

# **Third wave Cognitive Behavioral Therapy for adults with tinnitus: A literature review**

Tina Trones



Master's thesis at department of special need education

UNIVERSITY OF OSLO

Date 30.05 2019



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What do randomized controlled trials reveal about the effect of the  
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# Abstract

There is a constant need to assess and renew treatment programs when working with tinnitus patients, as there is no universal cure for tinnitus yet. This study is a **literature review** examining the effect of a treatment approach called Third wave CBT in tinnitus patients. The Third wave includes Acceptance and Commitment Therapy and Mindfulness-Based Therapy when treating tinnitus. Specifically, the study evaluates if the Third wave CBT approach is effective in treating psychological conditions and disorders associated with tinnitus.

**Research question:** *What do randomized controlled trials reveal about the effect of the Third wave CBT treatment on psychological conditions and disorders associated with bothersome tinnitus in adults?*

The electronic databases PubPsych, Pubmed, Cochrane library, Oria UIO and Web of Science were used in identifying high quality research for further evaluation. For this master's thesis, 6 randomized controlled trials (RCT) were selected and evaluated for their quality with a CASP appraisal tool. The selection contains trials comparing a Third wave intervention to *no* treatment, to establish if there *is* an effect, and compared to Cognitive Behavior Therapy (CBT), Relaxation Therapy (RT) and Tinnitus Retraining Therapy (TRT). Combined, these studies included 390 participants.

The **results** were categorized into *sustained effect* of the interventions, and the following psychological conditions and disorders: *tinnitus distress, depression, anxiety, insomnia, quality of life and perceived health*. The results were not one-dimensional, and the studies sometimes revealed contradicting findings. In **Tinnitus distress**, the compressed results revealed that 3 of the studies found the Third wave intervention to be more effective than other active treatments. The remaining studies found similar or other effects. In **Depression**, the results revealed improvement after *active* treatments, but the results were mixed as to Third wave being more effective than other treatments. Evaluating **Anxiety** there was improvements after active treatments, but the Third wave intervention was mostly *not* more effective than other treatments. Analyzing the studies revealed a lack of direct measurement when assessing **Insomnia**, which revealed that one study found no improvements in active treatments, and one study found improvement in the Third wave intervention compared to

another treatment. In **Quality of life and perceived health**, the results revealed mixed findings and no improvement. A major finding in the thesis was that most of the studies coincided in that the Third wave **Sustained the effect** from treatment longer and better.

In conclusion, the Third wave intervention might be a viable treatment option when treating some of the psychological conditions and disorders associated with bothersome tinnitus. On some psychological conditions and disorders, the Third wave seem to have *no more* effect than other active treatments like CBT, RT and TRT. Measuring tinnitus distress, the Third wave seem to be *as* effective, or *more* effective than other active treatments. The largest benefit however, might be the sustained effects on psychological conditions and disorders from the treatment. Following the participants months to a year after the intervention, those receiving a Third wave treatment mostly showed sustained and even further improved outcome compared to other treatments.

# Preface

I want to thank my guidance counsellor Guri Engernes Nielsen for not only helping me through this writing process, but also for introducing me to the topic of tinnitus and hyperacusis. She has inspired me and contributed in making the last two years exceedingly fascinating and educational. I would also like to thank all my internship guidance counsellors for their inspiring teachings and for being role models.

I would especially like to thank my husband Tom Alexander for endless support and love. When our son was nearly a year old, I went back to school and started this journey. The logistics with caring for a toddler, internship, exams and papers due, have not always been the easiest, but Tom has always stepped up with a smile. This master's thesis would not be possible without him, and I will be forever grateful.

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# 1 Introduction

This master's thesis in educational audiology is a literature review of scientific research on the topic of "Third wave" cognitive behavioral therapy (CBT) on patients with tinnitus. "Third wave" is the name of a newer approach in CBT. The treatments are no longer traditional in the sense that they have evolved into a new form, using techniques focusing more on mindfulness and acceptance (Baguley & Fagelson, 2015, pp. 17-18). These Third wave treatment forms are called ACT (Acceptance and Commitment Therapy) and MBT (Mindfulness-Based Therapy) (Flaxman, Blackledge, & Bond, 2010, p. 9; Ruiz, 2010),

CBT and elements from this treatment, has long been acknowledged as an effective treatment option for a variety of psychological sufferings and disorders, also those associated with tinnitus (Hagen & Kennair, 2016, p. 150; Wong & Hickson, 2012, p. 268). Lately the Third wave CBT approach has been incorporated in many practices aiming to treat tinnitus (Baguley & Fagelson, 2015, p. 320). There is already a substantial amount of research papers on Third wave CBT treatments and tinnitus, but few have compared the most solid research to see if there are any broader trends to examine (McKenna, Marks, & Vogt, 2018). More evidence is needed on the reformed CBT intervention focusing on mindfulness and acceptance (Duarte, Lloyd, Kotas, Andronis, & White, 2019) as prevalence is expected to increase (Langguth, Kreuzer, Kleinjung, & De Ridder, 2013).

## 1.1 Background, purpose and approach

After interning at an educational audiology center, where working with tinnitus and hyperacusis was the main focus, my interest in these disorders was sparked. Many tinnitus treatments are often regarded as lacking in the evidential rudiments (Wong & Hickson, 2012, p. 277), but traditional CBT is considered a viable evidence-based treatment. The aim of this study is to analyze research to see if the reformed CBT treatment is a suitable or more effective option for treating tinnitus patients and the psychological conditions and disorders that follow with bothersome tinnitus. Since there is no effective universal cure for tinnitus yet (Swain, Nayak, Ravan, & Sahu, 2016; Wong & Hickson, 2012, p. 269) one can argue that there is a need for constantly renewed and improved programs or practices in therapy for tinnitus. Evidence based practice (EBP) is a good approach for improving treatment, because it is an expert treatment practice based on updated scientific evidence (Fink, 2012, p. 4; Tye-

Murray, 2014, p. 21; Wong & Hickson, 2012, p. 4), thus challenging old ideas and practices (Fink, 2012, p. 3). According to Tye-Murray (2014, p. 22), practices in aural rehabilitation particularly require a foundation in evidence. This is because there are many different treatment interventions in audiology and a growing body of evidence that needs to be evaluated before being implemented (Wong & Hickson, 2012, p. 18).

## **1.2 Evidence based practice (EBP)**

Evidence based practice (EBP) is in sum a term to specify an approach to how clinicians merge the latest evidence to their practice while working with people (Wong & Hickson, 2012, p. 3). The EBP approach has guidelines as how to study and apply research, and it is encouraged in all professional settings that treats people (Spencer, Detrich, & Slocum, 2012). Thus, finding solid evidence that can improve treatment is not just important for my future practice, but for anyone working with tinnitus and CBT.

The purpose of this master's thesis is thus to provide a solid research paper that can be of value to many fields working with CBT and tinnitus. Accordingly, EBP is a foundational approach in this study that guides it towards using the best evidence, as evidence is a fundamental concept of the EBP paradigm (Leach, 2006).

## **1.3 Research question and PICO**

Having a focused question is an important first step to find the appropriate evidence and research material one seeks (Tye-Murray, 2014, p. 25; Wong & Hickson, 2012, p. 5). EBP offers steps in conducting research, and using these, it helps define a solid research question by breaking the questions down into a PICO acronym (Wong & Hickson, 2012, p. 4). In this study, the aim is to evaluate the effect of a newer CBT approach compared to the *traditional CBT, other similar treatments* or *no treatment* on psychological conditions and disorders associated with tinnitus. PICO addresses all these analytical components (Wong & Hickson, 2012, p. 12) and was accordingly chosen as a framework for the research question, screening and selection of studies.

**Participants:** adult people (+18) with tinnitus.



**Intervention:** Third wave CBT, ACT or MBT treatment for psychological conditions and disorders associated with bothersome tinnitus.

**Comparisons:** patients entering a wait list control, or received a different active treatment. CBT (Cognitive behavioral therapy), TRT (Tinnitus retraining therapy) or RT (Relaxation therapy). Achieved through randomized controlled trials (RTC) design.

**Outcomes:** standardized or validated questionnaires that measured the impact and psychological conditions and disorders associated with bothersome tinnitus like quality of life, depression and anxiety.

**Research question:**

**What do randomized controlled trials reveal about the effect of the Third wave CBT treatment on psychological conditions and disorders associated with bothersome tinnitus in adults?**

To answer the research question, a literature review design was the natural choice. Through critical evaluation of the existing research, a literature review provides an extensive overview and understanding of the recent high-quality research (Cronin, Ryan, & Coughlan, 2008; Fink, 2014, p. 3; Onwuegbuzie & Frels, 2016, p. 3).

## **1.4 Disposition**

This literature review consists of 8 chapters. Chapter 1 starts with an introduction that states the background, topic and purpose of this study, explaining the EBP approach of this master's thesis. After this the research question is explained in the format of PICO. The theory chapter is divided into 3 chapters. Chapter 2 is a theoretical review of what tinnitus is and what the psychological conditions and disorders associated with tinnitus are. Chapter 3 consists of treatment interventions such as CBT and Third wave approaches. Chapter 4 contains relevant theory needed to assess RCT's, evidence and the specific measurement tools used in the selected trials for this thesis. Chapter 5 describes the methods used in this literature review. It aims to clarify the precise procedures and actions used during data research and selection of studies. A portion of chapter 5 is also dedicated to considering validity and reliability in the methods used. Chapter 6 describes the results in several tables, and gives a summary of the selected studies, both individually and as categories. Chapter 7 discusses the major trends in

the findings, weaknesses and validity of this master's thesis. Chapter 8 consists of a conclusion, suggestions for further research and implications in the field of educational audiology.

# 2 Theory: Tinnitus and related psychological conditions and disorders

## 2.1 Tinnitus

The word tinnitus derives from the latin verb “tinnire”, which means “to ring” (Baguley, Andersson, McFerran, & McKenna, 2012, p. 3; Baguley, McFerran, & Hall, 2013; Kreuzer, Vielsmeier, & Langguth, 2013) Today tinnitus is described as a phantom noise (Baguley et al., 2013), or the perception of a sound or ringing in the head or ears, when there in fact is no external sound or sound stimulation (Cima, 2018; Jastreboff & Hazell, 2008, p. 4; Kreuzer et al., 2013; Langguth et al., 2013; B. C. J. Moore, 2012, p. 37; Plack, 2013, p. 254; Stach, 2008, p. 200).

Tinnitus is classified in two types. The most common one is subjective tinnitus, where the tinnitus is undetectable by anyone but the sufferer. Objective tinnitus is where the tinnitus sound is being produced in the body, and possibly can be measured or heard by the examiner (Baguley et al., 2012, p. 3; Baguley et al., 2013; Eggermont, Zeng, Popper, & Fay, 2012, p. 6; Langguth et al., 2013).

The causes of tinnitus comes from a broad diversity of mechanisms, diseases and illnesses (Celesia & Hickok, 2015, p. 428; Eggermont et al., 2012, p. 59) Tinnitus is linked to damage in the periphery of the auditory system (Eggermont et al., 2012, p. 59; Freberg, 2016, p. 127; Langguth et al., 2013; Plack, 2013, p. 246). Often it originates from abnormal neural activity or changes in the central nervous system, either from altered sensory input or auditory deprivation (Eggermont et al., 2012, p. 59; Langguth et al., 2013; B. C. J. Moore, 2012, p. 37). In a way, it is theorized that this dysfunctional neural activity is similar to phantom pain, and arises from partial hearing loss (Kreuzer et al., 2013).

The prevalence of tinnitus varies, but is often presented as between 10 and 25 percent in adult people, and between 1 and 7 percent for severe tinnitus (Bauer, 2018). The most common risk factors for getting tinnitus are: hearing impairment, increasing age and being a man (Langguth et al., 2013).

## **2.2 Psychological symptoms, conditions and disorders**

Tinnitus in itself is not a disease, but a symptom. However, bothersome tinnitus can be considered an illness or psychological disorder, where a maladaptive psychological response to tinnitus worsens or interrupts the wellbeing and daily function of people suffering from it (Cima, 2018). Tinnitus can be a large burden, and last for years (Savage & Waddell, 2014). Tinnitus can be accompanied by many other comorbidities, and sometimes it is merely a symptom of other underlying disorders or diseases (Langguth et al., 2013). Common symptoms and psychological conditions reported from patients with bothersome tinnitus are: impaired sleep, poor concentration, anxiety, irritation, depression, lack of social enjoyment, hearing difficulty and hyperacusis/decreased sound tolerance (Bauer, 2018; Chapin & Russell-Chapin, 2014, p. 149; Langguth et al., 2013; Savage & Waddell, 2014).

Many studies have confirmed the correlation between psychological distress and tinnitus severity (Fagelson & Baguley, 2018; Hebert & Lupien, 2009, p. 22; Khedr et al., 2010; Malouff, Schutte, & Zucker, 2011). It is also an established theory that the way people think about their tinnitus influences how they relate and are inflicted by it (Katz, Chasin, English, Hood, & Tillery, 2015, p. 650). Consequently, tinnitus can also appear because of emotional factors or stress (Langguth et al., 2013).

Tinnitus can reduce your quality of life from mild irritability to severe anxiety, stress and depression (Eggermont et al., 2012, p. 83; Ziai, Moshtaghi, Mahboubi, & Djalilian, 2017). In the following section, theory on the variety of psychological symptoms, conditions and disorders associated with tinnitus will be presented.

### **2.2.1 Distress and impact**

Stress is a normal physiological response to an environmental stimulant that helps people adapt to situations of threat (Szczepek & Mazurek, 2017, p. 2). However, when people fail to assimilate to stressors, hyperarousal and distress might occur (Szczepek & Mazurek, 2017, p. 141). Hyperarousal is a state of amplified psychological and physiological tension and is theorized as an important component of many disorders like insomnia, anxiety, reduced pain tolerance and tinnitus distress. Heightened stress levels are associated with symptom severity in tinnitus patients (Wallhauser-Franke, Schredl, & Delb, 2013), and this can lead to a

negative spiral of destructive responses (Szczeppek & Mazurek, 2017, p. 141). When people start avoiding situations to alleviate distress, tinnitus, anxiety and catastrophizing (irrational thoughts of fear or terror) might get worse (Baguley & Fagelson, 2015, p. 68; Cima, Van Breukelen, & Vlaeyen, 2017). Thus, the impact of tinnitus grows. The reaction to the emotions associated with stress is also theorized as an important component in how severely the negative symptoms impact people. A study has shown that people with lower tinnitus distress might be better at managing emotional responses to sounds, as the frontal regions of the brain show a different pattern than those highly bothered by tinnitus (Carpenter-Thompson, Schmidt, McAuley, & Husain, 2015).

### **2.2.2 Anxiety**

Anxiety is a broad spectrum of feelings from worry to panic. It can be described as an overreactive, irrational, unwanted and unwarranted emotional fear response. This fear response often involves behaviors of protection and avoidance of something that in reality is not a danger. Anxiety is uncomfortable, with symptoms like elevated heartbeat, sweating, nausea, shivering, dizziness, restlessness, breathing difficulties, sleep (Hagen & Kennair, 2016, p. 142) muscle tensions, sleep problems and concentration difficulties (Cima, 2018). There are many explanations for developing anxiety, and there are many types of anxiety (Hagen & Kennair, 2016, pp. 143-144). The best documented treatment for anxiety is CBT and exposure/habituation methods (Hagen & Kennair, 2016, p. 150).

### **2.2.3 Depression**

Depression is a common comorbid symptom of tinnitus patients (Baguley & Fagelson, 2015, p. 69; Ziai et al., 2017). Depression is a mood disorder that can affect people in various degrees. Symptoms can vary from low energy, lowered concentration levels, lack of interest and joy, reduced self-esteem and self-worth, pessimistic thought patterns and sleep problems, to mention a few (Hagen & Kennair, 2016, p. 127; Holt, Bremner, Sutherland, Vliek, & Passer, 2015, pp. 745-746).

## 2.2.4 Affectivity

Affectivity is categorized in two counterparts, negative and positive affectivity. Levels of positive affectivity is explained as the extent to which someone is pleasantly aroused and excited (Cooper, 2004, p. 203). Negative affectivity is explained as negative emotions, and the dimensions of this state is a construct similar to neuroticism, which is a trait that relates to stress vulnerability. People with high levels of negative affectivity are often distressed and have the tendency to exaggerate what they perceive as threatening situations, as they are biased to interpret stimuli as dangerous (Eysenck, 2004, pp. 171-172).

## 2.2.5 Quality of life and perceived health

Tinnitus becomes a problem mainly because of the reduction in overall quality of life according to a qualitative study completed by Watts et al (2018), especially in those suffering from hearing impairment *and* tinnitus (Prestes & Daniela, 2009). Quality of life is a difficult concept to define, as it is both a philosophical and psychological concept (Sirgy, 2012, p. 5). When speaking of psychological happiness, it is common to think of emotional well-being, and indeed many researchers conceptualize positive and negative affects to be able to measure quality of life (Sirgy, 2012, p. 11). For this study, it might be reasonable to define quality of life as prudential happiness, a high *state* of well-being. Prudential happiness is explained as leading a good life both mentally and physically, achieving personal growth and attaining moments of happiness in your life (Sirgy, 2012, p. 13). When conceptualizing the phenomena into a measurable entity, the term “quality of life” often boils down to satisfaction in salient life domains (Sirgy, 2012, p. 15), and for this study, Frish’s (2014) Quality of Life Inventory (QoLI) is used in some of the selected studies.

When considering quality of life, it is also common to recognize social well-being and health as an important aspect of life satisfaction (Sirgy, 2012, pp. 353, 124). State of health can be defined as the perceived quality of personal health (Sirgy, 2012, p. 384) and is often the most reported aspect influencing peoples quality of life (Sirgy, 2012, p. 124). In addition, quality of life is highly correlated with people belonging to a society or having meaningful relationships (Sirgy, 2012, p. 358). In fact, humans are highly motivated to belong to families and social units to achieve a state of well-being (Holt et al., 2015, p. 563; Sirgy, 2012, pp. 360-361).

## **2.2.6 Insomnia**

Psychological disorders like depression and anxiety can cause insomnia (Hagen & Kennair, 2016, p. 201), which is a sleep disorder where individuals have difficulty falling or staying asleep (Freberg, 2016, p. 392). A normal sleep cycle fluctuates between light and heavy sleep, but if anxiety levels are high, sufferers might wake up when entering the lighter sleep phases. This is a problem for some people with tinnitus, and laying in bed listening to the ringing in their ears can even further elevate the stress levels (McKenna, Baguley, & McFerran, 2010, p. 109). For about half of people with insomnia, the cause of the sleep problems is anxiety, but depression can also be the underlying culprit of insomnia (Horne, 2006, pp. 213, 225). In other words, insomnia often comes as comorbid to other psychological disorders. Disturbed sleep is a common problem for tinnitus sufferers, and the longer the tinnitus and insomnia persists, the more severe both symptoms get (Crönlein, Geisler, & Hajak, 2011, p. 506).

## **3 Theory: Tinnitus treatments**

There are many treatment components involved in psychological and behavioral therapies for tinnitus, like tinnitus-and psychoeducation, problem-solving behavioral intervention and relaxation training to mention a few therapeutic skills. All these components and more might be used in the common psychological and behavioral treatment CBT, which is the most frequently used therapy for alleviating psychological challenges associated with tinnitus (Thompson, Hall, Walker, & Hoare, 2017). In the following section, the relevant therapies and theory on managing problems related to tinnitus is presented.

### **3.1 Tinnitus retraining therapy**

Tinnitus retraining therapy (TRT) is a common treatment for those suffering from tinnitus. It contains counselling and sound therapy, teaching the patients how the body reacts to stress, and how the phenomenon of tinnitus can be controlled through specific behavior and habituation (Jastreboff & Hazell, 2008, pp. 64, 212-213). This therapy always contains the sound enrichment element, and in practice means that the patient avoids silence (Jastreboff & Hazell, 2008, p. 65). Over time, this leads to a habituation of the tinnitus perception (Jastreboff & Hazell, 2008, p. 224). The treatment differs from CBT in that it does not directly focus on the psychological or emotional problems associated with tinnitus.

### **3.2 Cognitive behavioral therapy and relaxation training**

In the 1950s and 60s, psychologists and clinicians began focusing on the idea that thought patterns were correlated with mental disorders, and that these thoughts could be altered in therapy (Teigen, 2015, pp. 353-354). These new ways (at the time) of thinking were a reaction towards the leading established psychological treatments, called behavioral therapy. In behavioral therapy, the treatment methods worked with associations between stimuli and response (Westbrook, Kennerley, & Kirk, 2017, p. 2), and it was very efficient and successful, especially for anxiety disorders. Its limitations lay in that the treatment did not



consider the mental and emotional processes of people, so from this, a movement called the “cognitive revolution” sprung (Westbrook et al., 2017, p. 3).

Albert Ellis was in many ways a pioneer in claiming that people with psychological disorders or problems often make their own situation worse by handling automatic destructive thoughts in a poor manner. The psychologist Aaron Beck took this idea further and started treating people with cognitive therapy, and as the practice evolved and the behavioral aspect of the treatment was integrated, it got its name Cognitive Behavioral Therapy (CBT) (Teigen, 2015, pp. 353-354).

Today, CBT is one of the most widely used therapies for managing tinnitus distress (Bauer, 2018; Jun & Park, 2013). It has an evidence based foundation and established effectiveness in alleviating many of the problems associated with tinnitus (Cima, 2018; Kreuzer et al., 2013; Langguth et al., 2013; Makar, Mukundan, & Gore, 2017; Martinez-Devesa, Perera, Theodoulou, & Waddell, 2010; Savage & Waddell, 2014) like anxiety and the common mood disorder depression (Fagelson & Baguley, 2018, p. 173; Jun & Park, 2013; Kaldo & Andersson, 2004, p. 24).

Like depressive patients, it is common for tinnitus patients to have negative and unrealistic ideas about their tinnitus, and when they evaluate the sound as harmful, anxiety occurs and an adjustment or habituation to the sound fails (Jun & Park, 2013). The goal of CBT is to decrease the negative effect from the tinnitus (Bauer, 2018; Kreuzer et al., 2013) and it does so by focusing on correcting or changing the psychological (internal) and environmental (external) challenges the patient has (Martinez-Devesa et al., 2010; Neenan & Dryden, 2015, p. 42). It helps patients identify negative automatic thoughts, appraise their legitimacy and over time change the thoughts to positive or manageable thoughts (Jun & Park, 2013).

Common tools for coping used in CBT for patients with tinnitus includes relaxation techniques, visualization techniques, focus training (listening to different sounds sequentially), exposure techniques, identifying negative thoughts, sleep and concentration advice, and changing the thoughts about tinnitus (Kaldo & Andersson, 2004, pp. 30-34). The goal is to make the patient feel like living with the tinnitus is manageable (Jastreboff & Hazell, 2008).

Although CBT is commonly used in therapy, there are times that a brief version of the treatment protocol is more practical. There are different ways these shorter versions of CBT are used, and what kind of psychological issue is being targeted has an impact on which elements from CBT are selected. Typically, some form of education in combination with relaxation training and coping techniques are taught (Bond & Dryden, 2005, p. 14). In research, a shorter version or a selection of elements from CBT is commonly executed, called brief CBT or Relaxation Therapy (RT) (Bond & Dryden, 2005, p. 4; Cully & Teten, 2008, p. 6). There are also specialized CBT versions for specific disorders. In this master's thesis the topic of CBT-I will be discussed briefly, which is CBT specifically targeted towards insomnia (Hagen & Kennair, 2016, p. 203).

From behavioral therapy, which also can be referred to as the first wave of clinical intervention, the second wave was established and is now considered traditional CBT. Over the last 10 years this treatment has evolved into something different (Hayes, 2016) and will now be presented in the following section.

### **3.3 Third wave of cognitive behavioral therapy**

The Third wave of CBT is a movement that builds upon the first and second wave but differs from traditional CBT in the way that it focuses more on *context* rather than *content*. The foundation of Third wave is based on the contextualized theory of mind, relational frame theory (RFT) (Hayes, 2016; Ruiz, 2010). RFT explains that language and cognition is dependent on *relational* frames, and these *relations* can change when we alter the *context* (Hayes, 2016). In other words, RFT focuses more on problematic thoughts and emotions and how we *experience* these. This is unlike traditional CBT which focuses on *changing* the thoughts and emotions, or *reducing* their frequency (Flaxman et al., 2010, p. 9). Instead of treating the thoughts, emotions and situations like something you must *change* or *avoid*, the Third wave focuses on *accepting* the situation and the relationship one has to the problem. The Third wave also focuses more on being *mindful*, aware of the “self” and moment-to-moment situations (Cima, 2018; Hayes, 2016).

In the Third wave approach, these ideas are developed into different psychological techniques and treatment methods (Flaxman et al., 2010, p. 9; Hayes, 2016). The most used treatment interventions are acceptance and commitment therapy (ACT), mindfulness based cognitive therapy (MBCT), and dialectical behavior therapy (DBT) (Flaxman et al., 2010, p. 9; Ruiz, 2010), however DBT is not common in treating tinnitus (Thompson et al., 2017) and will not be discussed here.

### **3.3.1 Acceptance and commitment therapy**

In acceptance and commitment therapy (ACT), several methods are combined to produce psychological flexibility. These core processes are acceptance, cognitive diffusion, the “self” and present moment (mindfulness), values and commitment (Flaxman et al., 2010, p. 19). Treating a patient with ACT involves teaching that it is the *function* of the thoughts and action that is important to be mindful of, not *judge* the thought as right or wrong. This approach will in turn make the patient aware of how thoughts and behavior create distress (Baguley & Fagelson, 2015, p. 317).

ACT targets the avoidance behavior and promotes *acceptance* through the creation of an alternative context where the behavior is in line with ones *values* (Hayes, 2016). For example, if one of your values are to socially support your friends by showing up for them, this value might be a motivation to guide you to *expose* yourself to situations that might be stressful. This value is important because stating your values as *goals* will help prevent the cognitive dissonance or uncomfortableness that occurs when your actions *contradicts* what you really want to do. In other words, not acting according to your values might make you compromise who you *want* to be. This is in line with the commitment part of ACT, stating that the treatment involves being true and consistent with one’s values. It also involves willingness to be open to experiencing both negative and positive emotions (Flaxman et al., 2010, p. 41).

Cognitive diffusion techniques involve being mindful and take a “step back” to experience ones thoughts and sensations as they are, without necessarily being attached to them (Ruiz, 2010). These techniques attempts to alter the function of the thought, instead of their form (Flaxman et al., 2010, p. 26). For examples, instead of avoiding a social setting that induces anxiety, cognitive diffusion encourage that thoughts (like fear) cannot dominate over a person’s behavior (Gaudiano, 2011).

It has become more common to use ACT as an intervention in patients with tinnitus, as it is speculated that this underlying foundation might be a key to reducing emotional problems associated with tinnitus (Riedl et al., 2015).

### **3.3.2 Mindfulness-based therapy**

MB(C)T (Mindfulness-based (cognitive) therapy) uses CBT as a theoretical framework in its treatment, and is getting more common in the management of many problems, like tinnitus (Crane, 2017, p. 7; Gans, 2010). MBT and CBT both focus on the consciousness of thoughts and emotions, but in different ways (Gans, 2010). Where CBT involves judging the thoughts and categorizing them as irrational or unrealistic, the concept of mindfulness is that all thoughts should be *accepted* without an the aim of changing them, and one should simply observe the thoughts as they come and go (Gans, 2010).

A necessary core of Mindfulness, is the willingness to *start over* again, and practice (Segal, Teasdale, & Kabat-Zinn, 2018, p. 150). There are many both formal and informal methods involving the practice of Mindfulness. The foundation of these are *meditation* and using *breathing* as a basis for focused attention (Crane, 2017, p. 7; Segal et al., 2018, p. 150). Body scans, mindful movements and practicing present-moment-awareness are also key techniques used to achieve a mindful state. MBT also teaches a specific attitudinal approach, where *kindness*, *curiosity* and an *open mind* to being vulnerable and in-the-moment is at the forefront (Crane, 2017, pp. 4-5). The aim of the intervention is to teach the patients to bring their awareness back to an anchor in the present moment (Segal et al., 2018, p. 44).

In a systematic review by Gotink, Meijboom, Vernooij, Smits, & Hunink (2016), they found that by learning cognitive techniques like recognizing automatic reactions and letting go of dysfunctional thoughts in a non-judgmental manner, the brain changes structurally and functionally. This might partially be because MBT is associated with changes in attention skills. Attention and working memory are closely related (Baer, 2010, p. 10), in their capacity to maintain and manipulate information in a focused manner in short intervals (Baer, 2010, p. 208). As directing attention is a central part of MBT practice, it might not be surprising that repeated exercise can lead to an enhancement in attention skills (Baer, 2010, p. 10).

The benefit from learning this new coping mechanism of MBT is not only an improvement in perceived stress and anxiety, but in several psychological aspects, like quality of life and

depression (Gotink et al., 2016). Other studies have also shown that MBT is especially effective at reducing the chance of depression returning at a later time (Crane, 2017, p. 83).

### **3.3.3 Nervous system, brain and meditation**

The nervous system is divided into the peripheral nervous system (PNS) and the central nervous system (CNS). The PNS is further divided into the somatic and autonomic nervous system, and part of the autonomic nervous system is responsible for stress reactions in the body (Smith, 2005, p. 20). This system is called the sympathetic nervous system, with its counter, the parasympathetic nervous system. Simply put, the sympathetic nervous system is responsible for the calming state (rest and repair) of the body (Freberg, 2016, pp. 54-56).

A stress response is an automatic mechanism, which involve all major body systems: the heart, brain, nervous system, lungs and circulatory system (Smith, 2005, p. 23). In the brain, the amygdala plays a vital role in managing stress stimuli. The amygdala is a structure of the limbic system in the brain, and is especially involved in emotion regulations like fear and aggression and motivation (Freberg, 2016, p. 42). The amygdala communicates with other structures in the brain, and the higher order of the prefrontal cortex is key in the collaboration of managing stress from stimuli. Some of the functions executed by the prefrontal cortex are executive functioning tasks like judgment, reasoning, attention, emotional regulation, focusing awareness and fear modulation (Gans, 2016).

A correlation between stress, illness and lack of relaxation is well established, and practicing relaxation techniques can reduce arousal and diminish problems related to stress (Smith, 2005, pp. 26-27). People with bothersome tinnitus often succumb to their fear and start avoiding stressful situations. MBT teaches people with chronic tinnitus to recognize the role of their thoughts and how they incite distress (Gans, 2010). Meditation is used as a tool to influence the brains' communicative fear and stress pathways, and thus calms down the sympathetic nervous system (Simpkins & Simpkins, 2016, p. 168).

Meditating about tinnitus and being open and accepting to the symptoms experienced with tinnitus gives the patients practice and tools to go in and out of awareness without struggling with their feelings and thoughts (Gans, 2010). However, this requires practice to master, and when mastered can easily be used to release stress and tension in the body (Smith, 2005, p. 162).

### **3.4 Pain management**

Pain is a construct that consists of both emotional and physiological qualities (Jay, 2007, p. 1). Pain can occur with or without tissue damage, and so in many cases it is mainly a psychological phenomenon (Arntz & Claassens, 2004). Tinnitus distress and pain have similar neural activity (Malouff et al., 2011), and in many ways, tinnitus management relates to pain management. The symptoms of poor attention and focus, catastrophic thinking, anxiety, sickening feeling, muscle tension and maladaptive coping strategies are common in patients with tinnitus *and* pain suffer (Gans, 2010; Moller, 2000).

### **3.5 Treatment modalities**

Most people are not distressed by their tinnitus as they have adjusted or habituated to it (Wong & Hickson, 2012, p. 276). However, those who are bothered by it, current treatment focuses on alleviating or altering the subjective experience. To do so, a main aspect is to control one's arousal mechanism, and there are several theoretical models that explain how the body reacts to stress and arousal (Cima, 2018). The neurophysiological model (NP) is the only theoretical frameworks used in treating tinnitus symptoms that will be mentioned in this thesis.

Evaluating if the treatment or therapy offered to the patient is effective or ethical, it is worth considering the treatment components and styles involved, when assessing trials. Therapies differ, and how the treatment is conducted has changed over the years as communication through the internet is becoming more popular and common (Andersson, 2014, p. 8).

In traditional therapy (face-to-face), the essence of helping is based on the human connection between two or more people (Nelson-Jones, 2012, p. 41). Cognitive therapists attests to Carl Rogers' vital condition for therapeutic change, which is the therapists empathic understanding of the patient (Nelson-Jones, 2012, p. 47). In CBT the relationship is regarded as necessary, though not the only essential element to bring about change, as the patient also needs to learn skills and techniques (Nelson-Jones, 2012, p. 42).

Another vital skill used when treating people's psychological distress, is active listening. It involves understanding the meaning of the sound or language presented. It entails being

sensitive to vocal cues, observing body language, and taking personal and social context into account when communicating with another person (Nelson-Jones, 2012, pp. 55-56).

To map out what the patient is struggling with, in CBT the therapist often interprets what the patient is saying, and reflect back what is the essence or the meaning of the words, often with additional insight (Nelson-Jones, 2012, p. 60). Often the true feelings of the patients are not obvious. Tone of voice, body language and verbal cues are not always consistent with what is being said (Gelso & Fretz, 2000, p. 160), and an effective therapist is skilled at listening to the deeper meaning or camouflaged feelings in what is being said (Nelson-Jones, 2012, p. 74; Wilkins, 2002, p. 12). In all, therapeutic presence in CBT propels the process of improvement when helping patients (Friedberg, Tabbarah, & Poggesi, 2013).

In recent years, I-CBT (Internet-Cognitive Behavioral Therapy) has been used in many clinical settings to treat a variety of psychological illnesses (Andersson, 2014, p. 8). A web-based intervention is a self-guided intervention program that is accomplished using an online program that is designed to help people by giving them educational material and guide them through interactive web-based components. Human support is supplied through the internet in various degrees. This contact might be forum, email, chat or face-to-face video (Andersson, 2014, pp. 2-3).

# 4 Theory: Evaluating evidence

When choosing a treatment practice, it is vital to base the treatment on solid and significant evidence. Not doing so fails in justifying its use in EBP, since evidence is the foundation in a claim (Machi & McEvoy, 2016, p. 120).

## 4.1 Material

Since the literature review provides a discovery of what is known about a given topic, it is the preferred design in finding research material that converts data to evidence that can justify the future treatment methods to be used on patients (Machi & McEvoy, 2016, p. 5).

To evaluate the data, it is reasonable to identify the level of quality the material has. There is an established hierarchy to evidence (Wong & Hickson, 2012, p. 9), and the most convincing and highly sought after evidence, is that from level 1 (Tye-Murray, 2014, p. 23). The following tables is an overview of the types of study and their designated level.

**4.1.1 Table 1. Levels of evidence**

Level	Types of evidence
1	Systematic reviews and meta-analyses of studies that are of high level or RCT
2	Well-designed RCT
3	Treatment studies that are not randomized (e.g., nonequivalent group designs, separate sample pretest/posttest design, and time-series designs)
4	Nontreatment studies (e.g., cohort studies, case-control studies, cross-sectional studies, and uncontrolled experiments)
5	Case studies
6	Expert comments



#### 4.1.2 Table 2. Grades of evidence

Grade	Types of evidence
A	Mostly Level 1 or 2 studies with conclusions that are consistent across studies
B	Mostly Level 3 or 4, <i>or</i> Level 1 or 2 studies with findings that are not fully relevant to the population or problem concerned but generalization could be made
C	Mostly Level 5 evidence <i>or</i> Mostly Level 3 or 4 studies with findings that are not fully relevant to the population or problem concerned but generalization could be made
D	Mostly Level 6 evidence <i>or</i> When most of the evidence lacks consistency or the conclusions are mostly uncertain or when most of the evidence exhibits a high chance of bias

Adapted from Wong and Hickson (2012, pp. 12,17).

## 4.2 Randomized controlled trials

An RCT is an A-graded study where the participants try different interventions to measure the effect on a problem or hypothesis. RCT involve an experimental treatment that is randomly selected to people that are randomly chosen to represent a population (Goodman & Gilchrist,

2013). The control group might be the “typical” treatment, the placebo or both at the same time. The outcome of these controls are measured against the experimental group, and it is commonly established that RCTs is the best way to demonstrate effectiveness of an intervention (Fink, 2012, pp. 108-109). The relevant control group in this thesis, are wait-list controls, which are where one group receives the treatment first and the second group receives the treatment after a while (Fink, 2012, pp. 111-115), and other active treatments.

## **4.3 Assessment**

If the method used in a study is weak, being a RCT will not produce solid evidence (Goodman & Gilchrist, 2013). To evaluate the quality of the study, as is important in EBP (Wong & Hickson, 2012, p. 17), a tool for appraising it is crucial, and there are many to choose from depending on what design is being appraised (Nadelson & Nadelson, 2014; Wong & Hickson, 2012, p. 14).

A tool that efficiently covers the fundamental and vital questions to be asked in evaluation of RCT, is the Critical Appraisal Skills Programme (CASP) (also referred to as CAT) (Centre for Evidence Based Medicine, 2019; Nadelson & Nadelson, 2014). This checklist includes questions that break the study down so that the individual elements of the study are more transparent.

For this study, the goal of selecting studies is to present sound and valid research with as little bias as possible. Accordingly, the assessment tool CASP (CAT) from CEMB (Centre for Evidence Based Medicine, 2019) was used in evaluating the selected studies in the method and design chapter. The following section presents the relevant theoretical content of what the appraisal tool examines in RCT's.

### **4.3.1 Randomization and sampling**

The principle of randomization is important, but not always the case when it comes to sampling. Sometimes, a convenience sample is used, but the treatment is always chosen randomly (Goodman & Gilchrist, 2013). Convenience samples are useful but increase the chances of bias in the results. To ensure the study has obtained a representative sample, there needs to be random sampling (De Vaus, 2014, p. 67; Fink, 2014, p. 83). Nearly all statistical methods need to have a basis in randomization to be reliable. If not, the assumptions and

calculations based on the chosen sample might not represent the true population, thus being less valuable (Diez, Barr, & Çetinkaya-Rundel, 2015, p. 20).

Furthermore, the sampling size used in the RCT should be large enough to ensure it represents the actual population (Coughlan, Cronin, & Ryan, 2007). A large size also enhances the study's capacity to detect effect (Fink, 2014, p. 87). The larger the sample size is, statistical estimates and calculations becomes more accurate, and thus important variances in the mean and null value are easier to detect (Diez et al., 2015, p. 202).

### **4.3.2 Blinding**

Preferably, the RCT should also involve a “blinding” method, keeping the participants and researchers oblivious of what intervention group they are in, as this reduces bias (Fink, 2012, pp. 108, 125; Goodman & Gilchrist, 2013). When participants do not know which intervention they are getting, but the investigators do, it is called a blinded trial. However, when both participants and researchers are unaware of what treatment is assigned to whom, it is a double blinded treatment. Blinding is considered very important in RCTs, since not blinding might produce bias and confounding variables. Confounding variables affects the outcome statistically and might lead to false conclusions (Bordens & Abbott, 2013, p. 112; Fink, 2012, p. 121).

### **4.3.3 Attrition**

When appraising research, it is important to consider attrition. Attrition is when the participants drop out of the ongoing study. It is likely that some participants will drop out, but if a larger number or a skewed number from only one group drops out, this impacts the results (Fink, 2012, p. 141).

### **4.3.4 Placebo effect**

The placebo effect is the positive response to an illusory stimulant. An example would be someone going through a trial believing they are getting a treatment or medicine, in reality not, and then having improved health benefits as a result (Schroeder, 2018, p. 1255).

It is explained as the psychological phenomena of expectancy and classical conditioning, and can have a substantial effect on a variety of cognitive-behavioral therapies and physiological responses (Benedetti, Enck, Frisaldi, & Schedlowski, 2014, p. 207; Schroeder, 2018, p. 1255). Not all illnesses have the same placebo effect, in fact, the strongest indicator for placebo is what type of illness is being treated. Some conditions are highly responsive to the placebo effect, while some are not. Generalized anxiety disorder, panic disorders, pain and depression are highly responsive, sometimes as much as conventional intervention (Benedetti et al., 2014, p. 207; W. A. Brown & Brown, 2013, p. 23).

RCTs use of control groups often minimize the placebo effect, especially if the trial is double blinded (Schroeder, 2018, p. 1255). For this thesis it is relevant to look for sustained effect and placebo in the selected studies, as the placebo effect ranges around 40 percent in tinnitus patients (Jastreboff & Hazell, 2008, p. 150), and since many of the treatments for tinnitus target depression and anxiety. In addition, measuring sustained effect might reveal important information compared to focusing on immediate effect only.

#### **4.3.5 Reliability**

Reliable data are data collected with few “measurement errors” (Fink, 2014, p. 105; Lund, Kleven, Kvernbekk, & Christophersen, 2002, p. 154). In other words, if the study’s precision is so consistent that the same outcome would be produced over and over, it is reliable (Bordens & Abbott, 2013, p. 126). Reliability is often categorized in three groups: within measure, between measures and between observers. For this thesis, it is relevant to consider between observer reliability, which comes in two forms, inter-rater and intra-rater reliability. Inter-rater is when more than one individual observes, or instrument score the same or agrees with the assessment. Intra-rater is when an individual observer is consistent over time (Fink, 2012, p. 184).

#### **4.3.6 Internal validity**

Validity in experimental research is explained as a trial studying what it actually wants to study (Bordens & Abbott, 2013, p. 129). In order to make a claim about an experimental trial, the study needs to have interval validity, and it is important when evaluating research to look for validity threats (Fink, 2012, p. 140). Common threats to internal validity are poor sampling methods (no randomization) and maturation changes in the participants. Other

threats are changes in measurement methods and instruments, statistical regression, attrition and no blinding which might lead to expectancy in the participants and evaluator (Fink, 2012, pp. 140-141; Lund et al., 2002, pp. 116-120).

#### **4.3.7 Measurement validity**

Measurement validity is sub-categorized in different types of validity. When examining the measurement validity in a trial, the focus is on studying the instrument that provides data about the concept that is being studied (Fink, 2012, p. 186).

Firstly, construct validity refers to the “study as a whole”. For example, if a trial is measuring if a treatment impacts tinnitus annoyance, the construct “tinnitus annoyance” is a variable that might not directly be observable. If construct validity is to be obtained, the test needs to demonstrate a predictive behavior based on the relevant theory. For example if someone was less annoyed with tinnitus, they might show less signs of negative affectivity (Bordens & Abbott, 2013, p. 130; Lund et al., 2002, pp. 176-177).

Secondly, content validity (internal validity) refers to the trials or experiments operationalized methods to measure what it set out to measure. In order to achieve a high level of content validity, the measurement instrument needs to cover all the relevant subjects being studied. The test instruments have to be precise in the way that they illustrate the essence of the content of what is being studied (Bordens & Abbott, 2013, p. 129; Fink, 2012, p. 186). In other words, content validity is high if it measures every aspect of the construct. In the previously mentioned example, the test instrument would have to measure different aspects of tinnitus annoyance and happiness.

#### **4.3.8 Assessment tools**

There are several relevant assessment instruments and questionnaires that measures different aspects of tinnitus and the psychological conditions and disorders that follows. Some of the recognized measurement devices for tinnitus assessment are:

The Tinnitus Questionnaire (TQ), Tinnitus Reaction Questionnaire (TRQ) and the Tinnitus Handicap Inventory (THI) (Wong & Hickson, 2012, pp. 268-269). The (TQ) is a 52-item questionnaire that measures several aspects of tinnitus severity, like emotional and cognitive

handicap, health and impact on lifestyle. The THI measures tinnitus disruption, emotional reactions and impact on daily function. Both THI and TQ are considered to have strong internal consistency and adequate construct validity for measuring handicap and global tinnitus impact (Newman, Jacobson, & Spitzer, 1996; Zeman et al., 2012). The TRQ was developed to measure different levels of tinnitus related distress. However, TRQ might be said to not directly assess tinnitus, as it is more attentive to psychological and emotional challenges associated with tinnitus. Impact of lifestyle and sleep is also covered, but nearly all questions involve the sentence “my tinnitus makes me feel”. Validation studies imply that TRQ is more similar in construct to assessment tools measuring depression or anxiety (Fackrell & Hoare, 2017).

The selected studies also recurrently used the Tinnitus Functional Index (TFI), which measures tinnitus handicap. TFI is considered to have acceptable construct validity and reliability when measuring tinnitus impact (Fackrell & Hoare, 2017; Meikle et al., 2012), but might have some limitations as to internal validity (Fackrell, Hall, Barry, & Hoare, 2016).

In addition, several other custom designed and psychological assessment tools are widely used in studying tinnitus effects (Wong & Hickson, 2012, pp. 268-269). Some of the most frequently used psychological measurement tools in the selected studies are: Insomnia Severity Index (ISI), Quality of Life Index (QOLI), and Hospital Anxiety and Depression Scale (HADS). ISI measures insomnia and sleep quality (Bastien, Vallieres, & Morin, 2001; Kaldo et al., 2008), and QoLI assesses psychological well-being and life satisfaction (Frisch et al., 2005). Both are considered to have acceptable internal consistency, validity and reliability (Bastien et al., 2001; Frisch et al., 2005).

The HADS measures depression and anxiety. It is considered an assessment tool that produces meaningful and predictable results (Herrmann, 1997). When it comes to measuring anxiety and depression in tinnitus patients, a study completed by Zoger, Svedlund and Holgers (2004) suggested that the HADS was superior on measuring depression, but not as good at measuring anxiety.

Some of the other tools used in the selection of studies for this master thesis are Tinnitus Acceptance Questionnaire (TAQ) and Tinnitus Psychological Impact Questionnaire (QIPA).

TAQ contains questions about acceptance and aspects of quality of life and is considered to have high internal consistency (Westin, Hayes, & Andersson, 2008) and satisfying test–retest reliability (Westin, Hayes, et al., 2008). QIPA on the other hand is a questionnaire that combines other questionnaires and evaluated psychological distress. However, it is not validated or published yet (Heeren et al., 2014).

#### **4.3.9 External validity**

External validity refers to the extent a study’s findings are generalizable. If it doesn’t make sense in other scientific disciplines for example, it has poor external validity (Fink, 2012, p. 140). Threats to external validity often include bias in the form that people act differently in the study than they would in real life. In experimental trials the participants might answer questions or behave in ways that do not represent the actual truth. The results will then in fact, not be valid for other people in normal settings (Fink, 2012, p. 142).

#### **4.3.10 Significance**

To determine if meaningful differences exist between two trial groups, researchers often use statistical methods, commonly the P-value (Fink, 2014, p. 117). While there are other statistical methods used to measure effect, the P-value confirms there is a large *enough* difference (Bordens & Abbott, 2013, pp. 84-85; Sullivan & Feinn, 2012), and for the scope of this study, only statistical significance will be analyzed.

# 5 Methods and design

## 5.1 Design

The fundamental purpose for this thesis is to be of use in EBP treating patients with tinnitus. To answer the research question “What do randomized controlled trials reveal about the effect of the Third wave CBT treatment on psychological conditions and disorders associated with bothersome tinnitus in adults?”, it was reasonable to choose a research design that includes a large body of significant evidence for evaluation. The literature review was thus a suitable design. Through critical evaluation of the existing research, a literature review provides an extensive overview and understanding of the recent high-quality research (Cronin et al., 2008; Fink, 2014, p. 3; Onwuegbuzie & Frels, 2016, p. 3)

Historically there are two branches of literature reviews, the traditional narrative literature review, and the systematic review (Onwuegbuzie & Frels, 2016, p. 12). Today the general literature review is a traditional literature review that aims to present a critical aspect of the most current knowledge on a specific topic (Onwuegbuzie & Frels, 2016, p. 3). In the expectation that this design will give new insight that advances knowledge (Fink, 2014, p. 3), and ultimately ends up being a scientific contribution (Rhoades, 2011), a traditional review was chosen for this master thesis as it fits the goal and research question. The methods of this literature review will also have the intention of closing in on a systematic approach to the traditional literature review, since the principles and structure might be useful in the presentation of data (Timmins & McCabe, 2005).

## 5.2 Search strategy and selection

In December and January (2018-19) several searches were made using Pubmed and Google scholar to scope out what research was done on tinnitus treatment with CBT. At this time the research question contained the word “biofeedback”. The research question had to be reconsidered after the conclusion that there was not enough research on “biofeedback and CBT” as a combination. Another search was conducted February 8<sup>th</sup> on CBT and tinnitus, and from this a refined research question was formed, focusing on the Third wave of CBT for



tinnitus patients. Several mock searches were then made to plan how the efficiency of gathering the material was to be executed. A final search where all the material was collected was completed on February 11<sup>th</sup>. During this time, it was not decided that RCT's would be the only included study designs in the thesis, due to the uncertainty of the amount of high-quality research on the topic selected. Since RCT's are considered the gold standard of research, the aim of the study was to find enough high quality RCT's to compare and analyze with CASP. Trials with large random samples was preferred, and in the case of there not being enough studies with random sampling, RCT with convenience sample would be selected. If there was not enough trials with double blinding, studies with less quality was to be selected, though this weakens the validity of the thesis (Goodman & Gilchrist, 2013).

The databases used during this search was PubPsych, Pubmed, Cochrane library and Oria UIO. These engines were selected from a list of suitable search engines from "helsebiblioteket" for health and psychology related subjects (Helsebiblioteket, 2019). A decision was also made to use Web of Science since this engine was observed being used in many systematic reviews for similar studies. Choosing these engines was considered to strengthen the validity of the study because of their combined wide scope health topic database. A survey of other relevant article references was also conducted to ensure no studies were missed during keyword search (Fink, 2012, p. 82).

### **5.3 Search terms**

The search terms were selected to strengthen the study by aiming to include all possible studies conducted on the topic. According to Timmins (2005), choosing suitable keywords is the foundation of an effective search. Before the final search, narrowing the focus of the topic was achieved through following PICO and excluding therapeutic themes and research designs not relevant for the goal in this thesis (Galvan & Galvan, 2017, p. 40).

In an RCT there is automatically a controlled group being compared to in the trial. The "other" trial group would be waitlist controls or other active treatment, and since other active treatments often are "typical" treatments (Fink, 2012, pp. 108-109), the decision was made to focus only on CBT, treatments with elements from CBT like Relaxation Therapy (RT) or Brief CBT, or Tinnitus Retraining Therapy (TRT). As CBT is the most common psychological treatment form for tinnitus distress (Bauer, 2018; Jun & Park, 2013), it was

reasonable that this, and versions of it was the main comparable active treatment. TRT is also a common treatment practice for bothersome tinnitus, and was thus included (Jastreboff & Hazell, 2008, p. 224). A prior search had been made to scope out if there was much research on TRT versus Third wave treatments for tinnitus, and the data was very sparse. TRT was thus not selected as a search term because the main focus would be on different forms of CBT. However, if all else search terms were met and TRT was a part of the data, an inclusion of this treatment type was relevant as a comparison to a Third wave intervention. Other treatments like medicine, exercise and acupuncture was considered not to be the “most typical” tinnitus treatment.

The databases responds to the keywords applied, so gathering the appropriate words that described the intervention, was important in making sure the search was unbiased (Timmins & McCabe, 2005). All possible keywords were considered through scoping research articles, other literature reviews and books on the topic, which are displayed in the appendix. After writing down all the relevant words, a pattern was clear on what words would be suitable as search terms as some words were more frequent than others. The keyword subject was carefully considered to not contain too many or different words, so that the search would not be too wide. Another mock search was conducted to estimate how many studies would be relevant to choose from (Galvan & Galvan, 2017, p. 25) .

### **5.3.1 Search terms selected**

The word *tinnitus* was chosen as the first search word. A decision was made to not include the word *bothersome* even though the research question contains the word. The reason for this is that experimental trials treating tinnitus patients usually don't use the word *bothersome*, as this is a given when patients are being treated. The following words and acknowledged acronyms were chosen on the basis of what was considered to define the Third wave CBT. *Cognitive Behavior Therapy (CBT)*, since this word is used in both the Third wave approach and the traditional intervention. What stands out in the Third wave movement of CBT is *acceptance* and *commitment* of one's situation, and *Acceptance and Commitment Therapy (ACT)* is one of the main treatment practices in the Third wave approach (Flaxman et al., 2010, p. 9; Ruiz, 2010). For this reason, *ACT* as an abbreviation and the two words *acceptance* and *commitment* was chosen to define this Third wave approach. *Mindfulness-*

*Based Therapy (MBT)* has many names for the same training and is often combined with *meditation-based* training. MBT might be the most common, but Mindfulness-based stress reduction (MBSR) and Mindfulness-based meditation training (MBMT) are also common. Since MBT, MBST and MBMT begins with the same name (Mindfulness-Based), and MBT only adds the word “therapy” which is already a word used in *Cognitive behavior therapy*, a decision was made to use MBSR. This way, two other words would broaden the search, *stress reduction*. In addition, the word *meditation* was chosen, as this is an important part of MBT. The words *third wave* and *mindfulness (alone)*, was also used as a search term.

### **5.3.2 Search keywords**

The formula for the search of material was set as follows; keyword from section 1 first, keyword from section 2 second, revolving keyword from section 3.

Section 1: Tinnitus AND/+

Section 2: Cognitive Behavioral Therapy, AND/+

Section 3: ACT, MBSR, Mindfulness-Based Stress Reduction, acceptance, commitment, third wave, meditation, mindfulness.

The searches were made in 8 rounds with shifting words from section 3. This procedure was implemented to ensure no studies were missed. The words AND in this format is called a boolean operator, and was chosen as it function impacts what is included and excluded in the search engines (Fink, 2012, p. 79).

### 5.3.3 Table 3. Search hits and results

Search terms: Tinnitus+Cognitive Behavioral Therapy +...	PubPsych	PubMed	Web of Science	Cochrane	Oria	SUM
+ ACT Hits	5	9	1	5	624	644
+ ACT Results	3	3	1	5	13	<b>25</b>
+ MBSR Hits	0	1	0	0	170	171
+ MBSR Results	0	1	0	0	61	<b>61</b>
+ Mindfulness based stress reduction Hits	0	3	0	0	170	173
+ Mindfulness based stress reduction Results	0	1	0	0	8	<b>9</b>
+ Acceptance Hits	13	22	4	13	483	535
+ Acceptance Results	9	13	4	10	31	<b>67</b>
+ Commitment Hits	5	22	2	5	100	134
+ Commitment Results	4	13	2	4	2	<b>25</b>
+ Third wave Hits	0	0	0	0	276	276
+ Third wave Results	0	0	0	0	1	<b>1</b>
+ Mindfulness Hits	3	11	1	4	301	320
+ Mindfulness Results	1	7	1	4	12	<b>25</b>
+ Meditation Hits	0	5	1	2	187	195
+ Meditation Results	0	4	1	2	9	<b>16</b>

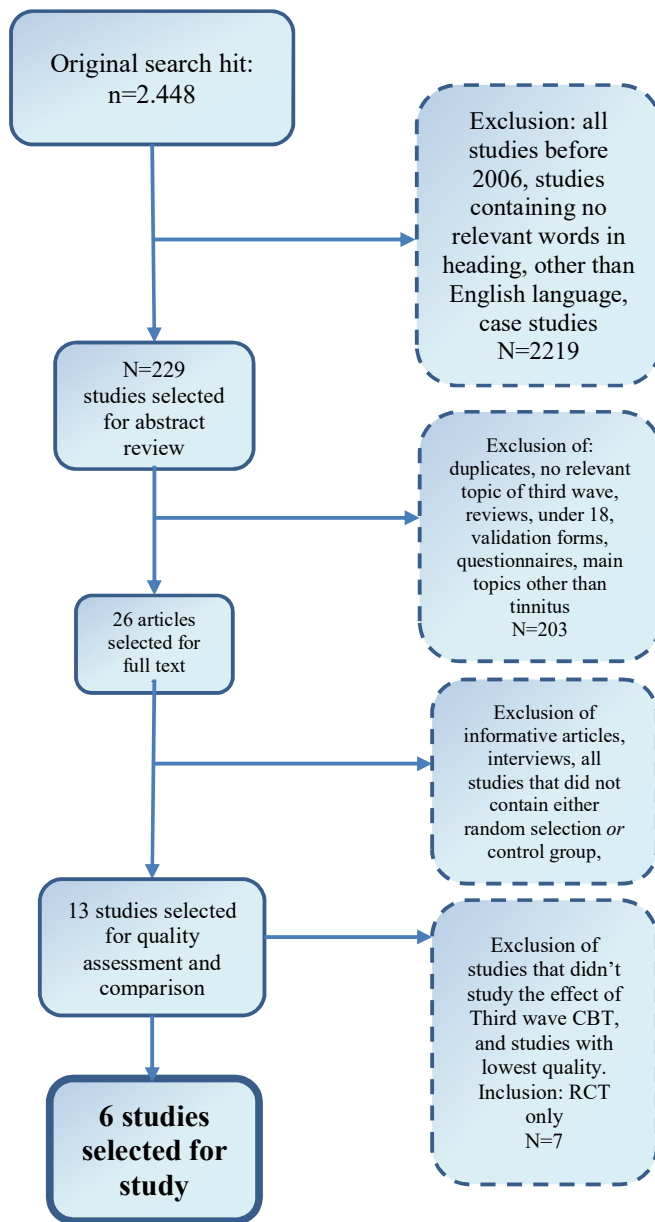
Sum of all hits: 2448

Sum of all relevant results: 229

## 5.4 Selection and search criteria

Selection of studies were accomplished through 4 stages. In each stage a set of exclusion and inclusion terms directed the selection of studies. This procedure was chosen with the aim to clarify the selection process to impact the reliability of this study.

### 5.4.1 Flowchart



### 5.4.2 Stage 1 of exclusion and inclusion

The search material had to contain the word from section 1 and the words from either section 2 or 3. No material from before 2006 was screened because research on hearing related issues is changing fast. Choosing research that is more than 13 years old on the topic might not shed

light on the latest trends and methods in CBT treatment. No case studies were selected due to the fact that these are evaluated as the lowest form of study with little or no external validity (Wong & Hickson, 2012, p. 17). Only papers with English or Norwegian language were selected. In Oria, a preset of “articles only” were checked, since this search engine needs more input to only select articles. Books and other material than research studies were not relevant.

229 relevant studies were selected for abstract review and categorized.

### **5.4.3 Stage 2 of exclusion and inclusion**

The studies were screened for duplicates and had to contain an intervention of the Third wave version of CBT, since this is relevant in the research question. A lot of the studies contained material that studied tinnitus and one other aspect, treated with CBT. These added interventions, like biofeedback, were excluded since these are not a part of my research question. Systematic reviews and literature reviews were excluded, studies conducted on children were excluded, validation of questionnaires were excluded and only studies where tinnitus was the main topic was included. All these criteria are manifested in the research question.

26 studies were selected for full text review.

### **5.4.4 Stage 3 of exclusion and inclusion**

Exclusion of all studies that did not have either random selection of participants or control groups. Interview studies were excluded. Exclusion of studies examining the meaning of acceptance. Inclusion of studies that were on topic, which left 13 studies for reassessment. See appendix for more detail.

### **5.4.5 Stage 4 of exclusion and inclusion**

Exclusion of studies that did not study the effect of Third wave CBT on psychological conditions and disorders in bothersome tinnitus, and qualitative research. Only RCT's were selected. This decision was made on the basis that RCT, as noted earlier, are considered the gold standard of research, and the aim for the study was to find solid evidence from quality

research. However, if the methods used in a study is weak, being a RCT will not produce solid evidence (Goodman & Gilchrist, 2013). Accordingly, an appraisal tool for RCT's was used to evaluate the quality of the selected studies.

#### **5.4.6 Evaluating quality research**

A tool that efficiently covers the fundamental and vital questions to be asked in CASP (CAT) (Centre for Evidence Based Medicine, 2019; Nadelson & Nadelson, 2014). Appraising the evidence critically is an important aspect of EBP (Wong & Hickson, 2012, p. 17). The checklist for RCT's include questions that breaks the study down so that the individual elements of the study are more transparent. After applying this tool to the 13 studies, they were arranged from those that suited the research question best and measured the effect of Third wave, and from the lowest to highest CASP score. The studies that were estimated with the greatest methodological strength, were those who scored highest on the appraisal tool. A decision was made during this stage to include a pilot study that included all other criteria, due to its high-quality score. The goal was to include 7 studies in the master's thesis, but due to the goal of appraising the highest quality studies available on the subject, only 6 were deemed "good enough" based on the CASP appraisal tool.

### **5.5 Reliability and validity considerations of the methods**

In light of the research question, several validity and reliability considerations were taken as one of the most important features of a study is that it measures the concept it intends to study, and that the findings are reliable (Coughlan et al., 2007).

#### **5.5.1 Validity**

Internal validity is best summed up: is the study measuring what it intends to measure? (Basheer, 2017). In this subsection the aim is to clarify how and what validity considerations were taken during this thesis's methods.

## **5.5.2 Design and material**

The literature review as a design, as noted earlier, is preferred for research that aims to find out what is currently known on a given topic (Machi & McEvoy, 2016, p. 3). This first step of choosing a design was considered to lay the foundation for internal validation, because it is appropriate in view of the research question.

After the design was chosen, the natural choice of research material was peer-reviewed journal articles. According to Wong and Hickson (2012, p. 6) this is where the best research evidence can be found. Wong and Hickson (2012, p. 12) also explains that RCT are preferred in literature reviews since these are of the highest grade and level (Wong & Hickson, 2012, p. 17). RCT's are also used in the classical review studies like Hesser, Weise, Westin and Andersson (2011), and Martinez-Devesa, Perera, Theodoulou and Waddell (2010). Influenced by these highly rated studies, a goal was to find enough RCT on the Third wave CBT treatment for tinnitus patients. After the initial searches it became clear that this was already a topic that had been researched in many settings. This made it possible to proceed with the topic, as to make a literature review based on evidence, enough data must be compared.

## **5.5.3 PICO, keywords and search**

To strengthen the validity of the methods, the goal and direction for this thesis is influenced by the EBP approach. The search term was thus guided by PICO, which kept the search narrow and on topic. The search terms and keywords were chosen to describe the words and phenomena of the topic, often called descriptors or identifiers (Fink, 2012, p. 74). The selected books and articles influencing the choice of keywords are considered to be of high quality, and the authors renowned. This is a useful way to find relevant keywords (Fink, 2012, p. 76). To ensure less bias in the search process, search and selection terms were set before conducting the final search. The identifiers were chosen to keep the search open enough to find relevant material. As a strategy, this method was used and followed by the exclusion criteria to get rid of those studies that did not suit the research question. This has an impact on the content validity of this study. A review of other relevant study citations and references on tinnitus and Third wave CBT, has revealed no missing studies useful for this study. This is considered to strengthen the content validity of the study because of its indication of a wide



enough scope and robust search inclusion (Fink, 2012, p. 82). All findings were written down both by hand and in a separate digital document to ensure less assessment errors.

#### **5.5.4 Assessment**

The RCT is often a very good research design to precisely find the efficacy of a treatment for a specific population, but there are always the risks of bias, and so the critical appraisal of internal and external validity should always be conducted (Basheer, 2017). Consequently, to ensure the data collected was precise, the quality and validity of the studies were assessed with the CASP appraisal tool. High quality data are a product of conscientious research practice (Machi & McEvoy, 2016, p. 48). With precision and using the appropriate appraisal tool, the validity of the data is strengthened (Basheer, 2017; Wong & Hickson, 2012, pp. 14-16), as asking the right questions magnifies the procedures in the studies. It highlights possesses like who the participants were, outcomes and effect of the treatment, ethical issues (Nadelson & Nadelson, 2014; Wong & Hickson, 2012, p. 14), randomization and blinding which in turn can impact the overall bias and validity of the study (Goodman & Gilchrist, 2013). Overall, in ensuring the selected data is of high quality, the validity of this master's thesis is strengthened as well.

#### **5.5.5 Construct and content validity**

To ensure construct and content validity, several measures were taken. Construct validity refers to the “study as a whole” (Bordens & Abbott, 2013, p. 130; Lund et al., 2002, pp. 176-177). The construct of this master's thesis might be said to be “improved psychological effect of Third wave”. The content validity is explained as the study's precision on measuring all the aspects of the construct being studied (Fink, 2012, p. 186). To ensure the construct validity was sound, the concept “Third wave” was thoroughly studied beforehand and categorized as a relatively narrow and detailed entity where only contained relevant therapies for tinnitus were selected. For construct validity to be obtained, what is being measured needs to demonstrate a predictive behavior based on the relevant theory (Bordens & Abbott, 2013, p. 130; Lund et al., 2002, pp. 176-177). As the findings later presented in this thesis will show, there is a consistency with other research. Thus, an argument can be made that the construct of this thesis is relatively predictable. The content validity refers to how well the trial has operationalized its methods to measure what it set out to measure. In other words, one needs

to cover the relevant elements and aspects when measuring a construct and illustrate the essence of what is being studied (Bordens & Abbott, 2013, p. 129; Fink, 2012, p. 186). In this thesis, the “psychological improved effect of Third wave” as a construct is measured through RCT’s, which is a solid design for accuracy in testing effect, strengthening the internal content validity. The findings, which will be presented in Chapter 6, will show the “psychological improved effect” in numerous categories, opting to present the psychological widespread effect that is comparable in the selected studies, and believed to describe the improved effect.

According to Cronin, Ryan and Coughlan (2008) the final stage of appraisal is making short summaries of all the studies. These summaries should include categorization of the important and relevant parts, like key thoughts and findings, strength and weaknesses of the study, and key elements important for the one appraising the studies. For this study the inspection and summary were conducted and gathered in several documents, in an effort to reach a clean and clear process.

The inclusion and exclusion criteria, and the CASP assessment tool strengthen the validity of the study by minimizing bias, however 100% validity will never be achieved (Basheer, 2017). If the selected studies reflected a convenience sample or was chosen to portray a certain view, the results would be biased. In this thesis, the goal was to find high quality research on a specific topic that met the criteria, regardless of what the results showed. The quality guided the selection.

### **5.5.6 External validity**

External validity refers to how the study is relevant to other patients, and generally how it fits the established scientific arena (Bordens & Abbott, 2013, p. 115). For example, if a study in tinnitus intervention claimed or speculated in the fact that in order for the participants to feel better after the treatment, they had to possess supernatural powers, not only is this in direct conflict with many other scientific disciplines, but it also fails to make a sound conclusion, misunderstanding the concept of evidence. Evidence needs to be able to be applied to other fields in order to be valid (Basheer, 2017). Using the methods to ensure external validity in this thesis, the selected peer-reviewed RCT’s has a foundation in solid research methodology. This strengthens this thesis since the evidence from the RCT’s which is being evaluated is already established as solid research material. In addition, the selection of the search engines

strengthens the external validity because the selected engines are databases which include journals that are peer reviewed. The methods in this master's thesis was furthermore guided by *Writing Literature Reviews* by Galvan and Galvan (2017), amongst others, ensuring a scientific methodology was followed.

### **5.5.7 Reliability**

To ensure the reliability of this study, the methods that have been used are described in detail so that reproduction can be precise (Fink, 2012, p. 179). The search that collected all the material was conducted within the scope of 16 hours on February 11<sup>th</sup>, 2019, after much planning and many mock searches, with plainly described search criteria. This way, it should be possible to find the same material at the same date if another search was made. The intra-rater reliability should be increased by this consistency (Fink, 2012, p. 184). Furthermore, if the collection of material was spread out over many days, the search hit might not be the same as new research is published every day. The search term was described in a formula, to make the replication of the search clear and reliable.

## **5.6 Ethical considerations**

In this master's thesis ethical issues have been taken into consideration and are being described in the following section.

Reading a substantial amount of research and books in several connecting disciplines to get a broad understanding of the field has been a focus. This strengthens the ability to evaluate what is considered factual and which domains have more contradicting findings and theories. An overall focus has been to only represent what is considered solid evidence from different perspectives when that is the case. Citations have been used frequently to clarify the origin of the statements made in the thesis, and no plagiarism has been carried out. Considerations have also been taken to not present data out of context, as manipulating data to get a preferred outcome is immoral (Machi & McEvoy, 2016, p. 11).

# 6 Results and analysis

## 6.1 The selected studies

The following section presents the selected studies for this master's thesis. The 6 selected studies are RCT's examining the effects of Third wave CBT interventions on psychological conditions and disorders in bothersome tinnitus compared to a waitlist control, or other common interventions. The Third wave CBT interventions are ACT (Acceptance and Commitment Therapy) and MBT (Mindfulness-Based Therapy) or similar treatment versions MBCT (Mindfulness-Based Bognitive Therapy) and MTMT (Mindfulness Based Mediation Therapy). The comparable interventions are: traditional CBT (Cognitive Behavior Therapy), elements from CBT called RT (Relaxation Training), and TRT (Tinnitus Retraining Therapy). First, a table of the major findings, bias and quality of the studies is presented in Table 4. Next, Table 5 presents the studies' content characteristics and demography to clarify the key traits used in assessing their quality. Table 6 displays all the assessment tools used to measure psychological conditions and disorders associated with tinnitus in the participants, as well as the different group assignments in the studies. A short explanation of the abbreviations of the assessment tools and group names is added (an acronym chart to make the reading of the next chapters easier is available in the appendix as well). After presenting the tables, a summary of the 6 selected studies follows. Finally, the results with major trends and categorization is summarized.

## 6.2 Tables

**Table 4:** Major findings, potential bias and a grading of quality of the studies selected.

	<b>Major findings</b>	<b>Potential bias</b>	<b>Quality</b>
<b>Study 1</b> <b>Hesser et al.</b> <b>2012</b>	Active treatments were significant. ACT and CBT had similar results with a few exceptions. ACT is a viable treatment option.	Internet -based treatment, questionable monitoring during trial.	Very good
<b>Study 2</b> <b>Philippot et al</b> <b>2012</b>	Psychoeducation gave the largest effect. Better sustained effect of Third wave treatment.	Small sampling size, Unpublished assessment tool QIPA.	Average
<b>Study 3</b> <b>Westin et al</b> <b>2011</b>	Significant difference in favor of ACT compared to TRT on acceptance, sleep, tinnitus impact and sustained effect.	Some of the participants already had treatment.	Good
<b>Study 4</b> <b>Kreuzer et al</b> <b>2012</b>	MBT group showed significant effect. Control showed no effect.	Pilot trial. Small sample.	Good
<b>Study 5</b> <b>Mckenna et al</b> <b>2017</b>	Active treatment effective. MBCT was significantly more effective on several psychological conditions.	Unclear recruitment. Previous treatment of the participants.	Good
<b>Study 6</b> <b>Arif et al</b> <b>2017</b>	Active treatment effective. MBMT superior compared to RT.	No random recruitment. Convenience sample. No follow-up.	Good

**Table 5** Selected studies content characteristics and demography.

	<b>Sample size</b>	<b>% Men</b>	<b>Mean age</b>	<b>Blinding</b>	<b>Random recruitment</b>	<b>Random assigned treatment</b>
<b>Study 1</b> <b>Hesser et al 2012</b>	99	57	48.5	Double	YES	YES
<b>Study 2</b> <b>Philippot et al 2012</b>	30	60	60	NO	YES	YES
<b>Study 3</b> <b>Westin et al 2011</b>	64	50	50	Semi	SEMI	YES
<b>Study 4</b> <b>Kreuzer et al 2012</b>	36	62	49.6	NO	SEMI	YES
<b>Study 5</b> <b>McKenna et al 2017</b>	75	66	50	NO	SEMI	YES
<b>Study 6</b> <b>Arif et al 2017</b>	86	45	53.8	NO	NO	YES

**Table 6** Assessment tools used and group assignment details.

	<b>Waitlist</b>	<b>Group assignment</b>	<b>Assessment tool</b>
<b>Study 1</b> <b>Hesser et al</b>	YES	CBT. ACT. CONT.	THI. HADS, QoLI, PSS, ISI, TAQ
<b>Study 2</b> <b>Philippot et al</b>	NO	MBT. RT.	QIPA, STAI, BDI, DSM interview
<b>Study 3</b> <b>Westin et al</b>	YES	ACT. TRT. CONT.	TAQ, THI, ISI, QoLI, HADS; CGI
<b>Study 4</b> <b>Kreuzer et al</b>	YES	MBT. CONT.	TQ, THI, BDI, num rating of tinnitus impact
<b>Study 5</b> <b>McKenna et al</b>	YES	MBCT. RT. CONT	TQ, CORE-OM, HADS, TFI, VAS, TCS, TfAS, TAQ, MAAS, WSAS.
<b>Study 6</b> <b>Arif et al</b>	NO	MBMT. RT.	TRQ, HADS, VAS, HT

**Explanation group assignment:** CBT= Cognitive Behavior Therapy. ACT= Acceptance and Commitment Therapy. MBT= Mindfulness Based Therapy. MBCT = Mindfulness Based Cognitive Therapy. MBMT= Mindfulness Based Meditation Training. RT= Relaxation Therapy/Training. TRT (Tinnitus Retraining Therapy), CONT= Control or waitlist group.

**Explanation Assessment tool:** BDI (Beck Depression Inventory), CGI (Clinical Global Impression-Improvement), CORE -OM (Clinical Outcome in Routine Evaluation, Outcome Measure), DSM (Diagnostic and Statistical Manual of Mental Disorders), HADS (Hospital Anxiety and Depression scale), HT (Health State Thermometer), ISI (Insomnia Severity Index), MAAS ( Mindful Attention Awareness Scale), PSS (Perceived Stress Scale), STAI (State-Trait Anxiety Inventory), TAQ (Tinnitus Acceptance Questionnaire), TCS (Tinnitus Catastrophizing Scale), TfAS (Tinnitus Fear Avoidance Scale) TFI (Tinnitus Functional Index), THI (Tinnitus Handicap Inventory), TRQ (Tinnitus Reaction Questionnaire), TQ (Tinnitus Questionnaire), VAS (Visual Analogue Scale), QIPA (Tinnitus Psychological Impact Questionnaire), QoLI (Quality of Life Index), WSAS (the Work and Social Adjustment Scale).

## 6.3 Summary of the selected studies

### 6.3.1 Study 1 (Hesser et al)

#### **A Randomized Controlled Trial of Internet-Delivered Cognitive Behavior Therapy and Acceptance and Commitment Therapy in the Treatment of Tinnitus.**

Hesser, Gustafsson, Lundén, Henrikson, Fattahi, Johnsson, Zetterqvist, Westin, Carlbring, Mäki-Torkko, Kaldo, Andersson. **2012**

This study's main objective is to investigate the effect on global tinnitus severity, comparing ACT and traditional CBT. The study is not performed in a traditional clinical setting, but rather in the form of self-help through internet-delivered psychological treatment. The patients never saw the therapist's face, and the trial was double blinded. A web page to conduct the study was created, and all contact in the trial was made through the internet, exclusively in written form.

The participants were recruited from advertisement in the media, and from an internet waitlist for people who wanted to participate in a study on tinnitus treatment. Criteria for entering the trial was the age of 18 or more, Swedish residency and a total score of equal or more than 38 on the THI (which estimates from moderate to severe tinnitus distress). The participants were randomly assigned to CBT ( $n = 32$ ), ACT ( $n = 35$ ), or a controlled waitlist condition (monitored internet discussion forum;  $n = 32$ ). The patients were assessed with standardized self-report measures; Tinnitus Handicap Inventory (THI) which was the main outcome measure, Hospital Anxiety and Depression scale (HADS), Quality of Life Inventory (QoLI), Perceived Stress Scale (PSS), Insomnia severity index (ISI) and Tinnitus Acceptance Questionnaire (TAQ), all secondary outcomes. After the study was completed, participants had a 1-year follow-up.

The results on the primary outcome measures showed significant improvement for both CBT and ACT on THI compared to the waitlist control, but the effect difference between CBT and ACT on THI was not substantial.

The results of the secondary outcome showed significant improvement on anxiety (HADS) and QoLI in CBT compared to waitlist control. No significant effect was found on depression



(HADS), PSS or ISI on CBT compared to waitlist control. In the ACT group significant improvements were found on HADS and PSS compared to waitlist, but no difference in ISI or QoLI. At a 1-year follow-up, there was sustained improvements in both groups, with a tendency in larger improvements in the ACT group.

In sum, there was a decrease in tinnitus distress and interference for both CBT and ACT, and ACT might be considered as effective as CBT and a viable treatment alternative in treating tinnitus.

**Strengths:** This is a large double blinded study ( $n=99$ ) that had several therapists involved in the intervention and follow-up, thus ensuring less bias in the treatment intervention as between-observer reliability is strengthened. There were several measures to assess the participants, which strengthens the trial and a 1-year follow-up, which takes the placebo effect into consideration.

**Weaknesses:** There might be some weaknesses in the method because of the internet-delivered treatment intervention. Possible bias might also be the recruited participants consisted only of people with higher education.

### **6.3.2 Study 2 (Philippot et al)**

#### **A randomized controlled trial of mindfulness-based cognitive therapy for treating tinnitus.**

Philippot, Nef, Clauw, de Romrée, Segal. **2012**

This is an RCT that sets out to investigate the effectiveness of two psychological treatments, Relaxation Training (RT) and Mindfulness-Based Therapy (MBT). There was no waitlist. Both groups received the psychoeducational intervention of the treatment, with a pause for two months before the second treatment was applied. Participants were recruited through advertisement in the local newspaper. 30 participants entered the study after meeting the inclusion criteria of tinnitus experience within the past 6 months, medical check of hearing disorder, adequate hearing levels, and upsetting levels of psychological distress or impairment resulting from tinnitus. Groups were treated equally and did not differ in age, gender,

education, depression, anxiety or clinical status. Participants were assessed through Tinnitus Psychological Impact Questionnaire (QIPA), State-Trait Anxiety Inventory (STAI), Beck Depression Inventory (BDI) and an interview with a full diagnosis from the diagnostic and statistical manual of mental disorder (DSM). Participants had a 3-month follow-up after the trial had ended.

Results showed that the psychoeducation was significant on the tinnitus frustration (QIPA). MBT and RT did not bring immediate improvement on tinnitus frustration. However, the effects of psychoeducation were preserved significantly more in the MBT group compared to the RT group. There was no improvement on anxiety and depression. The MBT group continued to show reduction in negative affectivity (emotions like anger, contempt, fear and nervousness), but the RT group did not. Effect on coping strategies showed that MBT treatment gave more cognitive control, and RT had the opposite effect. More acceptance was reached in the MBT group, but these findings were not significant.

In sum, the MBT and RT did not bring immediate significant improvements in most of the psychological conditions. The major finding was the effect-difference on cognitive control coping, where mindfulness-based therapy showed more benefits, and the maintenance of psychoeducation in the MBT group. The largest effect was the benefits of psychoeducation in the beginning of the trial.

**Strengths:** Though there were two psychologists teaching the participants, there was an independent observer that ensured the information was consistent with the manual content. The assessment was thorough with a full diagnostic examination of their mental state.

**Weaknesses:** This trial is relatively small ( $n=30$ ) and the participants were recruited locally. One of the assessment tools used to measure the impact of tinnitus, is not validated or published (QIPA). Furthermore, the same author of the trial also developed the QIPA, and because of this, there might be some bias when considering the reliability of the findings from this assessment tool.

### **6.3.3 Study 3 (Westin et al)**

#### **Acceptance and commitment therapy versus tinnitus retraining therapy in the treatment of tinnitus: a randomized controlled trial.**

Westin, Schulin, Hesser, Karlsson, Noe, Olofsson, Stalby, Wisung and Andersson. **2011**

In this trial, 64 participants entered an RCT where the goal of the research was to compare the effects of ACT (Acceptance and Commitment Therapy) versus TRT (Tinnitus Retraining Therapy). Participants were recruited through audiology departments, advertisements and articles in the newspaper. They were then randomly selected to three different groups: ACT (21), TRT (20) and a wait-list (22). The assessment tools used on the participants were Tinnitus Acceptance Questionnaire (TAQ), Tinnitus Handicap Inventory (THI), Insomnia Severity Index (ISI), Quality of Life Inventory (QoLI), Hospital Anxiety and Depression scale (HADS) and Clinical Global Impression Improvement (CGI-1 interview). All participants had a follow-up and were assessed at 10 weeks, 6 months and 18 months.

The primary outcome measure was the THI. The secondary outcome measure was ISI, QOLI, HADS and CHI-1. TAQ was used as a mediation outcome. ACT was compared to the waitlist and TRT on both primary and secondary outcome measurements.

At the immediate assessment after 10 weeks of treatment was completed, the results showed a significant improvement of THI measurement when comparing ACT to the waitlist. It also showed significant improvement of ISI and anxiety, but this was the only factor from the secondary outcome measurement that was significant in comparing ACT to waitlist.

Comparing ACT and TRT the results showed that significant improvement on primary and secondary outcomes of THI and ISI was found, but no difference on QoLI and HADS. After the 6-month and 18-month assessment was completed, results showed that the group receiving ACT treatment maintained the gains longer than the TRT group. The results on TAQ showed that the ACT group had significant change from baseline to the 10 weeks assessment. In the waitlist control and TRT group no significant changes on TAQ were found.

In sum, the study suggests that ACT is more effective in reducing tinnitus impact, distress and acceptance than TRT and a waitlist control. The results from the treatment was also maintained better than TRT after 18 months.

**Strengths:** The study had a wide range of assessment instruments. Comparison of ACT to both another active treatment and a waitlist control. This not only makes the effect noticeable compared to TRT, but calculations were made to analyze the effect compared to a waitlist control.

**Weaknesses:** Some of the participants were recruited through an audiology department, possibly biasing the external validity. Another weakness is that the inclusion criteria for entering this study stated that the participants was to have had no previous psychological or sound-generator treatment for tinnitus. The study revealed that 30 of the participants had received other treatment for tinnitus prior to the intervention. The relevant previous treatments that might bias the outcome measures were: Tinnitus group information ( $n = 5$ ), counselling ( $n = 4$ ), relaxation training ( $n = 5$ ) and pillow loudspeaker ( $n = 3$ ). This weakens the validity of the trial because these techniques are often used in CBT and Third wave intervention, and it is difficult to say if the impact of the trial was influenced by prior knowledge or training.

#### **6.3.4 Study 4 (Kreuzer et al)**

##### **Mindfulness-and body-psychotherapy-based group treatment of chronic tinnitus: a randomized controlled pilot study.**

Kreuzer, Goetz, Holl, Schecklmann, Landgrebe, Staudinger, Langguth. 2012

36 participants were involved in this pilot study, aiming to examine the effect of mindfulness-based psychotherapy (MBT) in people with tinnitus. Recruitment was done in the form of advertisement and direct referral from a local doctor. The treatment was given in groups, and participants were randomly selected for either the treatment or waitlist groups. The participants were assessed by TQ (tinnitus questionnaire), THI (tinnitus handicap inventory), BDI (Beck depression inventory) and numeric rating of tinnitus impact, discomfort and annoyances. The assessment was conducted at baseline (at 7 weeks which was the second training weekend, at week 9 and week 24).

The primary outcome measures were based on the TQ, while THI, BDI and the numeric rating of tinnitus impact was considered secondary outcome measures.

The results showed that MBT intervention differed more and faster than the control on the primary outcome measure. The results from the secondary outcome measures showed a similar finding in THI and BDI, but not in the numeric rating scales. The main finding was that MBT intervention was significant in TQ score, and though the improvements in symptoms stagnated over time, the results suggest that MBT was a viable treatment of tinnitus.

**Strengths:** This study had solid statistical testing with several testing rounds during the trial. This is a strength because it makes the comparison to different times during treatment instead of just before and after. Furthermore, the treatment was taught by an experienced therapist with expertise on stress related disorders.

**Weaknesses:** This was a pilot study with few participants (n-36) and no long term follow up. The intervention was performed in groups and recruitment was not a hundred percent random as clients were referred by a local physician. This doctor may have lived in an area which only represented a specific demography.

### **6.3.5 Study 5 (McKenna et al)**

#### **Mindfulness-Based Cognitive Therapy as a Treatment for Chronic Tinnitus: A Randomized Controlled Trial.**

McKenna, Marks, Hallsworth, Schaette. 2017

In this RCT 75 participants underwent the Third wave intervention Mindfulness Based Bognitive Therapy (MBCT) or Relaxation Treatment (RT). The aim was to see if MBCT was an effective treatment for patients with problematic and chronic tinnitus. The trial also consisted of a waitlist, and MBCT was compared both to RT and to the waitlist. The intervention was delivered in groups. Recruitment of the participants was not completely random, as the participants were referred from the clinic, not advertised.

The participants were assessed through Tinnitus Questionnaire (TQ), the Psychological Distress Screening Questionnaire: Clinical outcome in routine evaluation outcome measure (CORE-OM/NR), Visual Analogue Scale (VAS) which measured the perceived tinnitus

loudness, Hospital Anxiety and Depression scale (HADS), Tinnitus Functional Index (TFI), Tinnitus Catastrophizing Scale (TCS), Tinnitus Fear Avoidance Scale (TfAS), Tinnitus Acceptance Questionnaire (TAQ), Mindful Attention Awareness Scale (MAAS) and the Work and Social Adjustment Scale (WSAS).

The primary outcomes were tinnitus severity (TQ), and psychological distress (CORE-OM/NR). The secondary outcomes were: VAS, HADS, TFI, TCS, TfAS, TAQ, MAAS, WSAS.

Results showed that both groups had significant reduction in the primary outcome measure tinnitus severity (TQ), but the largest effect was in the MBCT pre to post treatment. After the 1-month and 6-months follow-up it was clear that MBCT had more improvement on TQ score, but the difference between treatments was not significant. The results for the primary outcome “psychological distress” (CORE-OM) showed improvement in both groups, but not significant difference in the groups post treatment scores, though the results were larger in the MBCT group.

Effects on the secondary outcomes showed that VAS was significantly lower in both groups post treatment but no significant difference between the two interventions. The TFI score was also significantly lower in both groups, but no group difference at post treatment. However, at the 6-months follow-up there was a significant difference between the groups on the TFI measure, as the MBCT group continued to improve. Scorings from the TCS (Tinnitus catastrophizing scale) showed a significant improvement in both groups, but significantly more in the MBCT group.

Both groups also showed improvement on TAQ, but more in the MBCT group. The maintenance was also better in those who had completed the MBCT treatment and after 6 months it was further improved, however not in the RT group. A similar trend was also seen in the WSAS, with continued improvement in the MBCT group. On the HADS score both groups had a reduction in depression and anxiety, but this was not significant. Both groups also showed a significant increase in mindfulness, but this was also greater in the MBCT group, and was maintained and grew in the MBCT group while lost its effect in the RT group.

To sum up, this study’s findings suggest that both interventions (RT and MBCT) are viable options for treating tinnitus. However, MBCT show significant improvement on a number of

psychological distress aspects of tinnitus, compared to RT. MBCT was more efficient on TFI, TCS, T-fAS, TAQ, WSAS and MAAS.

**Strengths:** This is a relatively large study and attrition was low (8 percent). The trial used many assessment tools which would contribute to the assurance that the different aspects of tinnitus distress was measured. The intervention was based on a standard 8-week MBCT protocol, which was adapted to tinnitus.

**Weaknesses:** Not everything is clear in the methods section, as recruitment is not plainly explained. 47 percent of the participants had previously tried treatment for tinnitus which might bias the outcome measurements.

### **6.3.6 Study 6 (Arif et al)**

#### **A randomized controlled study of mindfulness meditation versus relaxation therapy in the management of tinnitus.**

Arif, M.Sadlier, M.Rajenderkumar, D. James, J.Tahir, T. **2017**

This trial recruited people with intrusive tinnitus from a clinic. 86 participants were randomly selected for either Mindfulness-Based Meditation Therapy (MBMT), or Relaxation Therapy (RT). There was no waitlist control. The participants were assessed with Tinnitus Reaction Questionnaires (TRQ), Hospital Anxiety and Depression scale (HADS), the Health State Thermometer (HT), and Visual analogue Scale (VAS) which includes measurement of tinnitus severity, awareness, loudness and hyperacusis.

The primary outcome measure was TRQ, while the secondary measures used were the HADS, VAS and HT.

The results showed statistically significant improvement in the MBMT group on both primary and secondary outcome measures except for on the HT. The results showed an apparent difference on TRQ in both intervention groups, but only the MBMT group was significant. The results in the secondary outcome HADS showed similar improvements as in the TRQ, with a reduction in the patients distress and an improved state of mind. The measure of HT showed no improvement in either MBMT or RT intervention group. The conclusion of the

study is that MBMT is superior to RT in managing tinnitus symptoms and suffering, though both treatments work.

**Strengths:** This study had a clear description of the program for the participants and followed a standardized session plan for each program. It also had a relatively large sampling size ( $n=86$ ) and used experienced therapists in the intervention.

**Weaknesses:** This trial is based on a convenience sample and not randomly recruited. This might have weakened the validity of the study and generalizations about the findings are harder to justify. It also differs in the form that the patients had *severe* tinnitus distress and they only treated people who had not responded to other audiological interventions, like hearing aid, maskers or background music. There was no follow-up.

## 6.4 Results summarized

Combined, the 6 studies included 390 participants.

### 6.4.1 Tinnitus distress and impact

The measurement tools focusing on measuring tinnitus impact and distress were Tinnitus Handicap Index (THI), Tinnitus Reaction Questionnaire (TRQ), Tinnitus Functional Index (TFI), Tinnitus Questionnaire (TQ) Perceived Stress Scale (PSS), Tinnitus Catastrophizing Scale (TCS), Tinnitus Psychological Impact Questionnaire (QIPA) and Clinical Outcome (CORE-OM). The combined results for tinnitus impact, distress and handicap showed that 3 studies concluded that the Third wave treatment was more effective than an alternative treatment (Westin et al, McKenna et al and Arif et al). Study 4 (Kreuzer et al) also showed an improvement but had no alternative intervention to compare with. Study 1 (Hesser et al) found that both interventions (CBT and ACT) had an improvement, and a significant group difference on PSS in favor of ACT. Study 2 (Philippot et al) on the other hand did not find improvements on most of the factors in tinnitus distress and handicap using QIPA, but found a statistically improvement in negative affectivity in favor of the Third wave intervention compared to RT.



## 6.4.2 Depression

In this master's thesis, all studies had a specific instrument dedicated to measuring depression in the participants. In sum the findings point to significant improvements on depression after *active* treatment, with the exception of Study 3 (Westin et al) who did not find a significant improvement either against TRT or the waitlist. The results are mixed as to the notion of Third wave intervention being more effective than traditional or other interventions for depression. Study 6 (Arif et al) and 1 (Hesser et al) both found an improvement on depression compared to RT and CBT. Study 5 (McKenna et al) found improvement compared to the waitlist, but not against RT, and Study 4 (Kreuzer et al) only compared depression against a waitlist and found significant improvement. Study 2 (Philippot et al) found no improvement on depression.

## 6.4.3 Anxiety

Study 1 (Hesser et al), 3 (Westin et al) and 6 (Arif et al) all found that the active treatments had a significant improved effect on anxiety against waitlist controls, but not compared to an alternative treatment. In contrast, Study 5 (McKenna et al) found that the MBCT treatment was more effective than RT when measuring TFAS (Tinnitus Fear Avoidance Scale). However, when analyzing the score on HADS there was no significant difference between MBCT and RT in study 5 (McKenna et al). Study 4 (Kreuzer et al) found significant improvement on THI which mostly focuses on distress, but also has a question about anxiety. They found significant improvement on THI against a waitlist control. Study 2 (Philippot et al) found no improvement on anxiety in the active treatments.

## 6.4.4 Insomnia

2 studies (Hesser et al and Westin et al) had a dedicated measuring instrument for sleep problems (ISI), but Study 5 (McKenna et al) in addition used TFI which also addresses this issue. In Study 5 (McKenna et al) the TFI score was better in MBCT compared to RT after 6 months, meaning it continued to improve in the MBCT group and had significantly more effect on TFI. The study does not address sleep specifically, but TFI measures components of sleep disturbances (Fackrell & Hoare, 2017; Meikle et al., 2012). Study 1 (Hesser et al) found *no* significant improvement on ISI in either CBT or ACT compared to the waitlist control. On

the other hand, Study 3 (Westin et al) found a significant improvement on ISI compared to TRT and waitlist control.

#### **6.4.5 Quality of life and perceived health**

Measuring quality of life was completed using the Quality of Life Inventory (QoLI), Tinnitus Functional Index (TFI), the Work and Social Adjustment Scale (WSAS), Health State Thermometer (HT), Mindful Attention Awareness Scale (MAAS), and Tinnitus Acceptance Questionnaire (TAQ) in these trials. Study 1 (Hesser et al) found that CBT had some improvement on QoLI, but the ACT treatment showed *no* difference on the QoLI score compared to the waitlist control. Study 5 (McKenna et al) showed significant improvements on WSAS in favor of MBCT compared to RT. It also found that the score on MAAS and TAQ was better in the MBCT compared to RT. Study 3 (Westin et al) on the other hand found *no* significance in quality of life comparing ACT to TRT and waitlist control.

Study 5 (McKenna et al) also found that the score on TFI had better improvement in the MBCT group compared to RT. Though the study didn't specifically report quality of life measurements from this instrument, the overall score was beneficial, and aspects of the instrument covers quality of life factors. Study 6 (Arif et al) found *no* improvements on general health in using the HT.

#### **6.4.6 Sustained effect**

Study 2 (Philippot et al), 3 (Westin et al) and 5 (McKenna et al) found that the Third wave intervention gave the benefit of maintaining the positive effect from the treatment over time. On the other hand, Study 1 (Hesser et al) found that there was little difference between the groups on maintaining the beneficial aspects from treatment after a 1-year follow-up. Both sustained the benefits, and there was a tendency towards more improvement in the ACT group, but it was not significant. Study 4 (Kreuzer et al) had different findings, as the progress stagnated during the trial, even though MBT was significantly more improved than RT.

## 7 Discussion

In this master's thesis, the results and discussion divide the analysis of the findings in specific measurable entities of psychological disorders (anxiety, depression and insomnia), psychological conditions (perceived quality of life and tinnitus distress). In addition, sustained effect of the treatment is also categorized, as this was a major finding and overall impacts the effect of the psychological conditions and disorders. The distinction between tinnitus distress and psychological conditions or disorders, and tinnitus distress and quality of life is difficult as these elements are closely related and impact each other (Langguth et al., 2013). For this reason, some focus in this chapter will be on discussing whether or not the measurement tools are assessing more than one aspect of tinnitus related psychological conditions and disorders. For examples, the TRQ (Tinnitus Reaction Questionnaire) measures different levels of tinnitus related distress. However, it might be worth considering if it is possible to compartmentalize tinnitus distress from other psychological conditions. When assessing the construct validity of the TRQ it is clear that it is better at assessing emotional challenges *associated* with tinnitus, like depression and anxiety (Fackrell & Hoare, 2017). THI (Tinnitus Handicap Inventory) measures tinnitus disruption but also emotional reactions, anxiety, depression, daily function and concentration. The THI is considered to have adequate construct validity for measuring tinnitus handicap and global tinnitus impact (Newman et al., 1996; Zeman et al., 2012), which in turn indicates that these psychological conditions are difficult to separate.

In this thesis, it is taken into consideration that the psychological conditions in bothersome tinnitus might not be separate entities in reality, but intertwined and influencing each other. Nevertheless, this thesis separates the psychological conditions and disorders into categories, since the selected studies divide the measurement of the psychological states into separate categories. The chapter will contain a discussion about the findings comparing the effect of the *Third wave* intervention to *other* or *no* treatments. This chapter will also consider the quality of the trials, the validity of the measurement tools and discuss major findings and trends in light of other high-quality research and theory. The next section will also be structured into a discussion about *one* tinnitus related psychological "category condition" at a time. The categories discussed are divided into "Tinnitus distress and impact", "Anxiety", "Depression", "Insomnia", "Quality of life" and "Sustained effect". All categories contain subheadings to clarify what is being discussed and has a short summary at each section

ending. This decision was made to keep the discussion organized and focused on one aspect consecutively, considering the features from different perspectives.

## 7.1 Tinnitus distress and impact

Stress is a normal physiological response that help people react beneficially to threatening stimuli from the environment (Szczepek & Mazurek, 2017, p. 2). However, when people fail to adapt to a stressor, hyperarousal and distress might occur (Szczepek & Mazurek, 2017, p. 141). High levels of distress correlate with symptom severity in tinnitus patients (Wallhausser-Franke et al., 2013), and this might lead to dysfunctional downward spiraling behaviors like avoiding social settings and catastrophizing situations (Baguley & Fagelson, 2015, p. 68; Cima et al., 2017; Szczepek & Mazurek, 2017, p. 141). How people react to stress is theorized as a key component in severity of negative emotions, and Mindfulness-Based Therapy (MBT) has been shown to both alter the brain structures and behavioral and psychological management of distressing tinnitus (Carpenter-Thompson et al., 2015).

### 7.1.1 Findings of TQ and THI

The TQ (Tinnitus Questionnaire) measures tinnitus severity by assessing 5 aspects of tinnitus distress, emotional and cognitive handicap, sleep, auditory perception, health and impact on lifestyle (Fackrell & Hoare, 2017). Study 4 (Kreuzer et al) and Study 5 (McKenna et al) were the only trials using this assessment tool, reporting that the Third wave interventions (MBCT and MBT) gave significantly improved effect compared to waitlist controls. However, Study 5 (McKenna et al) found *no* significance in terms of MBT being more effective than RT (Relaxation Therapy). When using THI (Tinnitus Handicap Inventory) other findings were evident. The THI measures several aspects of tinnitus distress: disruptions of tinnitus, daily function, emotional reactions, anxiety and depression (Newman et al., 1996; Zeman et al., 2012). Study 3 (Westin et al) showed ACT was *more* effective in reducing tinnitus distress than TRT (Tinnitus Retraining Therapy) and waitlist controls. Study 4 (Kreuzer et al) also showed significant improvement on THI in the MBT group, however this was compared to no treatment.

In other words, it appears the two measurement tools come to different inferences regarding the effectiveness of the Third wave intervention when compared to other interventions. The

cause of this inconsistency between the findings on TQ and THI may reside in the way the measurement tools are constructed. The THI measures global tinnitus impact (Newman et al., 1996; Zeman et al., 2012), meaning it focuses more on broader concepts of well-being and psychological function, not being as tinnitus specific (Andersson, 2002). The TQ on the other hand, is more in line with measuring tinnitus specific effect (Zeman et al., 2012). It is important to have in mind that “tinnitus distress” is a concept being measured, and that the definition given of that concept greatly influences what is being measured. The fact that this concept is not always defined consistently may explain the difference here. This might be why the studies measuring tinnitus distress does not show consistent results, as the concept not always is defined consistently.

### **7.1.2 Measured effect of the Third wave**

Comparing the findings from the TFI, Study 5 (McKenna et al) found significant improvement on MBCT (Mindfulness Based Cognitive Therapy), more than the RT group, and in addition it continued to improve over time in the MBCT group.

The TFI is a measurement tool developed to assess eight aspects of tinnitus handicap. TFI is considered to have solid construct validity and reliability when measuring tinnitus impact (Fackrell & Hoare, 2017; Meikle et al., 2012). In other words, when measuring tinnitus distress, the findings on TFI in Study 5 (McKenna et al) have a high probability of being valid data. Study 6 (Arif et al) was the only trial using the TRQ (Tinnitus reaction questionnaire), which was developed to measure different levels of tinnitus related distress. The results in Study 6 (Arif et al) showed that there was a significant improvement in the Third wave MBMT (Mindfulness-Based Meditation Therapy) group on the primary (TRQ) outcome measure. There was also an apparent improvement in the RT group, however, only the findings in the MBMT group were significant.

The reason for this favorable outcome of the Third wave intervention could in theory be a result of enhanced focus through mindfulness practice. Simplified, the prefrontal cortex (in collaboration with other areas of the brain) conducts our executive functions (Freberg, 2016, p. 47), including judgement, emotional regulation, planning of behavior, reasoning, awareness and attention, to mention a few. The amygdala in the brain is an almond shaped structure in the limbic system that plays an important role in emotions, especially fear and aggression. The amygdala receives input from all the senses and produces a rapid emotional response

(Freberg, 2016, p. 42). The response is often faster than the processing of the prefrontal cortex, and thus an emotional response might occur first. The relevance of this is that some tinnitus patients experience the tinnitus sound, receives a fear response from the amygdala, and then “feeds into” that fear instead of regulating it. However, practicing mindfulness might result in more control over awareness and response flexibility so that the initial fear response from the amygdala is rapidly calmed down by the prefrontal cortex (Gans, 2016). In support, a study has shown that people with lower tinnitus distress might manage emotional responses to sounds better, as the prefrontal cortex of the brain show a different pattern than those severely bothered by tinnitus (Carpenter-Thompson et al., 2015).

### **7.1.3 Third wave versus other treatment**

The results from Study 1 (Hesser et al), revealed that the THI score was significantly improved on the THI in *both* traditional CBT and the Third wave intervention ACT. Comparing with the findings in Study 3 (Westin et al), 5 (McKenna et al) and 6 (Arif et al), the results might indicate that the Third wave intervention is *more effective* than TRT, RT and no treatment, however, *not more effective* than CBT.

CBT has long been associated with improvements on tinnitus distress (Baguley et al., 2013; Hesser et al., 2011; Martinez-Devesa et al., 2010). In other words, the findings in Study 1 (Hesser et al) is consistent with other solid research.

### **7.1.4 Assessing validity**

When considering the validity of the findings, it might be reasonable to point out that the assessment of tinnitus distress in Study 3 (Hesser et al), might not be completely trustworthy. The findings stated that ACT is more effective than TRT, however, one of the inclusion criteria for entering Study 3 (Westin et al) was that the participants was to have had *no* previous psychological or sound-generator treatment for tinnitus. The study then revealed that 30 of the participants *had* received other treatment for tinnitus prior to the intervention. An argument can be made that the inclusion criteria “psychological treatment” was too diffuse in the trial. Group information, counseling and relaxation training might be argued to be forms of psychological treatments, but nonetheless, 14 participants with this background were included in the trial, possibly biasing the results. Considering this bias, Study 3 (Westin et al’s) findings that ACT is more effective than TRT might not be accurate.

On the other hand, an abundance of research shows that ACT and MBT is effective for tinnitus distress (Malouff et al., 2011; Riedl et al., 2015; Roland et al., 2015; Westin, Hayes, et al., 2008). Considering Gans' (2016) explanation of how MBT trains the prefrontal cortex to regulate emotions better, it is peculiar that the findings in the selected studies are not *more* effective than CBT and mixed when comparing with RT. In fact, studies support Gans (2016) in finding that mindfulness training enhances emotional regulation through improved attention (Rahl, Lindsay, Pacilio, Brown, & Creswell, 2017) and reduces stress and worry (Course-Choi, Saville, & Derakshan, 2017; Shapiro, Brown, Thoresen, & Plante, 2011). Furthermore, another study demonstrates that functional and structural changes in the brain occurs as a result of MBT. The changes are observable in the prefrontal cortex, and the amygdala, consistent with improved emotional regulation (Gotink et al., 2016).

However, an establishment of the Third wave intervention as effective, does not mean it is *more* effective than other treatments. One review study found no evidence in the claim that meditation programs are more effective than other active treatments (behavioral therapies and exercise) (Goyal et al., 2014). Based on this, it might be that CBT is just as good as MBT in treating tinnitus distress.

Both Study 5 (McKenna et al) and 6 (Arif et al) contradicts Goyal et al (2014) findings, stating that MBT/MBMT is *more* effective than other behavioral therapies. When considering the quality of Study 6 (Arif et al), there might be some bias in the fact that the trial is based on a convenience sample and not randomly recruited. It also differed from the other trials in that they recruited participants with intrusive tinnitus, making it more possible that this group is not comparable to the other tinnitus groups. It is also possible that this group might have more difficulties with hearing impairment as well, since tinnitus severity and hearing loss are correlated (Prestes & Daniela, 2009). Hearing loss in turn might be a confounding variable influencing the results. Study 6 (Arif et al) also lacked a follow-up at a later time, making it difficult to assess the sustained improvements. There is also potential bias in the fact that tinnitus treatment is responsive to the placebo effect (Jastreboff & Hazell, 2008, p. 150).

Another aspect to consider is that the TRQ used by Study 6 (Arif et al) might not have the strongest construct validity. TRQ does not directly assess tinnitus, as it is more attentive to psychological and emotional challenges associated with tinnitus. Nearly all question in the TRQ involve the sentence "my tinnitus makes me feel". Validation studies implies that TRQ is more similar in construct to assessment tools measuring depression or anxiety than tinnitus

distress directly (Fackrell & Hoare, 2017). With this in mind, the validity in Study 6 (Arif et al) is weakened and the findings are harder to justify.

### **7.1.5 Distress and affectivity**

In study 1 (Hesser et al), other findings revealed that ACT had significant effect on perceived stress (PSS) compared to wait list controls. CBT did *not* show significance when compared to wait list controls. This was the only finding that favored ACT compared to CBT when considering distress, however, the PSS is not directed at tinnitus distress, only general perceived stress (Lee, 2012). The finding is peculiar as Study 1 (Hesser et al) did not find more improvements on measuring *tinnitus distress* in ACT but did find improvements in *distress* favoring ACT. Again, it raises awareness of the difficulty in separating the psychological conditions in tinnitus patients and questioning the accuracy of measuring constructs and concepts in trials involving bothersome tinnitus.

Study 2 (Philippot et al) differed in the way that *none* of the active treatment groups showed significant improvement on tinnitus distress and frustration measured with QIPA (Tinnitus Psychological Impact Questionnaire). The major finding was that it was the psychoeducation in the beginning of the trial that had the main effect. However, the MBT group preserved the psychoeducation better, and continued to show reduction in negative affectivity, while the RT group did not. Negative affectivity is explained as negative emotions like anger, contempt, fear and nervousness (Cooper, 2004, p. 203). The dimensions of this state are a construct similar to neuroticism, which is a trait that relates to stress vulnerability. Measuring negative affectivity is relevant because people with high levels of negative affectivity are often distressed (Eysenck, 2004, pp. 171-172). In other words, the findings in Study 2 (Philippot et al) might not be consistent, because they showed no improvement on *tinnitus distress*, but a significant improvement on *negative affectivity* (often involving distress). One explanation for this might be evident when considering the measurement tool.

The findings from QIPA might not be as valid as they claim. The QIPA assesses emotional reactions, everyday handicap and coping modes (Heeren et al., 2014). It is a combination of several other tinnitus distress assessment tools, but Study 2 (Philippot et al) reports that the QIPA is an unpublished work, and one can imagine that it is thus not thoroughly validated. Furthermore, the research authors of Study 2 (Philippot et al) are the creators of the



assessment tool QIPA. This might contain some bias, as the creators might be prejudiced in wanting the measurement tool to be consistent. However, another study states that the QIPA exhibits good psychometric properties, both in internal and external validity (Heeren et al., 2014).

When it comes to measuring affectivity, some studies also measure the aspect of catastrophizing. People high in negative affectivity often have the tendency to exaggerate what they perceive as threatening situations, as they are biased to interpret stimuli as dangerous (Eysenck, 2004, pp. 171-172). Catastrophizing is associated with fearful beliefs and increased attention toward tinnitus (McKenna, Handscomb, Hoare, & Hall, 2014). It appears that tinnitus catastrophizing in the early stages of tinnitus experience is crucial as to how distressed people become. Considering catastrophizing in the treatment interventions might therefore reduce the advance of distress (Weise et al., 2013). In Study 5 (McKenna et al) the results showed that the MBCT treatment was significantly more effective than RT when measuring TCS (Tinnitus Catastrophizing Scale). In other words, the Third wave intervention seems to be more effective when measuring some aspects of distress in tinnitus, but not in others.

### **7.1.6 Summary**

When comparing the findings in the selected studies, existing theory and other scientific research, it appears that when it comes to tinnitus distress and impact, an active psychological behavior treatment is effective. Whether its CBT, TRT, RT or a Third wave CBT approach, they all coincide in the findings that treatment has an effect compared to no treatment. However, the results are mixed when considering if the Third wave CBT approach is *more* effective than other psychological treatments. The findings in favor of a Third wave intervention was Study 5 (McKenna et al) and 6 (Arif et al) measuring distress with TFI and TRQ. Study 3 (Westin et al) favored a Third wave intervention to TRT measuring THI. Study 1 (Hesser et al) also favored the Third wave intervention when measuring distress with the PSS. Study 2 (Philippot et al) and Study 5 (McKenna et al) also favored the Third wave intervention when measuring QIPA and TCS. The findings *not* in favor of a Third wave intervention, but found improvement in both active treatments, were Study 1 (Hesser et al), when measuring THI and Study 5 (McKenna et al) measuring TQ and CORE-OM. In other words, different measurement tools does not always coincide, but tinnitus distress is reduced

by different active treatments. However, it might be worthwhile using the Third wave CBT approach when treating patients with intrusive tinnitus, as Study 6 (Arif et al) showed.

## 7.2 Anxiety

Many tinnitus patients suffer from anxiety (Bauer, 2018; Eggermont et al., 2012, p. 83; Langguth et al., 2013; Savage & Waddell, 2014), and research shows that effective control of anxiety can improve tinnitus (Ziai et al., 2017).

### 7.2.1 Third wave's potential for improvement

Study 5 (McKenna et al) found improvement on two measures studying aspects of anxiety. The score on TfAS (Tinnitus fear Avoidance Scale) and TCS (Tinnitus Catastrophizing Scale) showed that the MBCT (Mindfulness-Based Cognitive Therapy) gave increased improvement over RT (Relaxation Therapy). One explanation may be that MBCT is more focused on being in the moment than RT. It uses meditation and relaxation techniques to be aware of the present and teaches being vulnerable and accepting one-self (Crane, 2017, pp. 4-5; Segal et al., 2018, p. 44).

According to Cima, Crombez and Vlaeyen (2011) by being in the present moment, fostering a non-judgmental mindset, mindfulness may reduce negative cognitions which are known to be associated with anxiety. A study conducted by Brown and Ryan (2003) parallel this notion by showing that mindfulness is associated with greater well-being and lowered anxiety levels. Other studies have shown that mindfulness training effectively changes functional and structural areas in the brain and improve emotional regulation (Gotink et al., 2016).

### 7.2.2 Difference between active treatment

In contrast to this theory and findings, *most* studies in this thesis measuring anxiety directly, found that there was *no* difference between the Third wave intervention and other treatments. All studies on the other hand, found significant improvement on all *active* treatments compared to waitlist. Study 1 (Hesser et al) and 5 (McKenna et al) both found significant

improvement on anxiety in both CBT/RT and ACT/MBCT compared to waitlist, but no significant difference between the active groups. In other words, the Third wave treatment was *not* more effective.

### 7.2.3 Assessment and validity

When considering the validity and reliability of the findings in Study 1 (Hesser et al) and 5 (McKenna et al), their quality is considered strong. Both these studies are large studies (174 participants in sum). Study 1 (Hesser et al) is the only study that uses double blinding in the trial and both studies compares two active studies and waitlist controls. Study 5 (McKenna et al) and 1 (Hesser et al) show strengths in assessing the participants with a wide array of validated measurement instruments which strengthens their internal validity, and both have a follow-up period ranging from 6 months to a year. Study 5 (McKenna et al) also uses a standard MBCT protocol adapted for tinnitus and both studies have a high CASP score. In other words, the findings have a relatively high probability of being reliable and valid.

The findings of Study 1 (Hesser et al) and 5 (McKenna et al) are also in line with other studies, showing Third wave treatments are *not* more effective than CBT in regards to treating anxiety (Arch, Wolitzky-Taylor, Eifert, & Craske, 2012; Roland et al., 2015; Sadlier, Stephens, & Kennedy, 2008). Öst's (2014) meta-analysis showed that the Third wave treatment ACT is not yet established as an evidence based treatment for several psychological conditions, including anxiety, though it concluded that it *probably* is effective in treating anxiety.

The inconsistency in Study 5's (McKenna et al) measurements of anxiety aspects is worth considering. It showed significant anxiety improvement on TfAS and TCS, but not on HADS (Hospital Anxiety and Depression Scale). Comparing the findings to Study 3 (Westin et al) and 6 (Arif et al), these trials showed significant reduction in Third wave CBT (ACT and MBMT) treatment managing anxiety compared to waitlist controls, but *not* significantly better than TRT or RT in managing anxiety.

HADS is a commonly used measurement instrument for assessing anxiety in tinnitus patients, and were used in Study 1, 3, 5 and 6 and found *no* significant improvement in favor of Third wave CBT treatments. The contradiction to TfAS and TCS might raise the question, does the instruments measuring anxiety contain adequate construct and content validity? According to

Zoger, Svedlund, and Holgers (2004) the HADS assessment tool is better at assessing depression than anxiety. In other words, is the TfAS and TCS better at measuring anxiety aspects, and thus these findings more dependable? This question might be answered by considering the meta study of Hacker, Stone and McBeth (2016). This study included many different assessment tools for anxiety (including HADS) and found a statistical consistency in all measurement instruments assessing anxiety. The conclusion in Hacker, Stone and McBeth (2016) was that there is *no* sufficient evidence to confidently say that ACT is more effective at treating anxiety than CBT.

#### **7.2.4 CBT versus Third wave interventions**

It is common for tinnitus patients to have negative and unrealistic thoughts about their tinnitus. When they evaluate the sound as harmful, succumb to their fear and start avoiding stressful situations, anxiety occurs and an adjustment or habituation to the sound fails (Gans, 2010; Jun & Park, 2013). Smith (2005, pp. 23-27) explains that a stress response is an automatic mechanism, which involves all major body systems. The correlation between stress, illness and relaxation is well established, and practicing relaxation techniques can reduce arousal (Gans, 2010). For tinnitus patients, MBCT teaches how the role of thoughts can induce stress, and meditation (when mastered) can be used as a tool to influence the brains' fear and stress pathways, resulting in calming the sympathetic nervous system (Gans, 2010; Simpkins & Simpkins, 2016, p. 168). When comparing MBCT to CBT, Romer and Orsillo (2006) stresses the idea that traditional CBT might be missing some components for treating anxiety and that in theory, mindfulness should be more effective because of its focus on the present, and its focus on relaxation training through meditation. Romer and Orsillo (2006) further argues that the current theory makes a strong case for mindfulness and ACT techniques being integrated in therapy for general anxiety disorder.

However, the findings in this master's thesis does not support this theory. One explanation why the Third wave interventions are not more effective than CBT, might be that the intervention programs are too short, as mindfulness requires practice to master fully (Smith, 2005, p. 162). However, one study suggests that 8 weeks of training mindfulness induces brain changes similar to long term meditation practice (Gotink et al., 2016). Another theory why the Third wave approach might not be more effective than CBT might be that the Third wave intervention is not that different than CBT. In fact, some studies suggest that when it

comes to treating anxiety, the Third wave CBT approach is not different enough from traditional CBT, and that it might merely be the same mechanisms with a different name (Arch & Craske, 2008). In contrast, others have argued that there indeed is a fundamental difference in the ACT approach, as the strategies for emotional regulation and cognition is very different (Hofmann & Asmundson, 2008). For examples, cognitive diffusion involves not letting your emotions dominate your behavior (Gaudiano, 2011), it teaches how to alter the function of the thought, instead of the form or content, as CBT does. Cognitive diffusion and commitment teach a person to act accordingly with their *goals* and who they want to be, instead of managing or changing different settings to *cope* with their emotions (Flaxman et al., 2010, p. 41; Hayes, 2016).

### **7.2.5 Summary**

In all, the studies in this thesis suggest that treating anxiety with ACT (Third wave), MBCT (Third wave), CBT, RT, and TRT has a significant effect, but the Third wave treatment was *not* significantly more effective than the other treatments.

## **7.3 Depression**

In study 1 (Hesser et al) the findings showed significant improvement in the severity of depression in the ACT (Acceptance and Commitment Therapy) groups, but not in the CBT (Cognitive Behavioral Therapy) group. Both these groups were compared to a waitlist, but the Third wave ACT intervention was the only outcome with significant findings. One reason ACT was more effective in treating depression, might be explained by considering the execution of the training program. Although Mindfulness and CBT both focus on the consciousness of thoughts and emotions, CBT differs in that it involves judging one's thoughts and categorizing them as negative or unrealistic. In this traditional approach it might seem like one is striving for control and being "hard" on yourself. In contrast, the concept of mindfulness teaches that all thoughts should be accepted and observed with kindness (Gans, 2010). The willingness to start over again is also a core in mindfulness (Segal et al., 2018, p. 150). Mindfulness-based therapy focuses on reducing stress, and teaches people to recognize their automatic reactions, and letting go of dysfunctional patterns without judgement or

critique. It is the opposite of control, it is “letting go” (Gotink et al., 2016). Mindfulness therapy was originally designed to treat depression (Segal et al., 2018, p. 343), and teaches a coping mechanism that has been demonstrated to improve depression (Gotink et al., 2016). Furthermore, it is proven to be especially effective at reducing the probability of recurrent depression (Crane, 2017, p. 83; Kuyken et al., 2008).

### **7.3.1 Contrasting findings on CBT**

It is an interesting find that ACT was significantly effective against depression, however, CBT was *not*, because CBT treatment has been widely associated with reducing depression (Fagelson & Baguley, 2018, p. 173; Jun & Park, 2013; Kaldø & Andersson, 2004, p. 24; Martinez-Devesa, Perera, Theodoulou, & Waddell, 2010). When compared to waitlist controls, a meta-analysis found that CBT significantly improves depression when compared to no treatment (Martinez-Devesa et al., 2010). CBT is commonly used to change and alter negative thoughts and does so by helping the patient identify negative automatic thoughts, appraise these thoughts, and changing the psychological (internal) mindset. It also adjusts the environmental (external) challenges the patient has (Jun & Park, 2013; Neenan & Dryden, 2015, p. 42). The finding of Study 1 (Hesser et al) is a counter to these established ideas. CBT did not show improvement compared to the waitlist. One reason for this might be found when assessing the method.

### **7.3.2 Assessing internet-based intervention**

Study 1 (Hesser et al) is the only study that executed its trial through internet, and it might be worth questioning if the method interfered with the study’s findings. A central part of CBT is the connection between the therapist and the patient, and how the therapist uses active listening to establish this connection (Nelson-Jones, 2012, pp. 41, 55-56). To help the patient, the therapist needs to understand what the patient is going through, and in CBT the therapist often interprets what the patient is saying directly, *and* indirectly. The true feelings of the patient are not always obvious, and a skilled therapist analyze tone of voice, body language and verbal cues together (Gelso & Fretz, 2000, p. 160; Nelson-Jones, 2012, pp. 60, 74). In the trial of Study 1 (Hesser et al), the therapist and the participants never saw each other’s faces. It is reasonable to ask if some of the effect of the CBT treatment was lost in this trial. Gelso and Fretz (2000, p. 161) stresses the importance of the therapists facial expressions in contact

with a patient, as the face is the primary source of giving information. Based on this, it might be that some of the information was not received by the patients as it should have been in Study 1 (Hesser et al), and that the results are not as accurate as they would have been if the study was conducted face-to-face. According to Friedberg, Tabbarah and Poggesi (2013), therapeutic presence and immediacy propels the therapeutic process when two people work goal-directed together.

On the other hand, another trial delivering CBT via the internet found significant improvement on depression compared to a control group receiving no treatment (Weise, Kleinstaubler, & Andersson, 2016). Fairly few RTC's comparing ICBT (Internet-Delivered Cognitive Behavior Therapy) and face-to-face CBT exist (Andersson, 2014, p. 79). Nevertheless, the research conducted indicates that there is *no* significant difference in the treatment effect. In other words, face-to-face CBT and ICBT produces the same results in treating mild to moderate depression (Andersson, 2014, pp. 79-80). This research adds to the trustworthiness of Study 1's (Hesser et al's) findings, but then the question remains why Study 1's (Hesser et al) findings contrasts with existing theory on CBT's effect on depression.

A positive outcome of the method (internet-based) in Study 1 (Hesser et al), is that it makes it possible to execute the trial double blinded. In fact, this was the only selected study that had double blinding, strengthening the trials validity by managing confounding variables (Fink, 2012, p. 125). In other words, Study 1 (Hesser et al) has the trademarks of a solid research trial, making the findings more trustworthy.

### **7.3.3 Assessing measurement tools and validity**

In comparison to Study 1 (Hesser et al), Study 5 (McKenna et al) found significant reduction in depression in both the Mindfulness Based Cognitive Therapy group (MBCT) and Relaxation Therapy (RT) compared to waitlist controls, but *no group difference* in favor of MBCT. Meaning both treatments worked well. Study 4 (Kreuzer et al) also found improvement of depression in the treatment receiving MBT (Mindfulness-Based Therapy), but this was only compared to a waitlist. Study 4 (Kreuzer et al) used a different measurement instrument (Beck Depression Inventory, BDI) than some of the other studies (HADS) that assesses depression. Nevertheless, both BDI and HADS are considered high in criterion

validity, meaning they are measuring the concept of depression (Aalto, Elovainio, Kivimaki, Uutela, & Pirkola, 2012; Zoger et al., 2004). Another study that used the HADS measurement tool was Study 6 (Arif et al) who compared MBT and RT. The findings showed significant improvement in the Third wave group (MBT) measuring depression before and after trial. These findings were *not* significant for the RT, concluding that MBT was *superior* in treating depression.

The findings in Study 6 (Arif et al) are a contrast to Study 5 (McKenna et al), who compared the same type of intervention groups, only adding the waitlist control. When considering which trial is most trustworthy, they are both relatively large studies and followed clear standardized treatment protocols. Both would be considered relatively high in CASP score, however, both had weaknesses in the recruitment method, as Study 5 (McKenna et al) was not completely randomized, and Study 6 (Arif et al) was based on convenience sample, weakening the representativeness of the studies. Blinding was not implemented either, which can lead to bias in the results, however, RTC's containing therapy intervention are typically not blinded (Martinez-Devesa et al., 2010). In other words, there is no clear superiority of the two trials, making it difficult to say one finding is more trustworthy than the other.

### **7.3.4 Conflicting findings in ACT and TRT**

Study 3 (Westin et al) showed *no* significant improvement in depression comparing ACT, waitlist or TRT. *None* of the groups showed improvement in depression, making this the only study analyzing depression that did not find any effect of the active treatments.

It might be considered a surprising finding that none of the treatments were deemed effective. Though TRT does not target depression directly, it is considered to alleviate bothersome tinnitus symptoms and psychological conditions (including depression), because it promotes specific behavior training to induce tinnitus habituation that might otherwise have led to depression (Bauer, Berry, & Brozoski, 2017). When considering the effect from ACT it might be viable to compare the treatment with other conditions. Tinnitus related distress shows similar neural activity as pain and depression (Malouff et al., 2011). A review of Malouff, Schutte and Zucker (2011) found that acceptance in itself reduces tinnitus related distress and associated symptoms like depression. This is supported by an experimental study on sensory pain, stating that acceptance-based instructions lower the sensation of pain. This study compared 2 experimental groups receiving sensory pain, with different instructions as the



pain was induced. The findings concluded that acceptance-based coping may be particularly useful in moderating the way in which individuals, especially women, cope with pain (Keogh, Bond, Hanmer, & Tilston, 2005). Furthermore, other studies have also concluded that ACT targeting depression is effective (Heydari, Masafi, Jafari, Saadat, & Shahyad, 2018; Walser et al., 2015). However, it is worth mentioning that both Heydari et al (2018) and Walser et al (2015) were not directed at depression in tinnitus patients.

One explanation for this contrasting finding of no effect might be that Study 3 (Westin et al) contains some bias. 30 of the 64 participants (nearly half) had already tried similar treatments. This might have biased the outcome as the participants willing to complete the trial probably did not find the previous treatments alleviating. In other word, the sample in the trial might consist of people unresponsive or skeptical of psychological treatment for tinnitus, influencing the results.

### **7.3.5 Summary**

In this thesis, 5 studies had a specific instrument dedicated to measuring depression in the participants (Hesser et al, Westin et al, Kreuzer et al, McKenna et al and Arif et al). In sum, the findings point to significant improvements on depression after *active treatment*. The results are mixed as to the notion of Third wave intervention being more effective than CBT or related interventions for depression. The selected studies are mostly in line with other high-quality research, which state that CBT and Third wave CBT both work in treating depression. However, the exception was Study 1 (Hesser et al) who found no effect in CBT, and Study 3 (Westin et al) who found no effect in any active treatment.

## **7.4 Insomnia**

Insomnia and disturbed sleep has long been associated with tinnitus, and the longer the tinnitus and insomnia persists, the more severe both symptoms get (Crönlein et al., 2011, p. 506). Two of the selected studies in this thesis measure sleep disturbance and insomnia directly, Study 3 (Westin et al) and Study 1 (Hesser et al). TFI also assess sleep disturbances in a sub section, and this tool was used by Study 5 (McKenna et al).

### **7.4.1 Findings in Study 1**

Study 1 (Hesser et al) used the ISI (Insomnia Severity Index) to measure sleep problems in their participants. The results found *no* difference in improved ISI score. Compared to the waitlist, there was *no* significant improvement in sleep quality in the participants receiving the active treatments (CBT and ACT). This finding contrasts with other findings, who conclude CBT is effective for treating insomnia (Edinger, Wohlgemuth, Radtke, Marsh, & Quillian, 2001; Morin et al., 2009). Hesser et al (Study 1) also contrasts with other findings measuring and concluding that Third wave approaches in managing insomnia is effective (Gross et al., 2011; Ong et al., 2014; Ong, Shapiro, & Manber, 2008, 2009). However, the majority of these mentioned studies did not assess insomnia in *tinnitus* patients. However, Kaldo et al (2008) measured insomnia in tinnitus patients with ISI, the same instrument as Study 1 (Hesser et al), and found significant improvement in sleep disturbances. The findings in Study 1 (Hesser et al) thus contradicts other solid research.

### **7.4.2 Assessment and comparison of Study 1 and other research**

In assessing if the findings in Study 1 (Hesser et al) are trustworthy, examining the methods reveal that Study 1 (Hesser et al) is a large trial ( $n=99$ ) using double blinding, all arguments of trustworthiness of a study. However, one reason Study 1 (Hesser et al) is divergent from most other studies, might be that it was executed through the internet. As previously discussed, therapeutic presence and face-to-face therapy might influence the therapeutic effect (Friedberg et al., 2013; Gelso & Fretz, 2000, p. 161). In other words, since Study 1 (Hesser et al) differs from many other studies, with this particular methodology, the findings might not be trustworthy. On the other hand, a meta study analyzing internet delivered CBT for insomnia, concluded that CBT is an effective method that reduces problems with sleeping (Zachariae, Lyby, Ritterband, & O'Toole, 2016). This study also concluded that internet-delivered CBT was *nearly as* effective as face-to-face CBT. The findings in Zachariae et al (2016) could be used as an argument to support the findings in Study 1 (Hesser et al). However, the treatment methods might not be comparable enough when considering many of the studies mentioned examining CBT-I, a specialized CBT program for sleep disturbance. When treating tinnitus and sleep problems associated with tinnitus, none of the selected studies in this thesis reported using CBT-I. In other words, the methodology of the treatment might be different. This might be an explanation for why the results contradict other findings.

Another aspect to consider is that even though the study from Zachariae et al (2016) might be an argument for the benefits of internet delivered CBT, it might not be an argument for the use of *Third wave CBT* delivered through the internet.

### **7.4.3 Findings in Study 3**

In contrast to Study 1 (Hesser et al), Study 3 (Westin et al) found significant improvement on sleep disturbances, comparing ACT to a waitlist *and* TRT. The Third wave approach was *superior* in managing sleep disturbances in the tinnitus patients. This finding is in line with Brand et al's (2012) conclusion that mindfulness meditation has a favorable influence on sleep. Why Study 3 (Westin et al) was better than TRT might be because TRT does not directly target psychological illnesses and insomnia (Jastreboff & Hazell, 2008, pp. 212-213). On the other hand, TRT focuses on teaching the patient how the nervous system is aroused and how this might impact sleep (Jastreboff & Hazell, 2008, p. 97). TRT also emphasize the importance of sound therapy in improving sleep difficulties. A background sound that masks the tinnitus is effective, such as the sound of a waterfall or rain (Jastreboff & Hazell, 2008, p. 113). Nonetheless, the findings in Study 3 (Westin et al), favors ACT.

One reason the ACT was superior might be found in Ong, Ulmer and Manbers (2012) arguments that the Third wave approach of CBT has a different framework in treating insomnia symptoms. Ong et al (2012) states that mindfulness in theory should be more effective at influencing peoples thoughts in managing insomnia. Psychological distress is related to people's attachment to an expected outcome that didn't go as planned. It might be reasonable to think of this mindset as more rigid as opposed to an accepting and flexible mindset. A rigid mindset with the urge to control the surroundings might lead to mood dysregulation and stress (Gotink et al., 2016; Ong et al., 2012). On the other hand, practicing mindfulness enhances the ability to respond to mental and physical states in a more flexible manner. Instead of changing or controlling the surroundings that induces stress, the *relationship with* stress is changed. Mindfulness is thus a treatment that produces a metacognitive shift, where the person is "observing" their thoughts, instead of letting the thoughts "happen" to them. This reduces arousal, which in turn improves problems with sleeping (Gans, 2010; Ong et al., 2012; Simpkins & Simpkins, 2016). This theory is also in line with a study that found effective outcomes of mindfulness on sleep disturbances and cortisol secretion (stress hormone) (Brand et al., 2012).

#### **7.4.4 Considering measurement validity**

One other study in this thesis measured sleep disturbances, but this study did not use assessment tools specifically directed at measuring sleep. The TFI (Tinnitus Functional Index) has a section in the questionnaire dedicated to sleep assessment. In Study 5 (McKenna et al) the TFI score was in favor of MBCT compared to RT after 6 months, meaning it continued to improve in the mindfulness intervention group and had significantly more effect in TFI. Study 5 (McKenna et al) does not address sleep specifically, so the findings are difficult to analyze when it comes to improvement on sleep alone. The TFI is also questionable as an assessment tool when it comes to measuring sleep disturbance in tinnitus patients (Fackrell et al., 2016). Accordingly, the findings from the TFI when analyzing sleep might not be valuable.

#### **7.4.5 Hyperarousal as a denominator in sleep and tinnitus**

Very few of the selected studies measured insomnia and sleep problems directly. This might be considered strange as sleep problems has been associated with tinnitus for decades (Crönlein et al., 2011, p. 506). One interesting aspect to reflect on is the causality of insomnia in tinnitus patients. One RCT found no difference in objective parameters measuring sleep problems in patients with insomnia, compared to patients with insomnia *and* tinnitus (Cronlein, Langguth, Geisler, & Hajak, 2007). It is not known why there is a correlation between tinnitus and insomnia (Cronlein et al., 2007). Compared to healthy people, tinnitus patients do have more sleep difficulties (Cronlein et al., 2016), however it might be inappropriate to assume that tinnitus *causes* insomnia. There is evidence that suggest that the common denominator for distressing tinnitus and insomnia is psychological hyperarousal (Wallhausser-Franke et al., 2013). Insomnia (when isolated without tinnitus) is correlated with depression and anxiety, just like tinnitus. Those affected has a tendency to be worried about their sleep problems and tinnitus (Wallhausser-Franke et al., 2013). Most people with tinnitus are not bothered by it, so it is possible to have tinnitus and sleep well (McKenna et al., 2010, p. 109).

In other words, people that suffer from tinnitus and insomnia, might suffer from it because their nervous system is more active than others with tinnitus, who are not bothered by it. The neurophysiological model states that tinnitus distress occur when the tinnitus signal gets linked to a stressful stimulus. When the person perceives a stimulus as fearful, the autonomic nervous system gets aroused and activated, and this prevents habituation of the sound

(Jastreboff, 2010, p. 579). Wallhausser-Franke et al (2013) points out there is evidence that hyperactivity of the autonomous nervous system is evident in insomnia, similarly to tinnitus. Accordingly, people that suffer from tinnitus, insomnia and other psychological distresses, might be more *vulnerable* in the first place. Furthermore, there might be a downward spiral where insomnia makes the perception of tinnitus worse (Folmer & Griest, 2000), which might lead to more stress and arousal, again, making insomnia worse.

By this theory, it might be reasonable to think the Third wave approach of CBT is viable in treating insomnia. Practicing mindfulness and ACT enhances cognitive flexibility and develops metacognitive shifts. Flexibility increases the ability to “let go” and decrease the arousal stemming from lost sleep. Metacognitive shifting changes the relationship with dysfunctional sleep related thoughts. For example, a person with insomnia practicing mindfulness might *value* sleep differently. Instead of being aroused and worrying about failing to fall asleep, the person *accepts* and *observes* that these thoughts occur, not engaging in them, instead feeling thankful for the hours slept (Ong et al., 2012). A recent study suggests that cognitive training in mindfulness leads to reduction in *emotional vulnerability* in people considered “high worriers”. It also showed meditation practice led to great reduction of worry and sustained the benefits over time (Course-Choi et al., 2017).

When considering that insomnia and tinnitus distress might both be symptoms of hyperarousal of the nervous system (Wallhausser-Franke et al., 2013), treating or measuring insomnia as an isolated factor might not be necessary. It might be that some of the studies measuring tinnitus impact and quality of life contained data on sleep quality, however these issues were not addressed in the selected studies. Nonetheless, lack of data doesn’t conclude there is no effect. There might be more improvement in insomnia and sleep disturbances in the participants of the selected studies, but because of incomplete data, no conclusion can be made in this master’s thesis.

#### **7.4.6 Summary**

In sum, the results were mixed regarding insomnia. The largest study of the selection (Hesser et al) did not find significance on sleep disturbances in either CBT or ACT, contradicting other existing research. Study 3 (Westin et al) found that ACT was superior to both waitlist and TRT, and the data from TFI might not be valuable although they reported a more effective outcome on the Third wave intervention compared to RT.

## 7.5 Quality of life

Quality of life is a difficult concept to define, as it is both a philosophical and psychological concept (Sirgy, 2012, p. 5). For this thesis, quality of life is defined as a high state of well-being, where personal growth, moments of happiness and leading a good life both mentally and physically is attained (Sirgy, 2012, p. 13). According to Watts et al (2018), tinnitus mainly becomes a problem because of the reduction in overall quality of life.

Assessment devices measuring psychological management of tinnitus, are often divided into those that are global (meaning broader concepts of well-being and psychological function) and tinnitus specific (Andersson, 2002). The measurement tools containing direct questions about quality of life in the selected studies, are Frish's (2014) QoLI (Quality of Life Inventory) and TFI (Tinnitus Function Index). As quality of life is highly correlated with people belonging to a society or having meaningful relationships (Sirgy, 2012, p. 358), additional measurement tools were analyzed. This thesis' definition of quality of life also opens up to include the WSAS (the Work and Social Adjustment Scale), HT (Health State Thermometer) and TAQ (Tinnitus Acceptance Questionnaire) when measuring relevant information about aspects impacting quality of life, since these assess social life, subjective well-being and general health status.

### 7.5.1 Findings in QoLI and comparison to other research

The findings in Study 1 (Hesser et al) found that CBT had some improvement on quality of life when compared to waitlist. However, the Third wave intervention ACT, showed *no* difference on the QoLI score compared to the waitlist control. Study 3 (Westin et al) also used the QoLI comparing ACT to TRT and found *no* significant improvement on quality of life in either treatment. From these findings, it might appear that the Third wave interventions and TRT are not as effective on impacting quality of life, however, this is in contrast to many other findings.

One study examining the effect of ACT on chronic tinnitus patients revealed that the patients with a higher score of tinnitus acceptance also correlated with higher quality of life, better mental health, lowered tinnitus distress and less negative influence on social activities (Riedl et al., 2015). Another study found that ACT improves quality of life in people with anxiety disorders (Arch et al., 2012). Arch et al (2012) did not study tinnitus patients, however, it

might be a relevant study when considering the fact that anxiety and tinnitus are not only comorbid, but in theory might be connected in the sense that they both might be products of a hyper-aroused nervous system (Jastreboff & Hazell, 2008, p. 96; Wallhausser-Franke et al., 2013). Indeed, high stress levels are associated with symptom severity in tinnitus patients (Fagelson & Baguley, 2018; Hebert & Lupien, 2009, p. 22; Hebert, Paiement, & Lupien, 2004; Khedr et al., 2010; Malouff et al., 2011), and tinnitus distress, anxiety and lowered quality of life is closely related (Eggermont et al., 2012, p. 83; Ziai et al., 2017).

Another aspect to consider why ACT might be a helpful coping mechanism for tinnitus patients, is the theory that the way people think about their tinnitus, influence how they relate and are inflicted by it (Katz et al., 2015, p. 650). In fact, tinnitus might be triggered by how you react in a stressful situation (Langguth et al., 2013; Wallhausser-Franke et al., 2013). If this is the case, mindfulness could in theory help tinnitus patients see their tinnitus in a different way, and thus, improve their quality of life.

One study found that people with lower tinnitus distress operate differently in their frontal regions of their brain, resulting in better management or control of their emotional response to sounds (Carpenter-Thompson et al., 2015). Another trial found that people who completed training programs for mindfulness and acceptance, showed improved emotional regulation on frustration attention tasks (Rahl et al., 2017). Yet another study found that acceptance had a great improved impact on quality of life in tinnitus patients, discussing the theory of the relationship to the sound changing, because of acceptance as a mediator. These results all emphasize the importance of acceptance in the emotional regulation and subjective state of well-being of distressed patients, like those suffering from tinnitus (Westin, Hayes, et al., 2008).

### **7.5.2 Findings on acceptance**

Study 5 (McKenna et al), and 3 (Westin et al) found that the score on TAQ (tinnitus acceptance questionnaire) was better in the MBCT and ACT group compared to RT and TRT. The TAQ contains questions about experiential avoidance of tinnitus, life adjustment and quality of life. Questions like “I am leading a full life, even though I have chronic tinnitus”, or “My life is going well, even though I have chronic tinnitus” target both the persons subjective evaluation of their quality of life, and their acceptance (Westin, Hayes, et al., 2008).

In other words, the participants in Study 5 (McKenna et al) and 3 (Westin et al) that received a Third wave intervention accepted their tinnitus and life situation more than the RT and TRT groups. They had higher scores indicating they evaluated their quality of life (among other aspects) as improved. TAQ is considered to have good internal consistency, but is not yet a standardized measurement tool (Westin, Hayes, et al., 2008). However, an important aspect to consider when measuring quality of life, is the TAQ's construct validity.

### **7.5.3 Construct validity**

Construct validity refers to the construct being measured “as a whole”. If the assessment instrument is measuring quality of life, the construct “quality of life” is a variable that might not directly be observable. If construct validity is to be obtained, the test needs to demonstrate a predictive behavior based on the relevant theory (Bordens & Abbott, 2013, p. 130; Lund et al., 2002, pp. 176-177), and in this instance, the construct of TAQ is not *quality of life*, but *acceptance*. It might be that the TAQ needs to contain relevant questions on quality of life, to ensure *content validity*, which refers to the operationalized methods used to assess the chosen construct (*acceptance*) (Bordens & Abbott, 2013, p. 129; Fink, 2012, p. 186). In other words, TAQ might have solid construct and content validity, when considering the construct is *acceptance*, but as a measurement tool on *quality of life*, the validity of the findings might not be accurate. On the other hand, the findings from the TAQ instrument might indicate the importance of acceptance in the pursuit of higher quality of life (Baer, 2010, p. 265; Westin, Hayes, et al., 2008), but no conclusion can be made due to insufficient data.

### **7.5.4 Considering contradictions**

In theory, the findings in Study 1 (Hesser et al) and 3 (Westin et al) contradict that acceptance and mindfulness is necessary or helpful in achieving quality of life satisfaction. Study 1 (Hesser et al) as mentioned earlier is the largest study ( $n=99$ ) in the selection for this thesis. The study's CASP score is strong, and some of Study 1's (Hesser et al's) findings are supported by other studies. Study 1 (Hesser et al) found an improvement on quality of life in the intervention group receiving traditional CBT. In a meta-study by Martinez-Devesa et al (2010) they found significant improvements in quality of life in tinnitus patients receiving CBT treatment. This can be made as an argument that the finding in Study 1 (Hesser et al) is consistent with other findings, however, Martinez-Devesa et al (2010) did not analyze



internet-based interventions, and an argument can be made that Study 1 (Hesser et al) differed too much in this aspect, not being comparable. On the other hand, another study researching internet-delivered CBT for tinnitus found that there was significant improvement on quality of life for tinnitus patients (Weise et al., 2016). This research supports Study 1's (Hesser et al) findings, adding to the notion that the results might be trustworthy.

### **7.5.5 Findings on social life**

In contrast to Study 1 (Hesser et al) and 3 (Westin et al), Study 5 (McKenna et al) had other findings in favor of the Third wave intervention measuring aspects of quality of life. Study 5 (McKenna et al) showed significant improvements on WSAS (Work and Social Adjustment Scale) in favor of MBCT compared to RT. It is common in the field of quality of life research to treat social well-being as an important aspect of life satisfaction (Sirgy, 2012, p. 353). People often have the highest score on quality of life in communities where social capital is high, meaning societies where people value closeness, trust and helpfulness (Sirgy, 2012, p. 358). Questions from the WSAS like “My ability to form and maintain close relationships with others, including those I live with, is impaired”, or “My ability to work is impaired” or “My social leisure activities with other people are impaired”, include the aspects of forming relationships with others. It is commonly established in the field of psychology that humans are motivated to belong to families and social units to achieve a sense of quality of life (Holt et al., 2015, p. 563; Sirgy, 2012, pp. 360-361). Considering this, the finding on WSAS in Study 5 (McKenna et al) might be a valuable finding on measuring quality of life. They are also in line with Riedl et al (2015) who concluded that Third wave intervention with tinnitus acceptance correlated with higher quality of life and less negative influence on social activities.

However, an important aspect to consider, is the confounding variable of hearing loss. Study 5 (McKenna et al) did not control for all factors affecting tinnitus symptoms, such as use of hearing aid and level of hearing impairment. This might impact the results significantly. A study that measured the impact of tinnitus on quality of life, found that the handicap caused by tinnitus differs greatly depending on your hearing loss. People with hearing loss *and* tinnitus have a poorer quality of life than those with tinnitus without hearing loss, both in physical and psychological domains (Prestes & Daniela, 2009). Having this in mind, the results in Study 5 (McKenna et al) might not reveal the whole aspect of reality.

In addition, Study 5 (McKenna et al) also found that the score on TFI (tinnitus function index) had better improvement in the MBCT group compared to RT. However, the study didn't specifically report quality of life measurements from this instrument, the overall score was beneficial, and parts of the TFI instrument covers quality of life factors. In addition, the scores on TFI continued to improve in the MBCT group 6 months after the intervention was over. Again, the argument for poor construct validity in TFI might weigh in, weakening the validity of the findings on TFI measuring quality of life (Watts et al., 2018). A study conducted by Fackrell, Hall, Barry and Hoare (2016) measuring the psychometric properties of TFI, found that the TFI is a very good tool for measuring tinnitus impact, but *not* a good measurement tool for assessing generic quality of life aspects. In other words, the findings on TFI in Study 5 (McKenna et al) might not be valuable in considering quality of life impact.

### **7.5.6 Findings on health**

When considering aspects of quality of life, state of health is one of the most reported parts influencing quality of life (Sirgy, 2012, p. 124). The HT (Health state thermometer) was used by Study 6 (Arif et al) and might be interesting to consider when analyzing aspects of quality of life. However, a limitation in this study was that it did not make any reference to which measurement tool this health state thermometer was, so an accurate assessment of the content of the questionnaire cannot be made. Study 6 (Arif et al) states that HT uses a generic measure to characterize current health state and arranges 100 points from “the worst health state” to “the best health”. Although this is lacking in information, it is worth mentioning that there was no significant difference in Study 6's (Arif et al) assessment of health state when comparing MBMT (Mindfulness based meditation therapy) and RT (Relaxation therapy). In other words, neither the Third wave intervention or the RT groups had any health improvements reported. All other outcome measures in Study 6 (Arif et al) showed significant improvement in both intervention groups assessing tinnitus distress, severity, depression and anxiety. When considering that health and quality of life is closely related (Sirgy, 2012, p. 124), it is a strange finding in Study 6 (Arif et al) that all other aspects of distress and illnesses was improved, but health state was *not*. In fact, the conclusion of the trial was that the Third wave intervention is *superior* to RT in treating tinnitus related symptoms and suffering. An explanation for this might be that the HT was not an appropriate measurement tool for this particular setting, but it might also be that there are confounding variables that have not been addressed.

Study 6 (Arif et al) did not use any waitlist controls and has another limitation in that the recruitment was not randomized. The overall CASP score was good and the sampling size (n=86) was one of the largest studies selected for this thesis. The findings should in theory be somewhat trustworthy, however when considering other findings, it sheds doubt on the consistency of the trial. Studies have shown that mindfulness training results in greater subjective feeling of well-being (Shapiro et al., 2011), and better physiological and mental health states (Baer, 2003; Grossman, Niemann, Schmidt, & Walach, 2004; Morone, Greco, & Weiner, 2008). Though these studies didn't measure tinnitus directly, they point in a direction of improved quality of life with better perceived health through mindfulness training. A study specifically targeting tinnitus distress also concluded that mindfulness cognitive behavioral therapy resulted in better life satisfaction (Sadler et al., 2008).

### **7.5.7 Summary**

In sum, the findings from the selected studies in this master's thesis measuring quality of life and health benefits (4 out of 6), showed mixed and incomplete results. Study 1 (Hesser et al) found no improvements on the Third wave intervention but found improvement in CBT. Study 3 (Westin et al) didn't find any benefits in either treatment intervention (ACT and TRT) measuring quality of life with the dedicated measurement tool QoLI. However, Study 3 (Westin et al) found a significant improvement on aspects of quality of life in the TAQ favoring the Third wave intervention. Yet, this finding might not be valid when considering the construct validity of quality of life might be weak in the TAQ.

Study 6 (Arif et al) didn't find any improvements on health in either treatment intervention (MBMT and RT). Study 5 (McKenna et al) was the only study reporting improvements on aspects of quality of life from two assessment tools, the TAQ and WSAS, but these measurement tools are not specifically designed to directly measure quality of life. The findings contrast to many other trials and research conducted on quality of life in patients with tinnitus or other health and psychological issues. No conclusive statement can be made whether or not the Third wave intervention improves quality of life in the narrow scope of this master's thesis. However, an observation was made that the selected studies might not be focusing enough on measuring quality of life and thus, the data might be lacking, or the results might seem worse than they actually are.

## 7.6 Sustained effect

In light of the research question, several of the selected studies in this thesis reported the sustained long-term effects of the active treatments.

### 7.6.1 Findings of the selected studies

Study 3 (Westin et al) reported that ACT was more effective than TRT on treating anxiety, sleep problems and tinnitus distress. Study 3 (Westin et al) also reported the improvements from the ACT treatment was better *preserved* after 18 months compared to the TRT group. Study 2 (Philippot et al) and 5 (McKenna et al) had similar findings. Study 2 (Philippot et al) didn't find a large difference in the two treatment groups measuring tinnitus frustration, but what it did find, was a significant maintenance effect of the psychoeducational training in the beginning of the trial. Both groups received the same psychoeducation, before receiving either RT or MBT. The groups receiving MBT showed a better sustained effect over time compared to the RT group. Study 5 (McKenna et al) also demonstrated better sustainability effect on TFI (Tinnitus Functional Index) measuring tinnitus handicap, TCS (Tinnitus Catastrophizing Scale) measuring irrational thoughts of fear or terror, T-fAS (Tinnitus fear Avoidance Scale), TAQ (Tinnitus Acceptance Questionnaire), WSAS (the Work and Social Adjustment Scale) and MAAS (Mindful Attention Awareness Scale). In other words, several of the selected studies showed a superior sustained effect of the treatment when compared to other treatment. This might be considered a major finding, as it can be argued that sustained effect is what EBP seeks.

### 7.6.2 Assessment of the selected studies

The primary outcome measure of Study 3 (Westin et al) was the THI, which measures tinnitus disruption, emotional reactions, concentration, daily function, depression and anxiety. THI is considered a valid and reliable measurement tool in assessing tinnitus handicap and global impact (Newman et al., 1996; Zeman et al., 2012). Study 3 (Westin et al) is also a relatively large study ( $n=64$ ), with a wide variety of assessment tools. It compares two active treatments to a waitlist control and has a high CASP score, all characteristics of an RCT with a solid method. The same can be said about Study 5 (McKenna et al) ( $n=75$ ), giving rise to the notion that the findings are valid and dependable.

Study 2 (Philippot et al) is a smaller study ( $n=30$ ), with no waitlist control and a weaker overall CASP score. A study's sampling size should be large enough to represent the actual population (Coughlan et al., 2007), as a large size improves the capacity to detect real effect (Fink, 2014, p. 87). Though Study 2 (Philippot et al) might have a tolerable CASP scores, being the study of the selection with the smallest sampling size, it might be reasonable to question the statistical accuracy of the study. The larger the study, the less errors the statistical estimates contain (Diez et al., 2015, p. 202). In other words, the studies selected have a high probability of being of solid evidence, but among all the RCT's, Study 2 (Philippot et al) might be the statistically weakest study, and precautions need to be taken in relying on the findings.

### **7.6.3 Third wave enhance focused attention**

The findings in Study 2 (Philippot et al), 3 (Westin et al) and 5 (McKenna et al) are all in line with another study demonstrating that MBT improved bothersome tinnitus, and further improved the symptoms over time (Gans, Cole, & Greenberg, 2015). One reason for this might be that what is learned in training is memorized or understood better in the Third wave approach. Zeidan, Johnson, Diamond, David and Goolkasian (2010) conducted a study that demonstrated brief mindfulness training significantly improved several cognitive functions. Working memory, executive functions and visuo-spatial processing were all enhanced in the group practicing meditation. Working memory is explained as the capacity to sustain and manipulate information over a short period of time, without becoming distracted by irrelevant information. Working memory thus contains attentional processes as well, and the two depend on each other to guide and process information (Baer, 2010, pp. 208, 210). It is reasonable to think that mindfulness would enhance working memory and attention, as repeated practice in mindfulness target directed attention and focus (Baer, 2010, p. 10).

Several other studies have also confirmed that mindfulness training enhances the ability to focus the attention (A. Moore & Malinowski, 2009; Rahl et al., 2017; Valentine & Sweet, 1999). One study also concluded that ACT had enhanced results on attention, and that acceptance might be a good strategy in treating tinnitus patients (Westin, Östergren, & Andersson, 2008). It might be reasonable to think that focused attention is a vital part of learning, as learning and attention are not separate processes, but a complex cooperation (Mitchell & Pelley, 2010, p. 1). With this in mind, the findings of sustained benefits from a

Third wave intervention in Study 2 (Philippot et al), 3 (Westin et al) and 5 (McKenna et al) might be explained as an effect of enhanced attention from practicing mindfulness in the Third wave therapy.

#### **7.6.4 Third wave and placebo effect**

Another aspect to consider, is that the Third wave interventions are less vulnerable to the placebo effect. The placebo effect is explained as the positive response to a false stimulant (Schroeder, 2018, p. 1255). It is not uncommon for tinnitus treatment to produce placebo effect (Jastreboff & Hazell, 2008, p. 150), and to measure this, long-term follow-up is a good practice, as the placebo effect commonly doesn't last more than 2-3 months (Jastreboff & Hazell, 2008, pp. 178-179). Study 3 (Westin et al) had several follow-ups, with the latest 18 months after the trial had ended. Study 2 (Philippot et al) had a 3-month follow-up, and Study 5 (McKenna et al) conducted both 1-month and 6-month follow-ups.

In other words, the selected studies have taken the measurement of the placebo effect into consideration, making it more plausible that the findings are accurate (Jastreboff & Hazell, 2008, pp. 178-179). The findings in Study 2 (Philippot et al) 3 (Westin et al) and 5 (McKenna et al) might then suggest that the Third wave treatments are less vulnerable to the placebo effect. Not only did the ACT and MBT sustain the effect from the treatment better than RT and TRT, but some of the findings also reported further improvement after the trial had ended in the MBT group (McKenna et al).

#### **7.6.5 Contrasting findings**

The largest study selected for this thesis (Hesser et al), contradicted to the other findings when comparing group differences on sustained benefits of the ACT and CBT groups. The conclusion in Study 1 (Hesser et al) was that the treatment benefits were equal in the ACT and CBT groups. Study 1 (Hesser et al) has a high CASP score, was double blinded and had a 1-year follow-up, all criteria's for being categorized as a solid RCT. It is peculiar that the finding in Study 1 (Hesser et al) contrasts to the other studies selected, but a reason for this might be that this trial was the only trial of the selected studies comparing sustained effect in a Third wave approach to traditional CBT, not just an element from CBT like RT.

Another explanation might be that being an internet-based intervention, the results might have been different had the treatment been face-to-face. However, there are other studies supporting the notion that mindfulness does not enhance cognitive learning skills, making the argument for sustained benefits from mindfulness misguided. These studies reveal findings that show *no* enhanced attention and working memory in mindfulness meditation training (Lykins, Baer, & Gottlob, 2012; MacCoon, MacLean, Davidson, Saron, & Lutz, 2014), but these results were not clear and concluded further research was needed.

### **7.6.6 Summary**

In sum, of those studies reporting on sustained benefit over time, most studies selected for this thesis coincided in their findings. mindfulness and acceptance-based therapy was superior to TRT and RT in sustaining therapeutic improvements. Thus, Third wave intervention might be better than some active treatments, but according to Study 1 (Hesser et al) it might not be better than traditional CBT when it comes to sustained benefits over time, however, this might be impacted by the fact that treatment was internet-based.

## **7.7 Critique of the master's thesis**

Since Evidence Based Practice (EBP) is the preferred clinical approach in all fields treating people, especially aural rehabilitation (Fink, 2012, p. 4; Tye-Murray, 2014, p. 21; Wong & Hickson, 2012, p. 4), it was important in this master's thesis that the studies selected for evaluation was of a higher grade in the hierarchy of evidence as explained in heading 4.1. EBP supports constant advancement of treatment practice, and that is essentially what the goal for this master's thesis is, being a contribution to the field of educational audiology.

### **7.7.1 Validity and reliability in the master's thesis**

It might be argued that the validity of this master's thesis is strengthened, as the foundational approach of EBP was a guideline in producing this paper. Using EBP as a guideline, the design literature review was chosen to include enough people so that broader trends in the tinnitus population could be discussed. This way, the findings might be used to influence

more people in treatment, as the findings have a higher probability of being generalized to the population.

When using EBP as an approach, focusing the research question to find the appropriate research material resulted in using the PICO acronym as a framework. This helped define a solid research question by breaking the questions down (Wong & Hickson, 2012, p. 4). An argument can be made that this choice strengthened the validity of the thesis, as the direction of the search was narrowed, thus ensuring the concept studied was not too broad.

Having a defined research question, the inclusion and exclusion criteria was directed without too much leeway in selecting keywords. A-graded RCT's of high quality was chosen, and this ensures the treatment studied is compared to other or no treatments. This way, the thesis has more data to compare and synthesize broader trends with. To further ensure the selected data was of high quality, the critical appraisal tool CASP was used. Using these tools to strengthen the methodology, might also be argued to strengthen the thesis as a whole (Bordens & Abbott, 2013, p. 129), as it increases the probability of the study examining what it intended to examine. In other words, this thesis is believed to contain strong internal validity.

A weakness in the study may be that the final search where the collection of the studies was made, was done in one day (16 hours) to ensure the reliability of going back and conducting the same search on the same date. Even though the search was efficiently organized and prepared for, as mock searches had been made beforehand, this method might also raise the question if fatigue interfered with the calculations of the collected studies. Accordingly, this strategy might have both strengthened the reliability, but also weakened it.

Although the literature review design provides a discovery of what is known about a given topic (Machi & McEvoy, 2016, p. 5), and thus was suitable for the goal of this master's thesis, it also contains possible weaknesses as a design. It is based on partially subjective evaluation of the available research (Befring, 2015, p. 86), even though using an appraisal tool helps. The search for relevant material for this study was conducted by one person, possibly weakening the strength of objective appraisal and precision of the method. The lack of a second person to compare findings and measurements with, is referred to as inter-rater reliability. If another person conducted the same search at the same time, using the same search criteria, found the exact same articles as me, the inter-rated reliability would be higher for this thesis (Fink, 2012, p. 184).



When it comes to evaluating construct validity, the concept “improved psychological effect of Third wave” is a difficult construct to measure directly. This thesis has focused on defining and categorizing the term “Third wave”, and “psychological effects”, keeping the latter quite broad, meaning it has measured several psychological disorders and conditions associated with bothersome tinnitus. This was done to reveal a broader understanding of how the measured components related and influence different aspects of bothersome tinnitus. The term “effect” was measured in different psychological “category conditions” and was consistently comparing *significant findings*. There might be potential bias in this as significance is not as detailed as measuring effect size, however, for the scope of this thesis, significance was chosen as the measurement threshold.

There might be potential bias in how the construct was interpreted, and there might also be bias in the selection of keywords, as these were based on subjective critique of what other articles and books on the subject use.

Another possible weakness in the methods of this thesis might be that the treatment types selected could be argued to be subjective, as TRT was selected, but other treatments (like different types of exercise) was not selected. An argument can be made that TRT should have been a key search-word, even though the search check after the selection was done did not find any additional research that would have fit the criteria for this thesis.

In this study there is no statistical method used, and the size is relatively small (6 studies), due to the timeline and restrictions on one person per thesis. This in turn might inflict the study’s validity, as a larger sample is important when measuring statistical effects (Befring, 2015, p. 87).

However, the findings in this master’s thesis mostly coincide with other high-quality research, and this strengthen the validity of this study. Furthermore, most of the selected studies had a follow-up at a much later time, meaning it was possible for this master’s thesis to consider the sustained effect over time. This takes into consideration the placebo effect as well, which strengthen this master’s thesis as the “true” effect is what is relevant when conducting research (Basheer, 2017).

## 8 Conclusion, further research and implications in educational audiology

The results in the selected studies are difficult to sum up as one statement, as the results were mixed and differed when comparing the variety of psychological conditions and disorders.

In tinnitus distress and impact, the results showed that an *active* psychological behavior treatment is effective. However, the results are somewhat mixed when considering if the Third wave CBT approach is *more* effective than other psychological treatments. Most studies concluded that the Third wave approach was more effective on several psychological conditions, but some studies revealed the same effect in both active treatments. The same results were evident in depression, as the findings mostly point to significant improvements after *active treatment* but are mixed as the Third wave being more efficient.

When treating anxiety, the findings showed that using a Third wave intervention or other treatment options like CBT, RT or TRT all had significant effect. However, there was *no* significant improvement in the Third wave intervention compared to other treatment options.

When considering these findings, it might be safe to say that treating tinnitus distress, depression and anxiety with CBT or a Third wave CBT approach, will have an immediate improvement effect. However, there might not be a large enough immediate effect difference that one treatment is to be recommended above the others.

The findings for insomnia were mixed and somewhat in contrast to other existing research. Some findings found no significant effect in either CBT or ACT, and some findings concluded ACT was superior compared to TRT. Somewhat similar findings can be said about measuring quality of life, as the results were mixed and found no effect on improvement in quality of life.

Arguably, one of the most relevant finding in this master's thesis might be that several studies showed that the Third wave intervention was more effective than other interventions when it came to sustain the psychological benefits from treatment. 3 studies conclusively revealed that the Third wave intervention sustained or further improved benefits from the treatment over time. However, 1 study did not see this pattern (Study 1). An argument can be made that

3 studies are not enough to generalize about the sustained effect in Third wave interventions for tinnitus. However, the findings coincide with a substantial amount of theory on the subject and other research indicating attention and brain structures involved in focus change when practicing mindfulness.

In other words, although the immediate effects from a Third wave intervention might not be more effective than some other treatments, especially CBT, the long-term effect might have more impact.

## **8.1 Future research**

It can be argued that the difference in treatment is less substantial when comparing Third wave to traditional CBT, however, there was only one study (Hesser et al) that used CBT, all the other studies used elements from CBT (RT) or TRT. In other words, further trials using full CBT programs might be viable to fully compare if the Third wave approach differs enough and considerably contributes new benefits.

It was evident in this thesis that many of the selected studies' findings were contradicting when comparing different assessment tools. This can be considered a challenge, and future research might focus on defining different constructs and concepts in bothersome tinnitus more precisely. For example, considering insomnia and quality of life, these findings were difficult to interpret due to the lack of enough data, conflicting results and questionable measurements. Further research might focus on measuring more aspects on quality of life in tinnitus patients, or maybe use both quantitative and qualitative research to get a broader understanding of what quality of life indicates in bothersome tinnitus. Although this thesis might not have broadened the understanding on the role of a Third wave intervention on quality of life, the role of acceptance in quality of life and distress amongst tinnitus patients might be viable to further investigate due to its strong correlation in other studies (McKenna et al., 2018; Riedl et al., 2015). Furthermore, more consideration of the impact of hearing loss as a variable might be viable in future research, as focusing on adjustments for hearing loss impacts social life and thus quality of life. It might also be reasonable to use CBT-I (specific CBT for insomnia) in future trials in both intervention groups when measuring sleep

problems, as this is a specific program directly and more efficiently targeting insomnia (Hagen & Kennair, 2016, p. 203).

Another aspect that possibly is worth considering in future trials, is combining quantitative and qualitative research when investigating the difference of impact in face-to-face and internet-based intervention. It might be worth considering if measuring the effect could be done differently, not just looking at the improved categorized effects, but measuring other aspects that might contribute to different aspects of quality of life that might overall be beneficial. It would have been interesting to interview the participants after the trial in Study 1 (Hesser et al), to learn how they perceived their own therapeutic process, and if they felt isolated or “missed” something in the internet-based intervention. In addition, an added intervention group in the same trial receiving face-to-face treatment might also broaden the understanding of this process.

One other fascinating finding that emerged in this study, was Study 2’s (Philippot et al) finding that the psychoeducation was what gave the significant improvement, whilst the MBT and RT did not result in large effects or differences. It might be interesting to further examine what is the specific effect of psychoeducation, and how much of the effect comes from the following treatment. Further research on psychoeducation might shed light on how to further improve or make this element of treatment more efficient.

## **8.2 Implications in the field of educational audiology**

There is no effective universal cure for tinnitus yet (Swain et al., 2016; Wong & Hickson, 2012, p. 269), and the need for improved or renewed programs in treating tinnitus is important. EBP focuses on using solid, updated scientific evidence when adjusting treatment options. When considering EBP, this master’s thesis might be a contribution that can shed some light on when and if to merge the Third wave CBT approach in tinnitus treatments. Mindfulness can be argued to currently be “in”, in many disciplines, and shedding some light on when the newest “hype” actually results in an improvement, and when it does not, is an important input to the field of educational audiology and other disciplines treating people.

The Third wave CBT approach might be more *resistant* to the placebo effect as the findings indicate there is a sustained effect compared to other treatments. One can argue that sustained

effect is what one is looking for when treating bothersome tinnitus, not just immediate improvements, but improvements that lasts and continue to develop in a positive direction. On that notion, the Third wave intervention might be a viable and sometimes preferred treatment option for people struggling with bothersome tinnitus and the psychological conditions and disorders that follows.

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# 1 Appendix 13 selected studies for closer evaluation

**Following 6 selected studies met all the inclusion criteria:**

**-A Randomized Controlled Trial of Internet-Delivered Cognitive Behaviour Therapy and Acceptance and Commitment Therapy in the Treatment of Tinnitus.**

Hesser, Gustafsson, Lundén, Henrikson, Fattahi, Johnsson, Zetterqvist, Westin, Carlbring, Mäki-Torkko, Kaldo, Andersson 2012.

**-Mindfulness-Based Cognitive Therapy as a Treatment for Chronic Tinnitus: A Randomized Controlled Trial**

McKenna, Marks, Hallsworth, Schaette, R. 2017

**-Acceptance and commitment therapy versus tinnitus retraining therapy in the treatment of tinnitus: a randomized controlled trial**

Westin, Schulin, Hesser, Karlsson, Noe, Olofsson, Stalby, Wisung and Andersson. 2011

**-A randomized controlled study of mindfulness meditation versus relaxation therapy in the management of tinnitus.**

Arif, M.Sadlier, M.Rajenderkumar, D. James, J.Tahir, T. 2017

**-Mindfulness-and body-psychotherapy-based group treatment of chronic tinnitus: a randomized controlled pilot study**

Kreuzer, P. M. Goetz, M. Holl, M. Schecklmann, M. Landgrebe, M. Staudinger, S. Langguth, B. 2012

**-A randomized controlled trial of mindfulness-based cognitive therapy for treating tinnitus.**

Philippot, Nef, Clauw, de Romrée, Segal. 2012.



**Following study met all the inclusion criteria (but with lower quality):**

**-A Pilot Randomized Clinical Trial Comparing Three Brief Group Interventions for Individuals With Tinnitus.**

Martz, Chesney, Livneh, Jelleberg, Fuller. 2018

**Following 6 selected studies not suitable for the research question (not about Third wave or not an RCT):**

**-Clients' in-session acceptance and cognitive defusion behaviors in acceptance-based treatment of tinnitus distress**

Hesser, Westin, Hayes, Andersson 2009

**-Acceptance as a mediator in internet-delivered acceptance and commitment therapy and cognitive behavior therapy for tinnitus**

Hesser, Zetterqvist, Westin, Andersson. 2014

**-Effects of Mindfulness Based Stress Reduction Therapy on Subjective Bother and Neural Connectivity in Chronic Tinnitus**

Roland, Lenze, Hardin, Kallogjeri, Nicklaus, Wineland, Fendell, Peelle, Piccirillo. 2015

**-Tinnitus rehabilitation: a mindfulness meditation cognitive behavioural therapy approach**

Sadlier, Stephens, Kennedy. 2007

**-Specialised treatment based on cognitive behaviour therapy versus usual care for tinnitus: a randomised controlled trial**

Cima, Maes, Joore, Scheyen, Dyon, Amr, Baguley, Anteunis, Breukelen, Vlaeyen, 2012.

**-Internet-Delivered Cognitive-Behavior Therapy for Tinnitus: A Randomized Controlled Trial**

Weise, Kleinstäuber, Andersson, 2016.

## 2 Appendix Search word library

Books and articles used in the pursuit to find suitable search words.

### Books

-*Acceptance and Commitment Therapy*: Flaxman, Blackledge, & Bond,( 2010)

-*An Introduction to Cognitive Behaviour Therapy*: Westbrook, Kennerley & Kirk (2017)

-*Assessing Mindfulness and Acceptance Processes in Clients*: Baer (2010)

-*Core Principles of Meditation for Therapy: Improving the Outcomes for Psychotherapeutic Treatments*: Simpkins & Simpkins (2016).

-*Håndbok i kognitiv terapi*: Berge & Repål (2015).

-*Handbook of Brief Cognitive Behaviour Therapy*: Bond & Dryden (2005)

-*Mindfulness-Based Cognitive Therapy: Distinctive Features*: Crane (2017)

-*Mindfulness-Based Cognitive Therapy for Depression*: Segal, Teasdale, & Kabat-Zinn, (2018)

-*Psychology: The Science of Mind and Behaviour*: Holt et al. (2015)

-*Relaxation, Meditation, & Mindfulness: A Mental Health Practitioner's Guide to New and Traditional Approaches*: Smith (2005)

## Articles

- Baer, R. (2003). Mindfulness Training as a Clinical Intervention: A Conceptual and Empirical Review. *Clinical Psychology: Science and Practice*
- Chiesa, A., & Serretti, A. (2009). Mindfulness-Based Stress Reduction for Stress Management in Healthy People: A Review and Meta-Analysis. *Journal of Alternative and Complementary Medicine*
- Cima, R. F. (2018). Bothering tinnitus : Cognitive behavioral perspectives. *Hno*
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- Makar, S. K., Mukundan, G., & Gore, G. (2017). Treatment of Tinnitus: A Scoping Review. *Int Tinnitus J*
- McKenna, L., Marks, E., & Vogt, F. (2018). Mindfulness-Based Cognitive Therapy for Chronic Tinnitus: Evaluation of Benefits in a Large Sample of Patients Attending a Tinnitus Clinic. *Ear and Hearing*
- Ong, J. C., Manber, R., Segal, Z., Xia, Y., Shapiro, S., & Wyatt, J. K. (2014). A randomized controlled trial of mindfulness meditation for chronic insomnia. *Sleep*
- Ruiz, F. (2010). A Review of Acceptance and Commitment Therapy (ACT) Empirical Evidence: Correlational, Experimental Psychopathology, Component and Outcome Studies. *International Journal of Psychology and Psychological Therapy*
- Sadlier, M., Stephens, S. D., & Kennedy, V. (2008). Tinnitus rehabilitation: a mindfulness meditation cognitive behavioural therapy approach. *Journal of Laryngology and Otology*

Thompson, D. M., Hall, D. A., Walker, D. M., & Hoare, D. J. (2017). Psychological Therapy for People with Tinnitus: A Scoping Review of Treatment Components. *Ear Hear*

### 3 Appendix Acronym chart

**ACT** = Acceptance and Commitment Therapy (*treatment*)

**BDI** = Beck Depression Inventory (*assessment tool*)

**CBT** = Cognitive Behavioral Therapy (*treatment*)

**CBT-I** = Cognitive Behavior Therapy for Insomnia (*treatment*)

**CGI** = Clinical Global Impression-Improvement (*assessment tool*)

**CORE-OM** = Clinical Outcome in Routine Evaluation, Outcome Measure (*assessment tool*)

**CONT** = Control (*Waitlist group, used in Table 6*)

**DSM** = Diagnostic and Statistical Manual of Mental Disorders (*assessment tool*)

**EBP** = Evidence Based Practice (*approach*)

**HADS** = Hospital Anxiety and Depression scale (*assessment tool*)

**HT** = Health State Thermometer (*assessment tool*)

**I-CBT** = Internet-Based Cognitive Behavioral Therapy (*treatment style*)

**ISI** = Insomnia Severity Index (*assessment tool*)

**MAAS** = Mindful Attention Awareness Scale (*assessment tool*)

**MBCT** = Mindfulness-Based Cognitive Therapy (*treatment*)

**MBMT** = Mindfulness-Based Meditation Training (*treatment*)

**MBT** = Mindfulness-Based Therapy (*treatment*)

**MBSR** = Mindfulness-Based Stress Reduction (*treatment*)

**PICO** = Participant, Intervention, Comparison, Outcome (*methodological framework*)

**PSS** = Perceived Stress Scale

**RCT** = Randomized Controlled Trial (*treatment*)

**RT** = Relaxation Therapy/Training (*treatment*)

**STAI** = State-Trait Anxiety Inventory

**TRT** = Tinnitus Retraining Therapy (*treatment*)

**TAQ** = Tinnitus Acceptance Questionnaire (*assessment tool*)

**TCS** = Tinnitus Catastrophizing Scale (*assessment tool*)

**TfAS** = Tinnitus fear Avoidance Scale (*assessment tool*)

**TFI** = Tinnitus Functional Index (*assessment tool*)

**THI** = Tinnitus Handicap Inventory (*assessment tool*)

**TRQ** = Tinnitus Reaction Questionnaire (*assessment tool*)

**TQ** = Tinnitus Questionnaire (*assessment tool*)

**VAS** = Visual Analogue Scale (*assessment tool*)

**QIPA** = Tinnitus Psychological Impact Questionnaire (*assessment tool*)

**QoLI** = Quality of Life Index (*assessment tool*)

**WSAS** = Work and Social Adjustment Scale (*assessment tool*)