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Cognitive Behavioural Therapy as Guided Self-help to Reduce Tinnitus Distress

VIKTOR KALDO



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Abstract

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Tinnitus is common, and some individuals with tinnitus display high levels of distress. Cognitive behavioural therapy (CBT) is effective in reducing tinnitus distress, but is rarely available. CBT-based self-help, with or without guidance, has yielded positive results in other problem areas, and one initial randomized controlled trial (RCT) has shown promising results for tinnitus.

This thesis is based on four studies;

Study I showed that Internet-based self-help treatment with e-mail guidance alleviated tinnitus distress among consecutive patients and was rated as credible as traditional treatments. Active participation in treatment predicted outcome.

Study II, an RCT, showed that an extended and more interactive version of the Internet-based self-help treatment with e-mail therapist support appeared to be equally effective as a group treatment. In study III, another RCT, a self-help book with weekly telephone support was superior to a wait-list control group. No strong evidence for the importance of telephone contact on outcome was found. In both study II and III, the positive outcome remained after one year and self-help approaches appeared more therapist time-effective compared to group treatment. Also, the received treatment-dose for patients in guided self-help was not lower than in the group treatment.

Study IV found that the 'Stages of Change', from the transtheoretical model, are probably not the right theoretical framework to use with tinnitus patients. Predictors of outcome were found, but they were not in line with the theory behind the Stages of Change. The predictors were better understood when conceptualized as coping, showing that helplessness and less coping before treatment correlated with better outcome.

In sum, guided cognitive behavioural self-help can decrease tinnitus distress. It appears to be therapist time-effective and shows effects comparable to or slightly below traditional CBT for tinnitus. Effects remain one year after treatment and generalize to a routine clinical setting.

Keywords: Tinnitus, Cognitive Behavioural Therapy, Self-help, Internet, Stages of Change

Viktor Kaldo, Department of Psychology, Box 1225, Uppsala University, SE-75142 Uppsala, Sweden

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To Volmar, Arvid and Susanna

Included Papers

This thesis is based on the following papers.

- I. Kaldo-Sandström, V., Larsen, H. C., & Andersson, G. (2004). Internet-based cognitive-behavioral self-help treatment of tinnitus: Clinical effectiveness and predictors of outcome. *American Journal of Audiology*, *13*, 185-192
- II. Kaldo, V., Levin, S., Widarsson, J., Larsen, H. C., & Andersson G. (In press). CBT for tinnitus – in a group and via the Internet. A randomised controlled trial with 1-year follow-up. *Behavior Therapy*.
- III. Kaldo, V., Renn, S., Rahnert, M., Larsen, H. C., & Andersson, G. (2007). Use of a self-help book with weekly therapist contact to reduce tinnitus distress: a randomized controlled trial. *Journal of Psychosomatic Research*, *63*, 195– 202.
- IV. Kaldo, V., Richards, J., & Andersson, G. (2006). Tinnitus Stages of Change Questionnaire: Psychometric development and validation. *Psychology, Health & Medicine*, *11*, 483 – 497

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Abbreviations

CBT	Cognitive behavioural therapy
dB	Decibel
HADS	Hospital Anxiety and Depression Scale
HADS-A	Anxiety subscale of Hospital Anxiety and Depression Scale
HADS-D	Depression subscale of Hospital Anxiety and Depression Scale
HL	Hearing Level
ISI	Insomnia Severity Index
MML	Minimum masking level
MML	Minimum masking level
NICE	National Institute for Clinical Excellence
PET	Positron Emission Tomography
PSOCQ	Pain Stages of Change Questionnaire
RCT	Randomised Controlled Trial
rTMS	repetitive Transcranial Magnetic Stimulation
SL	Sensation Level
THI	Tinnitus Handicap Inventory
TRQ	Tinnitus Reaction Questionnaire
TRT	Tinnitus Retraining Therapy
TSOCQ	Tinnitus Stages of Change Questionnaire
TTM	Transtheoretical model
URICA	University of Rhode Island Change Assessment Scale
VAS	Visual Analogue Scale

Introduction

Tinnitus

What is tinnitus?

Tinnitus is usually defined as the experience of sound in the absence of any external stimulus (Jastreboff & Hazell, 2004; Tyler, 2000b). It can also be more narrowly defined by explicitly excluding possible sources for the perceived sound, as for example in Waddell and Canter (2004):

Tinnitus is defined as the perception of sound, which does not arise from the external environment, from within the body (e.g., vascular sounds), or from auditory hallucinations related to mental illness.

This can be seen as a definition of “subjective tinnitus” which is the most common form of tinnitus (Andersson, Baguley, McKenna, & McFerran, 2005). Sounds that originate from an internal acoustic source, activating the cochlea and the rest of the auditory pathways by air and/or bone conduction, can be defined as “objective tinnitus” (Dobie, 2004). With the right equipment, another person should be able to hear “objective tinnitus”, at least in theory, in contrast to subjective tinnitus where the source of the sound is neurologic rather than acoustic and tinnitus is only audible to the person having it. Objective tinnitus could be generated by for example vascular or muscular activity close to the cochlea, by spasms in the stapedius or the tensor tympani muscles in the middle ear, by temporomandibular joint dysfunction, or by spontaneous otoacoustic emissions (Lockwood, Salvi, & Burkard, 2002; Perry & Gantz, 2000). However, since it is often impossible for another person to detect ‘objective tinnitus’ Dobie (2004) and Hazell (1995) have proposed the term ‘somatosound’.

Most people do experience temporary tinnitus from time to time. Sometimes it is spontaneous and last for seconds or minutes, sometimes it is triggered by external noise, lasting minutes to hours (Dobie, 2004). To separate these phenomena from more chronic tinnitus, Henry, Dennis and Schechter (2005) have suggested that tinnitus should be diagnosed or seen as pathological when it exceeds a duration of five minutes and occurs more than once a week. The definition can also specify that the sounds should occur not only after being exposed to loud noises, (e.g Davis 1995).

The tinnitus sound can resemble other sounds like hissing, buzzing, escaping steam, engines, humming, static, and cicadas. But it is often described as being somewhat, or much, qualitatively different from these real-world sounds. Jastreboff and Hazell (2004) and others (Andersson, Baguley et al., 2005; Henry & Meikle, 2000) have argued that tinnitus often differ from real-world sounds in a number of ways;

- it is difficult to imitate
- it is more easily masked from perception by a masking sound of another frequency compared to an external sound that needs the masking sound to be close in frequency,
- it is as effectively suppressed by an external sound whether this sound is applied to the same ear as tinnitus or to the opposite
- when presenting an external tone with a frequency very close to that of a tonal tinnitus, the so called “beating of tones”-phenomenon (a cyclical fluctuation of loudness) does not occur, as it does when two external tones close in frequency are played at once

Throughout the rest of this text, “tinnitus” will include both subjective and objective tinnitus, and refer to chronic tinnitus (although not always stable) present not only after exposure to loud noise.

Measuring tinnitus

There is no direct way to measure what tinnitus sounds like, except in some rare occasions of objective tinnitus. One relatively objective method to measure tinnitus sound is positron emission tomography (PET) studies of brain activity (Andersson et al., 2000; Lockwood et al., 1998; Mirz et al., 1999), but this method does not say much about the perceived auditory characteristics of tinnitus and is impractical to use.

The most straightforward way of measuring tinnitus is to ask the patient to describe it. In 30-37% of the cases, tinnitus is described as a ringing sound (Meikle & Taylor-Walsh, 1984; Stouffer & Tyler, 1990). Other descriptions are crickets, metallic sounds, bag-pipe, buzzing, and flushing water (Andersson, Baguley et al., 2005). Some descriptions are quite complex and colourful, for example “leaves falling on metallic foil” or “a loud cutting sound surrounded by buzzing in colour”.

The perceived localization of tinnitus can sometimes be difficult for the patient to decide, but 52% report having it in both ears, 37% in one ear, 10% in the head and less than 1% outside the head (Stouffer & Tyler, 1990).

To get more quantitative measurements of tinnitus, some basic audiometric methods have been developed (Tyler, 2000a).

Tinnitus pitch matching

Finding an external tone or noise to match the frequency of tinnitus is difficult. The reliability of such measures is low. In addition to tinnitus not following the same psychoacoustical rules as real-world sounds, this is probably due to many patients reporting fluctuating tinnitus, having more than one tinnitus sound, and often suffering from a hearing loss as well (Henry, 2004).

Tinnitus loudness matching

Tinnitus can be matched on loudness to an external tone at about the same frequency as tinnitus. Loudness can be reported at a “hearing level” (HL - the absolute loudness in decibels of the external tone) or at a “sensation level” (SL - the *difference* in decibel between the matching tone and the patients hearing threshold at that particular frequency) (Andersson, 2003). Using SL to match tinnitus loudness, is assumed to give a better picture of how tinnitus is perceived, since it ‘controls’ for possible hearing deficits, as opposed to HL. Unfortunately, even though this procedure has quite good reliability (Henry, 2004), it does not capture the patients’ subjective experience of loudness (Penner, 1986) and the clinical usefulness has been questioned (Andersson, 2003).

Minimum masking level (MML)

Another way to measure the ‘impact’ of tinnitus is via the minimum masking level (MML). This is the minimum level of a broadband noise that is needed to completely mask an individual’s tinnitus. Different types of “masking curves” have been found (Feldmann, 1971). External sounds affect tinnitus differently in different people; some find tinnitus completely masked after exposure to external sounds, others find that it disappears for a while (“residual inhibition”), still others find tinnitus impossible to mask, and even experience an increase in loudness as a reaction to external sounds (Tyler, 2000a).

Prevalence of tinnitus

In an early experiment in 1953, Heller and Bergman found that when inside a completely quiet room, 94% of their subject reported hearing some kind of sound. Later studies have shown less extreme results (Graham & Newby, 1962; Levine, Abel, & Cheng, 2003). It should be noted, however, that prevalence studies require tinnitus to be present in every-day life.

Henry et al (2005) summarized epidemiological studies from different countries and concluded that about 10-15% of the adult population has tinnitus. They also noted that the definition of tinnitus varies across studies. This probably explains why the prevalence figures summarized by Hoffman and Reed (2004) ranged from 4.4% and 15.1%. When using the definition

“prolonged spontaneous tinnitus that last for more than five minutes and occurs not only after loud sounds”, Davis (1995) reported a prevalence of 10.2% .

Adults above 50 years of age have a higher prevalence of tinnitus (Hoffman & Reed, 2004). The data on tinnitus among children and adolescents are very heterogeneous, with prevalence figures between 6% and 36% (Holgers & Juul, 2006). There are mixed results on whether tinnitus is more common among men or women (Hoffman & Reed, 2004), but some studies have found a weak tendency for women to be more affected by tinnitus (Davis & Razaie, 2000).

In Sweden, four prevalence studies have been conducted. Axelsson & Ringdahl (1989) reported that 14.2% of the population suffered from tinnitus 'often' or 'always'. Two later studies found a prevalence of 15.8% (Scott & Lindberg, 2000) and 13.2% (Johansson & Arlinger, 2003). Andersson et al (2002) found a point prevalence of 17.8%, out of which 60% reported having tinnitus 'often' or 'always'.

Henry et al (2005) concluded that most individuals with tinnitus do not seek treatment, indicating they do not find it to be an important problem. Andersson, Baguley et al (2005) summarized that 0.5 - 3% of the population has tinnitus that constitutes a significant problem. In Sweden, Andersson et al (2002) found that 8.6% report a 'moderate' and 2.2% report a 'strong' negative impact of tinnitus.

What causes tinnitus?

Baguley (2002) stated that “Given the heterogeneity observed in the tinnitus population, it may be considered that no single theory, model or hypothesis will explain the presence of tinnitus in all those affected”.

Some of the causes for objective tinnitus have been listed above. Dobie (2004) stated that almost all subjective tinnitus is associated with some degree of hearing loss, although not everyone with a hearing deficit has tinnitus, and not everyone with tinnitus has a hearing loss.

One cause of tinnitus may be an imbalance between the inner and outer hair cells (Jastreboff & Hazell, 2004). In case of disease or loud noise, the outer hair cells are often damaged first, sometimes leaving the inner hair cells undamaged. This could explain why 20% of tinnitus occur in persons with normal hearing (Davis & Razaie, 2000), since outer hair cell damage does not necessarily produce a hearing deficit.

Other possible causes are noise induced damage to large-diameter nerve fibres in the cochlea (Bauer, 2007), different kinds of neural “cross-talk” (Eggermont, 1990), or the same ‘grind-control’ mechanisms as those suggested in chronic pain (Möller, 1997; Melzack & Wall, 1965).

Schreiner and Cheung (2004) have argued that central auditory structures in conjunction with influences from non-auditory limbic structures, sustain chronic tinnitus. The distinction between peripheral and central causes was commented on by Möller (2003); ”Despite symptoms that indicate the ear is

the site of the pathology, there is strong evidence that most forms of severe tinnitus are caused by functional changes in the central nervous system". Thus, causes attributed to the central auditory system do not have to exclude peripheral causes to tinnitus and vice versa.

In Table 1, a list of risk factors for tinnitus is shown.

Table 1. *Factors Associated with Tinnitus. Adapted from Hoffman and Reed (2004), some explanations in italics added.*

Loud noise exposure
Presbycusis (<i>hearing loss due to old age</i>)
Cardiovascular and cerebrovascular disease
Drugs or medications: Salicylate analgesics, nonsteroidal anti-inflammatory drugs, antibiotics, cardiac medications, "loop" diuretics, chemotherapeutic agents
Ear infections/inflammation
Head or neck trauma and injury
Hyper- and hypothyroidism (<i>insufficient production of thyroid hormone</i>)
Meniere's disease (<i>vertigo attacks, tinnitus, hearing impairment and nausea</i>)
Otosclerosis (<i>disease of the middle ear</i>)
Sudden deafness (<i>fluctuating hearing deficit with rapid onset</i>)
Vestibular schwannoma (<i>benign tumour on the auditory nerve</i>)

Psychological models and theories

To design adequate treatments for tinnitus distress, theories for how tinnitus affects the individual are important. Psychological tinnitus models tinnitus are not opposing the more biological attempts to explain tinnitus. More often they broaden the view and add another perspective. Importantly, they might give ideas on how to handle intrusive tinnitus in the absence of a medical cure. Also from a neurological point of view, it has been noted that active behavioural training "...may be the most promising regimen to modify the central nervous substrate of tinnitus and, consequently, its percept" (Schreiner & Cheung, 2004).

According to Tyler (2005), the important psychological factors to consider are:

- *Habituation*: Bothersome tinnitus is the effect of failure to habituate
- *Learning*: Emotional and behavioural responses to tinnitus are learned
- *Attention*: Failure to shift attention away from tinnitus
- *Cognitive aspects*: Non-adaptive and less functional ways of thinking about tinnitus

Habituation theory

The first general psychological theory of tinnitus was developed by the psychologist Richard Hallam (1984). This psychological approach specifies that the most natural reaction to tinnitus is tolerance, since the nervous system

is built to adapt and habituate to continuous sensory stimuli judged to be irrelevant. According to this theory, tinnitus might become a problem if the signal through learning gets associated to negative emotions, if it varies in different ways or has a sudden onset, or if the nervous system is affected in some way that intervenes with habituation, for example during excessive levels of input and a high arousal in the central and autonomic nervous systems. Habituation theory points out the filtering function of the central nervous system as important in determining which signals to attend to, and which to ignore.

When habituation is disrupted, attention is more often oriented towards tinnitus and away from normal, every-day behaviours and tasks. This leads to a decreased level of functioning, negative emotional responses and increased arousal, which in turn further reduces habituation to tinnitus.

The neurophysiological model

The “neurophysiological model” of tinnitus is suggested by Jastreboff and Hazell (1993). This global tinnitus model is mostly focused on higher neural processes and often refers to psychological concepts. In spite of its medically oriented name and focus on brain structures, it is therefore here presented as a psychological model, a categorization supported by other authors (e.g. McKenna, 2004; Wilson, 2006).

The neurophysiological model does not exclude peripheral processes as origins of a tinnitus signal, but does not see them as necessary for the perception of tinnitus. The model states that the level of distress depends exclusively on the activation of the limbic and autonomic nervous systems (Jastreboff & Hazell, 2004). If tinnitus becomes classically conditioned to negative emotions, these systems prevent habituation. In Jastreboff and Jastreboff (2006), the authors have argued that the cognitive, evaluative parts of tinnitus perception are crucial at the initial stage of the development of tinnitus distress. Later on, the influence of conditioned reflexes becomes dominant.

A comparison between the models

In many ways, these models overlap in advocating the importance of central rather than peripheral processes and focus on attention, learning and emotions. In short, both see habituation as a key process, but the psychological model highlights the cognitive processes while the neurophysiological model stresses more basic, classic conditioning between tinnitus and negative stimulus (McKenna, 2004).

According to Andersson, Baguley et al (2005), neither model has been much investigated. Parts of the neurophysiological model have some support in animal studies (Jastreboff & Sasaki, 1994), and Andersson, Baguley et al (2005) have reported on some studies on psychophysiological measures of habituation, for example Carlsson and Erlandsson (1991). Wilson (2006)

suggest that the models can be included in a more psychological framework with less tension between basic learning and more complex cognitive functions (Wilson, 2006).

Tinnitus distress

Tinnitus is associated with several negative consequences. Below is a review of some of the most common areas of concerns for tinnitus patients, indicating that these problems might be important to consider when treating tinnitus patients.

Sleep problems

Difficulty with sleep is one of the most common complaints (Axelsson & Ringdahl, 1989; Jakes, Hallam, Chambers, & Hinchcliffe, 1985; Sanchez & Stephens, 1997; Tyler & Baker, 1983). Among tinnitus patients in a clinical setting, 71% reported sleep problems (Andersson, Lyttkens, & Larsen, 1999). There have also been repeated findings that sleep problems are associated with higher levels of tinnitus severity (Folmer & Greist, 2000; Meikle, Vernon, & Johnson, 1984). Folmer and Greist (2000) also found that this relationship might become more and more pronounced over time. Scott and Lindberg (2000) found that sleep problems were more common in a help-seeking group of individuals with tinnitus compared to a non-help-seeking group.

One recent study with older individuals compared tinnitus patients to an age- and health-matched control group and found that tinnitus patients had more problems, especially with sleep efficiency and sleep quality (Hebert & Carrier, 2007). Asplund (2003) also found elevated sleep disturbances among an elderly population with tinnitus compared to those without tinnitus.

McKenna (2000) assumes that sleep problems often are secondary to tinnitus, but it is difficult to sort out whether they are a direct effect of tinnitus or mediated by the psychological distress caused by tinnitus. Also, severe sleep problems (insomnia) are known to be self-maintaining regardless of the original cause (Morin & Espie, 2004).

Problems with concentration and memory

Andersson et al (1999) found that 70% of the tinnitus patients in an audiological clinic reported concentration problems. Scott and Lindberg (2000) found that for both help-seeking and non-help-seeking individuals with tinnitus, concentration problems were more common than in a control group. Also, the help-seeking group had significantly more problems. There are some indications that these problems are more pronounced in patients with complex tinnitus sounds (Hallberg & Erlandsson, 1993) and they seem to be closely related to emotional distress and tinnitus intrusiveness (Hallam, 1996; Hiller & Goebel, 1992). Impaired cognitive functioning is more often found when looking at self-reported everyday cognitive failures than when running

cognitive tests. In one study tinnitus patients only performed worse in one of five cognitive tests (Hallam, McKenna, & Shurlock, 2004). Cognitive tasks that are boring, for example reading (Edlund 2001), and tasks that do not require full attention, are probably more easily disrupted by tinnitus than cognitively demanding tasks (Andersson & McKenna, 2006).

Emotional problems, psychiatric diagnoses and stress

Associations between anxiety, depression and tinnitus distress are commonly found (Di Pietro et al., 2007; McKenna & Hallam, 1999; McKenna, Hallam, & Shurlock, 1996; van Veen, Jacobs, & Bensing, 1998; Wilson, Henry, Bowen, & Haralambous, 1991) and it seems clear that negative consequences of tinnitus, rather than having tinnitus per-se, predict help-seeking behaviour (Attias et al., 1995; Scott & Lindberg, 2000). However, the relationships between these factors are not very clear. Sullivan et al. (1988) found that the levels of distress experienced by tinnitus patients were correlated to the presence of depression. In one study, no difference of self-rated tinnitus loudness was found between patients with and without depression, but depressed patients scored significantly higher on tinnitus severity (Folmer, Greist, Meikle, & Martin, 1999).

The proportion of severely distressed tinnitus patients in a clinical setting having at least one psychiatric diagnose ranges from 63% (Simpson, Nedzelski, Barber, & Thomas, 1988) to 77% (Marciano et al., 2003). The presence of a current depression or mood disorders has been reported to be 46% (Simpson et al., 1988), 60% (Sullivan et al., 1988), and 39% (Zöger, Holgers, & Svedlund, 2001). A corresponding figure for anxiety disorders was 45% (Zöger et al., 2001). Using an Internet-based diagnostic procedure, a 12-month prevalence of 69% for depression and 21-83% for a range of anxiety disorders was found (Andersson, Carlbring, Kaldo, & Strom, 2004), but the validity of this procedure could be put in question.

When broader samples of tinnitus patients are used, the levels of psychological and psychiatric problems drop (Wilson et al., 1991). Andersson, Wallinder et al. (2003) included *all* consecutive patients with tinnitus, also those who did not primarily seek help for tinnitus. The point prevalence for mood disorders was 14%, and 31% for anxiety disorders. Overall, the proportion of patients who had suffered from at least one psychiatric diagnose during their life-time was 59%, which is high but not very high compared to the 50% found in a study of the normal population (Kessler et al., 1994).

Andersson, Batuley et al (2005) have summarised research on stress and tinnitus and concluded that a sub-group of tinnitus patients experience an onset of tinnitus during or after a period of stress, for example prolonged social or work related stress. Furthermore, stress probably has a moderating effect on perceived tinnitus loudness, and the ability to cope with tinnitus. However, the evidence for a stress-tinnitus relationship is rather weak, since none of the studies looking at onset of tinnitus were longitudinal.

It is not very clear what the causal relationships between tinnitus, stress and emotional problems are. It is reasonable to assume they go both ways; tinnitus can affect the level of emotional distress and emotional distress can affect the perception of tinnitus and the ability to cope with it. Sullivan et al. (1988) proposed that from a therapeutic point of view, alleviating one factor would probably be beneficial for the other factor too.

Hearing deficit and sensitivity to sound

Sensitivity to sound, sometimes called hyperacusis (Klein, Armstrong, Greer, & Brown III, 1990), and hearing deficit often accompany tinnitus. These factors have to be taken into account when designing a treatment. It has been estimated that 70% of the individuals with some hearing impairment also have tinnitus (Sheldrake & Jastreboff, 2004) and that 40-60% of tinnitus patients in a clinical setting also have hyperacusis, although this figure is probably lower in individuals with tinnitus not seeking help (Andersson, Baguley et al., 2005). Both sensitivity to sound and hearing loss can be profound problems in themselves, affecting the over-all quality of life (Andersson, 1995). Therefore, it is not unrealistic to assume that the co-occurrence of one or both of these phenomena with tinnitus makes the situation for the individual even worse. A hearing deficit affects the social life of the patient (Andersson, 1995; McKenna, 1993) and tinnitus can probably worsen this by acting as a partial masker of speech, and as a distractor. Sensitivity to sound makes noisy environments even more exhausting, and external noise can also raise the perceived loudness of tinnitus for minutes, hours or sometime days (Tyler, 2000a). The tendency for noise sensitive patients to seek out quiet environments can also heighten their awareness of tinnitus.

Audiometric factors and distress

Henry et al (2005) have stated that “results of psychoacoustic testing of tinnitus perception have been shown repeatedly to have little if any correlation with the degree of tinnitus impact”. This has been supported by many studies (Jakes et al., 1985; Meikle et al., 1984; Risey, 1989; van Veen et al., 1998), although there is some evidence to the contrary (Unterrainer, Greimel, Leibetseder, & Koller, 2003; Hiller & Goebel, 1999). Also, Andersson (2003) have pointed out that the way tinnitus loudness is measured (at a SL or HL) is important, and also found that maskability predicted future distress, whereas hearing-deficit did not (Andersson, Vretblad, Larsen, & Lyttkens, 2001). The last finding is supported by two other studies (Scott, Lindberg, Melin, & Lyttkens, 1990; Andersson et al., 1999).

Subjective ratings of tinnitus loudness, using for example visual analogue scales, have been found to correlate with distress (Hiller & Goebel, 2006) and to do so to a higher degree than audiological measures of loudness (Kuk, Tyler, Russell, & Jordan, 1990). However, one study found no relation between self-rated loudness and distress (Jakes et al., 1985).

Measuring tinnitus distress

An early attempt to categorize tinnitus distress was made by Klockhoff and Lindblom (1967). The Klockhoff tinnitus severity scale, with minor modification by Scott et al. (1990), defines three severity levels;

- Grade I Tinnitus audible only in silent environments
- Grade II Tinnitus can be masked by loud environmental sound. Tinnitus can be disturbing when going to sleep, but does not disturb sleep in general
- Grade III Tinnitus is always audible, disturbs going to sleep and can disturb sleep in general, and is a dominant problem that affects quality of life

This system has several shortcomings; the conceptual problems of mixing “audiological” and distress aspects of tinnitus, using both very narrow markers of sleep-related distress and global ratings of quality of life, and the assumption that maskability of tinnitus is closely related to distress, and that the tinnitus sound itself can affect sleep in general. However, Andersson, Baguley et al. (2005) have pointed out that it has an advantage in being a single global measure of tinnitus severity that has been used in research.

Two structured interviews for assessing tinnitus distress in regular care and clinical trials have been proposed by Andersson et al (1999) and Hiller and Goebel (1999). When it comes to self-report measures of tinnitus distress, Hiller and Goebel (1999) review the nine most common. Andersson, Baguley et al. (2005) concluded that all these measures have some shortcomings, tend to overlap each other to a great extent and that there is no consensus in which one to use. Usually, most questionnaires tend to measure one global factor of tinnitus distress. Other ways of measuring tinnitus distress has been the use of visual analogue scales (Wewers & Lowe, 1990) and open-ended questionnaires (Sadlier & Stephens, 1995).

Treatments for tinnitus

Medical treatments aimed directly at tinnitus

In 1999, Dobie reviewed 69 randomized controlled trials and concluded that no treatment has been found to eliminate tinnitus above placebo level. In later reviews, albeit not systematic, Henry et al. (2005) and Andersson, Baguley et al. (2005) found that only a minority of tinnitus patients can expect tinnitus to be alleviated by medical interventions aimed directly at the tinnitus sound, and that these sub-groups can be hard to define and find.

Intravenous administration of the local anesthetic lidocaine has been found to suppress tinnitus partly or completely for a short period of time. Although an important finding for the understanding of tinnitus mechanisms, lidocaine is

not a practical treatment for tinnitus because of its temporary effects and problematic side effects (Henry et al., 2005). Other drugs, such as antispasmodic and anti-epileptic substances, vasodilators to increase the supply of oxygen to the cochlea and diuretics have been found to be of little use.

Andersson, Baguley et al. (2005) have described two kinds of surgical operations. One aims at destroying parts of the auditory system thought to be involved or necessary for tinnitus perception, often the cochlear nerve. Improvement in tinnitus is seen in about half the patients, but the results are variable and there is a consensus that this procedure is only applicable in cases of no remaining hearing and when other options have been tried. Another method tries to reduce the pathological impact of close-by blood vessels on the cranial/auditory nerves, succeeding in 40-77% of the cases.

Recent reviews by Kleinjung (2007) and Pridmore, Kleinjung, Langguth, and Eichhammer (2006) found repetitive transcranial magnetic stimulation (rTMS) on areas in the cortex involved in the processing of tinnitus to be a promising treatment for patients with certain forms of tinnitus. However, they also concluded that these presumed subgroups need to be defined, and that larger trials with longer follow-ups are needed. Also, apart from these authors' conclusions, a brief overview of the articles included in these reviews show that many use a quite liberal definition of 'responders' and that most often tinnitus related distress or discomfort is being measured, rather than loudness.

Direct electrical stimulation of the ear can reduce or completely suppress tinnitus, but there has been no clinically useful treatment derived from these findings (Andersson, Baguley et al., 2005). Cochlear implants have been found to have a positive effect on tinnitus in 53-83% of the cases, and can be a viable option for deaf or almost deaf patients with severe tinnitus (Henry et al., 2005). In the very small group of patients where tinnitus is a symptom of a temporal mandibular joint dysfunction, dental treatment can relieve tinnitus (Henry et al., 2005).

Szczepanik and Møller (1996) have proposed that benzodiazepines might have a suppressing effect on tinnitus, but according to Andersson, Baguley et al. (2005) their usefulness is limited due to risk of dependence. Antidepressants have been proposed both as a treatment to silence tinnitus and as a way to reduce tinnitus distress. A recent Cochrane review included five trials of antidepressants and found no support for any reliable effect above placebo on tinnitus intensity. In addition, the small effects that were indeed found may be due to methodological shortcomings, such as high drop-out rates (Baldo, Doree, Lazzarini, Molin, & McFerran, 2006).

Medical treatments aimed at tinnitus distress

In their review, Baldo et al. (2006) also looked at the effect of antidepressants on overall disability and tinnitus distress. Mostly, positive results were found, but no conclusion as to whether these would be due to a direct effect on tinnitus distress or via a lowering of depressive or anxiety

symptoms could be drawn. Also, the highest quality study, including non-depressed tinnitus patients, showed no difference between SSRI and placebo (Robinson, Viirre, Bailey, Gerke, & Harris, 2005).

A Swedish study on SSRI was not included in the review due to drop-out rates of 31% in the treatment group (Zoger, Svedlund, & Holgers, 2006). In this excluded study, positive effects were found on tinnitus distress and subjective loudness measured on visual analogue scales. However, a majority of the patients in this study were diagnosed with depression and/or anxiety disorders and it was also more common for non-diagnosed patients to drop-out. This makes conclusions regarding the therapeutic mechanism unclear.

Considering the relationship between tinnitus and insomnia, one interesting treatment for tinnitus patients could be melatonin to enhance sleep. Two less methodologically strict studies have investigated the effect and found promising results, especially for patients with more pronounced sleep difficulties (Megwalu, Finnell, & Piccirillo, 2006; Rosenberg, Silverstein, Rowan, & Olds, 1998).

Audiological treatments for tinnitus

There have been many studies investigating the effect of using noise generating devices (maskers) in order to mask tinnitus partly or completely (Henry et al., 2005). When it comes to complete masking of tinnitus, some controlled studies (Erlandsson, Ringdahl, Hutchins, & Carlsson, 1987; Stephens & Corcoran, 1985) have not found the same effectiveness as in previous retrospective studies. The combination of group therapy and masker was not found to result in better outcome than group therapy alone (Jakes, Hallam, McKenna, & Hinchcliffe, 1992).

Since many patients with tinnitus also suffer from a hearing deficit, hearing aids are often used to help in their every-day life. It has been suggested that hearing aids could have a direct positive effect on tinnitus, mainly by enhancing environmental sound and thus make tinnitus less pronounced (Sheldrake & Jastreboff, 2004). Andersson, Baguley et al. (2005) found the evidence for hearing aids to be mixed, and there is at least one controlled study that shows no effect on tinnitus distress (Melin, Scott, Lindberg, & Lyttkens, 1987).

A widely spread audiological method to help tinnitus patients is Tinnitus Retraining Therapy (TRT). It is derived from the neurophysiological model for tinnitus and promotes the long-term use of noise generators to interfere with, but not mask, the tinnitus sound in order to re-condition it (Jastreboff & Hazell, 2004). This is complemented with “directive counselling” sessions, focused on explaining the neurophysiological model and on how to use the sound generators. Both Andersson, Baguley et al. (2005) and Henry et al. (2005) have found it problematic that the claims of the efficacy of TRT are not backed up by peer-reviewed, randomized controlled studies. Other problems are uncertainties regarding the use of unstandardized outcome measures with

sometimes rather liberal criteria to define improvement (commonly a 20% reduction resulting in success rates between 70% and 85%).

More recently, there has been a controlled comparison between TRT and regular masking treatment, using well established measures of tinnitus distress (Henry et al., 2006). The treatment lasted 18 months and showed an improvement in both groups, with the fastest improvement for regular masking treatment but an increasing effect for TRT. This is encouraging data, although the long treatment period and lack of an untreated or placebo control make it difficult to rule out the effect of time or treatment expectations. One study questions the need for the noise generator in TRT. The treatment program also includes so called “directive counselling” where the therapist gives structured support and information to the patient. Henry et al. (2007) used the directive counselling part of TRT only to design a four-session group treatment and compared to a non-specific group treatment and a no-treatment control group. No differences were found post-treatment, but at a 6- and 12-month follow up the counselling group had better outcome. A drop-out rate of about 30% confounds these results and the effects sizes were not as big as in the TRT versus masker study, but it merits further investigation of “TRT-counselling only” without the actual noise generator compared to regular TRT.

Complementary medicine

For bothersome problems affecting many people and lacking well established solutions, there tend to be a creative, though sometimes commercial, exploration of so called alternative treatments. Patients with chronic tinnitus have been treated with magnesium, zinc, ginkgo biloba, magnesium, St John’s wort, homeopathic remedies, vitamin B, acupuncture, yoga, reflexology, aromatherapy, ear-canal magnets, ear candles, hyperbaric oxygen therapy, ultrasound, and low-power laser (Andersson, Baguley et al., 2005; Henry et al., 2005). These approaches are often only supported by anecdotic or uncontrolled evidence. However, in some areas there are a number of more methodological sound studies, showing effects of temporary nature but seldom above placebo (Andersson, Baguley et al., 2005; Henry et al., 2005).

Psychological treatments for tinnitus

Tyler (2005), and Andersson, Baguley et al. (2005) have listed different forms of psychological treatments that have been used to help tinnitus patients: behavioural, cognitive, humanistic, existential, biofeedback, clinical hypnosis and psychodynamic. In addition, there are many interventions that have a less clear theoretical or traditional framework mixing educational, psychological, and audiological aspects. In his review, Dobie (1999) also included psychological treatments (though his search was limited to Medline-indexed articles only). Dobie has taken a rather sceptical position in concluding that the effects of these treatments have not been shown to be superior to placebo-effects. He does acknowledge the clinical usefulness of placebo effects, but his

conclusion suffers from a rather medically oriented view of placebo. Still, he is right in his observation that there is no specific therapeutic ingredient in the psychological management of tinnitus that has been isolated and proven effective. Thus the positive effects could be general rather than specific factors.

Overall, the effect sizes (Cohen's *D*) for psychological treatments for tinnitus (dominantly cognitive behavioural therapy, relaxation, and stress management/problem solving) have been estimated to be 0.86 for controlled studies, 0.50 for uncontrolled pre-post designs and 0.48 at follow-up after an average of 5.4 months (Andersson & Lyttkens, 1999). Drop-out rates were 14% for the controlled studies and 31% for the pre-post studies. Effects on loudness, negative affect and sleep were found, but these were smaller and the effect on loudness had disappeared at follow-up.

More specifically, Henry et al. (2005) deemed the studies on hypnotherapy and biofeedback to be inconclusive because of methodological problems. Relaxations techniques have been used in isolation or as a part of more comprehensive treatment programs. Ireland, Wilson, Tonkin, and Platt-Hepworth (1985) found minor effects of relaxation when used alone, but Davies, McKenna, and Hallam (1995) found applied relaxation to be as good as cognitive therapy and better than passive relaxation, though all these effects had disappeared at follow-up.

Cognitive behavioural therapy for tinnitus

Cognitive behavioural therapy (CBT) aims at identifying and modifying unhelpful behaviours and thoughts (Barlow, 2001). It is an active treatment; first in the sense that the therapist takes an active part in educating and proposing methods for change to the patient, and secondly because the fundamental principal for relieving distress is that the patients actively try new ways to handle their problems. The latter part is most obvious in the use of homework between session, where the therapist and the patient jointly agrees on what to try out for the next session. The efficiency of CBT for a broad range of psychological problem has been established (Roth & Fonagy, 2005), which should encourage the use of CBT for individuals suffering from tinnitus.

Recently, a Cochrane review was conducted to explore the efficiency of CBT for tinnitus (Martinez-Devesa, Waddell, Perera, & Theodoulou, 2007). Six trials of enough good quality were included; Andersson, Porsaeus, Wiklund, Kaldo, and Larsen (2005) evaluated a group treatment for the elderly against a wait-list, Henry and Wilson (1996) compared CBT to education-only, Kröner-Herwig et al (1995) compared CBT to yoga, Kröner-Herwig, Frenzel, Fritsche, Schilkowsky, and Esser (2003) compared CBT to two minimal-contact groups and wait-list, Rief, Weise, Kley, and Martin (2005) compared CBT to wait-list, and Zachriat and Kroner Herwig (2004) compared CBT to a habituation-based treatment. No significant change in subjective loudness of tinnitus ($d = 0.06$) or depression ($d = 0.29$) were found when compared to a

control group, but a significant reduction of tinnitus distress both when compared to a wait-list control group ($d = 0.70$) and to another intervention ($d = 0.64$).

An earlier meta-analytic review of psychological treatments for tinnitus distress utilized broader inclusion criteria and included eleven CBT-groups (Andersson & Lyttkens, 1999). The non-weighted average within-group effect size for these studies was $d = 0.62$ for tinnitus annoyance/distress at post-treatment. Compared to all other studies in the review, the CBT trials showed a significantly larger effect on tinnitus annoyance.

The positive effects of CBT have also been supported by Henry et al. (2005); “It would appear that the evidence favours cognitive-behavioural over the other forms. It also appears that there have been more controlled studies evaluating cognitive-behavioural therapy than any other type of tinnitus treatment.”

One interesting study added the use of a noise-generator to a 10-session CBT group treatment. Although the noise generator was found helpful for patients with a co-occurrence of hyperacusis, it did not add to the effect of CBT (Hiller & Haerkotter, 2005). Long-term positive effects of CBT have also been found. Andersson et al. (2001) found that patients who had received CBT subsequent to a psychological tinnitus assessment at an audiological clinic had lower levels of distress compared to non-treated patients at a follow-up of on average 4.9 years. However, they still had rather high levels of distress since the majority was defined as Grade II on the Klockhoff scale for tinnitus severity (Klockhoff & Lindblom, 1967).

The theoretical foundations of CBT for tinnitus distress may vary. Henry and Wilson (2001) have a treatment manual with a clear cognitive framework, using the situation-thought-emotion/action model described by Beck (1991). Cognitive restructuring is seen as very important in this tradition, and most methods used in the treatment aims at altering non-functional thoughts in one way or another. Lindberg, Scott, Melin, & Lyttkens (1988) have a more behavioural approach, where relaxation and attention controlling skills are essential, as well as a behaviour analysis to explore and alter the reinforcing or punishing contingencies that maintain the tinnitus distress. Wilson (2006) have discussed this difference but does not find any dilemma in combining these two theoretical viewpoints. In practice, the basic content of CBT for tinnitus is rather much the same although the emphasis on different aspects can differ (Andersson, Baguley et al., 2005):

- Structured clinical assessment/ behavioural analysis
- Treatment rationale and psychoeducation
- Some form of relaxation
- Imaginary techniques and focus exercises
- Modification of negative thoughts and beliefs
- Management of stress, sleep and concentration

- How to relate to environmental sound
- Relapse prevention program

Although the effects of CBT are promising, a study in England showed that few tinnitus patients will ever see a clinician with a CBT-orientation (Coles, 1992). In Sweden, the proportion of therapists educated in CBT is very low, approximately 5% being behaviour or cognitive behaviour therapists and 13% being cognitive therapists (Larsson, Kaldo, & Broberg, In Press). Hence, the availability of CBT for tinnitus patients is almost nonexistent.

Self-help and guided self-help

Introduction to self-help

In the mid-1800s, reading in the hospital as a part of patients' therapy and treatment was recommended (Silverberg, 2003). One of the oldest articles found among the literature on self-help was titled "Bibliotherapy" (Menninger, 1937), and analysed the therapeutic effects of popular presentations of psychiatry given to various psychiatric patient categories.

Today, the general public interest in self-help is considerable; in 2004, the self-improvement industry was estimated to be an almost \$10-billion business, with a market growth of 50% between 2000 and 2004, and more than 3,500 self-help books being published in 2003 (Menchola, 2007). An open website providing computer-based CBT for the general public¹ has shown a large increase in number of visitors since 2001 and had 38 791 registrants between 2003 and 2004 (Christensen, Griffiths, Groves, & Korten, 2006).

Menchola (2007) have observed that self-administered treatments are popular not only among the general public, but also among mental health professionals. For instance, psychologists have been much involved in developing and promoting self-help materials as well as the notion that self-help may be cost-effective, non-intrusive, first-line treatments. In a UK survey among cognitive behavioural therapists, 89% reported that they used self-help material, mostly as a supplement to individual therapy (Keeley, Williams, & Shapiro, 2002). Adams (2000) found that 68% of Canadian therapists used self-help, and that it was more common among more experienced therapists. Another study found that 60% of American psychologist had prescribed self-help as a supplement and that dynamic/analytic psychologists were less likely to do so than psychologist of other orientations (Starker, 1988). Even if making the very conservative assumption that none of the non-responders in these three survey studies (55%, 53%, and 45% respectively) used self-help materials, there would still be 38%, 47%, and 27% respectively who did.

A growing acceptance of using self-help is also shown by the fact that two computerized CBT-based self-help programs, "Beating the Blues" for depression and "FearFighter" for panic and phobic disorders, have recently been approved and recommended by the English regulatory body, the National Institute for Clinical Excellence (NICE) ("National Institute for Clinical Excellence (NICE): Technology Appraisal TA097," 2006). In Sweden, the corresponding authority, The Swedish Council on Technology Assessment in Health Care, has made an announcement that computer-based CBT for depression, panic disorder and social phobia does have empirical support and

¹ <http://www.moodgym.anu.edu.au/welcome>, visited 29-03-08

are to be seen as evidence based treatments of the third level, meaning ‘having a limited evidence base, supported by at least two studies with average evidence level’ (Linton, 2007).

The research on self-help did increase markedly around 1970 (Gould & Clum, 1993). Self-help interventions of some kind has been tested for many different problem areas, for example; parental competency (M. Feldmann, 2007), health anxiety (Jones, 2002), deliberate self-harm (Evans et al., 1999), schizophrenia (Alexander & Buggie, 1967), emotional consequences of infertility (Jacobs, 2004), dating skills (Conner, 1982), flight fobia (Muhlberger, Herrmann, Wiedemann, Ellgring, & Pauli, 2001), rehabilitation of people on long-term sick leave (Brattberg, 2006, 2007), and daily physical activity (Steele, Mummery, & Dwyer, 2007).

Looking through the literature on psychological interventions where the role of the therapist is reduced or eradicated, many different labels appear; bibliotherapy, self-management, telepsychiatry, self-administered treatments, E-therapy, minimal therapist contact, Internet-based self-help, support groups, eHealth, guided self-help, web-based interventions, self-improvement, online therapy, Interactive Health Communication Applications, Interapy and so on. Sometimes these are just different names for the same thing, sometimes the interventions are quite different from each other.

A definition of self-help and guided self-help

Definition of self-help

In an attempt to sort out what is meant by “eHealth”, Oh, Rizo, Enkin, and Jadad (2005) found 51 unique definitions. It is beyond the scope of this thesis to make a thorough review of the literature to find consensus definitions of important concepts. The following definition of self-help, inspired by previous literature on the subject (Andersson, Bergström et al., In Press; Andersson, Cuijpers, Carlbring, & Lindefors, 2007; P. Cuijpers, 1997), is used to summarize what is meant by “self-help” in this thesis:

A self-help intervention can be defined as a standardized, psychological full-length treatment which not only consists of information or psychoeducation and which the patient could work through independent of a therapist.

This means that even though self-help treatments are often rather brief, they are not by default different from face-to-face treatments per se in terms of scope and length. A patient often spends as much time, or sometimes more, in going through a self-help program as he or she would in a corresponding face-to-face treatment. From the self-help treatment material, the patients are taught, often in a step-by-step manner, what they can do to apply specific therapeutic procedures to their problem. General facts about the problem at hand and psychoeducation are often part of a self-help program, but it can not be the

only part. The self-help material can take many different forms - printed text, digital text or multimedia, video, audio and interactive computer applications – and can be made available to the patient through many different channels – books, booklets, CD-ROMs, DVDs, video- and audio-tapes, television, Internet or telephone.

Definition of guided self-help

The treatment has to be described in sufficient detail, so that the patient can go through it without any therapist contact. If the treatment includes any contact with a therapist, it should instead be labelled “guided self-help”. The therapist contact is often not primarily aimed at developing a traditional relationship between therapist and patient, but rather to support and facilitate the use and completion of the self-help treatment and involve guidance on where to seek more help if needed. Sometimes the therapist-contact is better described as an administrative and technical support and sometimes the therapist’s involvement in the treatment is profound and on a more personal level in relation to the patient. Contact with therapists can be by personal contact, by telephone, by e-mail, by mail, or any other communication method.

Four levels of therapist contact is proposed (adapted from Newman, Erickson, Przeworski, and Dzus (2003) and Scogin, Bynum, Stephens, and Calhoun (1990):

1. Self-administered self-help (no therapist contact, or contact only for assessment but not for treatment purposes).
2. Minimal contact self-help (therapist contact for assessment and periodic check-ins, teaching patients how to use the self-help tool, and/or for providing the initial therapeutic rationale. The active, specific therapeutic ingredients are thought to be within the self-help program, the purpose of the therapist contact is mainly to support the patient going through the self-help program).
3. Therapist-guided self-help (a more active involvement of a therapist, though to a lesser degree than in traditional therapy. The therapist interaction is meant to have a more specific therapeutic effect rather than being just supportive).
4. Therapist-administered treatments including self-help (clients have regular contact with a therapist and the self-help tool is used to enhance the impact of the traditional therapy).

One final note on the communication between patient and therapist is that it can be either synchronous or asynchronous. The first includes direct speech face-to-face, on a telephone, in a videoconference or in a chat-room. The second refers to written text or sometimes recorded audio-messages where the receiver does not respond immediately but after some delay, as in mail, e-mail or web-based forums.

Different forms of self-help

According to the above definition of self-help, interventions such as social support-groups (Barlow, Burlingame, Nebeker, & Anderson, 2000), information and psychoeducation, non-standardised e-mail therapy or Online therapy (Rochlen, Zack, & Speyer, 2004), bibliotherapy in the sense of “the therapeutic use of fictional books” (du Plock, 2005; Gottschalk, 1948; 2003), virtual reality tools used to for example aid exposure therapy (Tate & Zabinski, 2004) and the broad labels of “telemedicine” or “telepsychiatry” (Carignan & Krebs, 2006) is not equivalent to self-help. On the other hand, self-help groups following a structured treatment manual, could be seen as self-help, and the many commercial self-help books could in some cases probably also be considered self-help according to the above definition.

The two forms of self-help most relevant to this thesis are self-help books and computer-based self-help.

Self-help books

The use of self-help books means that the patient receives a text-based psychological treatment program with psychoeducation and practical advice on how to work with a specific problem. They are written to be read directly by the patient and to be easily understood, and they often propose the patient to go through the treatment in a structured and step-by-step manner. Forms or questionnaires for self-diagnosing, self-monitoring or performing different kinds of exercises or tests are often included.

Computer-based self-help

This is used as a broad term to include all sorts of self-help that are mainly administered by the use of a stand-alone or Internet connected personal computer, whether or not it is based on text or multimedia, presents static or interactive treatment material, includes computer-mediated communication with a therapist, or use decision algorithms or computed feedback to guide the patient through the treatment.

Marks, Cavanagh, and Gega (2007) coined the expression “computer-aided psychotherapy”, but this is a broad term and it is unclear *what* the computer aids in. To clarify, “computer-guided self-help” is here defined as computer-based self-help where the computer, rather than the therapist, is the active counterpart in the interaction with the patient, making decisions, suggestions or presenting personalized feedback based on patient input.

Internet-based self-help means computer-based self-help that is using the Internet to provide the patient with therapeutic material, and a way to communicate with a therapist. This term needs to be further specified, e.g. whether this is a standardized, text-based self-help treatment with no interaction, or if it includes interactive feed-back and guidance by either a computer, a human therapist, or both. Another distinction to make is whether

the websites are open to public access or closed for everyone except referred and/or assessed patients. The former, for example Christensen et al. (2006), can be seen as interventions aimed at enhancing the public health on a broad level, whereas the latter is more closely related to psychotherapy with diagnosed patients in a clinical setting.

A treatment via the Internet, in contrast to one on a stand-alone computer, can in itself incorporate patient-therapist communication, and is easily accessible and up-dated. These are the main advantages of Internet-based self-help compared to computer-based self-help delivered via DVD's or CD-ROM's.

Outcome of self-help and guided self-help

Outcome of self-help in general

Before Scogin et al. (1990) made their meta-analysis, reviews of self-help treatments were not very structured and came to different conclusions on which problems were suitable for self-help (Glasgow & Rosen, 1978; Riordan & Wilson, 1989; Schrank & Engels, 1981; Stevens & Pfof, 1982). Scogin et al found that the effect size (Cohen's D) for (mainly) text-based, self-administered treatments was 0.96 and 1.19 for minimal-contact self-help. They did not find effects due to therapist contact or differences between self-help and traditional treatment; although they observed that the traditional treatments in these studies might have been presented in less potent forms.

Gould & Clum (1993) included 40 studies which covered a wide range of problem areas in different settings. The overall effect size was 0.76 and 0.53 at follow-up. Marrs (1995) summarized 79 studies (80% using self-help books, 14 unpublished) and found an effect size of 0.57 but with significant heterogeneity among the studies. Estimates of follow-up effects showed no decline from post-treatment.

In a meta-analysis regarding clinical depression and anxiety (den Boer, Wiersma, & Van den Bosch, 2004) the authors found an effect size of 0.84 at post-treatment and 0.76 at follow-up compared to control groups, and no differences when self-help was contrasted to another active treatment.

Menchola (2007) noted that previous reviews were difficult to interpret and thus limited their meta-analysis on clinical depression and anxiety to studies with self-administered or minimal-contact self-help with a maximum of 15 minutes therapist contact a week and found an effect of 1.00 which was maintained at follow-up.

In the first review of Internet-based self-help, Ritterband et al. (2003) included 12 studies. Four years later, Barak et al. (In Press) found 92 independent studies. Tate & Zabinski (2004) made a selective review of some Internet- and computer-applications for psychological treatments. All these reviews yield positive results but suffer from using broad inclusion criteria and

less stringent methodology. Kaltenthaler et al. (2006) made a review of twenty studies of computer- and Internet-based self-help treatments, often with low levels of therapist support, and these treatments seemed to be more effective than treatment as usual and as effective as traditional CBT.

A recent meta-analytic review that focused solely on Internet-based self-help for anxiety and depression was presented by Spek et al. (2007). This review included 12 studies with both self-administered (sometimes computer-guided) and minimal contact therapist-guided treatments. The latter tended to use closed sites with more careful pre-treatment assessments and diagnoses, and the former used open sites with shorter or no screening procedures. The treatment studies showed an overall effect size of 0.60. However, the effect of therapist support was quite large, and the interventions with minimal contact showed an effect size of 1.00.

Taken together, this is promising results for self-help and guided self-help in general, regardless if given via the Internet or as a self-help book.

Self-help studies relevant for tinnitus distress

The literature on self-help for tinnitus is very scarce. One study of bibliotherapy based on fictional books, and thus not really defined as self-help here, has been found within the audiological area. Bryant & Roberts (1992) used this approach for audiological counselling of deaf and hard-of-hearing individuals and their family members. No specific effort for addressing tinnitus distress was undertaken and no quantitative evaluation was done. There are a number of self-help books for tinnitus (Davis, 1995; Dunmore, Riddiford, & Tait, 2003; Goebel, 2003; Hallam, 1989; Henry & Wilson, 2002) but though they sometimes are based on treatments evaluated in clinical trials, the actual books have not been empirically tested.

Axelsson, Nilsson, and Coles (1995) did propose some guidelines on how to best design information texts about tinnitus, but did not test any therapeutic effect of information. One study investigated if a short leaflet could be used to reassure patients complaining of tinnitus (Loumidis, Hallam, & Cadge, 1991). Tinnitus distress for the informed and non-informed subjects did not differ, although the leaflet group reported having significantly fewer 'unfulfilled needs' and were less likely to want a medical cure or professional guidance.

The above studies do not give much information on the possible success of a self-help approach to tinnitus. A more relevant study is the one performed by Henry & Wilson (1996) which compared education alone to a combination of education and cognitive therapy, both delivered in a group format. The education-only group had better results than a wait-list control group on knowledge about tinnitus, coping skills and irrational beliefs, but the groups did not differ on tinnitus distress. Compared to the group with combined education and cognitive therapy, the education-only group had significantly lower improvements on tinnitus and emotional distress but not on any other measure.

Another study compared minimal contact group therapy to regular group CBT (11 sessions) for tinnitus (Kröner-Herwig et al., 2003). One minimal contact group (2 sessions) presented a model of tinnitus distress and gave advice on different self-help strategies. The other minimal contact group (4 sessions) presented the same model but focused on relaxation. The regular group treatment was found to be superior to the minimal-contact interventions, but not on all measures, and the same was true when comparing the minimal-contact treatments to a wait-list control group.

The most relevant study is an RCT of a Swedish CBT-based Internet self-help treatment, which preceded the clinical trials in this thesis (Andersson, Strömberg, Ström, & Lyttkens, 2002). 117 tinnitus patients from all over Sweden were recruited via media. Screening was done with a structured interview for tinnitus distress (Andersson et al., 1999) adapted to the Internet. The self-help treatment included the possibility for patients to send e-mails to the therapist and the therapist sent a short, generally encouraging e-mail when the patients had reported their homework on the website.

The main problem with this study was the large drop-out and attrition; 51% in the treatment group and none in the wait-list group. The design of the website did not allow drop-outs to easily access the post-treatment questionnaires, which makes drop-out from treatment equivalent to attrition from the study.

The results showed a significantly greater reduction on tinnitus distress for patients in the treatment group compared to the wait-list group. These results basically remained at the follow-up (with a better response rate of 81%), also showing lower distress for the control group now having received the treatment. The results could be summarized as promising, but hampered by large drop-out and attrition rates.

Considering the shortage of previous tinnitus self-help studies, a brief review of specifically relevant studies is also presented here.

A review (Cuijpers, van Straten, & Andersson, In press) of cognitive behaviour therapy Internet-based self-help for different health problems included twelve studies and showed effect sizes close to those found in traditional treatment for chronic pain, headache and a mixed symptoms group.

Considering the relationship between tinnitus and sleep difficulties, self-help studies aimed at insomnia are of interest too. Results from a number of studies have shown significant improvement compared to control groups, also at follow-up (Alpers & Biglan, 1979; Bastien, Morin, Ouellet, Blais, & Bouchard, 2004; Mimeault & Morin, 1999; Morawetz, 1989; Morin, 2005; Riedel, Lichstein, & Dwyer, 1995). Morin (2005) wanted to see if these results also held true for individuals not necessarily fulfilling all diagnostic criteria for primary insomnia and found significant but small to moderate effect sizes ($d = 0.10 - 0.33$). This was probably also due to less therapist contact, lower initial levels of sleep difficulties and a briefer treatment manual compared to previous studies. In an Internet-based self-help treatment for insomnia, Ström,

Pettersson, and Andersson (2004) found low effect sizes, although these results are difficult to interpret because of an unexpected decrease of sleep problems in the wait-list control group.

The role of the therapist

Looking at the promising results of self-help, it is possible to question the importance of the traditional therapist role (Marks et al., 2007). Maybe somewhat surprisingly, preliminary results have shown the alliance between patient and therapist to be as strong in online e-mail therapy as in face-to-face treatments (Cook & Doyle, 2002; Prado & Meyer, 2006).

For self-help, outcome, drop-out and cost-effectiveness seem to be related to degree of therapist-contact (Baer, Greist, & Marks, 2007; Palmqvist, Carlbring, & Andersson, 2007), but the results are mixed and rather inconclusive. Earlier meta-analyses on self-help books and audio/video-based self-help (Gould & Clum, 1993; Marrs, 1995) have not reported any major impact of therapist contact on outcome. However, considering the diverse problem areas, treatment modalities and outcome measurements in these reviews it is almost impossible to draw any firm conclusions. In addition, among the problem areas with a higher number of studies (and thus higher statistical power), the correlation between therapist contact and outcome was actually significant (Marrs, 1995).

Menchola (2007) also found that individual therapist-administrated treatments were significantly better than minimal contact self-help in his selected sample of studies with minimal contact self-help and patients with higher levels of initial distress. Spek et al. (2007) found a significant effect of therapist contact on outcome. Likewise, correlating effect sizes and “minutes spent on each patient” in Internet-based self-help, Palmqvist et al (2007) found a positive correlation of $\rho = 0.75$.

In one study of a no-contact, open website treatment for depression, it was found that the initial lack of efficiency was somewhat dealt with using simple mail or telephone reminders to engage in the treatment (Clarke et al., 2005). On the other hand, in a study on headache by Andersson, Lundström, and Ström (2003), adding scheduled telephone contact did not boost the effect.

Cost-effectiveness

Self-help might be a cost-effective treatment, but very few studies are actually looking at this aspect (den Boer et al., 2004). Kaltenthaler et al. (2006), and Palmqvist, Carlbring, and Andersson (2007) found it too early to draw any firm conclusions regarding the cost-effectiveness of self-help. However, some positive indications exist. An economic evaluation of the depression program *Beating the Blues* showed that it was cost-effective compared to treatment-as-usual when analyzed as cost per quality-adjusted

life-year (QALY) (McCrone et al., 2004). One recent study found that over 1 year, internet-delivered CBT for GAD generated lower costs as compared to care as usual (Paxling et al., 2007). Strom et al. (2000) concluded that headache treatments with reduced therapist contact has been well studied and produce results better or equivalent to in-clinic treatments or drugs, with an time/cost-effectiveness estimated to be five times as good as standard treatments.

Drop-out from treatment and loss of post-treatment data

Drop-out from treatment and attrition (loss of post-treatment data) can be serious problems in self-help studies. For example in Strom, Pettersson, and Andersson (2004) and Andersson, Strömngren et al. (2002), about half of the subjects in the treatments groups finished treatment prematurely and/or did not report any post-treatment data. Drop-out varies a lot between different trials, and Baer et al. (2007) have argued that participants seem more likely to complete computer-based self-help if they are screened, given a personal login to a closed website, and are supported briefly by phone, email or face to face. On the other hand, dropout rates may increase markedly on directly accessible, unmonitored websites. From an evaluative perspective, attrition from the study leading to loss of data regardless if patients drop out from treatment or not, is a crucial problem. Without post-treatment data for the drop-outs, it is impossible to find out if these are related to deterioration (maybe less easily detected in self-help treatments), to patients reaching their treatment goals before the last step in the self-help treatment or to any other reason. Weekly distress assessments and therapist contacts, scheduled follow-up interviews and an extra effort to collect post-measurements can be solutions to this problem.

Critique of self-help

Gerald Rosen is one of the most prominent sceptics in the area of self-help research and implementation. Having conducted his own research on self-help, in the late eighties he did warn for the more and more widespread and commercially coloured use of self-help books, including one of his own (Rosen, 1987). Exaggerated claims and examples of failures of self-help when used without any therapist contact, together with the risk of negative self-attributions and lowered belief in the possibility of improving even by traditional psychotherapy are some of the proposed problems. This makes Rosen state that self-help is less of “giving psychology away” and more of “finding new ways to sell it”. Since his first article he has repeatedly (Rosen, 1993; Rosen, 2004) criticized non-tested books being sold on the market and being widely recommended by therapists. Floyd, McKendree Smith, and Scogin (2004) have agreed that the primary problem is the lack of quality control of self-help books being marketed to the public, but have also argued

against the possibility to make conclusions on the overall impact of self-help books. They also point out that requiring rigorous research support prior to publication would be holding self-help books to a higher standard than is currently required for therapists, and that also self-administered treatment without any therapist contact is probably at least benign and potentially helpful.

Pros and Cons of self-help

Table 2 summarizes some of the possible advantages and disadvantages with self-help, mainly based on comments found in the literature (Andersson et al., 2007; Ellis, 1993; Menchola, 2007; Ritterband, Andersson, Christensen, Carlbring, & Cuijpers, 2006; Rochlen et al., 2004). Some of these aspects might be supported in the current empirical literature, but for the present they are first and foremost to be viewed as more or less plausible hypotheses.

Table 2. *Summary of possible advantages and disadvantages with self-help*

Advantages	Disadvantages
A cost-effective use of health resources	Possibly more useful and accessible for some patient groups, could increase inequities in health care if widely used
Can reach more patients (geographically and groups with special needs)	Cost-effective but possibly overall lower quality of care
Increased diversity and choice for the patients in health care	Risk for higher proportion of failed treatments, might lead to negative self-attributions, hopelessness, and a decrease in further help-seeking behaviour
Increased patient knowledge of the problem and possible treatments	Might lead to further commercialization and non-evaluated self-help programs
Opportunities for continuous evaluation and research	Less clear responsibilities between patients and therapists
Possible therapeutic strengths:	Poor assessment of problems leads to mismatch between diagnose and treatment
More disinhibition (Joinson, 1998), making self-disclosure easier	Risk for lower security and personal integrity
Therapeutic effects of writing	Possible therapeutic limits:
Time for reflection in asynchronous communication	Might encourage clients to cherry-pick easy but less effective methods
Easier to focus on the presenting problem	Misunderstandings and loss of information due to lack of non-verbal or visual cues
Enhance patients' responsibility and self-efficacy	Fragmented communication.
Manuals minimize the risk of important aspects being left out	Less flexible to patients needs
More frequent and available information, contact, and monitoring	Undetected crisis and problems
	Increased patient workload might lower motivation and cause drop-out

Coping, readiness to change and predicting outcome

Coping strategies

Coping has been defined as the process of managing demands that are appraised as taxing or exceeding the resources of the person (Lazarus & Folkman, 1984). How an individual copes with chronic symptoms are probably important for both for long term and short term distress. Coping is important to study in itself, but also in relation to treatment because it can give ideas on which strategies could be helpful to patients currently not dealing very well with a problem. Also, there might be an positive or negative interaction between coping strategies used by a patient before treatment and the strategies advocated by the treatment

There have been a number of studies on coping and tinnitus, with rather inconclusive results. Hallberg, Erlandsson, and Carlsson (1992) found that men with severe tinnitus tended to engage in “escape coping”, compared to controls. George and Kemp (1991) showed that tinnitus sufferers tried different ways to cope, even when these coping strategies were not effective, and that patients with more severe tinnitus used more coping strategies.

In one study, maladaptive coping, such as “Asking what you have done to deserve your tinnitus”, was significantly correlated with tinnitus severity (Budd & Pugh, 1996). But also coping defined as effective, for example “Reminding yourself that you can still enjoy life despite your tinnitus”, was positively correlated to tinnitus problems, although not significantly.

Henry and Wilson (1995) and Andersson, Kaldo-Sandström, Strömberg, and Ström (2004) used only one scale for overall coping, divided into two aspects of coping; *frequency* and *benefit*. These studies focused more on behavioural coping strategies and less on cognitive and emotional coping. In both studies there were tendencies for more coping to be related to more tinnitus distress. In Andersson et al. (2004), when controlling for depression, anxiety and anxiety sensitivity, the association between coping benefit and distress disappeared, but the association between coping frequency and distress remained. Only one coping strategy out of 33 had a significant negative correlation with tinnitus distress; “I continue with my daily life as if the tinnitus is not there”, suggesting that acceptance might be a fruitful way to cope.

These studies show that it is often problematic to separate ‘coping strategies’ from ‘negative consequences of tinnitus’, which calls for a conceptual clarification and refined measurement of the coping concept with regard to tinnitus.

Predictors of treatment success

The possibility to early on identify patients who might not benefit from a specific treatment would be valuable (Newman, 2000). These patients could then be given extra attention or support or could be referred to another treatment with a better chance of helping them.

Regarding tinnitus, no studies on which factors predict treatment outcome have been found. Considering self-help, Newman (2000) have made the point that self-help approaches may not be appropriate for everyone, and that more effort should be used to find individual predictors of treatment outcome. Marrs (1995) reported some findings of a positive relation between internal locus of control and outcome. An Internet-based self-help program for depressed patients had the same predictive factors as found in traditional therapy; number of previous episodes and low quality of life were negatively associated, while levels of depression and anxiety were positively correlated with improvement after treatment (Andersson, Bergstrom, Hollandare, Ekselius, & Carlbring, 2004). Other factors that have been found to be important are initial expectations of benefit (Ogles, Lambert, & Craig, 1991) and anxious personality disorder and agoraphobic avoidance in a study on panic disorder (Andersson, Carlbring, & Grimlund, In Press).

Stages of Change and the transtheoretical model

One way to find predictors might be to use the concept of ‘Stages of Change’, that are an important part of the transtheoretical model (TTM), developed by Prochaska and DiClemente (1983). The Stages of Change are designed to investigate how prepared patients are to change their behaviour in regard to a problem. Patients not prepared for change might benefit from therapy aimed at motivating or enhancing insight, whereas patients who feel ready to change their behaviour, or already have started to do this, might benefit more from a more direct self-management approach. Thus, in theory, the current stage of a patient together with its match (or mismatch) to a specific treatment should predict outcome.

The Stages of Change has mainly been applied to cigarette smoking, drug and alcohol problems, diet, and exercise (Prochaska & DiClemente, 1983; Prochaska, Rossi, & Wilcox, 1991; Sutton, 2001). Usually, five different stages are used;

- Precontemplation (not recognizing the problem or believing that it cannot be solved by behavioural or attitude change)
- Contemplation (considering the possibility that behavioural or attitude change might influence the problem, but not being very interested in actually doing anything differently)
- Preparation (being more interested and ready to try out different ways of coping with the problem)

- Action (actively changing behaviours and attitudes)
- Maintenance (changes have been made and are now maintained)

Contemplation and Preparation are sometimes combined into one single stage, and Action and Maintenance have in some studies been merged (Dijkstra, Vlaeyen, Rijnen, & Nielson, 2001; Rollnick, Heather, Gold, & Hall, 1992; Strong, Westbury, Smith, McKenzie, & Ryan, 2002).

Strong et al. (2002) and Kerns & Rosenberg (2000) evaluated the ability of the Stages of Change to predict outcome in CBT for chronic pain, an area closely related to tinnitus. It showed low predictive value, although the Contemplation and Precontemplation scales in the latter study did predict if patients engaged in a self-management treatment or not. After the publication of study IV in this thesis, two German studies on a questionnaire of the Stages of Change adapted for tinnitus patients have been found. The first found four scales in accordance with the theory (Maurischat, Battlehner, & Harter, 2006) and the second confirmed these findings (Harter, Battlehner, Munscher, Graul, & Maurischat, 2005). However, none of these studies did test the predictive abilities of the questionnaire.

The Stages of Change and the TTM have been criticized for tending not to find discrete stages rather than continuums, not succeeding in reliably placing patients in a specific stage, and not being able to match patients and treatments (Littell & Girvin, 2002; Sutton, 2001). However, Clarkin and Levy (2004) concluded that it appeared that the Stages of Change can have predictive value, although almost all research has been done on habit disorders and its application to other areas would need further investigation.

In summary, the potential use of the Stages of Change to predict treatment outcome for tinnitus sufferers is worth investigating, both in order to find useful clinical tools and to explore the generalizability of the Stages of Change and the TTM.

The Empirical Studies

Aims

Overall aim of the thesis

This thesis intends to evaluate the immediate and long-term outcome of a CBT-based, structured self-help treatment with varying degrees of therapist guidance, given via the Internet or as a self-help book, aimed at lowering tinnitus distress. Secondary aims were to:

- examine the treatment effects on secondary measures of sleep problems, depression, anxiety and subjective self-ratings of tinnitus loudness
- investigate if the effects could be generalized to a routine clinical setting with consecutive patients
- estimate the therapist time-effectiveness (therapist time spent on treatment in relation to treatment outcome) as one aspect of cost-effectiveness
- find pre-treatment and process factors, including amount of therapist contact and treatment credibility, that predict outcome
- specifically investigate if the Stages of Change could be applied on tinnitus patients and be used for predictive purposes
- study and possibly reduce attrition and drop-out

The aims of the specific studies

Study I *Internet-Based Cognitive–Behavioural Self-Help Treatment of Tinnitus: Clinical Effectiveness and Predictors of Outcome.*

To evaluate the outcome of an older version of an Internet-based self-help treatment with e-mail support in a sample of consecutive tinnitus patients in a clinical setting, in order to confirm the previous positive results of an RCT. Another aim was to explore if pre-treatment and process factors could predict outcome.

Study II *Internet versus group cognitive-behavioural treatment of distress associated with tinnitus. A randomized controlled trial.*

To examine the effectiveness of a new, expanded version of the Internet-based treatment and compare it with a traditional face-to-face group treatment. Secondary aims were to estimate therapist time-effectiveness, to examine treatment credibility and preference

and the effects these factors have on outcome, and to investigate if the new version of the Internet treatment differed in drop-out and outcome compared to the earlier version.

Study III *Use of a self-help book with weekly therapist contact to reduce tinnitus distress: A randomized controlled trial.*

To investigate the effectiveness of a self-help book with weekly telephone calls on reducing tinnitus distress. Secondary aims were to estimate therapist time-effectiveness and to preliminarily test the difference between weekly therapist telephone contact and one initial telephone call only.

Study IV *Tinnitus Stages of Change Questionnaire: Psychometric development and validation.*

To develop and test the psychometric properties and predictive abilities of the Stages of Change Questionnaire (TSOCQ), derived from previous work on Stages of Change and the transtheoretical model. The TSOCQ intends to assess tinnitus patients' readiness to change their behaviour and attitudes in relation to tinnitus and could thus possibly predict treatment outcome.

Methods

Design and procedure

Study I

Study I evaluated a slightly modified version of the Internet-based self-help treatment being used in Andersson, Strömberg et al. (2002), used in a routine clinical setting. No control group or randomization procedure was used. Distress was assessed at pre- and post-treatment and at a three month follow-up. All self-report assessments were done with Internet-based questionnaires, included in the same website as the self-help treatment. Before treatment, a structured clinical tinnitus interview (Andersson et al., 1999) was performed face-to-face (n=66) or as a questionnaire on the Internet (n=11).

Study II

Study II was a randomized controlled trial with pre-, post- and one year follow-up assessments, comparing a newer version of Internet-based self-help treatment to traditional group treatment CBT. No untreated control group was used.

The pre-treatment assessment was preceded by a brief telephone call and a short Internet-based screening form. At each following assessment point, a battery of paper-and-pen self-rated questionnaires was used. At pre- and post-assessment these were complemented with one week of daily VAS-ratings of tinnitus distress, tinnitus loudness and perceived stress. To get a better picture of the participants and to reduce attrition, pre- and post-treatment face-to-face assessment interviews were scheduled. These included a therapist global rating of tinnitus distress. The questionnaires were filled out at the clinic just before the interview. At follow-up, no meeting was scheduled, although telephone calls were made to remind the participants to return the questionnaires.

Study III

Study III was a randomized controlled trial with pre-, post- and one year follow-up assessments, comparing a self-help book with telephone support to a wait-list control. In many respects the procedure was the same as in study II, with some exceptions;

- The wait-list control group received the self-help book and an initial telephone call after they completed the post-treatment assessment. Six weeks later, they filled out a second post-treatment assessment. This was done for ethical reasons (not withholding treatment) and to be able to estimate the importance of therapist contact by comparing this group receiving one telephone call with the original treatment group receiving seven telephone calls.
- The pre- and post-treatment interviews were performed via the telephone and the paper-and-pen questionnaires were mailed to the participants.

Study IV

Study IV consisted of the participants from the study II and III, who were given a long version of the TSOCQ at the pre-treatment assessment. After a factor-analytical process to remove the less useful items and define the scales of the TSOCQ, the results on these scales were correlated with the participants' change score in tinnitus distress to explore their predictive abilities.

Participants

For study I, all participants were recruited from tinnitus patients waiting to receive psychological treatment at the audiological clinic at Uppsala University Hospital. A small minority of participants in the other trials was also recruited this way, but study II and III mainly recruited participants via advertisements in media and on websites relevant to tinnitus.

For study I, II, and III, participants could be included if:

- they had undergone a medical examination for tinnitus, either at the clinic where the treatment was held or by an external Ear–Nose–Throat specialist or an audiological physician. This was done to ensure that tinnitus was not a

symptom of a more serious medical condition needing further attention and that no medical intervention would be likely to affect the tinnitus sound

- they were at least 18 years old
- they had a tinnitus duration of at least 3 (study II) or 6 (study III) months. No participant in study I had had tinnitus for less than 5 months
- tinnitus was the main problem and of major concern. In study I, this was operationalized as Grade II or III on the Klockhof tinnitus severity scale (Scott et al., 1990) and in study II and III as scoring 10 or above on the TRQ and below 19 on both the anxiety and depression subscales of the HADS. An overall estimation of these criteria was also made by the assessor
- they did not experience problems that might obviously interfere with the treatment, for example psychiatric, social, or medical problems, practical obstacles like vacations, travelling long distances (in study II), no access to Internet (study I and II), very low reading abilities, or very low computer skills (study I and II)
- they agreed to work towards the main goal of the treatment; i.e. to reduce tinnitus distress and not tinnitus loudness

In study I, five patients were excluded because the referring physician did not find them eligible for treatment and therefore they were not requested to participate. Unfortunately, no data on the number of patients declining to participate in the Internet treatment was collected.

In study II, 26 out of 77 (34%) were excluded or declined to participate before randomization, and in study III the corresponding figure was 54 out of 126 (43%).

Study IV did include some of these excluded participants in the initial factor analysis of the TSOCQ ($n = 151$), since they had filled it out before they were excluded. However, the predictive analyses were only made for participants included in study II and III who also filled out the post-treatment questionnaires ($n = 123$).

The characteristics of participants are found in Table 3, which also includes the treatment group from the former RCT by Andersson, Strömberg et al. (2002) as a comparison group (in italics).

Measurements

Main outcome measure

In all studies, the Tinnitus Reaction Questionnaire (TRQ) was used as the main treatment outcome measure (Wilson et al., 1991). The TRQ assesses tinnitus annoyance and distress with 26 zero- to four-point items summated into a total score. Wilson et al. (1991) reported an internal consistency (Chronbach's alpha) of $\alpha = .96$ and a test-retest correlation of $r = .88$. A 50% reduction of the mean TRQ score was used throughout the studies to define a

Table 3. Background data and initial distress level at pre-treatment measurement in study I-III and a previous study not included in this thesis (Andersson, Strömberg et al., 2002).

Characteristic	Internet treatments			Self-help book		
	<i>Andersson, Strömberg et al. (2002)</i>	Study I	Study II	Study III		
		<i>Old website in previous study</i>	Old website (Clinic)	New website	Group treatment	Weekly telephone
Number of participants	53	77	26	25	34	38
Initial tinnitus distress; Tinnitus Reaction Questionnaire, M (SD)	42.6 (21.6)	33.0 (17.0)	26.4 (15.6)	30.0 (18.0)	38.7 (23.1)	36.7 (24.5)
Age in years, M (SD)	48.5 (12.3)	46.1 (13.8)	47.4 (12.9)	45.0 (12.8)	45.9 (13.0)	48.5 (15.7)
Gender, %						
Female	46	48	42	44	50	47
Male	54	52	58	56	50	20
Marital status, % ^a						
Married or living with partner	-	-	65	64	68	52
Single or divorced	-	-	8	16	18	24
Missing data	-	-	27	20	14	24
Years of education, M (SD) ^a	-	-	14.9 (3.9)	13.9 (3.1)	13.4 (3.0)	14.1 (2.9)
Occupational status, %						
Retired	-	-	8	8	9	26
Full/part time work/study	-	-	65	80	65	55
Unemployed or on sick leave	-	-	27	12	26	19
Years since onset, M (SD)	6.2 (5.6)	7.0 (8.0)	9.9 (13.5)	5.6 (6.1)	8.6 (8.4)	12.4 (11.7)
No. of previous treatments for tinnitus, M (SD)	-	1.16 (1.26)	0.5 (1.1)	0.6 (1.2)	1.4 (1.7)	1.7 (2.0)
Tinnitus location, %						
Left	40	25	58	40	33	32
Middle / Both / Head	41	27	31	52	52	47
Right	19	48	11	8	33	21
Does tinnitus change? %						
Yes	-	-	81	92	79	87
No	-	-	19	8	21	13
Constant tinnitus sounds, %						
None	-	-	0	4	3	3
One	-	-	77	60	56	60
Two or more	-	-	23	36	41	37
Intermittent tinnitus sounds, %						
None	-	-	28	40	38	37
One	-	-	52	36	41	10
Two or more	-	-	20	24	21	53
Absolute tinnitus loudness, dB						
HL, M (SD)	-	35.6 (18.3)	-	-	-	-
Relative tinnitus loudness, dB						
SL, M (SD)	-	9.5 (10.3)	-	-	-	-

Table 3. *Cont.*

Masking/distraction possible? %						
Not at all	-	-	4	4	6	6
A little or rather much	-	-	58	76	82	68
Very much or completely	-	-	38	20	12	26
Minimal masking level, dB HL,						
M (SD)	-	50.3 (24.3)	-	-	-	-
Hearing deficit, %						
No	31	-	28	28	29	35
Not distressed at all or only a little distressed	<i>unknown</i>	-	36	40	29	19
Rather much, much or very much distressed	<i>unknown</i>	-	36	32	42	46
Pure-tone average, dB HL,						
M (SD)	-	15.2 (14.3)	12.8 (7.4)	16.2 (15.7)	-	-
Using one/two hearing aids, %	-	10	12	16	21	21
Sensitive to external sounds? %						
Not more than others or just a little	40	-	31	24	26	18
Rather much	<i>unknown</i>	-	23	32	29	34
Very or extremely much	<i>unknown</i>	-	46	44	45	48

^{a)} Data on “marital status” and “years of education” were collected at follow-up and hence was not applicable for participants not returning the follow-up questionnaire.

clinically significant improvement, indicating that a patient did not just improve or improve slightly but experienced a personally significant and marked improvement (Henry & Wilson, 1996). The TRQ was also the measurement used to compute effect sizes.

Complementary tinnitus distress measures

The Tinnitus Handicap Inventory (THI) (Newman, Jacobson, & Spitzer, 1996) consists of 25 items (scored 0, 2 or 4) and was used in study II and III to enhance the comparability with other tinnitus treatment studies (Berry, Gold, Frederick, Gray, & Staecker, 2002). Newman et al. (1996) reported an internal consistency of $\alpha = .93$.

In study II and III, daily ratings of tinnitus loudness, tinnitus distress and perceived stress were made on visual analogue scales (VAS) (Wewers & Lowe, 1990). A mean score for one week was calculated for each dimension.

Other distress measures

The Hospital Anxiety and Depression Scale (HADS) is widely used and has two subscales measuring depression (HADS-D) and anxiety (HADS-A) with 7 items (response scale 0–3) each (Zigmond & Snaith, 1983). HADS was designed to be particularly suitable for use with patients with somatic problems, since it focuses on symptoms of anxiety and depression that are less affected by somatic symptoms. Importantly, the psychometric properties for

HADS have been found to be basically the same regardless if it is delivered to tinnitus patients as a paper-and-pencil questionnaire or via the Internet (Andersson, Kaldo-Sandström, Ström, & Strömgen, 2003), with internal consistencies of $\alpha = .83$ for HADS-A and $\alpha = .88$ for HADS-D, and test-retest correlations of $r = .84$ for HADS-A and $r = .71$ for HADS-D.

To measure sleep problems, the Insomnia Severity Index (ISI) was used (Bastien, Vallières, & Morin, 2001). The ISI is a brief 5-item (scored 0-4) questionnaire assessing sleep duration and quality as well as negative impact on daily functioning and psychological well-being. It is suitable for detecting changes in perceived sleep difficulties. Bastien et al (2001) reported an internal consistency of $\alpha = .74$.

Overall distress was rated by the therapists in study II during the face-to-face interviews. The interviewer rated the distress from 0 (none) to 3 (large) in seven different areas; annoyance/irritation, depression, anxiety-worry-stress, concentration, sleep, hearing deficit, and sensitivity to noise. All the ratings were then summed into a global distress rating scale.

Measuring Readiness of Change

Study IV explored the possibility of profiling tinnitus sufferers in regard to the Stages of Change. To create a new questionnaire adapted to tinnitus patients, 29 items from the previously developed Pain Stages of Change Questionnaire (PSOCQ) (Kerns, Rosenberg, Jamison, Caudill, & Haythornthwaite, 1997) was converted to a tinnitus context. An additional 18 items were based on items from another Stages of Change questionnaire; the University of Rhode Island Change Assessment Scale (URICA) (Nabila et al., 1998).

Audiometric measures

As seen in Table 3, the degree of audiometric measurement of tinnitus and hearing deficit varies substantially between the studies. In study I, the patients had all undergone an audiological evaluation of hearing and tinnitus, either at the audiological clinic at Uppsala University Hospital or at the referring clinic. This included the pure tone average in dB HL for the better ear at the frequencies 0.5, 1, 2, and 3 kHz, a tinnitus loudness matching with both relative (dB SL) and absolute loudness (dB HL), and the minimal masking levels of tinnitus (MML). In study II, the hearing levels were measured but no tinnitus matching was done, and study III did not include any audiometric data. All studies included self-report questions on hearing deficit, the characteristics of tinnitus, including maskability and sound sensitivity.

Other measures

In study II and III the amount of therapist time needed to change one participant's TRQ score by one point was calculated to estimate the therapist time-effectiveness. This should be seen as only one of many aspects of cost-effectiveness.

Treatment credibility was measured in study I and II with a 5-item questionnaire (Borkovec & Nau, 1972), adapted to tinnitus patients. This measures the patients' beliefs about whether the treatment will help them or not. In study I, the participants filled out the credibility rating after completing module one in the Internet self-help treatment, but in study II the ratings were done in a screening questionnaire before the treatment started.

In study II, treatment preference (Internet or group treatment) were rated and a composite, overall score of 'satisfaction with assigned treatment' was computed from this score together with credibility and a therapist rating of satisfaction with assigned treatment made at the assessment interview.

Estimates of homework compliance and amount of patient-therapist interaction were made in study I, based on the patients' homework reports at the website and the e-mail correspondence.

Treatment

Structure and content

The basic content in the treatment manuals used in the studies was the same as for CBT for tinnitus in general. The treatments within this thesis can be categorized as follow:

Study I

- Old Internet treatment; Internet-based self-help with therapist guidance (low levels of patient input).

Study II

- New Internet treatment; Internet-based self-help with therapist guidance (high levels of patient input).
- Group treatment; Traditional therapy with self-help material as an adjunct for repetition and further reading.

Study III

- Self-help book plus weekly telephone contact; Therapist guided self-help book (high levels of contact).
- Self-help book with initial telephone only; Minimal contact self-help book (low levels of contact).

The treatment program for study II and III were almost identical, since the text from the newer tinnitus self-help website needed only minor adjustments to be adapted to a self-help book. This self-help manual has been published in Swedish (Kaldo & Andersson, 2004) and was also the foundation of the group treatment in study II, which presented the same information and methods (called "tools"), and used the same homework exercises and registrations sheets. Also, at the end of each group sessions the self-help texts for each of the tools that had been mentioned within the session were given to the participants in the group treatment.

Thus, the largest difference in the content and structure of the treatment protocol was between the newer version of the self-help manual and the older version of the website in study I. The older version was a slight adaption of the Internet-based self-help treatment used in Andersson, Strömberg et al. (2002) and is described in Andersson & Kaldo (2005) and in a single case study by Andersson and Kaldo (2004). Compared to the newer Internet-treatment, it was much briefer, less interactive, and less structured. It included considerably less text and put less explicit demand on planning homework, making paper-and-pencil registrations and reporting homework via the homepage. As a preparation for the treatment, the newer version included a written treatment contract between therapist and participant, a clear statement of treatment goals and a plan for how to prioritize to make time to practice with the tools in the treatment. None of this was included in the older version of the treatment.

Apart from these differences, the methods used in the treatments were very much the same, just as the suggested amount of homework. The older version had a very short section on physical activity that was removed in the new version, and replaced with general encouragement of activity in other tools. The newer version also divided the cognitive restructuring into two modules and had a specific tool for reinterpretation of tinnitus. Both treatments included a plan for how to maintain and increase treatment gains in the future.

Table 4. describes the treatment tools used in the (newer) self-help and group treatment manual. The short descriptions are taken from the yet unpublished English translation of the self-help treatment manual.

Table 4. *An overview of the tools/methods in the CBT-manual for tinnitus distress.*

Tool name and short description	Summary presented to the participants.
<u>Mandatory tools to be used by all participants</u>	
Applied relaxation, step one: Muscle by muscle, tension-first	<p><i>Applied relaxation teaches you two different ways to relax – deep relaxation and rapid relaxation.</i></p> <p><i>Relaxation helps reduce everyday tension and increases your ability to deal with problems such as tinnitus, noise sensitivity, stress, anxiety, irritability, concentration difficulties, and hearing impairment. If you don't feel tense or stressed, applied relaxation is still an efficient way to recover after a hard day at work. These types of skills are important to everyone.</i></p> <p><i>The first and relatively easy step in applied relaxation is to increase the awareness and control of your muscles by first tensing and then relaxing them.</i></p>
Applied relaxation, step two: Muscle by muscle, release-only	<p><i>Step 2 of applied relaxation teaches you how to relax without first tensing your muscles, which is faster and may result in deeper relaxation. You will begin by practicing how to breathe correctly and then by using a relaxation word that will help you achieve a relaxed state.</i></p>
Applied relaxation, step three: Controlled breathing	<p><i>You should now be able to relax even faster, (i.e., without first going through all muscle groups) and by applying the diaphragmatic breathing, focusing on your relaxation word and scanning your body for tense muscles only.</i></p>

Table 4. *Cont.*

Applied relaxation, step four: Rapid relaxation in non-stressful situations	<i>Step 4 of applied relaxation is also referred to as rapid relaxation, since it takes less than a minute to do. Using diaphragmatic breathing and your relaxation word, you should practice relaxation in a number of new situations, without closing your eyes or sitting down. The first task is to actually remember to practice five to ten times a day. Therefore, you will start with simple situations and focus on making regular rapid relaxation a new habit.</i>
Applied relaxation, step five: Rapid relaxation in more stressful situations	<i>To make rapid relaxation more practical you will need to be able to use it in more difficult situations, such as when you are stressed or when you have a lot going on. You should continue to relax in comfortable situations, but you should also start to add the rapid relaxation exercises when you are in a higher state of physiological arousal. The goal is to make rapid relaxation a positive response, and therefore you should practice seven to fifteen times a day.</i>
Applied relaxation, step six: Establish relaxation routine in every-day life	<i>You will now continue to make relaxation a routine in your everyday life. You will do more rapid relaxation exercises, both in peaceful and stressful situations, and complement them with deep relaxation (steps 1-3). You should strive to create a relaxation schedule that suits you.</i>
Positive imagery: Focus on a relaxing image	<i>A “positive image” is the mental equivalent of muscular relaxation. Closing your eyes and creating an image associated with peaceful and positive experiences will also enhance your ability to control where you direct your attention. The positive image works as a distraction from tinnitus and helps you to unwind.</i>
Focus exercises: Shifting focus between stimuli	<i>It is not possible to focus on more than one thing at a time. These focus exercises enhance your ability to control where you direct your attention. If you are able to consciously decide what you want to focus on, you can keep tinnitus in the background more often. You can practice controlling your attention by moving it between different stimuli.</i>
Reinterpretation of tinnitus: Put tinnitus in a positive or neutral context	<i>Tinnitus can sometimes feel less troublesome and intrusive if you place it in a more neutral or positive context, or if you imagine that it is really just another type of sound. In the long run, this technique can reduce the need to avoid tinnitus and also increase your sense of control.</i>
Exposure to tinnitus: Reducing tinnitus related anxiety and avoidance	<i>Trying to avoid something distressing will often maintain the distress or even add to it. Exposure is a thoroughly tested treatment technique where you gradually challenge your distress, tinnitus in this case, in a controlled and gradual way. The exercises can be difficult and may temporarily make you more aware of tinnitus, but in the long run they will increase your tolerance of tinnitus.</i>
Sound enrichment: Using external sound to make tinnitus less noticeable	<i>Sound enrichment can be a successful way to deal with tinnitus. The background sounds shouldn’t mask tinnitus completely, but rather compete with it. Try various types of sound enrichment and in different situations to find out when the method is most useful to you.</i>
Cognitive restructuring, part one: Finding negative thoughts	<i>The way you think in different situations is of major importance to how you feel. Most of your thoughts are habitual and automatic and they are a reaction to what is going on around you that influence your actions and emotions. As long as there is a balance between positive, neutral and negative thoughts, this is not a problem. However if for some reason the negative thoughts become dominant, they can bring your mood down. The first step towards dealing with such problems is to identify your thoughts and write them down. The next step in the “Cognitive restructuring” tool deals with how to analyse, challenge and cope with these negative thoughts.</i>

Table 4. *Cont.*

Optional tools to be used for participants with specific needs	
<p>Cognitive restructuring, part two: Coping with negative thoughts</p>	<p><i>If your thoughts on tinnitus make you focus on the sound and add to your distress, it is important that you deal with them. Step 2 of the “Cognitive restructuring” tool teaches you to analyse and examine your thoughts and habitual ways of thinking. Here you learn how to deal with and reduce thoughts that increase your level of annoyance.</i></p>
<p>Sleep management: Established CBT-methods to deal with sleep problems (Morin, 2005)</p>	<p><i>Sleep problems are common both among tinnitus sufferers and others – the advice on sleep management presented in this chapter applies to anyone. Sleep problems can mainly be explained by stress, worrying about your sleep (or tinnitus) or unhealthy sleep habits. You will start by learning more about sleep, what affects it and what the effects of sleep deprivation are. If your sleep problems are minor, you can skip this tool entirely or only use some of the easier tips on sleep management. If your problems are great, you will have to use the more demanding techniques.</i></p>
<p>Concentration management: Taking breaks, structuring and solving problems</p>	<p><i>Tinnitus can have a negative effect on your concentration, endurance and memory. Irritability, continuous thoughts, tiredness, depression and stress are all factors that affect your ability to focus, whether you have tinnitus or not. This tool helps you deal with your concentration problems. You will select a number of practical techniques and situations where they should be applied. Some of the techniques can be applied to all types of concentration problems, and some are more suited for tinnitus-related problems.</i></p>
<p>Hypersensitivity to sound: Graded exposure to non-risk sounds</p>	<p><i>Physical injury to the auditory system, fear of loud noises, sound irritability and avoiding sounds by using earplugs excessively can all contribute to sound sensitivity. In this chapter you will find information on distressful sounds and ways of reducing your sensitivity to sound by increasing your tolerance. You can achieve this by gradually approaching and habituating to sounds you currently find distressing.</i></p>
<p>Hearing tactics: Advice on how to cope with a hearing deficit</p>	<p><i>Reduced hearing has a medical cause, but can still be very influenced by your behaviour. Hearing tactics provides you with information on how to deal with hearing loss more successfully by changing the way you behave in different situations.</i></p>

Each tool follows the same structure. First, an overview and a treatment rationale are presented, then information about the problem area and the proposed strategies to deal with it are provided. This is followed by instructions on how to design and follow through with homework exercises and how to register progress. At the end of the week, a report and evaluation of homework is done by the patients themselves (self-help book with initial telephone contact only), in a telephone session (self-help book plus weekly telephone), via webforms called ‘diaries’ and e-mails (old and new Internet treatment), or in the group session.

A section labelled “common problems and how to solve them” and a section with extra information about the tool and the problem area it deals with are also included in each tool, but only in the newer version of the manual.

Therapist guidance

In the Internet-based self-help treatments in study I and II, the contact consisted of e-mails with feedback on homework reports filled out on the websites, therapist answers on questions from the participants and reminders or “check-ups” from the therapist. In the newer Internet treatment, the participants also stated treatments goals and made priorities, chose tools and filled out homework plans on the webpage. This made it possible for the therapist to send e-mail feedback on these aspects too if needed.

The group treatment in study II included seven weekly sessions for two hours each. The sessions consisted of a review of the homework assignments, presentation of new tools, and discussion and planning of new homework assignments.

The weekly telephone contacts in study III lasted for about 15 minutes on average and included both a review of the homework and treatment progress, and making a plan for next week’s practice. The single, initial phone call for the low-contact treatment group in study III focused on answering questions, making a treatment plan, and making treatment goals and priorities to free some time for practicing the treatment tools.

In study I, the therapist was a newly examined clinical psychologist with one year of experience with treating tinnitus patients individually. In study II and III, therapists were two licensed clinical psychologists with extensive experience in working with CBT for tinnitus, together with therapists with 4.5 years of training to become clinical psychologists (i.e., students on the final semester of the M.Sc. program), who received additional training to master the required skills. They also received group supervisions by the more experienced therapists.

Data analyses

Results were most often calculated on an intention-to-treat basis (Newell, 1992), where missing data were replaced either according to the principle of ‘last observation carried forward’ (Study II and III) or by the pre-treatment value (study I). Follow-up data was sometimes calculated for completers only.

95% confidence intervals for the change scores were calculated to test if pre- to post/follow-up changes in the outcome measures were statistically significant. The interaction of a 2 (group) x 2 (time) ANOVA was used to test if groups differed from each other. To compensate for missing data within the summed scales, missing items were replaced with the mean of the rest of the items included in the scale, but only if the proportion of missing items was less than 20%.

In study IV, repeated principal component analyses were used to reduce the original 47 items of the TSOCQ and to find relevant factors among the items. Other aspects than the results derived from the principal component analysis were also considered in the process of choosing the most psychometrically

sound and useful items, such as each item's standard deviation, its possible ceiling or floor-effects, and its ability to predict treatment outcome.

Results

Study I – Clinical setting trial

Statistically significant improvements were found both at post-treatment and follow-up regarding tinnitus distress, depression, anxiety, and sleep problems. Attrition, effect sizes and clinical significance are presented in Table 5 and Table 6.

Three factors were found to significantly predict outcome, in the sense that they were correlated with change scores on the TRQ; the treatment compliance index ($r = .31$), how intensively the patients worked with the treatment (the compliance index divided by time spent in treatment; $r = .29$), and the total number of e-mails between the therapist and the patient ($r = -.32$). Further analyses of the latter correlation found that it was the e-mails dealing with negative aspects of treatment (e.g., delays in treatment, not completing homework, technical problems) that were negatively associated with outcome ($r = -.39$). Trends ($p < .10$) were found for better outcome to be associated with earlier having tried out a larger number of treatments for tinnitus, and with externally referred patients.

The credibility rating, together with nine other pre-treatment variables (such as audiological parameters, form of pre-treatment assessment interview and age) or treatment process factors (such as time spent in treatment and number of completed modules) were not significantly related to outcome.

Study II – Internet versus group treatment

No significant differences between the groups at pre-treatment were found, except on tinnitus localization. Significant pre-post improvements were seen on all outcome measures except for perceived stress (for both treatments) and depression ratings for the group treatment. At one year follow-up (calculated for completers only) all outcome measures were still significantly reduced as compared to pre-treatment, with the exceptions of depression for the group treatment and anxiety for the Internet treatment.

The 2 X 2 ANOVAs did not reveal any significant interactions for the two treatment modalities on any outcome variable. Nor were there any significant changes or interactions for distress, from post-measurement to follow-up.

Attrition, effect sizes and clinical significance are presented in Table 5 and Table 6. In addition, it should be noted that completely removing an outlier found in the Internet treatment group, gives a pre-post effect size of 0.73.

The average amount of therapist time (assessment excluded) spent on one patient was 1 hour and 58 minutes for the Internet treatment and 4 hours 29 minutes for the group treatment. An estimation of therapist time-effectiveness

showed that 0.23 (Internet treatment) and 0.39 (group treatment) hours of therapist work were needed to decrease the score on the TRQ by one point for one participant. The Internet treatment was thus 1.7 times as time-effective as the group treatment.

The average credibility rating for the treatments showed significantly higher ratings for the group treatment than for the Internet treatment. No significant differences were found on related measures of preference or the composite measure of 'satisfaction with assigned treatment'. Of these measures, only the therapist ratings of patient satisfaction with assigned treatment ($r=.31$) at the assessment interview was significantly correlated with outcome.

A post-treatment question; 'Do you think the other treatment would have helped you more?', showed that participants in the group treatment rated their treatment significantly higher both compared to the Internet-participants' ratings of their own treatment and compared to the cut-off score of 2 meaning 'no difference between treatments'. The Internet treatment participants tended to rate their own treatment below the 'no difference' answer. This post-treatment rating was also significantly correlated with treatment outcome at post-treatment ($r=.31$) and at follow-up ($r=.37$).

Study III – Self-help book

No significant group differences in the pre-treatment data were found, except that participants in the wait-list group had a higher number of intermittent tinnitus sounds.

At post-treatment, all outcome measures except the VAS ratings for perceived stress were significantly more improved for the treatment group than for the wait-list control. All distress measures were also significantly improved from pre- to post-treatment for the treatment group. This improvement was also shown (except for anxiety) for the wait-list group after this group had received the low-contact self-help treatment. Comparing the pre-treatment scores with the scores at one-year follow-up (adjusted for intention-to-treat), significantly lowered tinnitus distress on both TRQ and THI were found, as well as increased quality of sleep for the "initial telephone contact only" group. No significant effects on anxiety or depression were found.

Two differences in outcome due to amount of therapist contact were found at post-treatment: for anxiety, and for tinnitus distress as measured by the THI. Both showed greater reductions for the group high in therapist contact. No significant effects of therapist contact were found at follow-up.

The therapist spent on average 1 hour and 47 minutes for the more therapist-intensive treatment, and 39 minutes for the less therapist-intensive treatment on each participant (excluding the assessment telephone interview). The time-effectiveness (i.e. therapist time needed to reduce TRQ with one point for one patient) was thus 0.15 and 0.08 respectively;.

Overview of outcome, attrition and drop-out in study I, II and III

To get a better overview of the effects of the different treatment modalities, Table 5 and Table 6 present effects sizes and clinical significance at post-treatment and follow-up. Results are calculated both as Intention-to-Treat (ITT) and for completers only (Compl). Also included in Table 5 are data on attrition, drop-out and the treatment ‘dose’, i.e. how much of the total treatment the participants on average received.

Table 5. *Treatment outcome, attrition and drop-out from pre- to post-treatment.*

	<u>Clinical significance</u>		<u>Effect size^a</u>		Attrition (i.e. no post-measure)	Finished whole treatment	Treatment ‘dose’ ^b
	ITT	Compl	ITT	Compl			
<u>Internet treatments</u>							
<i>Andersson, Strömbergren et. al 2002. Old website in earlier study</i>							
	13%	29%	<i>unknown</i>	0.60	51%	49%	68% (4.1 of 6)
<u>Study I</u>							
Old website (Clinic)	27%	39%	0.54	0.66	30%	57%	72% (4.3 of 6)
<u>Study II</u>							
New website	38%	40%	0.58 ^c [0.52]	0.58 ^c [0.50]	4%	62%	75% (4.5 of 6)
<u>Self-help book</u>							
<u>Study III</u>							
Weekly telephone	32%	35%	0.51	0.67	9%	80%	86% (6.0 of 7)
<u>Study III</u>							
Initial telephone only (former Wait-list ctrl.)	28%	42%	0.34	0.35	37%	(63%) ^d	unknown
<u>Comparisons</u>							
<u>Study II</u>							
Group treatment	44%	46%	0.64	0.63	4%	76%	75% (5.3 of 7)
<u>Study III</u>							
Wait-list control	5%	6%	-0.01	0.00	5%	N/A	N/A

a) Bias corrected Cohen’s D, within-group pre-post

b) Average proportion of Internet modules finished, telephone calls held or group sessions visited

c) Corrected ES. Correction made by adjusting pre-treatment value for one extreme outlier down to the second highest pre-treatment value, keeping the same change score. Uncorrected ES within []. Completely removing the outlier gives an ES of 0.73 (ITT).

d) The inverted attrition-rate, due to lack of specific data on treatment completion

Table 6. *Treatment outcome and attrition from pre-treatment to follow-up (FU)*

	<u>Clinical significance</u>		<u>Effect size^a</u>		Attrition (i.e. no FU-measure)
	ITT	Compl	ITT	Compl	
<u>Internet treatments</u>					
<i>Andersson et. al 2002</i>					
<i>Old website in earlier study</i>	23%	31%	<i>unknown</i>	0.76	18%
<u>Study I</u>	23%	33%	0.50 ^c	0.68	29%
Old website (Clinic)			0.42 ^d	0.41 ^d	
<u>Study II</u>	35%	43%	[0.38]	[0.36]	19%
New website					
<u>Self-help book</u>					
<u>Study III</u>	26%	28%	0.30	0.40	12%
Weekly telephone					
<u>Study III</u>	29%	38%	0.37	0.37	21%
Initial telephone only (former Wait-list ctrl.)					
<u>Comparisons</u>					
<u>Study II</u>	44%	50%	0.60	0.72	12%
Group treatment					

a) Bias corrected Cohen's D, within-group pre-post

b) 3-months follow-up time, not one year.

c) To be comparable to the other studies, the ITT ES for Study I was here calculated according to the principle of "last-observation-carried-forward", even though replacement with the pre-treatment value was used in the original article.

d) Corrected ES. Correction otherwise made by adjusting pre-treatment value for one extreme outlier down to the second highest pre-treatment value, keeping the same change score till post-treatment. Uncorrected effect size within []. Completely removing the outlier gives an ES of 0.61 (ITT).

Study IV – Stages of Change

A five factor solution based on 23 items from the original TSOCQ was found to best represent the data and the underlying theory. It was supported both by the latent-root criterion and the scree-test and explained 58.5% of the variance. This solution was well in line with the transtheoretical model, although Action and Maintenance were merged into one factor and Precontemplation was divided into two sub-scales. The sub-scales found were; Precontemplation (Medical Solution) with four items and an internal consistency of $\alpha = .66$, Precontemplation (Helplessness) with three items and $\alpha = .54$, Contemplation (five items; $\alpha = .73$), Preparation (four items; $\alpha = .64$) and Action/Maintenance (seven items; $\alpha = .91$).

Outcome was significantly correlated with Precontemplation (Helplessness) ($r = 0.25$) and Action/Maintenance ($r = -0.21$) when analyzing the whole group. Stronger correlations were found when the sample was divided

according to gender (for women, the two Precontemplation sub-scales had correlations of $r = 0.37$ and $r = 0.47$ with outcome) and type of treatment; for the high-contact self-help book group, both Precontemplation (Helplessness) ($r = 0.55$) and Action/Maintenance ($r = -0.48$) were correlated with outcome, and for the group treatment the correlation between Action/Maintenance and outcome was $r = -0.54$.

Discussion

Study I – Clinical setting trial

The results in study I strengthen the findings from the previous RCT by Andersson, Strömgren et al. (2002), and showed that Internet-based treatment for tinnitus distress can be used with positive results also in a clinical setting and when analyzed on an intention-to-treat basis. At post-treatment, the drop-out from treatment and the study attrition rates were still high but lower than in the previous trial, and the amount of participants reaching clinical significance was higher.

The major limitation to this study was its uncontrolled design, making it susceptible to other explanations of the lowered distress. However, rapid, spontaneous decreases in tinnitus distress have not been reported in the tinnitus literature.

A few significant predictors of treatment outcome of modest strength but with theoretically reasonable explanations were found. Two closely related forms of compliance resulted in a better outcome, and increased patient-therapist interaction due to treatment problems was related to worse outcome.

The trend that externally referred patients tended to achieve better results might be explained by higher levels of motivation and expectations in these patients. Due to geographical distances and often some administrative difficulties to get a referral or to get information about the Internet self-help treatment, less motivated and enterprising patients were probably automatically sorted out. The finding that larger number of previous treatments tended to be related to better outcome is difficult to interpret, but perhaps “more previous treatments” indicate a willingness to try new solutions, also solutions aiming at the distress rather than the sound, more than being a sign of desperation to get rid of tinnitus. Treatment credibility ratings were not related to outcome, and it was interesting to find that the level of credibility was not significantly different compared to the traditional group treatment or individual CBT.

Study II – Internet versus group treatment

This randomized controlled trial showed significant positive results on a vast majority of all outcome measures for both Internet-based self-help and regular group treatment, with no significant differences between them. The low attrition rates strengthen the validity of the findings, but it is possible that

differences between the two treatments were not found because of the rather low statistical power of the study (for a further discussion on this, see the General discussion). The results remained rather stable at the one-year follow-up. The drop-out from treatment was lower and the attrition rate at the post-treatment assessment was much lower than in previous Internet treatments for tinnitus. Also, the proportion of Internet-participants being clinically significantly improved was significantly larger than in the previous randomized controlled trial (Andersson, Strömberg et al., 2002) and larger than in the Internet-based self-help treatment in study I. Thus, the extended and more interactive version of the Internet treatment used in this study appears to have somewhat better effects than the old version when looking at clinically significant improvement at post-treatment.

The effects on depression and anxiety were somewhat smaller than the effects on tinnitus distress and sleep problems, and the VAS for perceived stress failed to show any significant reduction. Relatively low initial depression and anxiety ratings may be one explanation for this, together with the fact that depression and anxiety are not directly addressed in the treatment.

Contradicting the finding in study I, the Internet-based treatment was rated as less credible than the traditional group treatment. One explanation may be that in study II, credibility was rated before randomization and for both treatments at the same time, and not after the first week in treatment. However, even after treatment, and without any obvious differences in treatment effects, participants in both groups believed that the group treatment was probably more helpful than the Internet treatment.

The estimation of the therapist time-effectiveness showed the Internet-based treatment to be more time-effective than the group treatment. This supports the idea that internet-based self-help treatments may be a good way of treating more patients within a given amount of therapist time.

Study III – Self-help book

This study showed that a CBT self-help book together with seven weekly telephone calls gave significantly better improvements on almost all distress measures compared to a wait-list control, with the exception of the VAS-ratings of perceived stress. The positive results for tinnitus distress were maintained up to a one-year follow-up, but depression and anxiety were no longer significantly decreased at this point, and neither were problems with sleep in the high-contact group.

The comparison between high- and low-levels of therapist guidance showed no clear difference in outcome and thus casts some doubt on the importance of adding weekly therapist support to the self-help material. Some tendencies for better result in the high-contact group were present, such as higher effect size and significantly more gain according to the supplementary tinnitus measure and the anxiety measure at post-treatment. Rather low statistical power, an

attrition rate of 37% for the low-contact group and the non-optimal design of the study to answer this question also make this result less final.

The estimated therapist time-effectiveness in this study was considerably higher than for traditional group treatment, and also high in comparison to Internet-based self-help. The clinical significance and effect sizes for the self-help book showed a trend to be somewhat lower than for group and Internet-based treatments. If future studies confirm this trend, this might create a difficult choice between giving moderate help to many tinnitus sufferers or more effective treatments to fewer.

Study IV – Stages of Change

The results in this study need to be discussed from two aspects; first, does the TSOCQ produce psychometrically and theoretically sound scales, and second, do these scales predict outcome in line with what can be expected from the transtheoretical model?

The first issue could be given a mostly confirmative answer. The reasonably good statistical result of the principal component analysis makes the solution satisfactory. The major problem was that the Precontemplation scale was divided into two subscales – Medical Solution and Helplessness. This made their internal consistency low, probably due to few items in each scale, and possibly shows a problem in applying the theory behind the stages of change to tinnitus patients. On the other hand, at no occasion did items theoretically belonging to one scale end up in a completely non-related scale. Also, previous factor analyses on other Stages of Change questionnaires, for example for chronic pain, have resulted in merging and splitting of subscales, indicating that this phenomenon is not unique for tinnitus patients.

The answer to the second question was on the other hand a quite clear “no”. Though some scales had predictive abilities, these were not in line with what could be expected from the theory behind the Stages of Change. Rather, they were in the opposite direction.

One explanation may be that the choice of items for the TSOCQ poorly represents the transtheoretical model and its proposed stages. Since the items were taken from previously used questionnaires designed to measure Stages of Change, the risk for an overall misconception is low. The Precontemplation scale, showing the largest theoretical and statistical weaknesses when applied to tinnitus patients, is perhaps not a very good operationalization of the original concept. This, however, could be due to an underlying conceptual incongruence between the Stages of Change and tinnitus patients, rather than to a poor choice or wording of items.

Precontemplation can be described as “not recognizing the problem or believing that it cannot be solved by behavioural or attitude change”. The first part, which is the most important part in the original use of the concept, is not really applicable to individuals with tinnitus; only the individual can say whether he or she has tinnitus, and if one does not recognize it as a problem

(i.e. not resulting in any distress), then it is not a problem. This is not the case for an individual with drug or alcohol abuse. Thus, for tinnitus patients, it is only the second part of the definition of Precontemplation that is applicable; a non-belief in that attitudinal or behavioural change can help in managing the sound and problems related to it. In this sense, the Medical Solution and Helplessness scales are good representatives of the theoretical model, but they still miss what is probably the most important original ingredient, that of denial that the problem exists.

It is hard to argue that the items in the Action/Maintenance scale do not cover the rather straightforward concept they are supposed to cover. Still, instead of the supposed positive correlation to outcome, this study found the opposite. There may be a conceptual mismatch between the transtheoretical model and tinnitus. In the traditional application of the Stages of Change, what you should do to reduce your problem is very straightforward; stop or reduce drinking, smoking etc, or start exercising, eating healthy food etc. In the case of tinnitus suffering, what you should do to lower tinnitus distress is not at all as obvious.

The conclusions of this study are that the TSOCQ can predict treatment outcome to some extent, but the theory behind the transtheoretical model and the Stages of Change may not apply very well to tinnitus patients. A more fertile way to conceptualize the present findings could possibly be found if using a 'coping perspective', where low levels of coping (i.e. the Action/Maintenance scale) and high levels of helplessness and passive coping (i.e. the two Precontemplation scales) are more logically related to positive outcome with a CBT approach to tinnitus distress.

General Discussion

Treatment effects on tinnitus distress

The main aim of this thesis was to evaluate what immediate and long-term effects CBT-based self-help treatments had on tinnitus distress. The findings in study II, and III show that tinnitus distress, as measured with the TRQ, and the THI and daily VAS-ratings for tinnitus distress, is significantly lowered at post-treatment and follow-up. Study I show that the positive results also extend to a clinical setting with consecutive patients.

The differences between the self-help treatments in study I-III are not very large. The proportions of participants reaching clinical significant reductions in distress are 27-38% (intention-to-treat) or 35-42% (completers) at post-treatment and 23-35% (intention-to-treat) or 28-43% (completers) at follow-up.

The within-group effect sizes at post-treatment and follow-up were 0.30-0.58 when calculated as intention-to-treat and 0.35-0.68 for completers. These can be seen as a small to medium effects and are lower than those found in general meta-analyses of self-help (den Boer et al., 2004; Gould & Clum, 1993; Marrs, 1995; Menchola, 2007; Scogin et al., 1990), as well as Internet-based, therapist guided self-help for depression and anxiety (Spek et al., 2007). They are more in line with the effects found for Internet-based, therapist guided self-help for other problems within the behavioural medicine area, (Cuijpers et al., In press).

Compared to previous brief or self-help oriented approaches to tinnitus distress, the newer version of the Internet-treatment in study II comes out rather favourably. The education alone group used as a control group in Henry and Wilson (1996) and the two minimal contact groups in Kröner-Herwig et al. (2003), showed significantly lower outcome on some measures when compared to traditional treatments. On the other hand, the Internet-based self-help treatment in study II showed no significant differences in outcome when compared to regular group treatment. In addition, compared to the previous study by Andersson, Strömngren et al. (2002), using the older version of the Internet-based self-help, the level of clinical significance was significantly better for the newer Internet-treatment. Since this comparison is done on an intention-to-treat basis, the lower drop-out and attrition rates in study II could possibly explain this difference. However, it might also be the effect of the new treatment being more extensive, interactive, and having a higher level of therapist contact compared to the old treatment.

Compared to CBT for tinnitus distress in general, the effect sizes of self-help in this thesis were lower than the post-treatment, between-group effect size (calculated as intention-to-treat) in Martinez-Devesa et al. (2007) of $d = 0.70$, but only somewhat lower than the group treatment in study II ($d = 0.64$) and the non-weighted average within-group effect size of $d = 0.62$ in the broader meta-analysis by Andersson & Lyttkens (1999). The inferior effect size at post-treatment are seen specifically in the low-contact self-help book condition, while the other conditions are at an effect size of $d = 0.51$ or above. Also, if the outlier in the new version of the Internet-treatment is completely removed, the effect size for this treatment is $d = 0.73$.

The direct comparison between Internet- and group treatment in study II gives some support for the argument that self-help can work as well as traditional treatment. The effect size for the difference between the two conditions was in favour of the group treatment but rather small ($d = 0.21$). If a moderate effect size of $d = 0.50$ would be considered to be a clinically important difference between treatments, study II had a power of only 43% to detect this difference, which is lower than the recommended power of 80%. Importantly, it is unlikely that the non-significant difference between treatment conditions found in study II was due to a poorly implemented traditional treatment, since the effect size of the group treatment was in the same range as the above presented effects for traditional CBT.

It is worth noticing that regardless of the mode of deliverance, CBT for tinnitus distress does not seem to achieve as large effects as CBT or other empirically researched psychotherapies in many other areas, as represented by the effect sizes reported in for example Wampold et al. (1997).

One interesting finding is that the subjective loudness of tinnitus, measured with one week of daily VAS-ratings, is also significantly lowered at post-treatment even though CBT for tinnitus explicitly does not aim at reducing loudness and this is also what the patients are told. The improvement could be explained by the way tinnitus loudness is measured. The subjective VAS is probably more susceptible to the influence of patients' general wellbeing compared to audiometric measurements of tinnitus (Wolfgang, Hiller & Goebel, 2006; Kuk et al., 1990). Another possibility is that CBT actually does decrease tinnitus loudness in all or in some subtypes of tinnitus, for example by lower levels of daily arousal and muscular tension. However, a more plausible explanation is that lower tinnitus distress may result in less focus on tinnitus and hence an experience of reduced loudness. Although speculative, this would also be in line with the findings that attention to tinnitus probably plays a role for tinnitus distress (Andersson & McKenna, 2006; Scott & Lindberg, 2000).

Therapist time-effectiveness

Study II and III did not include thorough cost-effectiveness analyses such as those in Kaltenthaler et al. (2006) and Paxling et al. (2007), but they did explore therapist time-effectiveness.

Using the group treatment in study II with 0.39 hours of therapist work to decrease the TRQ by one point for one participant as a benchmark, the Internet treatment was 1.7 times as effective, the high-contact self-help book 2.6 times as effective and the low-contact self-help book 4.8 times as effective. The last figure corresponds fairly well to the estimation that headache treatments with reduced therapist contact are five times as time/cost-effective as standard treatments (Ström et al., 2000).

The above figures stem from post-treatment data. If the effects of self-help treatments do not last as long as effects from regular treatment, this must of course be included in cost-effectiveness analyses. In study II, the reduction of tinnitus distress at the one-year follow-up is almost twice as large for the group treatment (albeit not significant) and table 6 shows that there is an even larger advantage for the group treatment compared to the other self-help treatments.

One ethical question that might emerge is if less therapist-supported and thus probably more cost-effective treatments are put in opposition to more therapist support, higher treatments effects but also higher costs. Preliminary signs of this can be seen in this thesis as the low-contact self-help book may be the most cost/time-effective but least effective treatment, but other studies have stronger indications that this topic may be more and more important to address (Palmqvist et al., 2007).

Treatment effects on depression, anxiety, sleep and stress

Tinnitus distress has been the main target of the treatments in this thesis, but the effect on other problem areas was also measured.

One consistent finding in study II and III is that there was no effect on the daily VAS-ratings of perceived stress (regardless if the stress is related to tinnitus or not). One explanation for this is that even though CBT for tinnitus does include applied relaxation and advice in how to handle poor concentration, it does not give the patients a whole stress management package. Also, from clinical experience and unpublished data in Kaldo & Andersson (2007) it is quite clear that some patients experience the rather high workload during the treatment as stressful. Because stress was only measured at post-treatment and only with a single, non-validated measurement, this finding needs to be replicated.

Relatively good effects were found for sleep problems, whereas effects on depression and anxiety sometimes were non-significant, especially at follow-up. This is perhaps not very surprising since the treatment manual did not include specific methods to deal with anxiety and depression whereas they do

include advice for sleep problems. Still, considering the consistent findings that tinnitus distress is related to both depression and anxiety levels (Di Pietro et al., 2007; McKenna & Hallam, 1999; van Veen et al., 1998), it might be expected that an improvement in one of these areas would be followed by an improvement in the other. However, a reduction in tinnitus distress may not be enough to lower anxiety and depression very much or for very long.

The initial levels of anxiety and depression were above the average for the Swedish normal population (Lisspers, Nygren, & Soderman, 1997), but below or on about the same level as the HADS cut-off score of 8 for ‘probable cases/diagnoses’ (Bjelland, Dahl, Haug, & Neckelmann, 2002), and clearly below the original cut-off score of 11 for ‘cases’ (Zigmond & Snaith, 1983). With low initial levels of anxiety and depression, reductions may be less pronounced.

From another perspective, the significant effects that were found on anxiety and depression could be due to unspecific treatment effects. That is, the treatments could be seen as unspecific interventions with a small but general effect on many areas rather than a specific and large effect on tinnitus distress. More probable, while the decrease in the mostly sub-clinical depression and anxiety levels could be due to an unspecific treatment effect, the effect on tinnitus can still be specific. That is, as long as the problems with anxiety and depression are below a ‘clinical level’, CBT for tinnitus might be enough to have a positive, nonspecific effect on these problems. But that may also mean that for tinnitus patients with clinical levels of depression and anxiety, there is a need to specifically target these problems since low effects on anxiety and depression for this category may be an obstacle to better long-term outcome.

Therapist contact

The amount of therapist contact varies between the different self-help treatment groups. The lowest level of therapist contact is found in the low-contact self-help book condition in study III, with only a telephone assessment and later on an initial telephone contact before treatment. No statistical comparison of therapist time spent on patients was made between the two Internet-treatments, but it is likely that the level of therapist involvement was higher in the newer version of the Internet treatment, just as it is plausible that both these treatments included more therapist-patient interaction than the previous RCT by Andersson, Strömngren et al. (2002).

It is hard to say whether the self-help book with weekly telephone calls includes more or qualitatively different therapist contact than the Internet-based treatments. It can be argued that telephone calls are more personal and relationship-focused than e-mail correspondence, but unpublished data in Kaldo & Andersson (2007) suggest that in a post-treatment evaluation of the treatment, there are only minor differences in quality of the relationship between “website plus e-mail” and “self-help book plus telephone contact”.

No obvious conclusions of the effect of therapist contact can be drawn from the studies within this thesis. At post-treatment, the intention-to-treat estimations of clinical significance in Table 5 show the best outcome for the new Internet-treatment and the self-help book with weekly telephone calls. At follow-up, the new Internet treatment still shows a higher level of clinical significance, but a somewhat lower effect size than the old Internet-treatment with presumably less therapist contact. Also, the self-help book plus weekly telephone contact does actually show a slightly *lower* level of clinical significance (and effect size) than the low-contact self-help book.

In sum, there are some indications that the self-help treatment with the least therapist guidance produces inferior results, but these effects appear weak.

Predictors of treatment success

Study I proposes that audiometric data are of little value for predicting outcome, which adds to the previous findings that they are not very good in predicting tinnitus distress.

Newman (2000) points out that finding individual predictors of outcome is an important task. The predictors found in study I, II and IV thus merit some further discussion, despite their rather low predictive value, explaining between 4% and 30% of the variation in outcome.

In study I, the estimation of amount of homework, rather than the number of completed modules, was a predictor of treatment success. This suggests that drop-out from treatment may not be equivalent to worse outcome if there has been an active utilization of the treatment tools.

Andersson (1997) finds that having tried many previous tinnitus treatments may indicate a narrow focus on getting rid of tinnitus and less suitability for distress-focused treatments, but this is contradicted by the findings in study I. Although speculative, this may imply that this subgroup of patients benefit more from self-help treatments, since Andersson (1997) studied traditional treatment. This is also somewhat supported by the findings from study IV, where more belief in a “medical solution” and higher levels of helplessness before treatment was associated with better treatment outcome, especially for the self-help approaches as compared to the group treatment.

Study I and II strengthen the findings of Andersson, Carlbring et al. (In Press) that self-reported treatment credibility does not seem to be a predictor of outcome. The finding in study II that therapist-rated ‘satisfaction with assigned treatment’ correlated positively with outcome is an indication of the usefulness of face-to-face therapist assessments. However, the correlation was not very strong and the procedure in which the patients are randomized to one of two treatments is not directly transferable to a routine clinical situation.

The results of study IV are most straightforwardly interpreted as ‘high degrees of helplessness and low levels of coping predicts better outcome’. This may mean that individuals with more and possibly firmly established coping

strategies are more difficult to help. Interestingly, the relation between helplessness and better outcome is more pronounced for the self-help treatments and non-existent for the group treatment. It was also indicated that patients with high levels of initial coping may benefit more from self-help treatment with little or only written therapist contact and less from face-to-face or telephone contact.

Although the evidence is weak, taken together these preliminary findings indicate that patients more prone to try out different treatments and feeling helpless in regard to tinnitus are more suitable to self-help approaches, while patients with high initial levels of coping are better suited for self-help approaches with less or less direct therapist contact, like e-mail contact.

Treatment credibility

Credibility might indicate if effective treatments will be accepted by patients. In study II, the credibility rating for the group treatment was significantly higher than for the Internet treatment, but study I was more in line with the previous literature, for example Carlbring et al. (2005), and no such difference was found. This may be partly explained by different timing of the credibility measurement; before randomisation in study II and after the first treatment week in study I.

These findings could be interpreted as a tendency for patients in general to rate Internet-based self-help treatment as less credible than a traditional treatment. However, after having made a decision to try the Internet-treatment and having completed the first week, it is rated as credible as traditional treatments. This interpretation is to some extent supported by the fact that a rather large group of patients finds it credible enough to choose and engage in, as seen in study I and confirmed by the ongoing use of the Internet-treatment in routine practice at Uppsala University Hospital.

Drop-out from treatment and attrition

If defined as staying in treatment until the end of it, the drop-out rates are higher for the old and new Internet treatments (43% and 38% respectively) when compared to group treatment (24%) and self-help book with weekly telephone contact (20%). However, for the group treatment and the self-help book treatments, it is possible to finish treatment even if one or some group sessions or scheduled telephone calls are missed, whereas this is not possible in the sequential structure of the Internet treatments.

When analysing the number of sessions/modules/telephone calls that the patients actively take part of, patients in the two Internet treatments received the same 'treatment dose' as those in the group treatment. Interestingly, regardless of which perspective is chosen, it seems that telephone contact may be the best way to foster frequent contacts between therapists and patients.

Telephone sessions are more practical and flexible for the patient than travelling to a clinic for a group session. In comparison to e-mail contact, telephone contact is also more structured and is probably also possessing a higher level of 'social pressure' to adhere to scheduled telephone calls and to keep up the contact with the therapist.

The old and new Internet treatments yielded similar drop-out rates, with perhaps a slight advantage for the newer one. This disconfirmed some initial fears that a treatment which put even more demand on the patient would increase drop-out rates. It is possible that drop-out is reduced if the patients invest more effort in the treatment, plan and report their homework more carefully and get more personalized feedback. As an illustration, many open-access Internet-based self-help programs, for example the Mood-Gym for depression (Christensen et al., 2006), shows extremely high drop-out rates, although it can be argued that drop-out from these interventions are in some aspects qualitatively different (Eysenbach, 2005).

Attrition (i.e. loss of data) ranged between 4% and 37%, where the last figure of course constitutes a problem when interpreting the results of the treatment (self-help book without weekly phone calls). Still, even this is lower than the post-treatment attrition in Andersson, Strömngren et al. (2002). Table 5 and Table 6 preliminarily support the notion that the amount of therapist contact may influence attrition. However, this conclusion is threatened by the fact that attrition is more sensitive to how and how intensely the participants not returning questionnaires are prompted to do so, and these procedures differed in a non-documented way between the studies.

Limitations

Only in study III, a no-treatment control group was used and only from pre- to post-treatment. This makes especially the long-term effects vulnerable to alternative explanations such as spontaneous improvement or improvement due to other treatments. Spontaneous improvement is not likely to have an effect in the short run (study III; Andersson, Strömngren et al., 2002; Andersson et al., 2005). In study III, 21% of the participants had tried one or more other treatments from post- to follow-up assessment. However, only one participant reported a great effect and only three reported some effect, making this less of a threat to the validity of the study.

The sometimes large attrition rates, with a maximum of 37% and a mean of 16.5%, are a threat to the validity of the results. However, the use of the intention-to-treat approach to calculate outcome compensates to some degree for this problem. Furthermore, no important differences among the background data were found in the participants not returning their questionnaire.

Audiological measurements of tinnitus, hearing and sound sensitivity were not conducted at all in study III and to a limited extent in study II. This is a limitation in so far that it gives less empirical data to describe the patient

groups and to explore relations to tinnitus distress and outcome. The self-reports on tinnitus, hearing and sound sensitivity somewhat compensate for this, and in regard to treatment outcome the lack of audiological data is not a problem since these variables were not expected to be affected by the treatment.

The use of Internet-based questionnaires in study I could constitute a psychometrical problem, but the HADS has shown equal properties regardless of the distributing media (Andersson et al., 2003) and this has also been the case for other questionnaires (Coles, Cook, & Blake, 2007).

Another concern about measurement is the definition of clinically significant improvement as a 50% reduction on the TRQ. This has previously been used in Henry & Wilson (1996), but it is still not an empirically and statistically based rating of clinical significance, as recommended by Jacobson and Truax (1991).

One possibly important difference among participants is the initial level of tinnitus distress (table 3). The participants in study II are almost 10 points lower on the TRQ than the participants in study III and about 5 points lower than the patients in study I. Although the effect of initial distress level is not known, this is a threat to the comparability between the studies within this thesis.

Finally, the search for predictors of outcome was limited to single correlational tests, which do not say anything on how a combination of different factors might succeed in predicting outcome.

Future considerations

The results in this thesis are of a small to medium effect size and future studies should explore ways to enhance the effect of both the CBT-protocol for tinnitus and the self-help treatment format.

More research on the design of self-help books, computer programs and websites would be helpful. Should they be brief, like the older version of the Internet treatment, or more comprehensive, interactive and information-dense like the newer one? Which one will help the patient to make the most out of treatment and prevent drop-out? Is it important to make the content of the self-help programs more flexible in regard to which methods to choose, how to give relevant homework and to adjust the workload and pace of the treatment? Self-help treatment in general and Internet-based self-help in particular could be individually tailored, probably to a larger extent than for example group treatments. Unpublished data from Kaldo and Andersson (2007) indicate that therapist guidance may be increasingly important if a treatment includes many choices, because patients could find it difficult to handle these decisions on their own.

Regarding the effect of therapist contact, trials directly addressing this issue are needed. Even though sometimes a very clear relationship has been found,

as for example in Palmqvist et al (2007), there is a need to separate therapist effects from the effects of possible other factors often accompanying trials with intense therapist contact, as for example more potent treatments, more thorough assessment, and stricter inclusion criteria. Also, the questions on *how much* input and feedback from a therapist or a computer is needed and *what* it should consist of need to be further explored.

Another important aspect, both in its own and in relation to the use of more flexible treatment programs, is the pre-treatments assessment and predictors of outcome. The importance of a thorough assessment is stressed by Andersson, Bergström et al. (In Press), and a broad assessment would also make it easier to systematically search for predictors. If enough predictors are found and their joint predictive capacity is deemed to be large enough, their ability to match patients and treatments should be tested in controlled trials. Also, the usefulness of predictors early on in treatment should not be underestimated. In study I, treatment process factors had a larger predictive ability than pre-treatment factors. Although they can not be used to choose the best treatment from the start, they can give information on how to proceed (or not proceed) with the treatment. ‘Rapid response’ in CBT treatments seem to be a good predictor of outcome (Wilson, 1999), and future studies should investigate this process factor in both self-help and regular CBT for tinnitus.

Considering the effects of CBT for tinnitus in general, it is not known which ingredients are the helpful ones, although it seems that CBT is more effective than psychoeducation alone (Henry & Wilson, 1996). A future use of active control groups, rather than comparing to wait-list only, should help determining if a treatment has specific effects on tinnitus distress. Dismantling studies investigating the different components of a CBT package could also reveal what methods are effective. Interesting aspects to explore is whether the emphasis on the treatment should be cognitive or behavioural. The work by Henry and Wilson (1996) have for example resulted in the possibly best effects yet, and a look in their treatment manual (Henry & Wilson, 2001) shows that they use a cognitive framework. In the treatment manual that is used in the current studies, cognitive restructuring is seen as only one of many tools and is not used as an overall rationale for the treatment, whereas behavioural change and actively trying out the treatment tools are.

It may be enriching to look at the research area of coping, but given the mixed result of coping and tinnitus distress reported in the previous literature, a clearer conceptualization on types of coping strategies and their effects are needed. In Henry and Wilson (1995), there was a tendency for more coping to be related to more tinnitus distress. This was also found by George and Kemp (1991) who also found that tinnitus sufferers kept using ineffective coping strategies. Budd and Pugh (1996) also found that many coping strategies (mainly cognitive/attentional ones) were not correlated to decreased tinnitus severity. In Andersson et al. (2004) only one coping strategy out of 33 had a significant negative correlation with tinnitus distress; “I continue with my daily

life as if the tinnitus is not there”, suggesting that acceptance instead of trying to control or avoid tinnitus may be useful. The findings from study IV suggest that it could be fruitful to look further at different types of coping. Strategies that give some temporary relief, but are not helpful in the long run, should be explored. Possibly, a more specific analysis on the function of a particular coping strategy for a particular situation or individual might result in less confusing conceptualisations of coping. The same behaviour could possibly be described as passive or mal-adaptive in one situation or for one individual, but active or adaptive for another. Finally, more research on the flexibility in coping style and willingness to try new ways to handle tinnitus would be interesting, not the least as predictors of treatment outcome.

The incorporation of CBT-techniques known to be effective in reducing anxiety, depression, and possibly stress might be a way to boost treatment effects, at least for tinnitus patients with clinical levels of other problems. Some support for this hypothesis was found in the positive effects of antidepressants on tinnitus distress (but not on tinnitus loudness) reported by Baldo et al. (2006), which not surprisingly seems to be most pronounced for depressed tinnitus patients (Robinson et al., 2005). This demands an extended initial assessment procedure to provide information on which extra treatment methods to add. Considering the good results with guided self-help for anxiety and depression, expanding self-help protocols might be a fertile way to go in the future. In some cases, it could be beneficial to consider tinnitus distress as not being the primary target for treatment. Would it for example be more effective to give tinnitus patients also fulfilling the criteria for insomnia a full insomnia treatment rather than to give them the whole tinnitus-package where sleep advice is only one of many parts?

Regarding implementation of self-help treatments, data from consecutive patients using the new Internet-treatment will provide important information on the use of self-help in regular care. Regular use of self-help books in clinical practice, with and without different kinds of therapist support, should also be explored. Things to consider are for example; who can be used as a therapist, what kind of therapist training is needed, can assessment over a distance be used, how to refer patients to the best treatment, and how the “effective” versus “cost-effective” ratio will turn out in a clinical setting.

Conclusions

Guided cognitive behavioural self-help, delivered as a book or as an Internet-based program, can alleviate distress associated with tinnitus. It appears to be a therapist time-effective treatment, with effects comparable to or slightly below traditional CBT for tinnitus. The effects last for as long as one year after treatment and generalize to a routine clinical setting where patients find self-help to be a credible treatment alternative. The amount of therapist contact is probably important for outcome and attrition, although this relationship is not

very clear. Compared to group treatment, the received treatment-dose is comparable, and for a self-help book with scheduled telephone contact possibly even higher. Tinnitus patients having tried more previous treatments, having been referred from distant clinics, feeling helpless in relation to tinnitus and reporting less existing coping strategies seems to benefit more from treatment, and during treatment the amount of reported homework predicts treatment outcome. The Stages of Change is probably not the right theoretical framework to use with tinnitus patients, and the predictive ability of the TSOCQ might be better understood when conceptualized as coping rather than as readiness to change.

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