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Development and technical functionality of an Internet-based intervention for tinnitus in the UK



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ABSTRACT

Purpose: Creative approaches to improve access to evidence-based tinnitus treatments are required. The purpose of this study was to develop an Internet-based cognitive behavioural therapy (iCBT) intervention, for those experiencing tinnitus in the United Kingdom (UK). Furthermore, it aimed, through technical functionality testing, to identify specific aspects of the iCBT that require improving.

Method: An innovative iCBT intervention for treating tinnitus in the UK has been developed using a cognitive-behavioural theoretical framework. This iCBT was evaluated by two user groups during this developmental phase. Initially, five expert reviews evaluated the intervention, prior to evaluation by a group of 29 adults experiencing significant levels of tinnitus distress. Both groups evaluated iCBT in an independent measures design, using a specifically designed satisfaction outcome measure.

Results: Overall, similar ratings were given by the expert reviewers and adults with tinnitus, showing a high level of satisfaction regarding the content, suitability, presentation, usability and exercises provided in the intervention. The iCBT intervention has been refined following technical functionality testing.

Conclusions: Rigorous testing of the developed iCBT intervention has been undertaken. These evaluations provide confidence that further clinical trials can commence in the UK, to assess the feasibility and effectiveness of this iCBT intervention for tinnitus.

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1. Introduction

Technological advances are transforming healthcare provision (Harris, 2013). The implementation of these innovations is important, particularly for chronic conditions, as they place a substantial burden on health organisations (West, 2012). One such condition is tinnitus, described as "the conscious perception of unwanted subjective auditory sensations, in the absence of a corresponding external stimulus"

Abbreviations: CBT, cognitive behavioural therapy; iCBT, Internet-based cognitive behavioural therapy; TFI, Tinnitus Functional Index; UK, United Kingdom.

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(McFadden, 1982). A cure for tinnitus is yet to be found, possibly due to its heterogeneous aetiology, varied clinical presentation and the limited understanding regarding its pathophysiology (Elgoyhen et al., 2015). Treating tinnitus remains challenging and exploring new interventions for tinnitus management is imperative (Hall et al., 2013).

An understanding of the impact of tinnitus is required prior to selecting possible intervention strategies. Tinnitus experiences are highly variable and not everyone with tinnitus is affected in the same way (Baguley et al., 2013). For some, experiencing tinnitus is a devastating medical symptom, leading to significant clinical problems (Belli et al., 2008). Many aspects of daily life are disrupted, leading to sleep and concentration difficulties, and indirect psychosocial effects, including hopelessness, anxiety and depression (Langguth, 2011). What adds to the tinnitus paradox is that tinnitus severity is not related to the loudness or character of tinnitus experienced, but rather to the psychological

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complaints thereof (Andersson, 2002). Tinnitus interventions targeting the tinnitus sound itself, are therefore less effective than psychological treatments which focus on improving functionality and minimising the effects tinnitus may have (Hoare et al., 2011). Psychological treatments, such as cognitive behavioural therapy (CBT), are the treatment with the most evidence of effectiveness in reducing tinnitus distress (see Hesser et al., 2011 for a systematic review). Despite positive outcomes, there is limited accessibility to CBT for tinnitus, largely due to a shortage of suitably trained clinicians (Hoare et al., 2015; McFerran and Baguley, 2009).

Andersson et al. (2002) utilised the Internet to overcome difficulties related to accessing CBT for tinnitus. They developed a guided self-help Internet-based cognitive behavioural therapy for tinnitus (iCBT). The recruitment, assessment and intervention were run via the Internet, over a six week period. The materials were text-based chapters to read together with weekly worksheets to complete. Results of the initial randomised control trial (RCT) with a waiting-list control group indicated a reduction in tinnitus-related distress and depression for those undergoing the intervention (Andersson et al., 2002). Following intervention improvements, a study run in Sweden indicated similar results to group-based CBT (Kaldo et al., 2008). A further study by Hesser et al. (2012) found both iCBT and Internet-delivered acceptance and commitment therapy to be effective when compared to a discussion forum control group. Furthermore, iCBT has been shown to be effective when implemented in regular clinics (Kaldo-Sandström et al., 2004; Kaldo et al., 2013).

Following the success of these studies iCBT has been subsequently translated into both English and German. Effectiveness of iCBT was indicated using the German version in studies performed using a German population (Nyenhuis et al., 2013; Jasper et al., 2014; Weise et al., 2016). In a study by Abbott et al. (2009) using the translated English iCBT version, no statistically significant benefit was found when compared to an information-only control programme (without CBT content) in Australia and attrition rates were high. This was partly due to a relatively low level of baseline tinnitus distress and possibly due to cultural differences not being considered. Cultural dissimilarities could include differences in attitudes towards text-based learning, on which the programme was based for the industrial population sample selected. It is, therefore, important to ensure that these interventions are adapted to account for cultural variances found in different populations.

In the UK, self-help methods for tinnitus management are advocated in the Good Practice Guidelines for tinnitus management (DOH, 2009). Self-help is promoted as a means of increasing an individual's knowledge of tinnitus and helpful information is freely available through tinnitus charities, support groups, and general practitioners. In addition, the Internet has been used in the UK to serve those experiencing tinnitus, by means of online tinnitus support groups and forums. Although there are no national Internet-based interventions, there is an Internet-delivered unguided tinnitus Programme (www. Tinnitusprogramme.org), developed by a hearing therapist. It consists of education, psychoeducation, relaxation and attentional-focus exercises running over 6 weeks, followed by a 4 week maintenance period (Greenwell et al., 2015). Since its inception in 2009, it has not been widely used, which may be linked to the fact that this intervention has never been formally evaluated, although a protocol to evaluate this intervention has been proposed (Greenwell et al., 2016).

What is clearly limited in the UK is CBT support, guided self-help and evidence-based Internet interventions for people with troublesome tinnitus. The additional treatment option of guided iCBT for tinnitus distress in the UK would complement existing tinnitus pathways and self-help information by providing an evidence-based, accessible, comprehensive and standardised intervention. As health-care in the UK is largely face-to-face, an Internet intervention would need to be specifically designed to be appealing and overcome potential barriers to usage. It would also be imperative to ensure that the intervention is

functioning well at a technical level and determine end user satisfaction prior to undertaking further clinical trials (Haynes, 1999).

This study aimed to address the need for an evidence-based iCBT intervention for tinnitus distress, specifically for a UK population. The specific objectives were as follows:

- i) Development of an Internet-based intervention for tinnitus adapted specifically for a UK population
- ii) Identifying technical functionality concerns that may cause barriers to the usability of iCBT in the UK
- iii) Evaluating the intervention in terms of content, presentation, suitability and materials provided

2. Method

2.1. Ethical considerations

The Faculty of Science and Technology Research Ethics Panel (FREP) of Anglia Ruskin University (FST/FREP/14/478) granted ethical approval for this study. The research was conducted in accordance with the tenets of the Declaration of Helsinki.

2.2. Development process

As tinnitus is best treated within a multidisciplinary team (Cima et al., 2009), a multi-professional collaboration, with a broad skill set, consisting of the authors of this paper, was formed to guide this intervention. Including professionals involved in developing the original iCBT intervention in Sweden was considered imperative. GA and VK's expertise from the original iCBT development was utilised together with their clinical proficiency in providing psychological interventions. Moreover, it was important to have Clinical Audiologists involved. DB and EB fulfilled this roll and their knowledge of the pathophysiology of tinnitus and tinnitus therapy was incorporated. VM and PA added proficiency in both quantitative and qualitative research methods as well as experience in the running of clinical trials. GV's expertise in web-design and Internet-intervention delivery was key to the successful development of this intervention.

Guidance on developing complex interventions was followed (Craig et al., 2008). The fundamental premise was based on proven conceptual models. The Internet was chosen as the delivery method, as overall studies using CBT delivered via the Internet show promise as an effective and cost-efficient treatment option to reduce tinnitus distress (e.g. Hesser et al., 2012; Kaldo et al., 2008, 2013; Nyenhuis et al., 2013; Jasper et al., 2014; Weise et al., 2016). Internet-based CBT interventions have also been shown to be effective for a range of conditions, including anxiety, mood disorders, headache, insomnia, and somatic problems such as chronic pain (see meta-analysis and systematic reviews by Cuijpers et al., 2008; Arnberg et al., 2014; van Beugen et al., 2014).

The theoretical model by Ritterband et al. (2009) was used to guide the development of this intervention. The key features known to add to the effectiveness of Internet interventions, such as those found by Andersson et al. (2009), were considered and the following eight principles were selected for the design of this intervention:

2.2.1. Evidence-based content

There are various approaches to tinnitus management that are currently in use. The objective was to present only evidence-based, informative, accurate and interesting content within the intervention.

2.2.2. Comprehensiveness

Andersson et al. (2009) reported that for maximum effectiveness an Internet intervention must be comprehensive. The intent was, therefore, to maximise behavioural change by offering various techniques within a comprehensive intervention that focuses on addressing the physical, emotional and daily effects of experiencing tinnitus. Key CBT

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