have little initial hope of improvement.

Nevertheless, expectations in the form of perceived suitability and fear of change failed to predict treatment outcome. One explanation for the missing relationship between treatment outcome and perceived suitability might be that we had asked for the perceived suitability prior to the start of treatment and randomization, thus the participants were only able to rate the suitability at that time according to theoretical information and not by personal observation or experience (Schulte, 2008). Our results may have been different had we asked that question after two weeks of treatment. Furthermore, the rather low internal consistencies displayed by the subscales “Suitability” and “Fear of Change” ($\leq .70$) in our sample lower the value of the regression analysis’ results (Cicchetti, 1994; Rosenthal, 1994).

Several study limitations should be noted (1) Although we only lost 12.5% of participants for post-assessment, our results are compromised by the fact that we lost 36% of participants for follow-up. It is possible that only those participants satisfied with the treatment answered the post-/follow-up- questionnaires. Our follow-up results must therefore be considered with particular caution. (2) As is true for many internet-delivered treatments, the sample is selective, that is, only participants having access to a computer and internet, and those with adequate reading skills and sufficiently motivated to work on the self-help program on their own were eligible for the study. In addition, perhaps only those tinnitus sufferers willing to work on a treatment without support participated in our study. Prior to the start of treatment and study registration, patients were told that their chances of being assigned to the non-support group were 50%. In addition, our sample consisted of participants with a high education level, as 40% earned an academic degree; that limits the generalizability of our results. (3) The severity of tinnitus distress in our sample was rather high compared to other studies (Jasper et al., 2014; Kaldo et al., 2008). As it is easier to achieve improvements in individuals complaining of greater initial tinnitus distress, this fact may partly account for the high within-group effect sizes detected in our study. (4) Another limitation concerns the fact that the non-support group may have been offered too much therapeutic and technical support. For example, the post-treatment interview (conducted in both groups) could be regarded as a kind of therapeutic support. Furthermore, therapists, rather than mere IT personnel, provided the technical support. The therapists may have answered in an overly-therapeutic manner, or the participants perceived even technical support as being very supportive and helpful. In a future study, it would thus be necessary to a) recruit a control group not receiving any kind of support, b) provide technical support via technical staff, and c) assess more precisely why some patients used the support-on-demand intensively whereas others rarely did. (5) Finally, another limitation of the present study is the fact that we did not assess negative effects with a validated outcome measure or an interview as recommended by Rozental et al. (2014). This would have been important to better understand why and how negative effects occur in order to minimize them in future treatments. This might have been particularly useful in the present study because of the difference in support offered, which could make a difference in experiencing negative effects (Rozental et al., 2014).

Despite its limitations, our study results constitute a good starting point for further research on iCBT. It is important that the impact of therapeutic support on the efficacy of iCBT be examined in order to build a case for the evidence-based implementation of iCBT within standard healthcare. For example, to test the amount of support needed, various factors could be included stepwise in a non-support condition (e.g., post-treatment interview, automated emails, or fixed deadline). In addition, the observation that positive outcome expectations in the form of hope of improvement can exert a beneficial effect on treatment outcome is important. Future research should investigate how outcome expectations can be improved prior to the start of treatment in iCBT for tinnitus patients, but in other patient cohorts as well. Moreover, it is essential to discover other predictors of treatment outcome in order to optimize iCBT interventions and to identify the initial steps that need to be taken to tailor iCBT for individual needs.

To the best of our knowledge, this study is the first to have systematically investigated the roles of ‘on-demand’ therapeutic guidance and of different aspects of outcome expectations in conjunction with reducing tinnitus distress in iCBT. We have demonstrated the efficacy of an internet-delivered treatment in reducing tinnitus-related distress, even when no support is provided. In addition, even when patients are offered the option of requesting support, much less time needs to be invested than during face-to-face therapy. This underlines the cost effectiveness of internet-delivered treatments. Our results confirm that iCBT can be a good option for the treatment of tinnitus patients, especially when face-to-face therapy is unavailable. With our study we have made one attempt to investigate predictors of treatment outcome in iCBT – an important step in improving internet-delivered treatments.

Conflict of interest

The authors declare no conflict of interest.

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