

**Efficacy of using Internet based Cognitive Behavioral Therapy
(iCBT) for Adults with Tinnitus in Indian context**

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for the Degree of Master of Science in Audiology
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CERTIFICATE

This is to certify that this dissertation entitled *“Efficacy of Internet based Cognitive Behavioral Therapy (iCBT) for Adults with Tinnitus in Indian context”* is a bonafide work submitted in part fulfilment for degree of Master of Science (Audiology) of the student Registration Number: 16AUD017. This has been carried out under the guidance of a faculty of this institute and has not been submitted earlier to any other University for the award of any other Diploma or Degree.

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This is to certify that this dissertation entitled *“Efficacy of Internet based Cognitive Behavioral Therapy (iCBT) for Adults with Tinnitus in Indian context”* has been prepared under my supervision and guidance. It is also been certified that this dissertation has not been submitted earlier to any other University for the award of any other Diploma or Degree.

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DECLARATION

This is to certify that this dissertation entitled “*Efficacy of Internet based Cognitive Behavioral Therapy (iCBT) for Adults with Tinnitus in Indian context*” is the result of my own study under the guidance of Prof. Rajalakshmi K, Department of Audiology, All India Institute of Speech and Hearing, Mysuru, and has not been submitted earlier to any other University for the award of any other Diploma or Degree.

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Abstract

The problem of tinnitus in India is as alarming and as severe as in the Western countries. In spite of such a pressing need for effective intervention options, there is a dearth of studies reporting on evidence for effectiveness of the various available tinnitus intervention programs. With no reports of Internet based Cognitive Behaviour Therapy (iCBT) in India so far, the study aimed to verifying the feasibility and acceptability of implementing iCBT platform in terms of presentation, suitability, contents and materials provided in Indian context. The assessment was carried out by 30 Adults with tinnitus and 30 Audiologists. The study was carried out in 4 phases with initial phase being Assessment of Screening questionnaire and administering of the Credibility and Expectancy Questionnaire (CEQ) in both the groups Final phase included the assessment of satisfaction of the programme using Intervention Satisfaction Evaluation tool. Results revealed high satisfaction of iCBT platform regarding its content, suitability, presentation, usability and exercises given in the programme as rated by both the groups. The following provides greater confidence to utilize the iCBT in Indian context considering some necessary modifications. Integrating Audiologist driven iCBT into regular clinical care with further intervention trials done could ensure the higher demand for tinnitus care to be met.

Key words: *Internet based Cognitive Behaviour Therapy, iCBT, Tinnitus Cognitive Behaviour Therapy, Tinnitus.*

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Chapter 1

Introduction

Tinnitus is one of the commonly reported disturbing and stressful hearing phenomenon and is generally described as the perception of noise or ringing in the ears. ANSI (1969) defines tinnitus as the sensation of sound without external stimulation. The word tinnitus, referred to as ringing in the ears is derived from the Latin word "tinnire" meaning "to ring". The individual with tinnitus generally report conscious perception of unwanted auditory stimulation even when there is absence of corresponding external stimuli. In a recent study review, prevalence rate of tinnitus has been reported to range between 5.1 and 42.7 (McCormack, Edmondson-Jones, Somerset, & Hall, 2016). Hymowitz (2016) reports that tinnitus is often reported to co-exist with other psychological and psychiatric conditions. Anxiety, depression, stress, problems with concentration, sleep disturbances, feeling of helplessness, anger, fear are few of the psychological co-morbidities frequently reported (Adoga & Obindo, 2013). Patients often report that tinnitus is associated with several other risk factors such as hearing impairment, ageing, noise exposure (Gopinath, McMahon, Rochtchina, Karpa, & Mitchell, 2010). It was noted that the severity of tinnitus vary depending on the risk factors causing it. On at least a considerable group of tinnitus sufferers, negative impact on the quality of life has been repeatedly reported in the literature (Alhazmi, Kay, Mackenzie, Kemp, & Sluming, 2016; Kennedy, Wilson, & Stephens, 2004; Nondahl et al., 2007; Prestes & Daniela, 2009; Refaie et al., 2004; Zarenoe & Ledin, 2014; Zeman, Koller, Langguth, & Landgrebe, 2014).

The diagnosis and rational management of tinnitus is one of the legacies of the past millennium, which the medical profession has carried unsolved to this century (Biswas, 2006). Diagnosis of tinnitus is usually based on the individual's description

which is supported by questionnaires, audiogram and neurological examinations. Although much research is underway into mechanisms and possible treatments, no effective drug treatments are available.

Over the years, various tinnitus intervention approaches have been developed. Many treatment protocols have been proposed for tinnitus management (Vernon, 1998). In some cases, the tinnitus sound itself can be reduced, but there is no systematic method for accomplishing this in patients. Practitioners generally follow the trial and error approach in their treatment strategy and mostly include generic treatment method to work on all types of tinnitus. Most patients thus cannot be helped by medical or surgical treatment, and therefore, seek other forms of professional intervention when the tinnitus becomes intrusive. A few of them include medical treatment, use of food supplements, sound-based interventions and cognitive-behavioural therapies. In spite of availability of such diverse options, unfortunately, even today, intervention for tinnitus still remains as an enigma and little is known about the mechanics by which these techniques in treating the tinnitus especially in India. Medical treatments largely have been ineffective in giving a cure or reduce the tinnitus. Tinnitus is often therefore managed as a chronic condition in the present health care systems around the world. The considerable fact is that tinnitus severity is not always related to the character of tinnitus, distressing factors related to tinnitus is also known to be a factor. As a result, sound therapy alone has failed to promise the long-term benefits in reducing tinnitus, which has shed light to the other strategies like Cognitive Behavioural Therapy (CBT).

Since the last three decades, CBT is one of the frequently applied tinnitus intervention options. It is a psychotherapeutic structured approach known to typically reduce the distress, which is associated with tinnitus. However, CBT is not typically followed in a structure and there are many treatment protocols around the world. The

applications of CBT have been addressed and implicated in diverse combinations of behavioural and cognitive therapies worldwide. The primary aim of CBT is to not reduce the perception of sound itself but to alleviate one's negative response towards it (Jun & Park, 2013). Psycho-education, relaxation techniques, cognitive restructuring, mindfulness-based training, attention/concentration-control techniques, positive imagery training, are a few of the common components of the CBT intervention programs.

In recent days, CBT is serving as one of the most promising tinnitus management options. Literature studies from more than 25 years have been discussing the applicability of CBT on tinnitus. Unlike most of the other tinnitus treatment options, there is a considerable accumulating evidence for effectiveness of CBT on tinnitus studied using randomized control trials (Hesser, Weise, Westin, & Andersson, 2011; Hoare, Kowalkowski, Kang, & Hall, 2011; Langguth, Kreuzer, Kleinjung, & De Ridder, 2013; Martinez-Devesa, Perera, Theodoulou, & Waddell, 2010) Owing to the fact that CBT has most evidence of effectiveness (Hesser et al., 2011), a few researchers have called it as 'the best treatment option' for tinnitus management (Seidman & Ahsan, 2015).

As an alternative option to traditional face-to-face CBT, in the recent years, internet-based CBT (iCBT) has slowly gained attention. In support of its development is the research evidence showing comparable efficacy between conventional and iCBT (Jasper et al., 2014; Kaldo et al., 2008). Probably due to its advantages like cost effectiveness, time efficiency and easy accessibility, in a short span of time it has attracted attention from researchers worldwide. Internet based CBT programme has been effective for reducing tinnitus associated with wide range of conditions including headache, mood disorders, chronic pain, anxiety disorders and other somatic problems

(Arnberg, Linton, Hulcrantz, Heintz, & Jonsson, 2014; van Beugen et al., 2014). A few researchers have developed their own protocols for implementing iCBT. In recent times, one such innovative tinnitus intervention iCBT protocol was developed by Beukes et al., (2016), is being implemented recently in the United Kingdom.

Preliminary clinical trials have confirmed the feasibility of its implementation on tinnitus sufferers with audiologists support (Beukes et al., 2016). The current study involves application of this structured iCBT program in the Indian context.

1.1. Need for the study

Many researchers have attempted to evaluate the effectiveness of different tinnitus intervention approaches (Hoare et al., 2011; Landgrebe et al., 2012; Langguth & Elgoyhen, 2012; Langguth et al., 2013; Seidman & Ahsan, 2015). In general, poor methodological quality, high individual variability and limited evidence-based intervention options have been reported for tinnitus intervention trials (Landgrebe et al., 2012; Hoare, Kowalkowski, Kang; Hall, 2011). A recent study examined the Strength of Evidence (SOE) of the literature studies reporting on the effectiveness of different tinnitus interventions (Pichora-Fuller et al., 2013). The SOE was determined based on the Grading of Recommendations Assessment, Development, and Evaluation (GRADE system) (Owens et al., 2010). Shockingly, they reported a low quality SOE for majority of the approaches including cognitive/behavioural approach. According to GRADE system, low quality SOE indicates that conducting further research in that area is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate (GRADE working group, 2004). Hence, there is a clear and urgent need for stronger evidence for each and every available tinnitus intervention approaches (Landgrebe et al., 2012).

1.2. Aim of the study

The aim of this study was to systematically evaluate the effectiveness and acceptability of the iCBT program by people suffering with tinnitus in India in terms of its content, suitability, presentation, usability and exercises. India is a South Asian developing country with considerably high prevalence rate of tinnitus. A prevalence rate of 9.6% has been reported in rural India (Konadath et al., 2013). Also, Thirunavukkarasu and Geetha in 2013 have reported a tinnitus prevalence rate of 16.81% amongst geriatrics with otological problems. It is evident that the problem of tinnitus is as alarming and as severe as in the Western countries' (Makar, Biswas and Shatapathy, 2014). In spite of such a pressing need of effective intervention options, there is a dearth of studies reporting on evidence for effectiveness of the various available tinnitus intervention programs. Thus, the current study is planned to be hosted in India.

Although, studies conducted in western countries provide considerable evidence for use of CBT, in India it is less commonly practiced. Here, less than 10% of the institutes offering tinnitus treatments have been reported to use CBT (Makar, Kumar, Narayanan & Chatterjee, 2012). There are no reports on use of iCBT in India so far. Thus, this study seemed relevant to explore the possibility of effectively using iCBT in the Indian context. Also, as per the study reports, currently, none of the audiologists are using CBT in India (Krishna R, Manchaiah & Rachna, 2016). None of them have received required training for its implementation either. The research team would involve experienced psychologists to provide necessary support to the audiologist.

1.3. Objectives of the study

To verify the feasibility of implementing iCBT platform in Indian context in terms of presentation, suitability, contents and materials provided and thereby to study the acceptability of iCBT for tinnitus sufferers in India

Chapter 2

Literature Review

Originating from the Latin word "tinnire" meaning "to ring", tinnitus is defined as the "sound perceived for more than five minutes at a time, in the absence of any external acoustical or electrical stimulation of the ear and not occurring instantly after exposure to loud noise". Levine and Oron (2015) define Tinnitus as "hearing of sound when no external sound is present". ANSI (1969) defines tinnitus as the sensation of sound without external stimulation. The word tinnitus, referred to as ringing in the ears is derived from the Latin word "tinnire" meaning "to ring". Though often described as a ringing sound, the sounds might vary to be hissing, clicking or roaring sound. Tinnitus can be loud or soft, high pitch or low pitch, sudden or gradual and can be unilateral or bilateral in nature (Baguley, McFerran, & Hall, 2013). Tyler and Baker (1983), report that tinnitus comprises of a number of negative effects. The negative effects could be depression, anxiety, poor concentration and so on.

Several risk factors are associated with tinnitus, such as hearing impairment, dizziness (Gopinath et al., 2010), age, gender and noise exposure (Sidhusake et al., 2004) among others and depending on the risk factors associated the severity of tinnitus has been found to vary (Sidhusake et al., 2004). A study by Thirunavukkarasu and Geetha in 2013, concluded that majority of the individuals with tinnitus had hearing loss (82.4%) and hence, reported that hearing impairment as one of the major risk factors associated with tinnitus. They added that majority of the individuals with tinnitus exhibited moderate degree of hearing impairment followed by mild category of hearing impairment with most of them having sensorineural hearing loss (52.12%). Headache, Giddiness, Hypertension and Diabetes were also noted by the authors to be the significant risk factors.

2.1. Incidence and prevalence

Tinnitus as a symptom is known to be associated with all types of hearing loss and as a result of this the higher prevalence of tinnitus can be expected (Axelsson & Ringdahl, 1989; Davis & Reface, 2000; Henry & Wilson, 2001; Vernon, 1998).

National Center for Health Statistics (2016) reports that tinnitus is more prevalent in older age adults and is more commonly seen in males than females. Kochkin, Tyler and Born (2011) reported based on their epidemiological study of tinnitus that the prevalence of tinnitus in United States to be 30 million with 13 million reported to have tinnitus without any significant associated hearing loss. The survey was carried out nearly on 80,000 households through online mode by mailing them tinnitus related questions. The survey focused on individuals suffering with hearing loss. The study stated that one person out of four reported their tinnitus as louder and one person out of five reported their tinnitus as disabling or nearly disabling. In another study conducted by Xu et al., (2011) it was found that the prevalence of tinnitus was 7.8% among the 28,000 participants. This study was carried out in the north of Shaanxi Province, China.

Two major cohort studies carried at Beaver Dam, Wisconsin, USA (Nondahl et al., 2002, 2010) and Blue Mountains Hearing Study, Sydney, Australia (Gopinath et al., 2010), have addressed the long-term incidence of tinnitus in the respective population. The study done on Beaver Dam, USA population study reported a 5-year cumulative incidence of tinnitus of 5.7%, and a 10-year expected cumulative incidence of 12.7%. Whereas the Blue Mountains Hearing study reported Five-year incidence of tinnitus in Blue Mountains, Sydney, Australia was 18.0%. It was also reported that the Tinnitus symptoms during the 5 years persisted in more than three-quarters of the cohort. Gallus et al., (2015) reported that individuals with any form of tinnitus among

Italian adults to be 6.2%, that of chronic tinnitus being 4.8%, and severe tinnitus 1.2%. The study also reports the effects of tinnitus in Italy which is said to be more than 3 million adults overall with 600,000 Italians finding it as a major problem, especially those aged 45 and higher. Wu, Searchfield, Exeter and Lee (2015) reported an overall weighted prevalence of tinnitus in total in New Zealand population to be 6.0% among those aged 14 years or above. This study also reported higher incidence of tinnitus among males with 6.5% compared to that of females who showed an incidence of 5.5%. The chances of males reporting tinnitus was 55% more likely as compared to females among young adults (14 to 24 years) and 32% more likely compared to females among older adults (50 to 64 years). They also reported that Adults aged 65 years and above had chance of being three times more incident than people who are aged below 65 years.

Adoga, Adoga and Obindo (2008) carried out a longitudinal study for a duration of 12 months (April 2006 March 2007) on out-patients reporting with tinnitus at Jos University Teaching Hospital, Nigeria. They reported 104 (15.1%) patients had tinnitus among the 687 patients who visited with various otologic problems. They also reported that among them the tinnitus individuals exhibiting associated problems of depression was 17.4% with females reporting higher prevalence than males with 7.6%. However the overall prevalence of anxiety was higher with males (22.8%) than females (10.9%).

Considering the incidence and prevalence of tinnitus in Indian context, there is limited number of studies and there is lack of information available. Thirunavukkarasu and Geetha in 2014 carried out a study on those who reported with the ear and/or hearing related complaints at All India Institute of Speech and hearing, Mysore, between July 2012 and June 2013 and estimated the prevalence of tinnitus and also to identify the risk factors of tinnitus in the individuals and reported that the prevalence of tinnitus reporting otological problem to be 14.33 %. Among 12325 clients, 1766

individual reported tinnitus and among these 349 individuals reported tinnitus as primary complaint and the remaining 1417 as secondary. They also reported that the incidence of tinnitus was higher among adults (65%) as compared to geriatrics (25.7). The incidence among adolescents was found to be 5.8 % and 3.3 % among children with males having higher incidence than females.

Similarly a door-to-door survey was carried out by Konadath et al., (2013) in 15 randomly selected villages of Mandya district of Karnataka state, India in order to determine the prevalence of communication disorders using a High Risk Resister (HRR) and reported that 9.6% of the total population had tinnitus.

2.2. Pathophysiology

Pathophysiology of subjective tinnitus is very vague in its mechanism as the cause is not just limited to the direct trauma of the inner ear, rather added causes such as temporomandibular dysfunction could also cause tinnitus. These causes are difficult to explain. Over-excited neural activity of the auditory nerve cells at the level of the brainstem could be one of the predicted causes. This theory is based on the assumption that tinnitus sufferers have an associated hearing loss. A review by Shore, Roberts and Langguth (2016), emphasized that the pathological causes of tinnitus involves a wide range and combinations which result in variety of symptoms to which specific therapeutic approaches are enforced.

Subjective tinnitus - Abnormal neural activity of the auditory cortex being considered as the cause which is a result of disrupted or modified input from the auditory pathway. As a result of which the new neural connections are constructed due to the loss of the suppression of the intrinsic cortical activity. Besides, conductive hearing loss also cohorts in the central auditory system by altering the sound inputs.

Objective tinnitus - Generally, the origin of noise in objective hearing loss are the blood vessels, either normal blood vessels or abnormal blood vessels. The physiology of this type of tinnitus being from the middle ear can sometimes also be associated with muscle spasms or palatal muscle myoclonus or middle ear muscles which results in the perception of clicking noise.

2.3. Major Causes of Tinnitus

Numerous causes constitute to the onset of tinnitus. While noise induced hearing loss composes of the major and most common causes, ear infections, neurological problems, brain tumors, blood vessel disruption, Meniere's disease, stress, ototoxicity, head injury and ear wax (Han, Lee, Kim, Lim & Shim, 2009) constitutes to the other causes. These causes can be further classified depending on if they cause subjective or objective tinnitus.

2.3.1. Major causes for Subjective tinnitus. Almost any disorder that affects the auditory pathway can form the source of subjective tinnitus, sensorineural hearing loss being the common of them. The causes includes Presbycusis, ototoxicity, Meniere's disease, noise induced hearing loss, infection of the ear, neural pathologies affecting the auditory pathway. Conductive hearing loss also plays its role in the onset of tinnitus in an individual, which constitute the outer ear and middle ear disorders. In some patients temporomandibular joint dysfunction may be associated with tinnitus.

2.3.2. Major causes for Objective tinnitus. Vascular regions and vascular flow constitutes to the commonly found causes, as it depicts the audible pulsating noise of the pulse/blood flow. This noise is synchronous to the pulse. The pulsating noise can be associated to the turbulent flow in the jugular vein, middle ear tumours, palatal muscle spasms, middle ear muscle spasms. This noise is commonly perceived to be

clicking or pulsating in nature. These spasms are idiopathic in nature and a variety of causes that are derived to explain.

2.4. Symptoms and Associated Problems of tinnitus

Tinnitus is a result of a number of underlying causes, which makes it a symptom and not a disease. Perception of tinnitus can be in one ear, both ears or in the head. Description of the noise varies from individual to individual and is based on the person's perception of the noise. Usually described as ringing noise, but can vary to be buzzing, humming, hissing, clicking, roaring, ringing or a whistling noise (Han BI, 2009). Tinnitus can be intermittent or continuous in nature and cause great distress. Simmons et al., (2008) have reported in their study that the intensity of tinnitus can be affected due to movements of shoulder, head, tongue, jaw or eyes. Most people with tinnitus have an associated hearing loss (Nicolas-Puel C et al., 2002).

Onset of tinnitus is associated with several risk factors, majorly to hearing loss and dizziness (Gopinath et al., 2010). Other factors include age, gender and noise exposure (Sidhusake et al., 2004). These risk factors are said to be directly proportional to the severity of tinnitus (Sidhusake et al., 2004). In a study done by Thirunavukarasu and Geetha (2015), they concluded that majority of the individuals with tinnitus had hearing loss (82.4%), which computes to the fact that hearing loss is one of the major risk factors. In addition, the degree of hearing loss varied from mild hearing loss to moderate degree of hearing loss, majority of which were sensorineural impairment (52.12%). They also reported that other significant risk factors that contributed to tinnitus were Headache, Giddiness, Hypertension and Diabetes.

Nagaraj and Bose (1997) carried out a tinnitus profiling study utilizing a specially developed questionnaire on 35 individuals suffering with tinnitus. They reported that the data obtained showed that the tinnitus among individuals was

independent of degree and type of hearing loss. They also reported that there was no significant variations of tinnitus severity with the subjective complaints. They also reported that when the severity of tinnitus increased it was found that the individuals experienced disturbed sleep and increased irritation, annoyance and botheration.

Makar, Jalvi and Sinha (2009) carried out a study on Audiological and psychological correlates of tinnitus in the age range of 18 to 60 years reporting subjective tinnitus with normal hearing bilaterally or sensorineural hearing loss of pure type ranging from mild to moderate severity. In all cases an audiological profiling for each subject was charted and prepared on the basis of case history, Otoscopic evaluation, Pure Tone Audiometry, Immitance evaluation and Effective Masking Level. To profile psychological aspects they utilized questionnaires like Tinnitus Reaction Questionnaire (TRQ) and Nature of Tinnitus Questionnaire (NTQ). Off the total participants, 60% reported no awareness to the probable cause of their Tinnitus. A significant correlation between disturbance of sleep and impact of Tinnitus was observed with increase in depression and anger ($r=0.483$) and no significant correlation was seen between the duration of tinnitus and distress caused by tinnitus ($r=-0.34$). They also noted Gender differences among individuals affected by tinnitus while assessing the measures of audiological and psychological profiling with females reporting a higher level (mean=35.9) of emotional distress and reactions to their tinnitus when compared to males (mean=32.7). They also noted that the patients exhibited a multifold impact because of their tinnitus, reporting feeling of unhappiness, tense, irritability, depression, annoyance, distress and frustration and interference with their enjoyment, relation, and sleep making them avoid quiet situations and social gatherings.

2.5. Treatments available

No effective drug treatments are available, although much research is underway into mechanisms and possible treatments. Treating of the underlying disorder of tinnitus may hinder effect of tinnitus on the individual. Educating patients regarding the importance of being aware of the issue and that tinnitus is not a serious medical condition is crucial. Treatment of tinnitus includes masking therapy, hearing aids, pharmacological treatment, sound therapy such as Tinnitus retraining therapy, biofeedback therapy, and neurofeedback therapy. Noise therapy includes providing tinnitus maskers, a device worn like a hearing aid that provides a low-level sound that can cover up the tinnitus or hearing aids that helps in diminishing the perception of the target tinnitus noise.

Despite not having a definitive treatment of any form such as surgical, medical or therapeutic practice, it is reported that the patients find the background sound maskers of great help to fall asleep. Occasionally it is noted that the electrical stimulation of the inner ear using an implanted device can reduce tinnitus. But this method is most suited and associated for individuals with profound hearing loss.

In the recent times, Tinnitus Retraining Therapy (TRT) has achieved all the attention in providing specialised treatment programmes for specific type of tinnitus reported. This is a therapeutic procedure in which both acoustical treatment along with mental strengthening is done. That is the therapy includes a session of treatment using low-level broadband noise followed by counselling, which in combination aims at achieving habituation of the problem. This process helps in redirecting the thought process of the brain away from the tinnitus noise.

In conclusion, the evidence from the earlier research suggests that TRT, Tinnitus Maskers and CBT all have their own unique benefits in the treatment of

tinnitus. Given the confounding variables that include length of therapy, tinnitus severity, and subject population, the overall level of evidence is equivocal. Cima, Andersson, Schmidt and Henry, (2014) claim that CBT treatment is the most evidence-based treatment option so far based on a systematic review of the peer-reviewed literature on treatment strategies and options available for tinnitus.

Another widely used approach for tinnitus is the Cognitive behavioural therapy (CBT). It is a structured and a time-limited psychological therapy approach which is usually offered on an outpatient basis which lasts between 8 and 24 weekly sessions. (Devesa, Perera, Theodoulou, & Wadell, 2010). The patient is provided with the combination of behavioural and cognitive aspects to modify their response to the positive thoughts and situations.

2.5.1. Cognitive Behaviour Therapy. CBT is primarily principled that a pattern of assumptions is developed on primary beliefs arising from a specific incident, a specific event or mood similar to the original or critical incident that can set up thought patterns which could reinforce the core beliefs. Furthermore Hallam, Rachman, and Hinchcliffe (1984) reports that tinnitus may be conceived as a failure to adapt to a stimulus and is considered analogous to anxiety states in such case. CBT involves collaborative work (Beck, Rush, Shaw, & Emery, G, 1979) in which both the individuals suffering from tinnitus and therapist view the patient's negative and fearful thoughts as hypotheses to be examined and tested critically.

Cima et al., (2014) reports that psychological form of therapies have been widely used for treating, as the reactivity of tinnitus is more based on psychological factors over the acoustic properties. Cognitive strategies are designed on the idea that negatively biased thoughts or thinking over specific experiences, events or situations, such as tinnitus, results in a dysfunctional behavioural and emotional state

(Beck, Rush, Shaw, & Emery, G, 1979). It thus works by identifying the irrational thought patterns or situations and further by interpreting, challenging, bringing modifications and /or to replace them totally through more realistic and also alternative beliefs leading to an adaptive state. Whereas Behavioural therapy approaches like Exposure therapy works by decreasing the overall impact of tinnitus on daily situations. The focus here is not to reduce the loudness level of tinnitus but to majorly work on tinnitus extinction learning and also generalisation. This ultimately helps the person to learn not to associate the emotional arousals with tinnitus and also apply this knowledge to events or situations beyond those learnt in the therapeutic set up. This results in a situation where the person re engages in activities that they had avoided because of the fear factor associated with tinnitus (Fuller et al., 2017).

Thus both cognitive and behavioural therapy components individually are hypothesised to have specific effects. This plays a major role for treating conditions like tinnitus who begin to understand that tinnitus is not a condition that is harmful and there isn't any reason to panic. These counselling and educational tips is said to provide a foundation for treating individuals with tinnitus. Hence the Cognitive behavioural approaches to tinnitus therapy are hypothesised to reduce the aversive reactivity to tinnitus through synergistic and positive effects included in an individual therapy and to reduce anxiety or depression where it is co-morbid, overall resulting in an improved quality of life.

The treatment was originally developed for depression, and now has spread its applications treating range of psychological conditions including depression, stress, anxiety, sleep disturbances, chronic pain (Hawton, Salkovskis, Kirk, & Clark, 1989), and Diabetes (Turner 2010; Uchendu & Blake, 2017). It is believed that the therapy based on the relaxation, cognitive restructuring, positive imagery, and exposure to

tinnitus aggravating situations is set to result and thereby promoting habituation which could benefit individuals with tinnitus. CBT therapy for tinnitus aims primarily to reduce the hypervigilance which is anxious preoccupation of negative thoughts associated with tinnitus, rather than the perceived loudness.

Relaxation, Positive Education, evidence based discussions on the already developed core beliefs, imagery modifications, attention manipulations, cognitive restructuring and exposure to stimuli are the significant strategies used in this form of therapy. (Devesa, Waddell, Perera & Theodoulou, 2007). It works by setting up achievable and a successful goals by identifying the potential pitfalls and obstacles. Hesser, Weise , Westin and Andersson (2011) based on the results of meta-analytic review have reported that CBT is effective for reducing the annoyance that is resulted by the tinnitus resulting in brining positive effects on other psychological symptoms associated with tinnitus. However they found little changes with respect to reduction of loudness.

Similarly on the same grounds there have been several randomized controlled research articles that have reported positive outcomes of the CBT on individuals with tinnitus. Henry and Wilson (1996) reported that there was a significant reduction in the distress caused and also handicap that was associated with tinnitus and also better tendency to tackle the dysfunctional cognition as compared with subjects who only received education. However, no significant effects were observed in reduction on measures of depression, subjective rating of loudness, tinnitus noticeability, or any other tinnitus resulted associated problems. Rief, Weise, Kley and Martin (2005) found significant improvement in reducing the emotional distress and annoyance of tinnitus in CBT treatment group. Several studies have focussed on to see the benefits of combining other tinnitus strategies with CBT. Weise, Heinecke and Rief (2008) using

Biofeedback technique carried out CBT. They reported that there was significant improvements in the controllability, annoyance of tinnitus and also on loudness rating which maintained over a 6 month follow up with medium to large effect sizes noted. Andersson, Porsaeus, Wiklund, Kaldo and Larsen (2005) in their study reported that with increasing age patients showed significant reductions in tinnitus-related distress.

Kaldo, Cars, Rahnert, Larsen and Andersson (2007) reported significant reduced tinnitus distress due to a CBT-based self-help book when compared to a formal CBT approach, attributing to the cost factor and also to shortage of CBT trained therapists. Kröner-Herwig, Frenzel, Fritsche, Schilkowsky and Esser (2003) reported that their study has found results with CBT superior to interventions like bedside education or music-supported relaxation. In a Cochrane study in 2010, it was found that the CBT had a positive effect on tinnitus management thus demonstrating a significant improvement in the quality of life with reduced depression. But there was no significant change noticed with the tinnitus with respect to loudness. (Martinez-Devesa, Perera, Theodoulou & Waddell, 2010).

CBT thus can be considered as an effective treatment and is applied as one of the depended option for tinnitus management. But it can also be noted that it does not have an effect on improving the acoustic characteristic of tinnitus, rather improves the response to tinnitus.

2.5.2. Internet based Cognitive Behavioural Therapy (iCBT). Hesser, Weise, Westin, and Andersson, (2011) report that major constraint in management of tinnitus in countries like United Kingdom is that the intervention programme not being readily available for individuals with tinnitus. This do not just imply to United Kingdom but also other countries around the globe including India. Further, there is shortage of trained specialists who can provide this structured approach (Baguley et al, 2013)

This demands a pressing need to make sure that the tinnitus intervention programme to be available easily and widely and at the same time being cost effective and clinically productive. One such work on overcoming these disadvantages of CBT was carried by Andersson et al., (2002) who utilised Internet as a mode for providing tinnitus intervention. The major aim of this work was to design a platform to overcome the difficulties with respect to the accessibility of CBT for tinnitus. A self-help guided Internet-based cognitive behavioural therapy for tinnitus (iCBT) was developed. There have been research done across countries in showing that a comparable efficacy was seen for iCBT and conventional CBT approach (Jasper et al., 2014; Kaldo et al., 2008), suggesting that it can be effective as an alternative approach to the formal face to face CBT programme. It has attracted the attention of researchers and clinicians worldwide in a limited time by demonstrating various advantages on the grounds of accessibility, cost effectiveness and also being time efficient. The application of iCBT to tinnitus comes from the already established conditions including depression, mood disorders, headache, anxiety and other somatic disorders. (Arnberg, Linton, Hultcrantz, Heintz, & Jonsson, 2014; van Beugen et al., 2014).

A pilot study carried by Kaldo et al., 2008 indicated comparable results to group-based CBT when administered on Swedish population (Kaldo et al., 2008). Similarly a study carried out by Hesser et al., (2012) found that when compared to a discussion forum controlled group, both iCBT and Internet-delivered acceptance and commitment therapy to be effective. Kaldo-Sandström et al., 2004; Kaldo et al., 2013 have shown that the intervention programme to be effective when implemented and used in clinical set up. The success shown from earlier studies have resulted in translating and implementing into both English and German languages. Weise et al., 2016 have shown that iCBT was effective using in the German version on German

population. However Abbott et al., (2009) carried a study to compare iCBT performance with information only control programmes group (without CBT content) and found no statistically significant benefit in Australia and attrition rates were high. They attributed this to a relatively low level of baseline tinnitus distress and probably due to cultural differences not effectively considered into account.

As health-care in the India and around the world is largely face-to-face, an internet based approach could be looked upon, specifically to make it more easily accessible method of treatment. However, it is also necessary to make sure that the intervention programme is technically strong and achieve a considerable amount of user acceptance before the trials and also to implement in clinical set-up. (Haynes, 1999). There have been few researchers who have developed their own protocols for implementing iCBT based on the works of Anderson. Recently, one such innovative tinnitus intervention iCBT protocol was developed by Beukes et al., (2016), is being implemented recently in the United Kingdom. She also reports that the programme has been designed with main objective of it being evidence-based, informative, accurate and providing interesting content within the intervention.

The major intent of the platform according to Beukes et al., (2016) was to maximise behavioural change offered along with various techniques in a comprehensive way and to focus on addressing the behavioural, emotional and other daily effects of experiencing tinnitus including anxiety, depression, sleep disturbances, sensitivity to sounds etc. Techniques such as analysis of applied relaxation, automatic negative thought analysis, exposure techniques, cognitive restructuring, imagery modifications, sleep hygiene and concentration management (Andersson, 2002) have been considered as important modules to include. In addition, the programme incorporates key Audiological approaches in treating tinnitus such as the use of sound

enrichment, hearing tactics and advice for sound sensitivity in order to ensure that the intervention programme is comprehensive. It also incorporates an interactive and guided approach through different learning styles like videos, quizzes, diagrams, and pictures are included. To make sure that the guided approach is possible effectively the iCBT approach incorporates a secure messaging system and is considered as an essential element to make sure that the intervention programme based on reports of Baumeister et al., (2014) who suggest that Guided Internet interventions is more effective and would achieve compliance rates of higher values, than information-only interventions. Other major aspects focussed involves reducing the technological barriers and to ensure that the information was straightforward to read with priority given to make sure that the information given was clear and all the features being easily accessed allowing it to reach a wider range of demographical groups experiencing tinnitus. Beukes et al., (2016) also report that the intervention programme is focussed on ensuring there is minimum chance of technological barriers making it a user friendly approach.

A detailed preference has also been provided to organise the layout and colour scheme to produce a calming effect on users as it is also focussed to the groups of anxiety and depression and thereby considering appearance into major account. As one of the key component to behavioural change is enabling patients to be actively involved in their own treatment which results in facilitating the patients to derive more benefit from the intervention (James, 2013). So the intervention programme have been designed to consider active involvement by supporting engagement throughout the intervention. Apart from this the individuals also receive tailored aspects such as receiving personal treatment goals, individualised feedback provided to them weekly and inclusion of both optional and obligatory modules added in subsequent revisions

of the original iCBT programme to improve outcomes and also reduce the attrition rates (Kaldo et al., 2007).

Chapter 3

Methods

The study focussed on evaluating the internet based Cognitive Behavioural Therapy (iCBT) intervention platform in terms of suitability, presentation, contents and materials. Two groups, namely group of Audiologists and group of adults with tinnitus were considered in the evaluation of the intervention programme. All the participants were explained regarding the iCBT, how it would work in treating tinnitus and also about who can obtain benefit from the programme. The purpose of the evaluation was clearly explained and every participant was given a duration of 1-2 hour/hours to go through the content and complete the evaluation process. Consent and commitment to complete the program was taken from all the participants.

3.1. Participants

The participants were divided into 2 groups.

3.1.1. Expert reviewer group. 30 Audiologists from both clinical perspective and academic background were considered and invited to evaluate the iCBT intervention module. The expert reviewers group involved Research officers, Academic and clinical professionals working in All India Institute of Speech and Hearing, Mysuru, India.

The subjects had to fulfil the following inclusion criteria to participate in the study,

- A minimum qualification of post-graduation in the area of Audiology
- Sound knowledge about tinnitus and the intervention options available.

3.1.2. Adults with tinnitus group. This group involved 30 adult individuals suffering from tinnitus and requiring tinnitus care. The tinnitus patients were screened for selection based on a random basis on their arrival to the Audiology clinic at All India Institute of Speech and Hearing (AIISH), Mysuru and based on their interest to

participate in the study. Apart from this, those individuals with complaint of tinnitus were also considered for the study on reviewing the database of patients, who visited AIISH audiology clinic from January 2017-February 2018.

Individual telephone interview was carried out to consider their details regarding tinnitus and based on their willingness they were considered and invited to participate in the study. Furthermore, as a part of recruitment of individuals for the study, only those with troublesome tinnitus lasting for at least 3months period that has caused significant levels of distress was considered and the selection was based on scores of Tinnitus Functional Index, (TFI) (Meikle et al., 2012).

The subjects had to fulfil the following inclusion criteria to participate in the study,

- Adults, aged 18 years and over, living in India, with the ability to read English.
- Experiencing significant levels of tinnitus distress for a period of at least 3 months.
- Tinnitus severity score indicating the need for tinnitus care (26 or above on the Tinnitus Functional Index (TFI; Meikle et al., 2012).

The following were the exclusion criteria considered,

- Patients reporting tinnitus because of conductive component or tinnitus because of medical condition.
- Not undergoing any other forms of tinnitus therapy.
- No major medical illness or psychiatric conditions.

3.2. Study Design and protocol

In order to evaluate the iCBT intervention platform in terms of suitability, presentation, suitability, contents and materials the two groups, namely group of Audiologists and group of adults with tinnitus were selected. All the individuals carried out the assessment based on the following study protocol which was designed on 4 major phases.

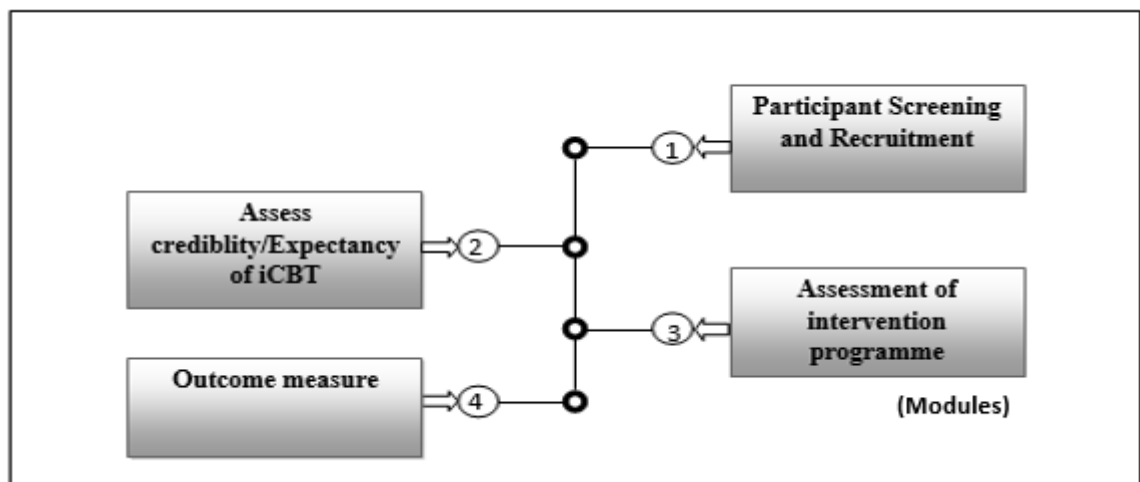


Figure 3.1. Study protocol showing the four steps involved.

3.2.1. Step 1: Participant Screening and Recruitment. A detailed audiological profiling with the following tests such as Pure Tone Audiometry, Immittance evaluation, Oto-Acoustic Emissions and Tinnitus evaluation was carried out in order to make sure that the tinnitus patients experiencing was not because of conductive component based on the audiological test battery approach.

To check the participants' eligibility, initially a self-developed screening questionnaire by authors was used. The screening questionnaire included Demographic details, tinnitus-specific questions, knowledge regarding iCBT. All the participants were explained regarding the iCBT procedure orally during this phase including how it would work in treating tinnitus and also about who can obtain benefit from the

programme. The iCBT program was implemented as an independent measures research design on participants with tinnitus and the audiologist groups.

3.2.2. Step 2: Assessing Credibility/Expectancy of iCBT. Further, the study involved assessment of Credibility/Expectancy Questionnaire (CEQ) (Borkovec & Nau, 1972; Devilly & Borkovec, 2000). The wording of the six-item CEQ was further modified slightly considering utilization of the questionnaire for tinnitus sufferers and audiologists to assess credibility and also expectancy of iCBT based on implementing it in Indian scenario.

The audiologists and the tinnitus sufferers were expected to fill this questionnaire before viewing the iCBT platform. The content is based on providing CBT materials. The participants were instructed thoroughly regarding the programme and were given details on how the programme is broken up into different modules and presented.

The questionnaire included 2 sets of questions. Set 1 focussed on questions on what the tinnitus sufferers and the audiologists think will happen. Questions like how logical is internet based intervention, how successful can be course in improving the quality of function and how much improvement is expected to occur by the end of 8 week programme. Set 2 focussed on questions on what the tinnitus sufferers and audiologists felt will happen. Furthermore questions like do they feel the course will help improving their overall functioning by end of the course was also included. The ratings included 10 point Likert rating scales and also rating in terms of percentage.

3.2.3. Step 3: Assessment of modules of intervention programme. All the participants were provided with login information and full access to the intervention, including the quizzes and worksheets (www.tacklingtinnitus.co.uk version 2). All the participants went through material with the assistance of a final year Masters Audiology

student, who guided them through the process. The purpose of the evaluation was clearly explained and participants were given a duration of 1-2 hour/hours to complete the intervention evaluation.

Table 3.1

Details on the modules covered in the iCBT tinnitus intervention program

Week	Module	Explanation	Application
1	About this treatment Tinnitus overview	Introduction to the module In-depth information	Reading Quizzes
2	Relaxation: step 1 Identifying negative thoughts Sound enrichment*	Deep relaxation The link between thoughts and feelings Using background sounds	10-15 min, twice/day Writing down thoughts Applying external sounds
3	Relaxation: step 2 Cognitive restructuring Sleep guidelines*	Diaphragmatic breathing Analysing thoughts Various Techniques	5-7 min, twice/day Writing down situations, thoughts, feelings Choose and apply techniques
4	Relaxation: step 3 Positive imaginary Concentration tips*	Entire body relaxation Use to enhance relaxation Techniques	2-3 min, twice/day Twice/day after relaxation Mentally engaging activities
5	Relaxation: step 4 Food exercises Sensitivity to sound*	Rapid relaxation Mindful awareness Gradual exposure	30-60 s, 5-10 times/day Twice/day after relaxation Listen to safe and pleasing sounds

6	Relaxation: step 5 Reinterpretation of tinnitus Hearing tactics*	Rapid relaxation in more difficult situations Change negative tinnitus associations Communication advice	30-60 s, 5-10 times/day Writing about tinnitus thoughts Follow advice
7	Relaxation: step 6 Exposure to tinnitus	Making relaxation a part of daily routines and habits Decrease negative emotions and avoidance of tinnitus	Rapid relaxation 10-20 times/day Actively listen to tinnitus for 5-10 min, once/day after relaxation
8	Key points summary Future planning	Highlighting key concepts Maintenance and relapse prevention	Online quiz Making plans to use designs in daily life

- Note : Optional modules include

* Sound enrichment

* Sleep management

* Concentration guidelines

* Sound sensitivity

* Hearing tactics

3.2.4. Step 4: Outcome measure. To evaluate the intervention programme, a satisfaction questionnaire used by Beukes et al., (2016) based on Client Satisfaction Questionnaire (CSQ) (Attkisson & Zwick, 1982) was incorporated. The questionnaire was further modified based on the inputs from an experienced Professor in Audiology in accordance to validate and utilize in Indian context. The satisfaction questionnaire was designed to consider the suitability, content, usability, presentation and exercises

on the platform. The questions consisted of a 15 five point Likert type scaled questions. The scale ranged from low to high, with 1 representing strongly disagree and 5 representing strongly agree. In addition, open ended questions was included, regarding their opinion on intervention as a whole, what are the best aspects of the intervention programme, and suggestions for further development.

3.3. Data Management and Statistical Analysis

The Statistical Package for Social Sciences (SPSS) version 23.0 was used for statistical analysis. Descriptive statistics were used to evaluate the sample characteristics. Kolmogorov-Smirnov test was performed to check for normality and none of the values were normally distributed and hence a non-parametric statistical analysis was considered. Mann-Whitney U test were used to compare usability evaluation of audiologists and participant's $p < 0.05$ was considered statistically significant.

Chapter 4

Results and Discussion

4.1. Participant Screening and Recruitment:

Phase 1 included carrying out administration of self-developed screening questionnaire. The screening questionnaire included Demographic details, tinnitus-specific questions, knowledge regarding iCBT. Table 4.1 shows the demographic details and questions related to tinnitus for adult with tinnitus and Table 4.2 for the audiologists group.

Table 4.1*Demographic details of the adults with tinnitus group.*

Adults with tinnitus group	Number
Age (in years) M, (SD)	45 (11.762)
Gender	
Males	22 (73.3%)
Females	8 (26.7%)
Highest educational degree	
School	2 (6.7%)
College	5 (16.7%)
UG	12 (40%)
PG	11 (36.7%)
Duration of tinnitus in years M (SD)	2.24 (2.25)
Employment	
Service occupation	4 (13.3%)
Administrative	2 (6.7%)
Unemployed	8 (26.7%)
Professional	11 (36.7%)
Skilled tradesman	5 (16.7%)
Previous tinnitus therapy treatment	
Yes	10 (33.3%)
No	20 (66.7%)

Note. M represents the Mean score and SD is the standard deviation.

Table 4.2*Demographic details of Audiologists group.*

Audiologists group	Number
Age (in years) M,(SD)	29.23 (4.23)
Gender	
Males	10 (33.3%)
Females	20 (66.7%)
Highest educational degree	
UG	-
PG	30 (100%)
Years of clinical experience M,(SD)	4.32 (1.932)
Role working with patients	
Audiologists	26 (86.4%)
Assistant	-
Researcher including doctoral students	4 (13.4%)
Others	-
Do they provide tinnitus therapy?	
Yes	16 (53.3%)
No	14 (46.7%)

Note. M represents the Mean score and SD is the standard deviation.

Question 7 in the screening questionnaire for audiologists and adults with tinnitus relates to the accessibility to management options that tinnitus sufferers have. The median value was found to be 4.5 (1-10) for both the groups with interquartile range (IQR) of 4 among the Adults with tinnitus group and 2.50 for Audiologists groups respectively.

The following question reveals that the current accessibility to tinnitus care and management is rated comparatively low by both the groups. One possible reason for this could be lack of a definitive treatment because of the complex pathophysiology and etiologies of tinnitus (Swain, Nayak, Ravan & Sahu, 2016). In support to this a study done by Baguley, McFerran and Hall (2013) reports shortage of trained professionals to treat tinnitus which is also reflected in Table 4.2 where audiologists were posed question on whether they provide tinnitus therapy. Among the Audiologists who have a post-graduation in Audiology only 53.3 % reported that they provide tinnitus management with most of them reporting that they provide Tinnitus Retraining therapy as reported by them. This was also supported from the findings of Adults with tinnitus group where only 33.3 % individuals who suffer from tinnitus for more than a period of 3 months, received previous tinnitus care.

Question 11 depicts the most preferred mode of rehabilitation by adults requiring tinnitus care and by the audiologist sand is depicted in Table 4.3. Individuals with tinnitus preferred Internet based approach (60%) over face to face (36 %) and group based (3%) approach while Audiologists preferred face to face mode of intervention (70%) over the other two modes of intervention.

Table 4.3

Preferred mode of intervention programme among Adults with tinnitus and the Audiologists group.

	Face to face	Internet based	Group based
Adults with Tinnitus	11(36.67%)	18 (60%)	1(3.33%)
Audiologist	21 (70%)	7 (23.33%)	2 (6.66%)

The open ended question posed on what mode of intervention is preferred by tinnitus sufferers, concerned that an internet based approach would be more time saving and cost effective and avoid travel constraints in comparison to face to face therapy. 70 % of Audiologists reported the need for personal training through face to face to provide better face validity and solve their problems in a better way. Audiologists also reported face to face approach could have higher validity over internet based approach citing to the technological limitations with respect to the access to internet and device that the patients may face.

4.2. Phase 2: Assess credibility/Expectancy of iCBT

This involved the assessment of Credibility/Expectancy Questionnaire (CEQ) (Borkovec & Nau, 1972; Devilly & Borkovec, 2000) under 2 sets of questions. Sample characteristics were evaluated using Descriptive statistics. Further Mann-Whitney U Test was performed to compare the ratings of adults with tinnitus and audiologist group.

Table 4.4*Median intervention ratings by Adults with tinnitus and audiologists group.*

	Adults with tinnitus Median	Adults with tinnitus IQR	Audiologists median	Audiologists interquartile range	Z-score
Set 1					
How logical to implement as internet based? (Q12)	7.00	2	6.00	2	-2.927**
How successful can iCBT be? (Q13)	7.00	1	6.00	2	-4.024***
How confident to recommend iCBT? (Q14)	8.00	2	5.00	1.25	-4.762***
Benefit expected at the end of 8 th week (%) (Q15)	70.00	20	60.00	30	-3.675***
Set 2					
Improvement expected in their overall functioning (Q16)	8.00	2	6.00	2	-4.918***
Expected benefit after the course (%) (Q17)	80.00	20	60.00	21.25	-4.469***

Note. * indicates $p < 0.05$, ** indicates $p < 0.01$, and *** indicates $p < 0.001$. Refer appendix C for complete details of the questions.

Table 4.4 reveals the median and interquartile range values for Set 1 and Set 2 of CEQ (Credibility/Expectancy Questionnaire). The median ratings was higher for all the questions for adults with tinnitus compared to Audiologists group. Question 12 and question 13 showed a median value rating of 7.00 (1-10 rating scale) for Adults with

tinnitus compared to Audiologists group with median rating of 6.00. Higher Median rating for Adults with tinnitus (8.00) was noted for question 14 compared to Audiologists group (5.00). Question 16 and 17 also showed higher median values for Adults with tinnitus compared to Audiologists group. Benefit expected out of Eighth week (Questions 15) and benefit expected after the end of course (question 16) was rated 70 % and 80% respectively by adults with tinnitus and Audiologists rated 60 % for both of these questions asked.

Lower median ratings were noted for Audiologists group for all the questions in comparison to the Adults with tinnitus group indicating a difference in perception among the audiologists (serving as an expert reviewer) and tinnitus sufferers (patient needing care). Question 12 (At this point, how logical does this Internet-based intervention for tinnitus seem to) and question 13 (At this point, how successful do you think this course will be in raising the quality of function of those with tinnitus?) were rated high by both the groups. Question 14 (how confident would you be in recommending the programme to a patients who experience problems with tinnitus) was rated lower by group of audiologists. One possible reason could be less knowledge and practical experience with CBT by audiologists. This was supported by question 8 (Have you heard of Cognitive Behavioural Therapy?), with 8(26%) among 30 audiologists reporting they had not heard about cognitive therapy. Among the Adults with tinnitus only 1(3%) of 30 individuals reported to have heard about CBT.

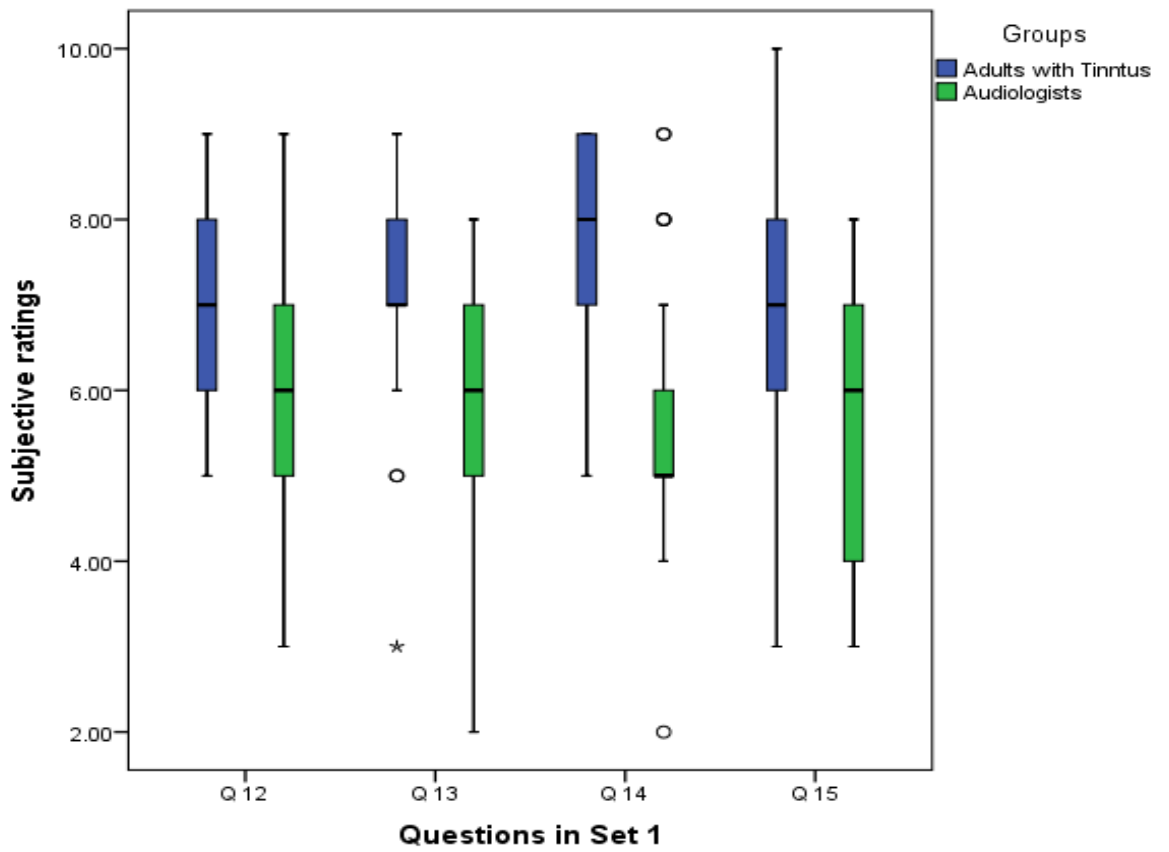


Figure 4.1. Box Plots representing Median, IQR along with the extremities for Set1 under CEQ

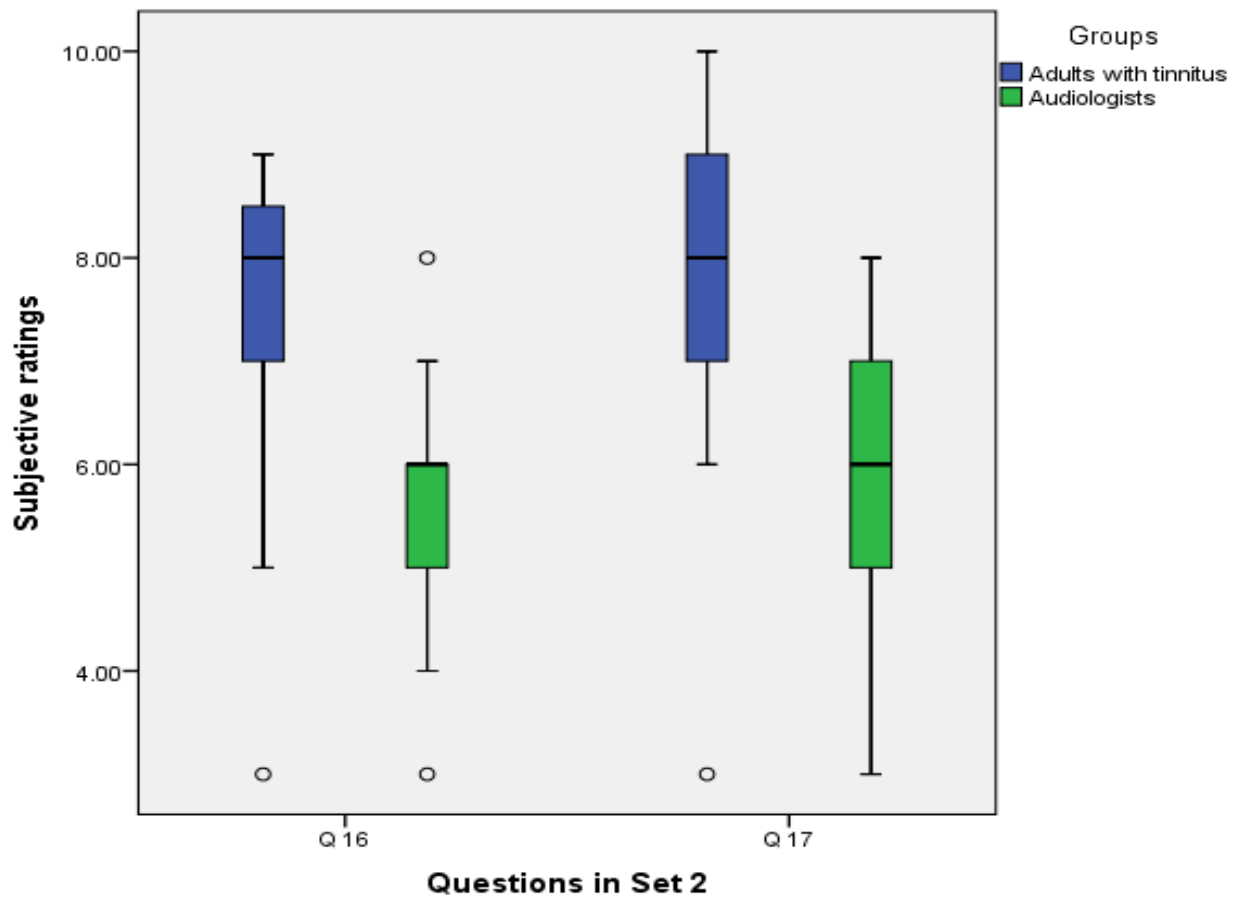


Figure 4.2. Box Plots representing Median, IQR along with the extremities for Set 2 under CEQ.

The same has been depicted in Figure 4.1. There was a general trend for audiologists to rate lower than those with tinnitus. A few extreme values could also be noted in both groups. Mann-Whitney U test for different questions asked were significantly different ($p < 0.05$) suggesting the difference in opinion towards the intervention programme among the two groups. Audiologists looking through his expert views and individual with tinnitus view as a patient who require care showed differences in the ratings provided.

4.3 Phase 4: Outcome measure

This phase involved assessment of using a satisfaction questionnaire incorporated by Beukes et al., (2016) based on Client Satisfaction Questionnaire (CSQ) (Attkisson & Zwick, 1982) to validate and utilize iCBT platform in Indian context. The intervention programme was assessed based on suitability, content, usability, presentation and exercises provided in the platform. Adults with tinnitus and Audiologists completed the intervention satisfaction evaluations using a five point Likert scale to evaluate for suitability, content, usability, presentation, and exercises.

Table 4.5

Median and IQR for section Usability for adults with tinnitus and audiologists group.

Usability	Adults with tinnitus Median	Adults with tinnitus IQR	Audiologists median	Audiologists interquartile range	Z-score
Straightforward (U1)	5.00	1	4.00	0	-2.512*
Easy to navigate (U2)	5.00	1	4.00	2	-2.450*
Appropriate module length (U3)	5.00	1	3.50	2	-4.649***

Note: * indicates $p < 0.05$, ** indicates $p < 0.01$, and *** indicates $p < 0.001$.

Table 4.5 represents the median and IQR scores for the statements under Usability category for U1 (It was straightforward to use the internet platform), U2 (It was easy to navigate through the materials) and U3 (The length of the modules was appropriate). The median values were found to be higher for both the groups of Adults with tinnitus scoring a median value of 5 for all U1, U2 and U3. The median value was found to be 4.00 for Audiologists group for U1 and U2 while U3 represented a median

score of 3.50. Mann-Whitney U test revealed that there was statistical differences between the two groups for all the statements ($p < 0.05$).

Higher scores were obtained for both the groups. However, the module length was found to be very tedious and lengthy by Audiologists group. The higher ratings for overall Usability could be attributed for intervention being evidence based (Hesser, Weise, Westin & Andersson, 2011) and self-help based. The intervention could serve as a vital tool in treating tinnitus considering the strong theoretical base it has. Higher ratings on U1 and U2 being higher for both the group could be attributed to the platform organised in a clear structure, providing an explanation of overview of treatment, rational to use iCBT, step-by-step instructions and giving details on further queries or help (Beukes et al., 2017). A guided Internet-support system could be something that differentiates the programme from any other programmes which provides only information (Beukes et al., 2017).

Table 4.6

Median and IQR for section Content for adults with tinnitus and audiologists group.

Content (C)	Adults with tinnitus Median	Adults with tinnitus IQR	Audiologists median	Audiologists interquartile range	Z-score
Level of information (C1)	5.00	1	4.00	1	-3.416**
Informative (C2)	5.00	1	4.00	1	-1.614
Interesting (C3)	5.00	1	4.00	0.25	-3.070**

Note: * indicates $p < 0.05$, ** indicates $p < 0.01$, and *** indicates $p < 0.001$.

Table 4.6 depicts the median and IQR scores for the statements under Content category for C1 (the level of information was at a suitable level), C2 (The materials

were informative) and C3 (The subject matter was interesting). Similar to the previous findings the median values were found to be higher for both the groups with Adults with tinnitus group scoring a median value of 5 for all C1, C2 and C3. The median value was found to be 4.00 for Audiologists group for C1, C2 and C3. Mann-Whitney U test revealed that there was statistical differences between the two groups for statement C1 and C3 ($p < 0.05$). However, statistical significant difference was not observed for statement C2.

Overall higher median scores are obtained for both the groups. The major notable reason for higher rating could be comprehensiveness of the whole programme, which is designed considering various resources and making it tailored to individual who require tinnitus care (Beukes et al., 2016). Andersson et al., (2009) reports that in order to achieve greater effectiveness any Internet based programme must be comprehensive. An ideal intervention programme thus has to consider various techniques to promote behavioural changes and also comprehensively focus on physical, emotional and other daily tinnitus effects experienced by the individuals. The content as a whole in iCBT is presented using bullet points to keep it as simple and clear as possible. The Initial modules included navigation instructions to provide information regarding the layout of the website e.g. what are the contents available under the heading Menu.

Beukes et al., (2016) also reports that high levels of reading is not generally required as per scores obtained for Fletcher reading ease scores and Flesch-Kincaid grade level. Basis of combining cognitive rationale and learning theory approach (Henry & Wilson, 2001; Hallam et al., 1984) along with Audiological principles tactics adds to the theoretical base. The programme initial modules focus on explanation about the treatment and description about tinnitus. It incorporates 15 Cognitive behavioural

therapy modules, of which 6 focusses on relaxation and covering 3 other modules targeting aspects of daily life like anxiety, sleep disturbances and concentration tips along with audiological principles like sound enrichment, hearing tactics and sensitivity to sounds. A positive imagery along with relaxation is included to deal with controlling the physical aspects of tinnitus and promote changes in behaviour to tinnitus. Additionally some of the major CBT principles to incorporate in the iCBT platform was cognitive restructuring, exposure and reinterpretation of tinnitus as modules of iCBT bringing a wide and broad range of content to the platform.

Table 4.7

Median and IQR for section Presentation for adults with tinnitus and audiologists group.

Presentation (P)	Adults with tinnitus Median	Adults with tinnitus IQR	Audiologists median	Audiologists interquartile range	Z-score
Well-structured manner (P1)	5.00	1	4.00	0.25	-2.337*
Suitable presentation (P2)	4.00	2	4.00	0.25	-.781
Easy to read (P3)	5.00	1	4.00	0	-2.547*

Note: * indicates $p < 0.05$, ** indicates $p < 0.01$, and *** indicates $p < 0.001$

Table 4.7 represents the median and IQR scores for the statements under Presentation category for P1 (the content was presented in a well-structured manner), P2 (The use of presentation of materials was suitable i.e. the use of diagrams, text, pictures, videos) and P3 (The text was easy to read). The median ratings noted to be high for both the groups with Adults with tinnitus group scoring a median value of 5 for statements P1 and P3 while median score for statement P2 was 4.00. The median value was found to be 4.00 for Audiologists group for P1, P2 and P3. Mann-Whitney

U test revealed that there was statistical differences between the two groups for statement P1 and P3 ($p < 0.05$). However, statistical significant difference was not observed for statement P2.

The higher scores for presentation was found for all the statements under Presentation category for both the groups. One thing that could be attributed to these high scores could be the appearance of website designed carefully to give a calming effect and also less cluttered. This was reported by individuals with tinnitus in open ended questions posed to individuals with tinnitus. As those with tinnitus have associated problems like anxiety careful consideration with respect to the layout and colour scheme could be noticed (Beukes et al., 2016). A white background with a blue coloured theme is provided for all the modules in the intervention programme. The appearance of the programme was enriched by providing visually stimulating and attractive pictures in order to not overwhelm the individual requiring tinnitus care. Careful considerations with respect to organising the layout and colour scheme to produce a calming effect could also be noticed, considering anxiety problems into picture.

Table 4.8*Median and IQR for section Suitability for adults with tinnitus and audiologists group.*

Suitability (S)	Adults with tinnitus Median	Adults with tinnitus IQR	Audiologists median	Audiologists interquartile range	Z-score
Suitable for tinnitus (S1)	5.00	1	4.00	0	-2.923**
Appropriate range of modules (S2)	5.00	1	4.00	1	-3.936***
Topics covered (S3)	4.50	1	4.00	0	-1.854

Note. * indicates $p < 0.05$, ** indicates $p < 0.01$, and *** indicates $p < 0.001$.

The following table 4.8 presents the median and IQR scores for the statements under Suitability (S) category for S1 (the intervention is suitable for those suffering with tinnitus), S2 (The range of modules were appropriate) and S3 (The topics covered were beneficial). A median rating of 5.00 was noted for statements S1 and S2 for Adults with tinnitus and 4.50 for statement S3 while audiologists group showed a median rating of 4.00 for all the three statements. Mann-Whitney U test revealed that there was statistical differences between the two groups for statement S1 and S2 ($p < 0.05$). However, statistical significant difference was not observed for statement S3.

Tinnitus being heterogeneous in nature, it is very important to make sure that the intervention is suitable for those suffering with tinnitus and at the same time to have appropriate range of modules. Kroeze et al., 2006; Richards et al., 2007; Sohl & Moyer, 2007 have demonstrated that when compared to non-tailored interventions, tailored interventions results in higher benefits which provides various behavioural changes including dietary control, physical activity etc. Kreuter, Strecher & Glassman 1999

reports that an intervention programme needs to take considerations of individual's unique needs and a programme more based on patient centred approach to have higher suitability than a standardised non tailored type of intervention.

Table 4.9

Median and IQR for section Exercises for adults with tinnitus and audiologists group.

Exercises(E)	Adults with tinnitus Median	Adults with tinnitus IQR	Audiologists median	Audiologists interquartile range	Z-score
Worksheets and quizzes (E1)	4.00	2	4.00	1	-1.029
Clear instructions (E2)	5.00	1	4.00	0	-3.298**
Motivation to do exercise (E3)	5.00	1	4.00	0	-4.746***

Note * indicates $p < 0.05$, ** indicates $p < 0.01$, and *** indicates $p < 0.001$.

Table 4.9 represents the median and IQR scores for the statements under Exercises (E) category for E1 (the worksheets and quizzes asked appropriate questions), E2 (I clearly understood how to practice the various techniques) and E3 (I was motivated to do the exercises). A median rating of 5.00 was noted for statements S2 and S3 for Adults with tinnitus and 4.00 for statement E1 while audiologists group showed a median rating of 4.00 for all the three statements. Mann-Whitney U test revealed that there was statistical differences between the two groups for statements E2 and E3 ($p < 0.05$). However statistical significant difference was not observed for statement E1.

The motivation to do exercises and making the patient clearly understand the various techniques, a key component would be to enable patients active participation for their own treatment. Active involvement is said to bring better results (James, 2013).

Along with an active involvement a supporting engagement by the audiologists or the experts could be essential to result in better outcomes for the patient. Active involvement in the intervention has been given importance and various worksheets acting as diaries look at their progress over a period of time. The therapist assigned for this could also view all the worksheets and provide motivation and also his feedbacks individually according to the needs.

Table 4.10

Median and IQR all the sections combining their subsections for adults in both the groups.

	Adults with tinnitus Median	Adults with tinnitus IQR	Audiologists median	Audiologists interquartile range	Z-score
USABILITY (U)	13.5000	3.00	10.5000	3.25	-4.190***
CONTENT (C)	13.5000	2.00	12.0000	2.00	-3.414**
PRESENTATION (P)	13.0000	3.00	12.0000	1.25	-2.441*
SUITABILITY (S)	13.0000	1.50	12.0000	2.00	-3.802***
USABILITY (U)	13.5000	3.00	10.5000	3.25	-4.190***

*Note: * indicates $p < 0.05$, ** indicates $p < 0.01$, and *** indicates $p < 0.001$.*

Table 4.10 represents the overall median and IQR for various subsections combined under Usability, Content, Presentation, Suitability and Exercises to understand the overall satisfaction better. Maximum median ratings that could be obtained is 15.00 since each subsections is rated on 1-5 Likert scaling. Overall the intervention was highly rated. The median values obtained for all the 5 sections was found to higher for adults with tinnitus group compared to the group of Audiologists. Among adults with tinnitus group, higher median ratings were noted for Exercises

section (14.00) compared to Usability (13.50), Content (13.50) with Suitability (13.00) and Presentation (13.00) rated lower. Similar trend is also observed with the group of Audiologists with lower scores for Usability (10.50) as compared to Content, Suitability, Presentation and exercises, all scoring a median value of 12.00.

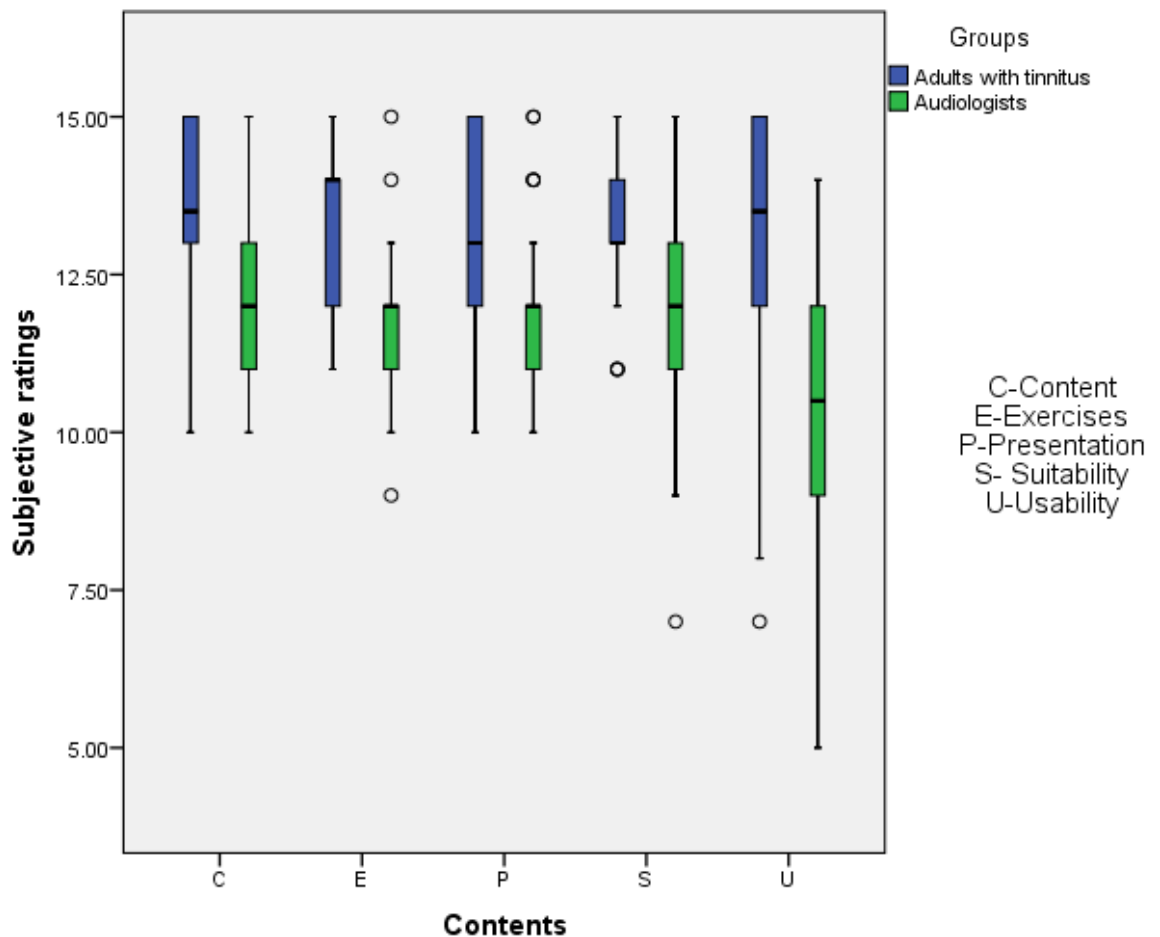


Figure 4.3. Box Plots representing Median, IQR for all the sections as a combined score along of their individual subsections.

The same has been depicted in Figure 4.3. Figure 4.3 represents overall median for all the three subsections combined. There was a general trend for Adults with tinnitus to rate higher than those with tinnitus for all the sections of the questionnaire. A few extreme values could also be noted in both groups indicating a difference in

perception among different individuals. Mann-Whitney U test revealed that all these differences were statistically significant between the two groups ($p < 0.05$) for all the sections. Lower median ratings by audiologists on Usability was observed with respect to ease of navigation through programme, straightforwardness and also on the length of the modules. This could be attributed to the fact that the audiologists reporting in the open ended questions regarding the length being tedious to go through. However the patient rating a comparatively higher score did not find the length of the modules to be tedious to go through.

3.3.1. Suggestions made by the adults with tinnitus. Major aspects reported by the group of audiologists were to reduce the length of the modules and to include pictures and videos to make visually attractive. Some of the additional suggestions made were inclusion of the hearing aid exercises for aid users, simplification of information and to look at the language compatibility according to the population in a country like India with diverse language culture. In addition to this, incorporating interactive audio files in the website instead of reporting what sounds the patients can find and use and developing a mobile based app for better accessibility was suggested in the open ended questions posed to them.

3.3.2. Suggestions made by the adults with tinnitus. Some of the difficulties reported included comprehending contents especially videos which are currently in English and a non-Indian accent. The participants suggested more with respect to bringing the intervention programme in local languages to make it easily comprehensible.

Chapter 5

Summary and Conclusion

This study aimed at systematically implementing and evaluating the effectiveness of the iCBT program in people suffering from tinnitus in the Indian population. This feasibility of implementing iCBT is described in terms of presentation, suitability, contents and materials provided in the Indian context. The study was carried out in 4 phases. Phase 1 included participant screening and recruitment. This questionnaire concentrated on finding the demographic details of the participants and tinnitus-specific information for every individual. The findings represent the dearth of treatment options available to tinnitus sufferers and number of audiologists (minimum qualification of post-graduation) providing therapy to tinnitus. It also sheds light into the most preferred mode of rehabilitation as rated by adults requiring tinnitus care and by the audiologists. The individuals with tinnitus preferred internet based approach while audiologists preferring face to face approach for tinnitus therapy. Phase 2 involved assessment of iCBT's credibility and expectancy using Credibility and Expectancy Questionnaire (CEQ) and Phase 3 involved assessment of modules of iCBT by both the groups. The ratings for all the questions were higher which included questions like expected benefit after 8 weeks and after termination of the programme indicating that a standard iCBT's better credibility and expectancy. Both the groups rated with higher values on question regarding the logic to implement internet as a mode of intervention to provide iCBT with individuals suffering from tinnitus rating higher. Phase 4 involved assessment of effectiveness of the iCBT program in terms of presentation, suitability, contents and materials provided.

A total of 60 participants categorized into 2 groups were evaluated. The participants evaluated the research using a five point Likert scale for suitability, content,

usability, presentation, and exercises. On an average it was noted that the rating was well marked by both the groups. The rating provided by the audiologists and the adults with tinnitus were significantly different suggesting the difference in opinions among audiologists and adults with tinnitus. Although the Likert rating scale showed high rating of the iCBT platform from both groups, adults with tinnitus rated the module to be higher for all the questions compared to audiologists. This could be due to prior knowledge on tinnitus, lack of appropriate treatment obtained or the information provided being completely new to the participant. The poorly rated module among all was noted to be usability by the audiologists and as reported in the open ended statements given by audiologists who considered the modules to be very lengthy and tedious for an individual with tinnitus going through the programme.

The technical functionality of the questionnaire assisted in obtaining individualistic views of the participants regarding the iCBT programme. It was noted that all the participants from both the groups had no difficulty completing the questionnaire, leading to a smooth running of the research. This can be as a result of clear instructions provided during the study and implementing necessary focus in recruiting study appropriate participants.

Implications of the study

1. Acceptability and feasibility of using iCBT programme in Indian context in terms of credibility and expectancy out of the programme.
2. Effectiveness of iCBT in Indian context in terms of Usability, Content, Suitability, Presentation, Exercises.
3. The results of the study will add to the knowledge about tinnitus involving intervention based on cognitive and behavioural aspects to audiologists enabling them to carry over the intervention.
4. It sheds light into different perspectives regarding the iCBT programme in the viewpoint of an audiologist and individual with tinnitus receiving tinnitus care.

Study limitations

One of the attribute reported in developed iCBT programme is the guided online secure messaging system which was not looked upon during assessment, as it did not fall in the scope of study design. However the following could be implemented only when a study is carried out on a long run basis involving homework given to the patient and follow up which is a major component of the iCBT programme.

The study was restricted to individuals with tinnitus who have a minimum Basic English reading and writing skills. Although it could not be considered as a limitation of the study considering it being available only in English language. However, this could be extended to a wider group of other language speaking individuals too with necessary translations of the programme according to Indian context.

Future directions

The following study assesses the content validity and acceptability of iCBT in Indian context. Considering the acceptability, validity and modifications to be made, further studies can focus on implementing a structured iCBT approach. Such studies will help to understand extent of training the patients can undergo and get a deeper understanding of what a patient does in iCBT.

Thus iCBT approach can be administered on patients on a long run basis with the already developed ready to use programme in its form. Further translation of the contents in regional languages of India considering the cultural differences could be a vital and an important factor to be looked upon. The initial pilot study carried out in United Kingdom indicated the feasibility and validity of using iCBT in terms of recruitment, attrition rates, compliance and use of audiological support.

Conclusion

A detailed assessment of the evaluation programme by audiologists and adults with tinnitus showed high satisfaction of iCBT platform regarding its content, suitability, presentation, usability and exercises given in the programme. Findings from the current study provides greater confidence to utilize the iCBT in Indian context considering some necessary modifications. Since a standard tinnitus intervention would require a long term care and cannot be solved with limited number of face to face sessions, an internet-based audiologist guided approach looks feasible in Indian context and thereby allowing patients to carry out intervention at their own convenience and time schedule. Integrating Audiologist driven iCBT into regular clinical care with further intervention trials done could ensure the higher demand for tinnitus care to be met.

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Appendix A

Screening questionnaire for Adults with tinnitus

THOSE WITH TINNITUS

1. Current Age

(Enter in years): _____

2. Gender (mark applicable category):

Male _____ Female _____ Transgender _____

3. Highest Current Degree

No education ____ School ____ college ____ Undergraduate degree
____ Postgraduate degree _____

4. What best describes your employment

Service occupation ____ administrative ____ unemployed ____
professional ____ skilled tradesman _____

5. Duration of tinnitus:

(enter in years): _____

6. Previous tinnitus treatment received:

Yes/No

If yes: what treatment :

7. Please rate the accessibility people with tinnitus have to help managing their tinnitus
1-10 rating scale 1 is low and 10 is excellent.

8. What kind of treatment options do you think are available for the management of tinnitus?

9. Have you heard of Cognitive Behavioural Therapy?
Yes____ No____

9a. Insert an explanation of CBT to clarify what this is.

10. Please rate how valid you think CBT would be for treating tinnitus?

1-10 rating scale 1 is low and 10 is excellent

11. What treatment format would you prefer: Please rank in order of preference, with 1 being the most preferred choice and 3 the least preferred choice

i) Face-to-face (going to a clinic and speaking to a professional) ____

ii) Internet-based treatment with an online access to a clinician (accessible anytime, without the need to attend a clinic. Able to send questions to the clinician via email and the clinician will send messages back) ____

iii) Group treatment (information provided by a clinician to a group of people with similar difficulties. The people in the group can then also learn from each other)

Please explain why this is your preference

Appendix B

Screening questionnaire used for Audiologists

CLINICIANS/AUDIOLOGISTS

1. Current Age

(enter in years): _____

2. Gender (mark applicable category):

Male _____ Female _____ Transgender _____

3. Highest Current Degree

No education _____ School _____ college _____ Undergraduate degree
_____ Postgraduate degree _____

4. Years of Clinical Experience (beginning with year you began seeing
your own patients & including current year) _____

5. What best describes your role working with patients

Audiologist _____ assistant _____ researcher _____ lecturer
_____ other (please
explain) _____

6. Do you provide tinnitus therapy Yes__ No__

If so, what do you provide? _____

7. Please rate the accessibility people with tinnitus have to help managing
their tinnitus

1-10 rating scale 1 is low and 10 is excellent

8. Have you heard of Cognitive Behavioural Therapy?

Yes _____ No _____

9. Insert an explanation of CBT to clarify what this is.

10. Please rate how valid you think CBT would be for treating tinnitus?

1-10 rating scale 1 is low and 10 is excellent

11. What treatment format would you think has the most benefit. Please rank in order of preference, with 1 being the most preferred choice and 3 the least preferred choice

- i) Face-to-face (going to a clinic and speaking to a professional)
- ii) Internet-based treatment with an online access to a clinician (accessible anytime, without the need to attend a clinic. Able to send questions to the clinician via email and the clinician will send messages back)
- iii) Group treatment (information provided by a clinician to a group of people with similar difficulties. The people in the group can then also learn from each other)

Please explain why this is your preference

Appendix C

Credibility/Expectancy Questionnaire (CEQ)

(Borkovec&Nau, 1972; Devilly&Borkovec, 2000).

QUESTIONNAIRE for Adults with tinnitus and Audiologists group

The wording of the six-item CEQ was modified slightly by authors of the study.

We have designed an Internet-based intervention for tinnitus. The content is based on providing CBT materials. It is broken up into different modules that are presented over an 8 week period. Throughout the programme a clinical can support clients online. We would like to hear your views on this programme

SET 1: This set addresses what you think will happen

1. At this point, how logical does this Internet-based intervention for tinnitus seem to you?

Rate 1-9 where 1 is not at all logical and 5 is somewhat logical and 9 is very logical

2. At this point, how successful do you think this course will be in raising the quality of function of those with tinnitus?

Rate 1-9 where 1 is not at all useful, 5 is somewhat useful and 9 is very useful

3. How confident would you be in recommending the programme to a patients who experience problems with tinnitus

Rate 1-9 where 1 is not at all confident, 5 is somewhat confident, 9 is very confident

4. By the end of the 8 week programme, how much improvement in functioning do you think will occur in those with tinnitus?

Rate 0% to 100

SET II: What you feel will happen

For this set, close your eyes for a few moments and try to identify what you really feel about the programme and its likely success. Then answer the following questions:

5. At this point, how much do you really feel that the course will help those with tinnitus to improve your functioning?

Rate 1-9 where 1 is not at all, 5 is somewhat and 9 is very much

6. By the end of the course, how much improvement in functioning do you really feel will occur for those with tinnitus?

Rate 0-100%

7. The programme is presently in English. Would this be suitable or would you prefer it in a different language. Is so, which language? _____

Appendix D

Intervention Satisfaction Evaluation (Beukes et al, 2016).

The questionnaire is slightly modified by authors for its use in Indian context. Please state the extent to which you agree or disagree with the following statements, where 1 is Strongly Disagree and 5 is Strongly Agree (choose one per statement). For example: 1 = Strongly disagree; 2 = Disagree; 3 = Don't know; 4 = Agree; 5 = Strongly agree.

- ABOUT THE USABILITY

- It was straightforward to use the internet platform
- It was easy to navigate through the materials
- The length of the modules was appropriate

- ABOUT THE CONTENT

- The level of information was at a suitable level
- The materials were informative
- The subject matter was interesting

- ABOUT THE PRESENTATION

- The content was presented in a well-structured manner
- The use of presentation of materials was suitable i.e. the use of diagrams, text, pictures, videos
- The text was easy to read

- ABOUT THE SUITABILITY

- The intervention is suitable for those suffering with tinnitus

- The range of modules were appropriate
- The topics covered were beneficial
- ABOUT THE EXCERSISES GIVEN
 - The worksheets and quizzes asked appropriate questions
 - I clearly understood how to practice the various techniques
 - I was motivated to do the exercises
- **Open-ended questions:**
- ABOUT THE INTERVENTION AS A WHOLE
- How long did it take you take to read each module's information on average?
- What was the best aspect of the intervention?
- What needs improving?
- Any further suggestions?