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Critical Review of the Literature – Abstract

Objectives: Tinnitus can cause extreme distress to a small proportion of sufferers. Research evidencing the effectiveness of using cognitive behavioural therapy (CBT) based interventions to reduce distress is growing. Participants' experiences of such interventions are beginning to be explored but are yet to be synthesised. This could be used to inform future interventions and increase clinician expertise in the treatment of tinnitus-related distress.

Methods: A systematic review of the literature was undertaken resulting in seven studies meeting inclusion criteria. These were synthesised using thematic synthesis.

Results: Three analytic themes of patient experiences of CBT based interventions for tinnitus-related distress were identified: 1) processes of treatment, 2) engagement with treatment, and 3) the wide-reaching impact of treatment.

Conclusion: Improvements in tinnitus were largely reported by participants as arising from a changed relationship with tinnitus, and in part this occurs through accepting that interventions are not necessarily curative. Furthermore, CBT led to perceived improvements in anxiety, depression, sleep and an overall more positive outlook. A number of recommendations have been suggested. Future researchers should continue to seek feedback from participants, particularly from individuals who do not complete the intervention.

Service Improvement Project – Abstract

Background: Hearing voices (auditory hallucinations) can be a distressing experience, which can be compounded by high levels of stigma, isolation and low self-esteem. Feeling more connected to those with shared experiences (in-group) has been suggested to improve individuals' self-esteem. Hearing Voices Groups (HVGs) are increasing in popularity in the NHS with Cognitive-Behavioural Therapy (CBT) based groups being the most effective.

Objectives: To explore the experience of group attendees and facilitators at a pilot HVG, evaluating the impact on participants' experience of hearing voices, self-esteem and how they relate to others with similar experiences.

Methods: Six participants (4 attendees, 2 facilitators) took part in semi-structured interviews to explore their experience of the group; thematic analysis was used. Group participants completed pre- and post-group measures assessing their auditory hallucinations, self-esteem and in-group identification. These were explored using descriptive statistics.

Results: Three over-arching themes were identified in relation to participants' experience of the group: making connections, valuing session specifics and the challenges of the HVG. All group attendees reported their in-group identification as higher post-group compared to pre-group.

Conclusions: This study found that the pilot HVG facilitated increased connection with others and offered opportunities to develop understanding and skills to manage voices. Limitations are discussed and recommendations for future HVGs provided.

Main Research Project – Abstract

Background: A significant proportion of individuals with distressing tinnitus also report insomnia. Evidence suggests tinnitus-related insomnia cannot be explained purely by the presence of tinnitus. There is some evidence that sleep-related cognitive behavioural processes may play a role in tinnitus-related insomnia, but this is limited.

Objectives: This study aimed to assess whether sleep-related cognitions and behaviours known to maintain insomnia disorder are present for individuals with tinnitus-related insomnia.

Methods: This between-groups study recruited 180 participants online for four groups: tinnitus-related insomnia (N=49), insomnia disorder without tinnitus (N=34), tinnitus sufferers who are good sleepers (N=38) and controls (N=59). They completed questionnaires assessing insomnia severity, sleep-related cognitions and behaviours, sleep quality, anxiety and depression. People with tinnitus completed measures of tinnitus severity and volume.

Results: Linear regression found that group was a significant predictor of sleep-related thoughts, behaviours and quality. Pairwise-comparisons showed the tinnitus-related insomnia group had significantly greater insomnia-related thoughts and behaviours and significantly worse sleep quality than tinnitus good sleepers. No differences were seen between tinnitus-related insomnia and insomnia groups. The tinnitus-related insomnia group had significantly higher depression, anxiety, tinnitus distress and volume than tinnitus good sleepers.

Conclusion: Findings suggest that tinnitus-related insomnia may be maintained by cognitive behavioural processes similar to those found in insomnia disorder, and such

processes are more important than tinnitus severity when understanding sleep disturbance. People with tinnitus-related insomnia may benefit from treatments such as Cognitive Behavioural Therapy for insomnia.

University of Bath Doctorate in Clinical Psychology

1. Critical Review of the Literature - Patient experience of Cognitive Behavioural Therapy-based interventions for tinnitus-related distress: What are the outcomes and how do people get there? A systematic review and thematic synthesis.

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This journal was chosen as it is one of the leading journals in the field of Clinical Psychology and promotes the role of literature reviews in consolidating clinical knowledge.

Introduction

Tinnitus is the term given to describe the experience of hearing sound, such as ringing or buzzing, in the absence of an external source (Cima, 2018). Estimates of its prevalence vary between 5-30% (McCormack, Edmondson-Jones, Somerset, & Hall, 2016). Estimating tinnitus prevalence within the population has proven difficult, as a result of studies using inconsistent measures, age bands and definitions relating to tinnitus along with studies containing high levels of bias (McCormack et al., 2016). More common in adults than in children (Andersson, 2002), it has been reported that extreme distress is experienced by 20% of tinnitus sufferers, with negative impacts on psychological wellbeing, mood, sleep and anxiety (Andersson, 2002).

Psychological model of tinnitus-related distress

Research has found the relationship between tinnitus volume and tinnitus-related distress to be non-linear (Basile, Fournier, Hutchins, & Hébert, 2013; Hiller & Goebel, 2006) leading to a shift in approaching the condition from a biological standpoint to a bio-psycho-social one. McKenna and colleagues (2014) proposed a cognitive-behavioural model of tinnitus-related distress theorising that distress is created and maintained through individuals' interpretation of their tinnitus (cognitions) and their resulting actions (behaviours). Though further research is warranted (McKenna et al., 2014), this aligns with current treatment recommendations for tinnitus-related distress. The National Institute for Health and Care Excellence (2020) guides clinicians to consider a referral for counselling or Cognitive Behavioural Therapy (CBT), including third wave approaches such as Acceptance and Commitment Therapy (ACT), mindfulness-based cognitive therapy and internet delivered CBT (iCBT) for patients with tinnitus-related distress.

CBT-based interventions for tinnitus-related distress

Research has found that a variety of CBT-based interventions, delivered in different ways, are effective in improving psychological wellbeing for tinnitus sufferers. A Cochrane review including 28 studies concluded that CBT is effective in reducing the negative psychological consequences of tinnitus (Fuller et al., 2020). iCBT has shown to be a cost-effective option for treatment (Andersson, 2015; Andersson, Strömgren, Ström, & Lyttkens, 2002; Kaldo et al., 2013; Rheker, Andersson, & Weise, 2015) with sustained benefits 1-year post-treatment (Beukes, Allen, Baguley, Manchaiah, & Andersson, 2018a). However, internet-based interventions sometimes report high attrition rates (Andersson et al., 2002). Acceptance of symptoms has been shown to be a key aspect of lowering tinnitus-related distress which supports the application of acceptance-based, third-wave approaches such as mindfulness-based therapies and ACT (Westin, Hayes, & Andersson, 2008; Westin et al., 2011). Studies assessing the efficacy of mindfulness-based interventions delivered in a group format have found it to decrease tinnitus-related symptoms (Gans, O'Sullivan, & Bircheff, 2014; McKenna, Marks, Hallsworth, & Schaette, 2017; Möschen et al., 2019) with sustained benefits seen at 12-month follow-up (Gans, Cole, & Greenberg, 2015). Interventions do not significantly reduce subjective volume of tinnitus experienced by an individual (Martinez -Devesa, Perera, Theodoulou, & Waddell, 2010). Longitudinal research testing effects beyond one year is lacking.

Patient experience of interventions

Overall, rigorous quantitative studies crucial to the development of evidence-based healthcare (Sackett, 1996) have shown CBT-based interventions as effective at reducing tinnitus-related distress. Recent research has turned towards exploring how patients experience CBT-based treatments for tinnitus, in recognition that this offers valuable insight into treatment acceptability and potential processes underpinning therapeutic change ("active ingredients"). This approach to enhancing our understanding of CBT is more established in other conditions such as chronic pain (Burns et al., 2015).

Qualitative research has shown the wide-reaching negative impact tinnitus can have on people (Watts et al., 2018) including on their thoughts, emotions and behaviours (Marks, Smith, & McKenna, 2019b). Also, the importance of active versus passive coping strategies (Beukes et al., 2017). Other qualitative studies have shown the effect of healthcare communications on tinnitus (Marks et al., 2019b), the impact of thoughts on tinnitus perception (Pryce & Chilvers, 2018) and the benefits of shared decision-making between clinician and patient (Pryce, Hall, Marks, et al., 2018). The latter informing the development of a new clinical tool - the Tinnitus Decision Aid (Pryce, Durand, Hall, et al., 2018). All have offered confirmatory evidence for the CBT-model of tinnitus. Research exploring "active ingredients" in tinnitus support groups found that the opportunity they provide for social connection can build resilience (Pryce, Moutela, Bunker, & Shaw, 2019).

Understanding more about how patients benefit from interventions could aid their future development. This may also help identify factors that present as barriers to successful treatment, improving clinical expertise and the effectiveness of CBT-based treatments for tinnitus-related distress.

Aims

This review aims to synthesise qualitative studies that have explored the experiences of patients who have received CBT-based psychological interventions targeting tinnitus-related distress. A further aim is to deepen our understanding of key aspects of therapies in shaping patient experience and outcome to inform clinical practice.

Method

Design

This review was conducted in three stages: systematic review of relevant literature, evaluation of the quality of research using the Critical Appraisal Skills Programme (CASP) (2018) qualitative checklist and synthesis of qualitative findings using thematic synthesis (Thomas & Harden, 2008).

Systematic literature review

Defining CBT. A recent Cochrane review assessing the effects of CBT for treating tinnitus distress defined 'CBT' as studies that used cognitive, behavioural, cognitive and behavioural (combined) ACT or mindfulness interventions, such as Mindfulness-Based

Cognitive Therapy (MBCT) or Mindfulness-Based Tinnitus Stress Reduction (MBTSR) (Fuller et al., 2020). This definition was replicated in this review.

Search strategy. Research exploring patient experience in this area is relatively new and has yet to be synthesised. Search terminology was kept broad without restrictions on publication dates, concentrating on combining tinnitus and psychological therapy.

The final search strategy was designed to align with agreed terminology currently reported in tinnitus literature (Fuller et al., 2020; D. M. Thompson, Hall, Walker, & Hoare, 2017) using the following databases: Embase, Pubmed (via Embase), APA Psychnet (PsycINFO, PsycARTICLES) and Web of Science. APA PsychExtra was used to search for grey literature. The final search strategy used words relating to cognitive behaviour therapy, abbreviations of treatment delivery and 'tinnitus' (see Appendix B for full search criteria).

The search (March 2020) resulted in 1976 papers being retrieved. Once all 443 duplicates were removed, the remaining 1533 papers were screened against the inclusion and exclusion criteria (Appendix C). A second reviewer screened a random 10% of studies with 91% agreement. All disagreements were due to the primary researcher including studies that the second reviewer had excluded, indicating a low risk of over-exclusion. Full text screen of 208 studies was completed by the primary researcher with 100% agreement from the secondary reviewer who screened a random 10% (Appendix D). Five studies met inclusion criteria. One study was retrieved through hand searching reference lists and another study was retrieved as it was referenced as being in preparation in one of the included studies. We included a total of seven studies in this systematic review (Andersson & Edvinsson, 2009; Beukes et al., 2018b; Gans et al., 2014; Greenwell, Sereda, Coulson, & Hoare, 2019; Marks, Smith, & Mckenna, 2020; Marks et al., 2019b; P. Thompson, Pryce, & Refaie, 2011).

Summary of included studies. The seven studies were published between 2009-2020 and include a total of 87 participants. Males (56%) and females were included in all samples, with ages ranging between 22-83. Two studies included views of participants who had received face-to-face individual or group CBT. Three studies included views from mindfulness-based group interventions; two of the studies used the same sample. Two studies included views of participants who had used online CBT-based interventions (one being iCBT). Tinnitus duration ranged between 1-35 years (see Appendix E).

Quality assessment

Quality assessment was undertaken using the ten question CASP (2018) qualitative checklist to critically assess domains such as methodology, design, analysis and ethics. No studies were excluded from the synthesis based on their quality assessment, given there is no agreed framework for doing so (Thomas & Harden, 2008) (see Appendix F).

All studies set out clear aims and used an appropriate methodology, recruitment strategy, data collection method, gave a clear statement of findings and produced valuable research. One study lacked information explaining the design rationale (Gans et al., 2014). The majority of studies considered the relationship between researcher and participant. Though all studies referenced ethical issues to some extent, only one (Greenwell et al., 2019) did this in sufficient detail. Two studies did not include sufficient detail relating to data analysis (Greenwell et al., 2019; P. Thompson et al., 2011) whilst one study included no information relating to data analysis (Gans et al., 2014).

Data analysis

Thematic synthesis (Thomas & Harden, 2008) was selected as the methodology as it was developed to address questions related to clinical intervention, appropriateness and acceptability (Barnett-Page & Thomas, 2009).

Data extraction was undertaken by the primary researcher. Thomas and Harden (2008) acknowledge the complexity of extracting study findings from qualitative studies to synthesise. Study findings were classified as all data listed under ‘results’ or ‘findings’ in relation to service user experience of cognitive-behavioural therapy-based interventions for tinnitus-related distress. This decision was made because not all studies had service user experience of intervention as their main objective. Raw data was extracted verbatim and imported into qualitative data analysis software QSR Nvivo 12.

Thematic synthesis consisted of three stages: line-by-line coding of free text, development of descriptive themes and development of analytic themes (Thomas & Harden, 2008). The analysis was conducted by the primary researcher, who takes a contextualist approach. This positioning means the synthesis was not looking to reveal a “true reality” in the data but acknowledges that meaning comes from and is influenced by an individual’s experiences and societies narratives. The primary researcher identifying as a white British woman and her experiences as a trainee clinical psychologist delivering CBT-based interventions will have influenced the analysis. These factors will have meant that coding of the data was both inductive and deductive. Line-by-line coding was undertaken in Nvivo by the primary researcher. Codes were grouped into descriptive themes and discussed with the project supervisor. The project supervisors clinical and research expertise in the field will have shaped the discussions around analytic themes. Discussions around descriptive themes was an iterative process between the primary researcher and project supervisor resulting in three analytic themes being defined which were all found to have subthemes.

Results

The three analytic themes identified relating to patient experiences of CBT-based interventions for tinnitus-related distress were 1) processes of treatment, 2) engagement with treatment and 3) the wide-reaching improvements following treatment.

Processes of treatment

This encompasses elements of interventions that participants across studies regarded as important aspects of their treatment; accepting tinnitus and paying attention to the experience of it, commitment to therapy, the impact of others and making sense through education.

Accepting tinnitus and paying attention to the experience of it. Four of the papers (mindfulness-based groups, individual and online CBT-based interventions) referenced progress towards accepting experiences of tinnitus as an important process in treatment, recognising the need to move away from controlling it. This is supported by quantitative research (Möschen et al., 2019; Westin et al., 2011) and in line with qualitative research highlighting the crucial role acceptance can play in allowing people to regain a sense of control over their lives (Pryce & Chilvers, 2018). In mindfulness-based studies, paying attention to tinnitus and associated thoughts and feelings meant participants became more aware of their fear about engaging with tinnitus. Tinnitus fear was also reported in a CBT-based study in association with the intervention reducing how scary the experience of tinnitus could be. Participants in one CBT study found exposure to tinnitus difficult.

"I'd never thought of it before, but just simply accepting that my body has decided to make this hiss and I've got to live with it. It's no good fighting it or ranting against it. I just accepted it. I must say that, that was the little jewel that I have got out of this tinnitus programme." Beukes (2018b) [participant, iCBT].

The process of acceptance can be slow and challenging. Interventions should offer adequate time and space for likely fearful participants to practice techniques that may foster acceptance. Across the studies acceptance was associated with knowledge that the intervention was not going to be curative, as there is no 'cure' to silence tinnitus.

Commitment to therapy. The importance of committing to the intervention as a process underpinning treatment was only referenced in group mindfulness-based studies. This was associated with acknowledging the need for patience when undertaking new interventions, described by authors as a sense of courage to persist with mindfulness. Two of the group mindfulness-based studies included reference to holding scepticism alongside a willingness to try new techniques. They recognised both as useful in bringing about change, welcoming scepticism as part of a commitment to treatment.

"Skepticism and open-mindedness came together, and both facilitated change. Open mindedness led people to engage, and the permission to express skepticism prevented people from feeling alienated. Adam feared the Buddhist origins of mindfulness might be too spiritual, but decided to "see what happens" Marks (2020) [author interpretation and participant, group mindfulness-based]

It is possible that this theme arose in only mindfulness-based studies because the interventions required a high level of input by the participant (regular home practice).

The impact of others. Participants in mindfulness based group settings, individual and group CBT and those completing an online intervention that included access to a discussion forum valued the process of connecting with other people with tinnitus. The impact of making people feel less alone with their suffering was consistent across group settings and related to creating a shared sense of identity, supporting research promoting the importance of social connectedness for people living with tinnitus (Pryce et al., 2019). Seeing other people's distress (particularly those struggling more) helped put their own problems in perspective. Participants across the groups found it helpful to see other people coping well with their tinnitus, even when severe, since this fostered hope that they could too. One study comparing individual and group treatment (P. Thompson et al., 2011) found that participants in individual therapy were more likely to regard their experience of tinnitus as worse than others.

"Group participants referred to their presence in the group as affecting the identity that they attributed to tinnitus. In particular, the comparison made between accounts helped participants to clarify their view of their tinnitus." Thompson (2011) [participant, group and individual CBT]

Participants who had access to an online forum reported mixed experiences. Some noted connecting with others as helpful for feeling less alone whereas another cited negative feelings about tinnitus identity as a reason for not engaging with the forum. The forum in this study was moderated, which the authors highlight as important in minimising negative experiences (Greenwell, Sereda, Coulson, & Hoare, 2016). The role of moderators in online forums has been shown to be important in enabling a space to remain therapeutic (Smedley & Coulson, 2017).

"Talking about it [tinnitus] with other people, I didn't really feel comfortable with that...because you are talking about it [tinnitus], it gets worse...I want to just be my

own person and be able to deal with it on my own and not let it take control of my life" Greenwell (2019) [author interpretation, iCBT]

Making sense through education. Participants across all types of interventions (mindfulness-based groups, group / individual based CBT and online CBT based interventions) identified a biopsychosocial understanding of tinnitus as an important part of intervention i.e. taking into account the biological and psychosocial factors influencing perception and distress when trying to understand tinnitus. Learning how previous or current coping strategies, particularly attempts to control tinnitus, often exacerbated distress was helpful to those looking for answers in relation to why their tinnitus had such an impact. By understanding and making sense of tinnitus, there was a shift in the emotional response, such as feeling less frustrated and perhaps less fearful. This relates to previous qualitative research that has highlighted the importance of healthcare communication in enabling people to understand tinnitus and how this is often lacking from more biomedical approaches (Marks et al., 2019b).

"She gave me a good diagram of the ear and explained exactly what happened to me... because she helped me understand it, it probably reduced the annoyance." Thompson (2011) [participant, group and individual CBT]

Two studies found that education was not always regarded as helpful, particularly when the information provided did not fit with an existing understanding of tinnitus, or if it raised anxiety about the future impact of the condition. This fits with existing quantitative literature on the role of catastrophic thinking and long-term outcomes in tinnitus (Cima, Crombez, & Vlaeyen, 2011).

Engagement with treatment

This encompasses aspects of interventions that participants across studies regarded as important in aiding engagement, along with aspects that made engagement more difficult. These have been summarised as; flexibility in taking part, structure and planning, feeling safe and being understood, valuing expertise and barriers to engagement.

Flexibility in taking part. Participants of both group mindfulness-based interventions and online CBT-based interventions valued home practices that could be done flexibly to fit into their lifestyles. In both of the papers where this was stated, they acknowledged a preference for shorter at home practices being popular, suggesting participants being able to utilise active elements of treatment in a way that suits their lifestyles as important.

"Users valued the breathing exercises, as they were brief, easy, and could be practiced anywhere and without anyone noticing." Greenwell (2019) [author interpretation, iCBT]

The flexibility internet-based interventions offered participants to choose when they engage in treatment was highly valued. Participants referenced not having to reschedule work, the privacy this offered to the intervention, stress being reduced as a result of being home, the possibility of reviewing past modules and the fact that it could start immediately was appreciated.

Structure and planning. Participants in both CBT group and online CBT-based interventions also noted how the predictability of weekly sessions promoted their engagement, giving them a sense of progression.

Differing views on how sessions should be structured was seen across studies, for example a participant receiving iCBT reflected on the pace being too slow. This highlights the need for treatment to be continually evaluated, with patient feedback taken alongside clinical expertise to feed forward into future treatments. Some participants in a group setting and using an iCBT intervention valued timetabling in at home practice to make it more likely that they wouldn't forget. Balancing structure and flexibility seems central to engagement, allowing participants to feel an intervention is predictable whilst retaining a sense of autonomy.

"Overall, I liked the structure and style of communication. I liked the regularity of the weekly check-ins and questionnaires. having that pattern set every week helped me maintain working through" Beukes (2018b) [participant, iCBT]

Feeling safe and being understood. Having experiences validated and feeling understood, by either professionals or peers was cited in four studies as highly valued, covering group mindfulness-based interventions, and individual and group CBT-based interventions. Though the direction of which is experienced first is not clear, it seemed that when participants felt safe they felt more confident to share information about themselves, which led to them feeling more understood.

"The most important thing is how I was made to feel. I felt that someone was listening to me and I was treated like a person...not like cattle and that makes a difference." Thompson (2011) [participant, group and individual CBT]

Engaging in a comfortable environment was reported as valued in an intervention carried out in participants homes and an NHS setting.

Valuing expertise. Referenced in all studies (group mindfulness-based, online CBT-based, group CBT and individual CBT), this encompasses expertise of the intervention facilitator and the overall credibility of treatment as a central part of intervention acceptability. Participants perceived expertise in various forms: facilitator knowledge, interventions being tinnitus specific, honesty about the trajectory of tinnitus, transparency around the provider's expertise and motivations, good organization and delivery and having direct experiences of benefit resulting from the facilitators' instructions.

"Discussions should shift from the medical view that tinnitus is 'incurable' to an equally accurate but more helpful and encouraging biopsychosocial view that tinnitus can be managed, distress reduced, and habituation facilitated to a point where tinnitus is no longer problematic for people (even if the noise does not stop)." (Marks et al., 2019b) [author interpretation, group mindfulness-based]

This may support engagement through increasing participants belief that the intervention would help, thus reducing scepticism. The iCBT study acknowledged that participants confidence in the intervention's developer fostered confidence in the intervention. Expecting an intervention to help has been linked to better outcomes in therapy (Joyce & Piper, 1998).

Barriers to engagement. Six papers reported on barriers to engagement, with two only referencing these indirectly. Reported barriers that detracted from engagement with therapy included worsening tinnitus, resource quality and demands. Three studies (two internet CBT-based and one group mindfulness-based) discussed how the initial increase in tinnitus-related distress when starting a new therapy could act as a barrier to engagement. Participants tended to see such an increase in their distress resulting from paying more attention to their tinnitus, both as part of the techniques used and in the broader sense of talking about their tinnitus and hearing about other peoples.

"There was an exercise where you had to tune in to listen to your tinnitus and I found that really difficult." Beukes (2018b) [participant, iCBT]

Participants who engaged in online interventions highlighted the quality of resources as important, with poor resources reducing the credibility of the intervention.

Time commitment, particularly in relation to home practice elements, were acknowledged in both group mindfulness-based and online CBT-based interventions as barriers to engagement, even with recognition that flexibility somewhat alleviated this. Participants of online interventions also noted that they felt unconfident at self-guiding techniques for homework. This fits with the understanding that guided internet-based interventions have better outcomes than un-guided ones (Baumeister, Reichler, Munzinger, & Lin, 2014).

The wide-reaching improvements following treatment

This analytic theme captures the ways in which therapy improved the lives of tinnitus sufferers. Participants described substantial benefits from therapy which have been summarised as; a changed relationship with tinnitus and thriving and resilience.

A changed relationship with tinnitus. This was the most commonly reported outcome, referenced in four of the seven papers (group mindfulness, online CBT and group CBT based interventions). Most often, participants reported noticing a reduction in tinnitus intrusions into their lives. This covered noticing tinnitus less and feeling less bothered by it. Participants tended to associate this shift in how they related to tinnitus, with changes in how they were paying attention to tinnitus and becoming more accepting of it, ultimately suggesting a new way of being with tinnitus. This came with a reduction in distress, rather than changes to volume or pitch (although one study mentioned a participant experiencing a decrease in tinnitus volume). The paradox of people gaining control of their tinnitus through acceptance of not being able to control it is interesting. It seemed that people's confidence increased in relation to no longer feeling a need to control their tinnitus and in essence this changed their relationship to it.

"He stated that because of his experience with the MBTSR class he now can "just be" with the sensation moment to moment, and experience it as a bare sensation, not something that is destroying his life." Gans (2013) [author interpretation, group mindfulness-based]

"I stopped focusing on the noise so much. It changed my perception of it. I felt power over it. It was like I could lower the volume, even though I really can't" Greenwell (2019) [participant, iCBT]

Thriving and resilience. Perceived improvements in participants wellbeing were discussed in four of the seven studies (group mindfulness and online CBT based interventions), encompassing different domains of their lives, evidencing the impact of treatment for tinnitus-related distress in allowing individuals to thrive. This is not surprising as we know tinnitus to negatively impact people's lives in a multitude of ways (Watts et al., 2018).

Thriving was linked to participants newfound confidence that they could cope with their tinnitus, seen in four studies (two mindfulness-based and two online CBT-based), suggesting an increase in resilience. This related to how the tinnitus relationship changed from one of control to acceptance, and that the benefits did not arise because difficulties disappeared, rather participants became better at living with difficulties, and more resilient to the challenges life threw at them. Self-compassion was reported as helpful by participants who attended group mindfulness sessions.

""James: You can appreciate things more.. . whether it be your pet cat or the squirrel running across the world.. . a good day or a bad day.. . if you take time you can appreciate it a bit more." As mindful awareness became more integrated into their

lives, joy and gratitude arose more spontaneously, with gratitude springing from connections with others, seeing kindness and generosity in other people. Simply paying attention transformed experience as "it just melts everything away for a moment" (Kelly)." Marks (2020) [author interpretation and participant, group mindfulness-based]

Both CBT and mindfulness-based interventions referenced being able to enjoy new or old hobbies that tinnitus had restricted. This allowed them to reconnect with people they had felt distant from and experience an overall more positive outlook. Participants in a mindfulness group and using an online CBT-based intervention reported feeling calmer.

Improvement in sleep was referenced by four of the seven studies, linked with developing skills to aid relaxation, highlighting the close association between sleep difficulties and tinnitus (Asnis et al., 2018). Interventions aimed specifically at treating insomnia-related tinnitus have demonstrated the benefit of alleviating this symptom

(Marks, McKenna, & Vogt, 2019). It is promising that interventions aimed more broadly at treating tinnitus-related distress have an impact on sleep disruption. Improvements were also seen in relation to anxiety and depression symptoms, with participants referencing how they have generalised skills learnt in therapy to support the resilience they have when faced with other distressing experiences.

"Participants also reported that the training contributed to better self-care practices and brought relief from fear in daily activities. "I am trying to relax more, sleep better and longer. I watch what food I eat and try to take a walk or other exercise each day. I am less afraid to be inside of a room or a building."" Gans (2013) [author interpretation and participant, group mindfulness-based]

It is likely improvements do not happen in isolation but that the changed relationship with tinnitus acts as a catalyst for improvements in other domains, thus allowing individuals to gain resilience and thrive.

Discussion

This synthesis of participant experience of CBT-based interventions targeting tinnitus-related distress has shed light on how and why participants can benefit from treatments and what factors may contribute to more successful outcomes. The aim of the review was to deepen our understanding of key aspects of therapies, to shape patient experience and outcomes and ultimately inform the development of clinical practice. This was achieved as three analytic themes were identified in relation to this: the processes of treatment, engagement with treatment and the wide-reaching improvements following treatment. Recommendations for clinicians delivering CBT-based treatments for tinnitus-related distress (Table 1.1.) are offered as considerations in light of the study limitations.

Accepting tinnitus was a central component across interventions and was associated with a realisation that there is no cure to alleviate tinnitus. This is in line with the theoretical model of tinnitus distress, which highlights the maintenance of tinnitus distress through the interpretation of and reaction to tinnitus (McKenna et al., 2014). The impact of talking with others who have similar experiences was central to helping participants gain a new perspective on their tinnitus, fostering hope in relation to coping in the future and ultimately creating a helpful shared sense of identity. Importantly, it seemed when this is done on-line, efforts need to be made to ensure the space for talking remains a helpful one.

Expertise of the facilitators was important in communicating credibility in the intervention. Participants valued both flexibility in home practice (as well as the flexibility offered by online interventions) alongside a reliable structure, which seemed to require balancing participants' sense of autonomy with the progression and predictability that comes with structure. Feeling safe and understood meant participants were more confident in sharing their experiences. A number of barriers to engagement, which include worsening of tinnitus, the demands of the intervention and resources seeming of a poor quality were raised by participants. It is important to highlight that the barriers to engagement identified in the review were drawn entirely from the group mindfulness-based studies and the online CBT based-interventions. This means that barriers relating to group and individual CBT interventions delivered in person have not been represented in this review.

The wide-reaching improvements following treatment were vast, which is in line with findings in the literature (Andersson, 2015; Fuller et al., 2020; Gans et al., 2014; Heinrich et al., 2016; McKenna et al., 2017) . The most prominent outcome was people's experience of a changed relationship with tinnitus, most often through acceptance that whilst the volume of tinnitus cannot be controlled the extent to which it impacts on life can. This aligns with the literature that highlights the crucial role of acceptance in interventions aimed at reducing tinnitus-related distress (Westin et al., 2008, 2011). It is possible that acceptance of tinnitus reduces overall stress levels, allowing the possibility to challenge catastrophic cognitions related to tinnitus and create space for individuals to experience exposure to their tinnitus (Marks et al., 2020; McKenna et al., 2014). This process may be what allowed participants to develop resilience and thrive, experiencing an increased ability to cope with their tinnitus, an overall more positive outlook and sleep, anxiety and depression related improvements.

As referenced throughout the results, some themes related more closely to certain interventions. For example, the theme of thriving and resilience was developed from the mindfulness-based and online CBT-based interventions, individual or group CBT delivered in person did not feed into the theme. It is positive that all themes, apart from commitment to therapy which was only seen in mindfulness-based studies, were derived from both mindfulness-based and CBT-based interventions. This likely reflects the fact that a variety of second and third wave CBT-based interventions are effective at alleviating tinnitus related distress. No firm conclusions can be drawn relating to how different themes relate to intervention type because of the small sample size. However, the field would benefit from future research exploring this further.

Limitations

The perspectives of participants who have not completed treatment was missing in all studies, so this is a considerable limitation. Future studies should aim to capture the views of participants who disengage from treatment. This is essential when considering acceptability of interventions as we are missing the views of those who perhaps have found them difficult to engage with or unacceptable. Without this, we are likely missing a crucial understanding of barriers to engagement.

Another limitation is the small sample size, with the majority of analysis being drawn from five of the seven studies (Beukes et al., 2018b; Gans et al., 2014; Greenwell et al., 2019; Marks et al., 2020; P. Thompson et al., 2011). Reviewing these five studies alongside the findings of the current review shows that this is likely because the original aims of the five studies, from which the majority of analysis has been shaped, align closely to the aims of the synthesis, in that they were broadly looking at participant experience of treatment. This highlights the limited amount of literature on this topic, which reduces the richness of the findings and indicates more qualitative research would further enhance our understanding. Additionally, this limits the extent to which recommendations should be generalised as it may not represent the experiences of the majority of participants who have received interventions.

Importantly, though the studies related to different types of CBT based interventions, the synthesis highlighted a great deal of similarities across studies. This could suggest that important elements of CBT based interventions for tinnitus-related distress are shared across intervention types and relate to the overall cognitive-behavioural model (McKenna et al., 2014) as opposed to being specific to different types of CBT-based approach (such as ACT or mindfulness). It is important to consider the impact of referring to interventions across all studies as CBT-based. As outlined earlier in the review, 'CBT-based interventions' has been used as an umbrella term to refer to second and third wave CBT, including Mindfulness-Based Cognitive Therapy and Mindfulness-Based Tinnitus Stress Reduction. This must be recognised as both second and third wave approaches show equal outcomes in treating tinnitus. Additionally, Mindfulness-based interventions, when used to treat tinnitus, incorporate a great many aspects that are also core to CBT, as interventions are based on the cognitive model of tinnitus (Mckenna et al., 2014). However, it should be recognised that these approaches are distinct, require different training and expertise to be delivered and should both continue to be evidenced as treatments for tinnitus related distress.

Conclusion

This review has systematically reviewed and synthesised the literature around participant experiences of CBT-based interventions for tinnitus-related distress, highlighting important processes in treatment, factors that aid engagement and the wide-reaching improvements that participants report. Future studies should continue to collect and synthesise the views of participants receiving these interventions , to further develop recommendations proposed by this study and improve clinical expertise alongside effectiveness of treatment.

Table 1.1

Recommendations for CBT-based interventions for tinnitus-related distress from thematic synthesis

Themes from analysis	Related recommendation for CBT-based interventions
Processes of treatment	
Accepting tinnitus and paying attention to the experience of it.	Normalise fear in relation to paying attention to tinnitus, particularly with a view to supporting participants in persisting with techniques that may cause fear. Offer a clear explanation for why this happens to promote participants trust in the techniques being beneficial. Ensure the intervention devotes adequate time to developing and practicing new techniques to help to increase participants confidence and competence in new skills to relieve tinnitus-related distress. Normalise how long it might take to notice a difference, and what the differences might be expected to be.
The impact of others	Promote the benefits of being with other tinnitus sufferers through moderated forums or tinnitus social support groups. This may help towards reducing feelings of loneliness and isolation.
Making sense through education	Provide a robust biopsychosocial understanding of tinnitus and work with participants to understand past experiences and the impacts of past coping strategies e.g. how and why trying to control tinnitus can increase distress. Explore the participant’s current understanding of their tinnitus to assess how well a biopsychosocial understanding fits their experience. With openness, encourage questions, curiosity and scepticism where different views may exist.

Themes from analysis	Related recommendation for CBT-based interventions
Engagement with treatment	
Flexibility in taking part	Encourage participants to fit home practices into their lives in a way that suits them. Offering a variety of home practice options, including shorter practices, may help participants find the technique best suited to them. Offer resources which allow participants the option to review session content e.g. session summaries or psycho-education related materials.
Structure and planning	Maintain an element of structure in the intervention that offers a sense of predictability. For online interventions, this may include an email being sent at the same time each week. For face-to-face interventions, use regularly scheduled or contracted sessions.
Feeling safe and being understood	Maintaining a space for individuals' experiences to be shared and validated may enhance how understood participants feel and promote a sense of safety. Ensuring the environment in which the intervention takes place is comfortable (and communicating this to participants using online interventions) may enhance engagement.

Themes from analysis	Related recommendation for CBT-based interventions
Valuing expertise	Clear communication around the intervention being tinnitus specific, the objectives of the treatment, honesty in relation to tinnitus trajectory, the facilitator / developers' experience of working with tinnitus may help to convey expertise. Explaining how the intervention has benefitted others in the past may enhance belief and hope in the intervention.
Barriers to engagement	Be transparent about the experience of tinnitus distress sometimes increasing during the intervention. Normalising that this is a common experience and explaining why it occurs may enhance participants willingness to persevere through very aversive experiences.
	Resources produced should be of high quality, easily accessible and developed in collaboration with tinnitus sufferers to assess for acceptability.
	Examples of guided techniques should be available for online interventions to increase participants confidence that they are doing them right. Techniques delivered face-to-face should be demonstrated by the facilitator.
	How much time commitment is required for the intervention should be explained to participants at the start of treatment to support them to make an informed choice about whether it suits their current lifestyle.
The wide-reaching improvements following treatment	
A changed relationship with tinnitus	Explain the aim of the intervention to participants is not related to changing the volume of tinnitus but about how they experience it. Highlighting that other participants have noticed an increase in their confidence to cope with their tinnitus may be beneficial.

Themes from analysis	Related recommendation for CBT-based interventions
Thriving and resilience	Monitor outcomes related to anxiety, depression and sleep throughout treatment to capture the wide-reaching impact of treatment. Work with participants to identify their own specific goal of what they would be able to do more of if tinnitus was less distressing to support motivation and broaden awareness around tinnitus to the rest of life. Share that possible benefits go beyond tinnitus distress and can be seen in relation to people's relationships, hobbies and overall outlook, and help participants to notice these when they arise.

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2. Service Improvement Project - Evaluating a pilot hearing voices group in an Assertive Outreach Team.

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Proposed Journal for Publication: Psychosis: Psychological, Social and Integrative Approaches

This journal encourages research exploring psychological treatments of psychosis. It invites a range of research papers including those looking at group treatments and studies exploring first person experiences of mental health services.

Introduction

Hearing voices

The experience of hearing voices (auditory hallucinations) is typically seen as a symptom of a mental health disorder, such as psychosis (Payne, Allen, & Lavender, 2017). It is also not uncommon, with estimates that 5-28% of the population may experience auditory hallucinations at some point during their lives (de Leede-Smith & Barkus, 2013). Although research has shown that voice hearing is not exclusively associated with becoming mentally unwell, the individual can experience extreme distress (Sartorius, 2002) and high levels of stigma and isolation (Longden, Corstens & Dillon, 2013). This, together with the detrimental impact it can have on self-esteem (Birchwood & Iqbal, 1998), can further exacerbate distress.

Hearing Voices Groups

The National Institute for Health and Care Excellence (NICE) recommends that individuals presenting with persisting and recurring symptoms of psychosis or schizophrenia be offered individual Cognitive Behavioural Therapy (CBT) to treat symptoms and related distress (NICE, 2014). However, service audits have found that provision within the NHS is low with only 10% of service users who hear voices having access to CBT for Psychosis (CBTP) (Hazell et al., 2018). Hearing Voices Groups (HVGs) may present an alternative, more accessible way of addressing this issue. HVGs are increasing in popularity across the NHS and are being implemented in teams as a way of meeting the needs of service users, though there is limited research around their effectiveness and cost-effectiveness (Ruddle, Mason, & Wykes, 2011). A review of

HVGs found the content of the groups varied greatly, with only CBT approaches evidenced in well-controlled studies (Ruddle et al., 2011). Other approaches to HVGs were found to be mindfulness-based groups, skills training groups or unstructured support groups.

Research has aimed to explore the mechanism of change that makes CBT-based HVGs effective in reducing the distress associated with hearing voices. A definitive understanding of this is yet to be identified, though testing negative beliefs about voices has been suggested as most strongly associated with a reduction in distress (Ruddle et al., 2014). Additionally, the opportunity to share experiences has been highlighted as important, resulting in the recommendation that HVGs should strive to balance a didactic style with unstructured space for service users to speak openly (Ruddle et al., 2014). A fully comprehensive understanding of the mechanisms that make HVGs effective remains unresolved and under-researched (Payne et al., 2017; Ruddle, 2017).

HVGs and social identity

In order to further understand what makes HVGs helpful, researchers have begun qualitatively exploring service users' experiences. Connecting with others, feeling supported and exploring voices are common themes that have been identified within studies (Oakland & Berry, 2015; Payne et al., 2017; Ruddle et al., 2014). A proposed understanding for why these are valued experiences is the impact that they can have on increasing self-esteem (Goodliffe, Hayward, Brown, Turton, & Dannahy, 2010; Oakland & Berry, 2015). Social Identity Theory proposes positive association with an "in group" as beneficial to an individual's self-esteem (Hogg, Abrams, Otten, & Hinkle, 2004), though a linear relationship between the two is debated (Brown, 2000). Conversely, in a heavily stigmatised “in group” such as for those hearing voices, internalising the stigma associated with developing a mental illness can be damaging. Not accepting this stigma as legitimate and connecting with others similarly affected can ameliorate these effects (Watson, Corrigan, Larson, & Sells, 2007). The value of being with others who have shared experiences is consistently highlighted as valuable by individuals who attend HVGs (Oakland & Berry, 2015; Ruddle et al., 2014), possibly explained by the opportunity that HVGs create to increase an individual’s connection with their “in group” (social identity). This could decrease the experience of stigma felt by individuals who hear voices and positively impact their self-esteem. This is in line with a study showing that social identification related to lower symptoms of paranoia (McIntyre, Wickham, Barr, & Bentall, 2018), which was strengthened partly through an increase in self-esteem. However, they did not find a direct association between identity and auditory hallucinations. The researchers acknowledge that more evidence is needed to fully develop our understanding of this likely complex relationship (McIntyre et al., 2018).

Context and Consultation

Assertive Outreach Teams (AOTs) are specialist services commissioned to work intensely with individuals who experience complex and enduring mental health difficulties to an extent that impacts their ability to engage with mental health services. AOTs receive referrals from community mental health teams (in this study, the Recovery Team) to work with individuals who are proving hard to engage due to the complexity of their needs. The development of AOTs within the NHS was based on the Assertive Community Treatment Model which found the assertive community engagement approach as successful in reducing in-patient admission (Wright et al., 2003). AOTs were mandated in the NHS Plan (Department of Health, 1999), however, fidelity to the model was reported as variable (Wright et al., 2003). A government shift in 2010 meant that these teams were no longer mandatory (National Institute for Health and Care Excellence, 2014). Many remained as they were central to their locality's community mental health teams and were highly valued by service users.

There is increasing emphasis on evaluating NHS psychological interventions (NHS England, 2016), resulting in increasing pressure for services to demonstrate their value to commissioners. Offering groups in mental health services provides a low-cost opportunity for service users to derive support to manage distressing experiences such as hearing voices. They also provide the solidarity and support associated with forming connections with peers and a shared social identity. At the time of this study a Gloucestershire AOT was exploring the idea of implementing a new group within their service. Consultation was carried out with service users following the conclusion of a 7-week mindfulness group that had run the previous year. This yielded an understanding that service users were looking for a space to learn skills to help manage their experiences of hearing voices but also, importantly, the opportunity to share skills and experiences with peers. Consultation with the clinical psychologist tasked with developing the group highlighted the importance of meeting the needs of the service users whilst ensuring the group be grounded in evidence-based practice.

A pilot HVG was planned and implemented within a Gloucestershire AOT over the summer of 2018.

Aims of study

The primary aim of this study was to explore the experiences of group participants and facilitators from the pilot HVG to inform future running of the group within the locality. Additionally, this study aimed to evaluate the impact of the HVG on participants experiences of hearing voices, their self-esteem and how they related to others with similar experiences.

Method

Design

The pilot HVG was informed by the evidence suggesting CBT-based HVGs to be the most effective group format (Ruddle et al., 2011). The HVG ran for 10 weekly sessions and had a closed format. Time was spent in sessions sharing understanding of why people may hear voices, discussing cognitive and behavioural techniques for managing the experience of hearing voices and discussing negative beliefs, stigma and the social impact of hearing voices. Time was allowed weekly for group participants to share stories and skills with each other, in line with the research suggesting a balance between structured and unstructured time being important (Ruddle et al., 2014). The group also provided a unique space for other professionals, such as the team Psychiatrist and Pharmacist, to join a session to answer questions from the group.

A mixed-methods design was used. Questionnaires were included to assess the impact of the HVG on group participants and semi-structured interviews were used to explore group participants' and facilitators' experiences of the HVG.

Ethical Approval

Ethical approval (18-133) was obtained from the University of Bath prior to completion of the study. The Research and Development team within the NHS Trust granted approval for the study to be completed within the AOT (Appendix H).

Participants

Group participants. All participants were male with an age range between 24-42 years old (M=33.75, SD= 7.41). The group was open to two teams within the secondary mental health service, the AOT and the Recovery Team, however, only one participant was referred from the Recovery team; three were referred from the AOT. One female was referred to the group but a clinical decision was made that it was not appropriate to have only one female group member based on other group attendees' past difficult experiences. There was initially a fifth group participant (male) who completed pre-group measures but became unwell. His data was excluded from analysis since it was not appropriate to contact him for interview. Two group members attended all sessions, one attended nine sessions and one attended eight sessions.

Group facilitators. Two group facilitators were involved in developing and running the group. Both worked within the AOT. It had been intended that the group be co-facilitated by a Recovery team member but this was not possible due to service constraints. One facilitator was a Community-Psychiatric Nurse (female) and the other a Clinical Psychologist (male).

Survey Procedure

The main researcher attended the first session of the HVG to outline the study aims. Group participants and facilitators were given information sheets and invited to ask questions about the study before completing written consent forms (Appendix I and J). Group participants were invited to complete pre-group quantitative measures, supported by group facilitators. The main researcher was not directly involved in delivering the group but attended at the start of the first session and the final session to collect pre- and post-group quantitative measures (Appendix K).

Measures

The Psychotic Symptoms Rating Scale (PSYRATS) (hallucinations scale) (Haddock, McCarron, Tarrier, & Faragher, 1999). Group participants completed this 11-item scale with a group facilitator to assess auditory hallucinations. Questions in the scale broadly assess symptom frequency, severity and duration whilst also evaluating voice specific experiences, such as controllability, degree of negativity of voices and beliefs about the origin of voices (Haddock et al., 1999). The auditory hallucination subscale of the PSYRATS has been shown to have very good reliability and good validity (Cronbach's α 0.79, Haddock et al., 1999).

The Rosenberg Self Esteem (RSE) Scale (Rosenberg, 1965). Group participants completed this 10-item self-report measure to assess their self-esteem. The scale has been found to have good reliability and validity (Cronbach's α,0.91) (Sinclair et al., 2010).

A Multicomponent Model of In-Group Identification (Leach et al., 2008). Group participants completed this 14-item self-report measure to assess how strongly they related to other people who hear voices (their in-group). They were required to respond to statements on a 7-point Likert scale ranging from strongly agree to strongly disagree. This measure consists of five components including satisfaction, solidarity and in-group homogeneity, reflecting the idea that in-group identification is multi-faceted. It has been found to have good reliability across group identities (Cronbach's α from 0.80-0.93) and good validity (Leach et al., 2008).

Rating what participants valued about the group. Participants were asked to rank from one to four (one being most useful and four being least useful) what they valued most about the group. The potential answers to this question were developed by reviewing the literature and identifying what other studies had reported as important components in HVGs. The following answers were agreed upon between the main researcher and supervisor who had clinical and research expertise in the field:

- The impact that the group has had on how I feel about myself.

- The opportunity the group provided me to develop connections with those who have had similar experiences to me.
- Developing skills to help me to think about my experiences in a more helpful way.
- Exploring new strategies of how to improve coping with distressing experiences.

Interview Procedure

On concluding the HVG participants were invited to individually attend a short semi-structured interview to discuss their experiences of attending the group (Appendix L). Originally we had planned to gather feedback through written questionnaires but discussion with group facilitators informed the decision to invite participants to interviews to hear about their experiences. Group facilitators were invited to attend a semi-structured focus group to discuss their experiences of running the group (Appendix L). The semi-structured interview was informed by the research questions, designed to address the aims of the study. All interviews were conducted by the main researcher and were audio-recorded and transcribed. The main researcher had no professional or personal relationships with any of the group attendees but had previously worked in the AOT so had professional relationships with the group-facilitators. Participants were verbally debriefed following data collection (Appendix M).

Results

Pre and post descriptive statistics

Given the small number of participants that completed quantitative measures (N=4), statistical analysis was not used to explore the data; descriptive statistics are presented (Table 2.1) together with graphs for each variable measured (Figures 2.1, 2.2, 2.3 and 2.4).

Table 2.1
Mean scores for pre and post measures for participants attending Hearing Voices Group

Measure	Pre–group		Post-group	
	Mean	SD	Mean	SD
Auditory hallucinations	29.25	9.91	26.5	7.77
Self-esteem	29.75	5.85	30.00	6.58
In-group Identification	49.50	10.88	60.00	7.39

Auditory hallucinations. The overall quantified severity of auditory hallucinations had reduced for two participants (indicated by a lower score on the PSYRATS) at the end of the group in comparison to the beginning of the group. The overall severity of auditory hallucinations for one participant increased whilst one remained stable.

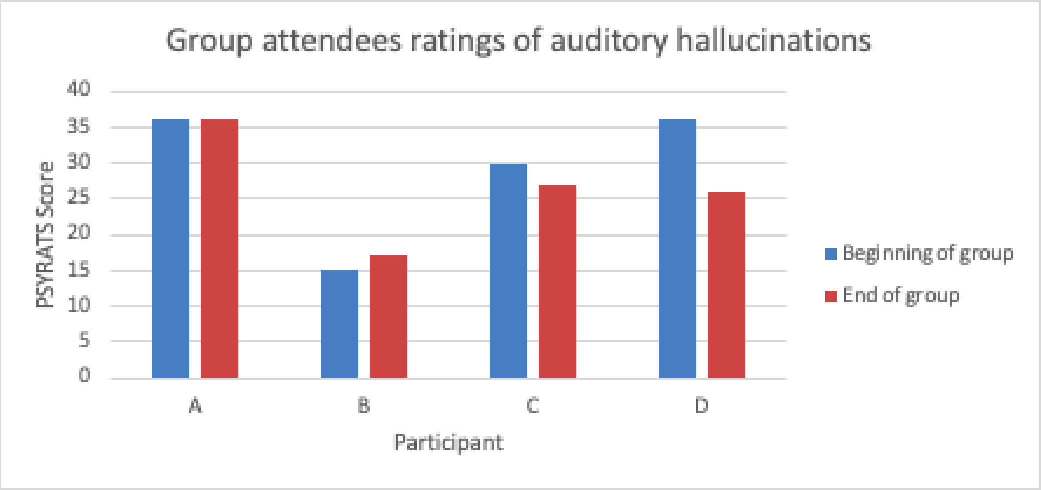

Figure 2.1 Participant ratings of auditory hallucinations pre and post Hearing Voices Group

Self-esteem. Two participants experienced an improvement in self-esteem at the end of the group (indicated by a **decrease** in scores) in comparison to the start of the group (participant B and D) whilst two participants experienced a decrease in self-esteem (indicated by an **increase** in scores).

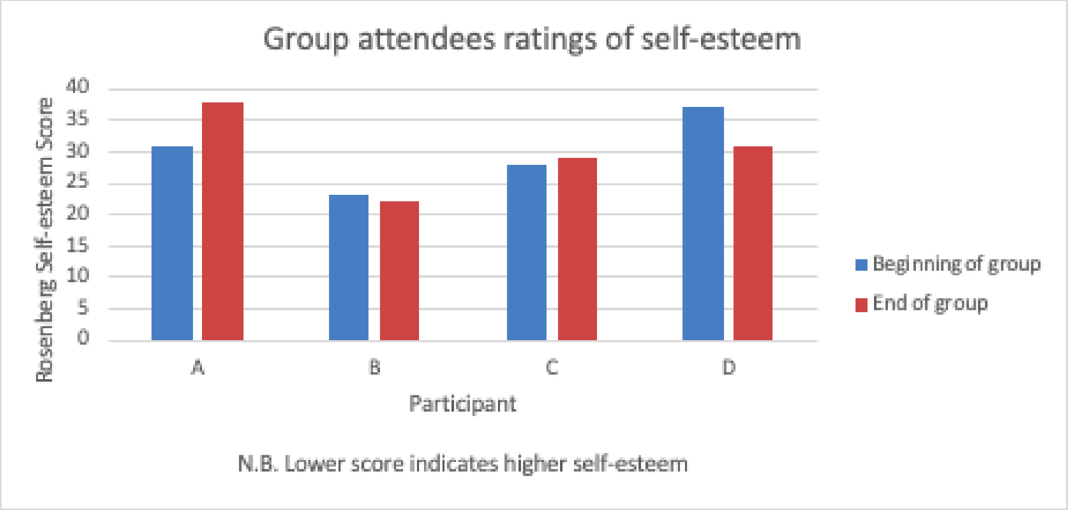

Figure 2.2 Participant ratings of self-esteem pre and post Hearing Voices Group

In-group Identification. All participants rated their in-group identification as higher (indicated by higher scores on the outcome measure) at the end of the group compared to their rating at the start of the group

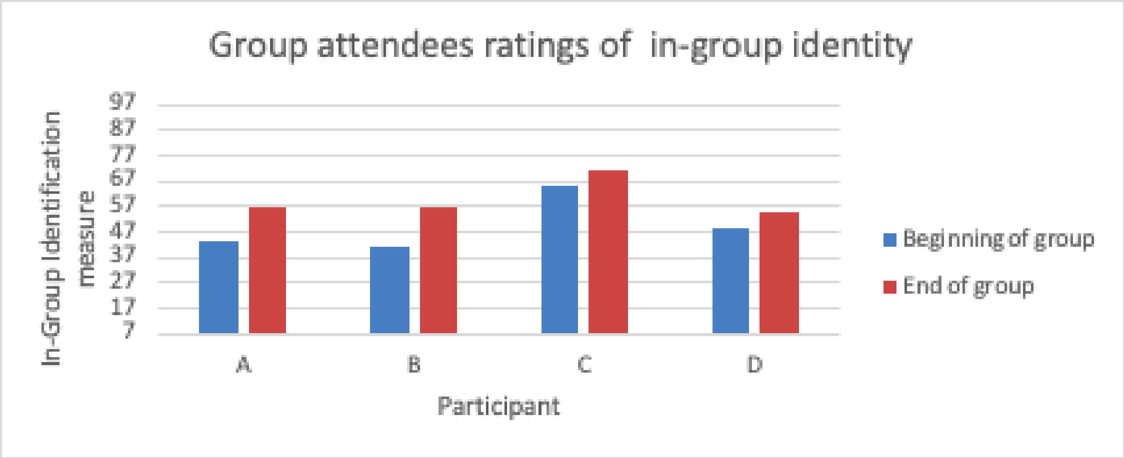

Figure 2.3 Participant ratings of in-group identification pre and post Hearing Voices Group

What service users valued most from the group. Participants reported that they valued the opportunity to connect with others within the group. Developing skills to think about experiences in a more helpful way (challenging negative beliefs) was identified as slightly more valuable than exploring new strategies to cope with distressing experiences. The impact of the group on how it made service users feel about themselves was consistently rated as the least valued aspect of the group. One service user rated all elements as equal.

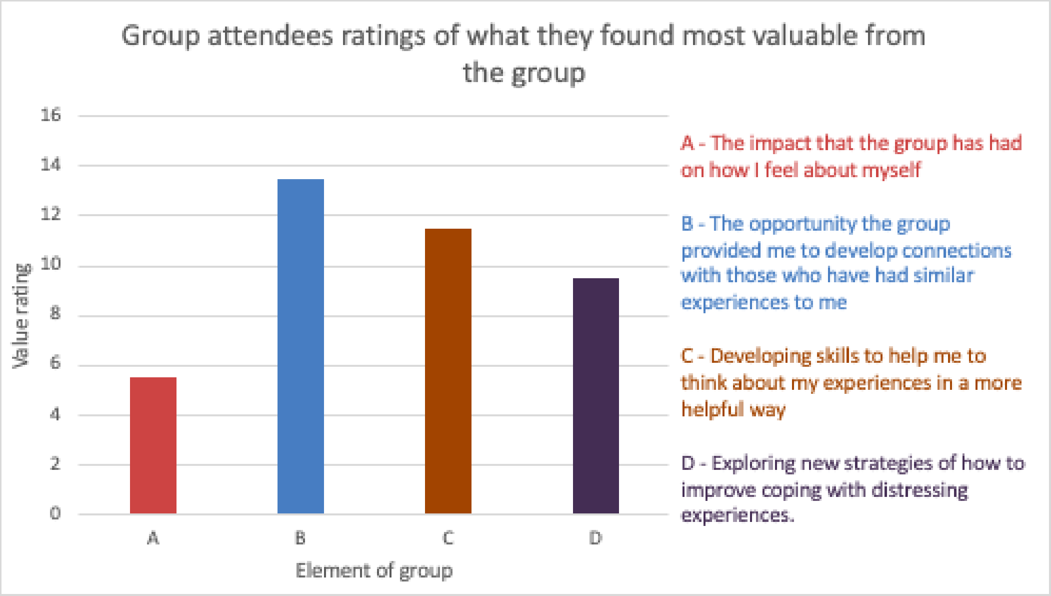

Figure 2.4 Participant ratings of what they found most valuable from the Hearing Voices Group

Qualitative Analysis

Thematic Analysis (Braun & Clarke, 2006) was used to analyse the data from the interviews. The data set consisted of interviews from all four group attendees and two group facilitators (N=6). The phases outlined by Braun and Clark (2006) were followed. The researcher first familiarised themselves with the dataset by reading all transcripts multiple times and noting initial observations. Similar data extracts were then grouped together as codes. These codes were then explored to look for themes within the data. Consultation with the project supervisor identified that participant and facilitator themes were consistent across the data so separate analysis was not necessary. Themes were then reviewed to ensure they were distinct from each other. The project supervisor identified overlap between sub-themes, so the main researcher returned to the coded data set to further review themes. Once themes were finalised, they were defined.

Analysis was primarily carried out inductively, however, the impact of the researcher's prior experience and knowledge will have influenced this process meaning pure induction would not have been possible; the primary researcher had previously worked in the Assertive Outreach team. A contextualist approach was taken, acknowledging that individuals make meaning through their own experiences and that this is influenced by societal narratives meaning there is not a "true reality" to be uncovered (Clarke, Braun, & Hayfield, 2015). Social Graces (Burnham, 1992, 2012) were considered and thought was given to the fact that the main researcher was female (gender) in her 20s (age) and a trainee Clinical Psychologist (education). Gender was a point of difference between the researcher and all group attendees whilst age and education were aspects of both similarity and difference for group attendees. These, along with other possible unvoiced and invisible aspects of difference (Burnham, 2012) will have influenced participants' responses and the interpretation of these responses.

Three overarching themes were identified by group attendees and facilitators relating to their experiences of the HVG and recommendations for improvement: 1) making connections 2) the session specifics 3) the challenges of the Hearing Voices Group (Figure 2.5).

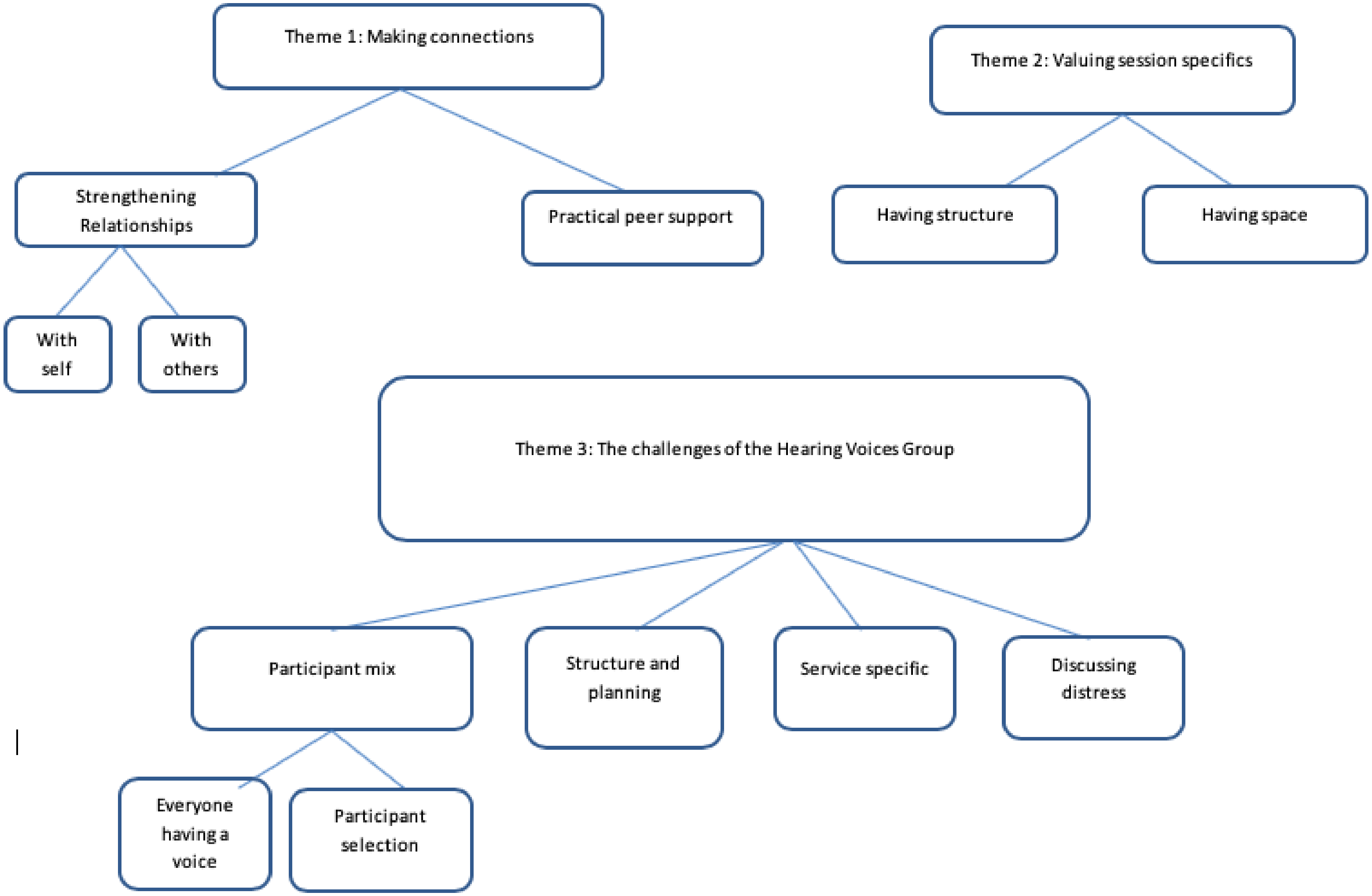

Figure 2.5 Thematic map relating to experiences of group attendees and facilitators of Hearing Voices Group

Theme 1 - Making connections

A prominent theme identified by both participants and facilitators was the opportunity that the group provided for making and strengthening connections, facilitated by exchanging experiences and practical skills.

Strengthening relationships with self. Not feeling judged, feeling understood and being listened to were referenced by participants as being associated with feeling better about themselves.

> Participant D: *"It's been helpful because really, no one really minds, yeah that's it, you can just feel comfortable knowing that people understand, it makes me feel better about where I'm at"*

Strengthening relationships with others. All participants and facilitators spoke with positive regard about the opportunity that the group provided for attendees to connect with others. Along with participants connecting over shared experiences, participants and facilitators commented on the positive impact of participants connecting with other professionals. Facilitators reflected on their own experience of the group allowing them to connect more with service users and change preconceptions.

> *Participant B: "Making those connections with others has been really good, yeah I'm not very good at socialising or being out in busy places but I do quite like meeting people"*

> *Facilitator B: "It's really nice you know; you see people in a slightly different light in that group"*

Practical peer support. A number of participants referenced the benefit of exchanging practical information about strategies and techniques to manage voices and the negative impact of voices. Facilitators referenced skill sharing as empowering and beneficial for fostering connections between attendees.

> *Participant B: "I'm hoping that people are finding my theories and ways of dealing with things helpful as well because well…that's mainly what I enjoy doing"*

> *Facilitator A: "That was the bit, the stuff that I found really good you know rather than us doing, as we normally do we come up with some coping strategies, it was to sit back and hear them say, well I do this this and this and have you tried this? and I was thinking, this is brilliant"*

Theme 2 – Valuing session specifics

Participants and facilitators spoke about their experiences of the content and organisation of weekly sessions. Interestingly, the views of facilitators and group participants were not completely aligned when it came to valuing the structure of sessions.

Having structure. All attendees spoke about valuing a plan for a session that was adhered to and led by facilitators. They referenced finding this reassuring and seemed to reflect a feeling that this separated the group from other social meetings. Group participants found sessions that were focused and boundaried most helpful. Facilitators seemed more comfortable with having less structure but reflected on being unsure of what the participants valued most.

> *Participant A: "People seem to be responding better knowing…oh next week we're going to be doing such and such and having handouts in preparation to do that"*

> *Facilitator B: "It comes to that point where I don't know if it would be better to have more structure… or less structure, you know if we kind of let them lead, then that's a ways around that I suppose, then they pick the structure and we can…we can help"*

Having space. Participants valued having a weekly space dedicated to them and their experiences. Some spoke about finding the fact that the group was there as beneficial in itself, regardless of the content covered.

> *Participant D: "sometimes you could come and, well say nothing and stare out the window, then other weeks you might say a lot, yeah that's been…it's been helpful"*

Theme 3 - The challenges of the Hearing Voices Group

Participants and facilitators highlighted a number of experiences that were challenging throughout the group, some of which they felt could be improved for future groups in order to better meet the need of the attendees.

Participant mix.

Everyone having a voice. It was difficult to ensure that everyone had the opportunity to say what they wanted to each week. Participants spoke about feeling overpowered by some group members and facilitators acknowledged the difficulty in hearing from participants equally.

> *Participant C: "Some people seem like they run it, but they are in the group"*

Facilitator A: "When people were just talking about experiences it seemed one or two people were being more vocal, and others were agreeing and were putting small snippets in, it was tricky"

Participant selection. Facilitators had to use careful clinical judgement when thinking about participant mix. This was time consuming and difficult as no one from the Recovery Team was involved in running the group. One participant wanted group members to be consistent across sessions and for information to be shared as to why someone stopped attending.

Facilitator A: "For me actually [participant selection] was the most difficult bit for the group actually … you know it's a judgement call, we discussed it with (Recovery care co-ordinator) and it's about clinical judgement"

Participant A: "You do kind of start, you know becoming interested in other people and how they're doing and what they're doing and things like that so that's, erm yeah that's important so, whoever's kind of doing the check in you know, doing apologies for people who aren't there you know saying - they're okay"

Structure and planning. Some participants said that they would like more structure in sessions set by the facilitators. Others said that they would value a co-created structure.

> *Participant A: "I'd say initially I came along, and I had expectations of some kind of structure, some kind of journey plan so… from point A to point B but that wasn't really there, that framework didn't seem to be there"*

Facilitators spoke of finding it difficult to strike the balance between structure informed by research and structure informed by group preferences.

> *Facilitator B: "Talking about you know vulnerability, bucket of stress, you know trying to introduce the cbt-ish model, just in the background just something to refer to, but I think the difficulty with that was it was trying to [pause] maybe we introduced that maybe a little bit too early it felt that we were shutting down their conversations"*

Participants and facilitators found it uncomfortable that there was no plan in place for when the group ended.

Service specific. Facilitators spoke about constraints within the service that hindered the planning and execution of the group. These included service pressures limiting the amount of time available to dedicate to group planning, the geography of the locality meaning not all who may benefit from the group could attend and the challenges of evidencing the group through outcome measures.

> *Facilitator B: "it's the organising and the practicalities, the actual group itself, similar to other groups is…easy, it's getting it organised and the time it takes just to get it up and running and all the preparation stuff"*

Discussing distress. All participants mentioned the group having a negative impact on their voices or on their mood at times throughout sessions. They spoke of this either with reference to remembering their own experiences or hearing other participants' stories.

> *Participant B: "I mean, I've walked away every now and then with my voices amplify a little bit…and erm, I struggle, however that's part of getting used to taking my guard down in a way"*

Discussion

This study explored the experiences of group participants and facilitators of a pilot HVG implemented within an AOT. It also assessed the impact of the group on participants in relation to the experience of hearing voices, their self-esteem and how they relate to others with similar experiences. The results suggest that group participants and facilitators valued the group and it yielded some positive experiences for attendees. The limited amount of data collected means that no firm conclusions can be drawn from the findings; a number of areas for improvement have been identified.

Quantitative data showed that all participants reported an increase in how much they identified with their in-group at the end of the HVG in comparison to the beginning. Social identity theory would suggest that this may have led to de-stigmatising experiences, thus increasing the amount that an individual felt connected to their “in group” (Brown, 2000; Hogg et al., 2004). This did not lead to a consistent increase in self-esteem for the group participants, likely reflecting the complex relationship that exists between the two constructs (Brown, 2000; McIntyre et al., 2018) and acknowledging the lasting impact that being part of a highly stigmatised in-group can have on an individual’s self-esteem. The group participants did not consistently experience a reduction in overall severity of auditory hallucinations, possibly explained by data in the qualitative analysis which highlighted that for some, hearing others’ experiences could result in an increase in severity of their own voices. Participants rated the opportunity the group provided them to connect with others with shared experiences as the most valued aspect of the group, which is in line with previous research (Ruddle et al., 2014). There remains a paucity of literature in relation to the mechanism of change for HVGs (Ruddle et al., 2011).

Results from the qualitative analysis indicated that all participants valued the opportunity the group provided to strengthen relationships with others and offer peer support. This is in line with previous research which has found ‘connecting with others’ and ‘feeling supported’ as highly valued by HVG participants (Oakland & Berry, 2015). Also central to what facilitators and group participants thought important to the group was the opportunity to develop skills and understanding around managing voices and this being delivered in a structured and planned way. Importantly, group participants fed this back as something they wanted more of, whilst facilitators were unsure of whether more structure was wanted. This will be beneficial for future groups. This strengthens the understanding that more research is needed into exploring the mechanism of change and factors that are central to HVGs being beneficial (Payne et al., 2017; Ruddle, 2017).

Limitations

It is important to highlight the limitations of this study. Most striking is the small number of participants from which the data is gathered. This limits the extent to which we can draw conclusions around the benefits of the group on individuals' experience of hearing voices, self-esteem and 'in group' identification. As such, firm conclusions informed by quantitative data have been avoided. Given the small number of group participants, changes to the format should continue to be reviewed to ensure it meets the needs of the majority of attendees and is not wholly informed by the experiences of the pilot group attendees. It may also be necessary to explore why the group was poorly attended in order to consider the cost-effectiveness of running the group for the service.

It is important to acknowledge that the themes from the thematic analysis do not capture the CBT nature of the group. Though themes do reference therapeutic elements that could be applicable to a wide range of therapies, such as valuing structure and feeling listened to in a non-judgemental way, components that are unique to CBT based HVGs, such as psychoeducation or thought challenging, are not highlighted as valued by participants. This is interesting as research has shown CBT-based HVGs to have the strongest evidence base. Whilst it is not possible to definitively say why participants did not mention CBT specific components of the group, it is important to consider hypothetical explanations to allow for future studies to further explore participants views on the CBT components of HVGs. One possibility could be that the facilitators willingness to be flexible with the structure of the group meant that the CBT components of the HVG did not feature as centrally as they had originally planned for them to. This will be important to monitor in the future to be sure that the group retains the CBT framework, as the evidence suggest it should in order to be most effective. It is also possible that the participants valued the trans-therapeutic components of the group over and above the CBT specific strategies and techniques. This would be important to know to ensure that an evidence base for CBT does not grow disproportionately to other approaches if it is not the CBT specific components that are the ‘active ingredient’ in HVGs. Though it is not possible to comment on participants views of the CBT specific elements in this HVG, future studies should investigate this to inform the development of future groups.

Quantitative data did not seek to establish a stable baseline on measures collected for participants pre-intervention. This limits the extent to which conclusions can be drawn around the impact of the group on participants as it is not clear whether participants’ scores were already moving in the direction they did prior to the group. Additionally, findings are limited by the absence of a control group and the fact that participants self-selected into treatment. This means no causal conclusions can be drawn about the effect of the intervention on outcome measures. The study would be further strengthened by collecting follow-up measures to see whether changes in outcomes were maintained. Exploring what participants valued most about the group was lacking the option for participants to elaborate on their answer or identify other aspects they may have valued more highly from the group.

Recommendations

Group participants and facilitators identified a number of challenges to the group including the impact of discussing distress, group related processes and service specific barriers. The following recommendations have been developed from the study with the aim of improving the HVG from its pilot phase (Table 2.2). These recommendations were fed back to the AOT Clinical Psychologist who is using them to develop the next group.

Table 2.2

Recommendations from the study aimed at improving the Hearing Voices Group in a Gloucestershire Assertive Outreach Team.

Area for development	**Recommendations for future group**
Preparation for group sessions	Consider a pre-meeting before the group starts, where attendees can hear about the aims of the group and discuss their expectations. Outline the aims of the group as being different to a purely social group to allow participants time to consider whether it is something they would like to commit to. Written material to support this would likely be beneficial. It is recommended that group participants are made aware of the possibility that conversations in the group could result in an increase in their voice hearing experience. Group participants identified this but felt unsure of why, being transparent about this may help to normalise the experience.
Structure of group sessions	
	The group should continue to spend time in the first session deciding together on group rules. It is recommended that a conversation should be had about how the group will recognise if

Area for development	Recommendations for future group
	they are going off topic / if someone is not feeling heard, and what could be done to kindly refocus the session. This has come from the feedback that facilitators and participants felt that if someone went off topic, it felt too uncomfortable to interrupt. The possibility of asking a group participant to be responsible for weekly time keeping could be discussed. It is recommended that sessions are structured with time frames dedicated to each part. This should include space for general discussion but with an awareness that it will be time limited. Though sessions should be structured, facilitators can take a flexible approach to weekly sessions by discussing with participants which order they would like to do things in sessions. Facilitators should be encouraged to experiment with different orders in response to participants' feedback.
Content of group sessions	
	Participants valued the experience to learn about different techniques for managing voices and to hear explanations as to how we understand voice hearing. It is recommended that the group

Area for development	Recommendations for future group
	maintains a CBT underpinning. Along with ensuring this remains a space for learning alongside peer support, a CBT approach is consistent with the NICE guidelines. It is recommended that facilitators acknowledge that group participants are missing and, if possible, share whether they are okay. Participants reported finding it concerning when people that they had come to connect with stopped attending the group. Ensuring everyone feels heard in the group is important. It is recommended that facilitators continue to hold a space for quieter group members to speak, even if most weeks they choose not to.
Ending the group	Facilitators and participants acknowledged the difficulty of not having a plan following the group. Towards the end of the group, it is recommended that time is spent discussing and recording in written form how participants can continue putting into practice the things they have found helpful.

Area for development	Recommendations for future group
	It is recommended that final sessions could be spaced out towards the end of the group to reduce the feeling of loss when the group ends.
Outcome monitoring	
	There is acknowledgement in the team that outcome monitoring is important but that service users find them burdensome to complete. Consideration should be given to choosing one outcome measure to be completed at assessment, at the start of the group and at the end. Establishing a baseline on an outcome measure for each client will help to better evidence the impact of the group. Alternatively, individual goals could be developed with clients before attending the group, which are measured throughout and at the end of the group.
Service specific	
	Facilitators spoke about how time-consuming setting up and running a group can be. Time should be created in facilitator's job plans to account for this and caseloads amended

Area for development	Recommendations for future group
	accordingly to allow time to be dedicated to group related tasks. This should be reviewed in supervision. Consider having the group jointly run by Assertive Outreach and Recovery clinicians to increase referrals and reduce burden on Assertive Outreach clinicians. The service should continue to review the relative benefits of providing mixed gender versus single gender groups. To ensure that male and female service users have equity of access to hearing voices groups, thought should be given to how the existing group can be adjusted to be mixed gender, or a new group developed for female service users.

Conclusions

This study has shown that the pilot HVG run in an AOT was a beneficial experience from the perspective of both group participants and facilitators for connecting with others and developing understanding and skills to manage voices. Caution is advised around generalising conclusions given the limited amount of data collected.

Recommendations for how to improve the group should be considered as well as continued evaluation in terms of its capacity to meet the needs of individuals who hear voices. Future research should aim to explore the relationship between ‘in-group’ identification and self-esteem for individuals who hear voices. This could both further understanding of how social identity operates within a stigmatised context but also inform interventions for people who have a mental health challenge associated with stigma and possible negative social identity.

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University of Bath Doctorate in Clinical Psychology

3. Main Research Project - Cognitive behavioural factors in tinnitus-related insomnia

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This is the British Society of Audiology's journal so was selected as it aims to develop a robust evidence base for audiology related issues.

Introduction

Tinnitus and sleep difficulties

Tinnitus is defined by the experience of hearing sound, commonly ringing or buzzing, in the absence of external stimuli (Beukes et al., 2017). Estimates vary, some suggesting it may affect 30% of the population (McCormack, Edmondson-Jones, Somerset, & Hall, 2016) with considerable impacts on psychological wellbeing and functioning reported by only 20% of sufferers. These estimates are limited by how tinnitus is defined and measured in the literature (McCormack et al., 2016). Common impacts of distressing tinnitus include emotional distress, anxiety, depression (Laurikainen, Johansson, Akaan-Penttila, & Haapaniemi, 2000), difficulties in sleep, relationships, work functioning and concentration (Asnis et al., 2018). A UK survey estimated societal costs of £2.7bn annually (Stockdale et al., 2017).

Those suffering with tinnitus commonly complain of sleep disturbance (Hébert, Fullum, & Carrier, 2011; Miguel, Yaremchuk, Roth, & Peterson, 2014). Our understanding of the comorbidity rates of insomnia and tinnitus is incomplete, with many tinnitus studies neglecting to use the Diagnostic and Statistical Manual of Mental Disorders (fifth edition) definition of insomnia disorder. A review examining the relationship between the two disorders (Asnis et al., 2018) found that 15 of 16 studies included in the review used variable and often inadequate assessment techniques and criteria to define insomnia. Most reported prevalence of insomnia above 40% in their tinnitus sample (Asnis et al., 2018). The remaining study used diagnostic assessment (Miguel et al., 2014) and reported an insomnia prevalence of 27%. This review led to predictions that individuals who suffer with both disorders will experience greater tinnitus distress than those with only tinnitus and highlighted that higher tinnitus-related distress is associated with greater levels of anxiety and depression.

Our understanding of why sleep disturbance is common in tinnitus is limited. One hypothesis suggests insomnia in tinnitus can be understood through the association between noise and difficulty sleeping (Izuhara et al., 2013). This study drew comparisons between the experience of living in a noisy neighbourhood and that of tinnitus, implicating tinnitus volume as maintaining insomnia. This theory is problematic since other research shows that interpretation of the tinnitus causes more distress than the sound (Basile, Fournier, Hutchins, & Hébert, 2013), making it unlikely that sleep difficulties are explained by tinnitus noise.

Insomnia disorder can co-occur with other psychological disorders, such as anxiety and depression (Harvey, 2001). Evidence showing that insomnia symptoms respond to treatment when other co-occurring disorders are not targeted and that it can precede and is a risk factor for the development of other disorders supports the idea that it is a primary disorder and not a symptom of other psychological disorders (Harvey, 2001). The cognitive model of insomnia (Harvey, 2002) proposes that insomnia arises from worry about insufficient sleep. This causes increased emotional and physiological arousal leading to selective attention and monitoring causing distorted perceptions (i.e. underestimated sleep and functioning). Such worries lead to safety-seeking behaviours intended to reduce insomnia and its impact (e.g. cancelling plans) but these often exacerbate sleep difficulties. This leads to escalating anxiety and further insomnia. Cognitive Behavioural Therapy for insomnia (CBTi) was developed to target unhelpful thoughts and behaviours around sleep through psychoeducation, behavioural experiments, sleep restriction, stimulus control and cognitive restructuring (Pigeon et al., 2012). Research shows that specifically targeting distorted perception of sleep leads to reduced sleep-related anxiety (Tang & Harvey, 2004) whilst challenging insomnia-related thoughts and behaviours enables individuals to establish healthier sleep patterns and improve quality of life (Okajima, Komada, & Inoue, 2011). A high-quality meta-analysis of RCTs using CBTi in insomnia (Okajima et al., 2011) found it to be effective, with medium to large effect sizes. Improvement on measures of dysfunctional sleep-related cognitions was a significant change following CBTi, suggesting these are central to maintaining insomnia and crucial to target in treatment.

Insomnia and comorbidities

The cognitive and behavioural characteristics that maintain insomnia are equivalent for those with or without comorbidities such as chronic pain (Tang, Goodchild, & Salkovskis, 2012). CBTi can successfully treat insomnia where comorbidities exist (Jungquist et al., 2010). Chronic pain shares many similarities with tinnitus (Moller, 2000); both are sensory perceptual disorders associated with hypersensitivity (Rauschecker, May, Maudoux, & Ploner, 2015) and related psychological difficulties, such as depression and fatigue (Rauschecker et al., 2015).

Evidence is emerging that people with insomnia and people with tinnitus may also share similar sleep processes, for example the physiological characteristics of sleep disturbance (Burgos et al., 2005). Polysomnography (PSG) is the ‘gold standard’ objective assessment for sleep disorders (measuring brain waves, heart rhythm, eye movement and other bodily functions during sleep). PSG has shown that tinnitus patients experience more awakenings and greater difficulty with sleep onset compared to healthy controls (Burgos et al., 2005), similar to when people with insomnia are compared to healthy controls.

Sleep difficulties in tinnitus studies are sometimes part of the severity assessment of the tinnitus or assessed separately as sleep quality (Alster, Shemesh, Ornan, & Attias, 1993; Izuhara et al., 2013). Attempts have been made to understand whether sleep difficulties in tinnitus share cognitive characteristics with insomnia. Crönlein et al., (2016) used the Regensburg Insomnia Scale (RIS) to assess sleep and psychological difficulties in a sample of individuals with and without tinnitus. The former experienced more difficulties with and greater worries about sleep. Conclusions from this study were limited by the use of the RIS as it is brief (10 items) and was developed as an outcome measure for CBTi, not to assess insomnia-specific thoughts and behaviours. Furthermore, there was no comparison with an insomnia group without tinnitus. This prevents exploration of similarities between tinnitus-related insomnia and insomnia without tinnitus. The authors highlighted the possibility that anxiety and depression could be confounding factors in their study stressing the need for future studies to collect anxiety and depression specific measures to mitigate for this in analyses.

Few tinnitus studies include measures of improved sleep as a primary or secondary outcome and few consider severity of sleep impairment in recruitment or analysis (Hesser, Weise, Westin, & Andersson, 2011). However, a recent clinic-based study evaluated outcomes from CBTi for tinnitus-related insomnia (Marks, McKenna, &

Vogt, 2019) and found that 66.7% of participants showed reliable improvement on the Insomnia Severity Index (ISI). Participants also reported reduced tinnitus severity and psychological distress. Though limited by the small sample size and lack of a control group, it was the first of its kind to evidence the efficacy of CBTi as a treatment for tinnitus-related insomnia. This offers tentative evidence that tinnitus-related insomnia is maintained by cognitive and behavioural processes equivalent to those seen in insomnia without comorbidities or insomnia disorder (Harvey 2002).

Summary

There is evidence that the physiological characteristics of insomnia are equivalent in populations with and without tinnitus (Burgos et al., 2006). There is also limited evidence that equivalent psychological processes may underpin the experience of insomnia in tinnitus (Crönlein et al., 2016; Marks et al., 2019). It is vital to clarify how psychological factors are associated with tinnitus-related insomnia to improve understanding of patient experiences and effective treatment of tinnitus-related insomnia.

Research aims and hypotheses

This study aimed to examine whether cognitive and behavioural factors known to maintain insomnia are important factors maintaining insomnia in people who have tinnitus. This will be achieved by comparing people with insomnia who reported distressing tinnitus (tinnitus-related insomnia) and those with insomnia without significant comorbidities (insomnia) with those with at least moderately distressing tinnitus who sleep well (tinnitus good sleepers) and people without distressing tinnitus or insomnia (controls). The following hypotheses were made:

1. Insomnia-related cognitions reported by people with tinnitus-related insomnia will be significantly greater than tinnitus good sleepers and controls, after controlling for depression and anxiety.

2. Insomnia-related behaviours reported by people with tinnitus-related insomnia will be significantly greater than tinnitus good sleepers and controls, after controlling for depression and anxiety.

3. Sleep quality reported by people with tinnitus-related insomnia will be significantly worse (indicated by higher score on measure) than tinnitus good sleepers and controls, after controlling for depression and anxiety.

4. Tinnitus distress, anxiety and depression will be significantly higher in tinnitus-related insomnia compared with tinnitus good sleepers.

5. Self-reported tinnitus volume will not differ significantly between tinnitus-related insomnia and tinnitus good sleepers.

Method

Design

This cross-sectional study used a between-groups design in which four groups were compared: 1) tinnitus-related insomnia; 2) insomnia; 3) tinnitus good and 4) controls. All responses were collected via the online platform Qualtrics.

Ethics and study development

The study received ethical approval from The University of Bath (reference: Ethics 18-245, received 05.11.18; Appendix O). The British Tinnitus Association piloted the initial questionnaire with 20 people with personal experience (PPE) of tinnitus, and their feedback informed study design. The questionnaire was deemed highly acceptable; feedback focused on question layout that was amended on their recommendations. Results from the pilot questionnaires were included in the study.

Inclusion / Exclusion criteria

Inclusion criteria was a minimum age of 18. Exclusion criteria were existing diagnosis of a sleep disorder other than insomnia, or belief that their insomnia was explained by a physical or mental health condition besides tinnitus.

Recruitment

We recruited via Twitter and Instagram. Relevant charities were contacted and agreed to share the study on their websites.

Procedure

All participants reviewed the information about the study (Appendix P) and provided full, informed consent (Appendix Q). They completed initial questions to assess presence of tinnitus and their view on the level of associated distress. They then completed The Insomnia Severity Index (ISI; Morin, 1993). It was agreed a-priori that this information would be used to sort participants into one of the four groups (Figure 3.1).

A maximum limit of 45 completed data sets was placed on each group to ensure groups were sufficiently equal in size (Appendix R for questionnaire). Debrief information included signposting to relevant support for participants experiencing distress (Appendix S).

Sample

A total of 773 participants initiated the study, of which 266 did not consent, and 73 exited the survey before completion. Significantly more (N=253) met criteria for the controls and tinnitus-related insomnia group than planned for and were prevented from taking part. Qualtrics error meant the controls group continued collecting passed the count of 45. One participant was excluded as they wrote “333” in all free-text boxes. The final sample consisted of 180 participants who had completed all questionnaires (all but the GAD-7 and PHQ-9 were counted as complete data sets). This was broken down as follows: tinnitus-related insomnia (N=49); tinnitus good sleepers (N=38); insomnia (N=34) and controls (N 59). Twelve in the insomnia group and 23 in the controls group reported tinnitus as either no or a minor problem.

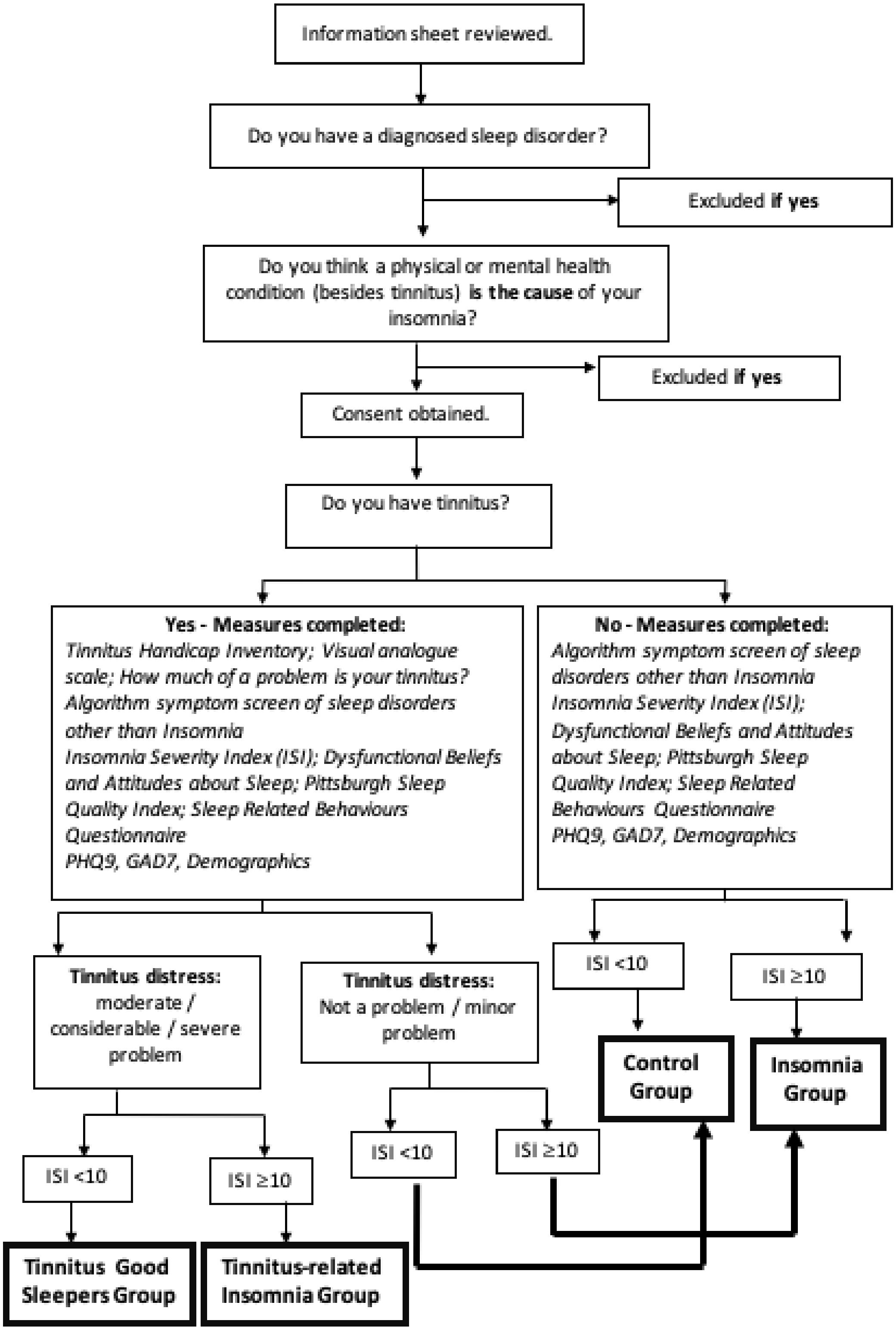

Figure 3.1 Flow chart for recruitment strategy for Main Research Project

Measures

All participants completed the following self-report questionnaires:

The Insomnia Severity Index (ISI; Morin, 1993). This 7-item measure uses a five point Likert scale, ranging from 0 to 4 and offers a clinically-relevant tool for assessing insomnia, The ISI has good reliability and validity (Bastien, Vallières, & Morin, 2001). A score of 10 or above is deemed appropriate for identifying clinically-relevant insomnia in a community sample (Morin, Belleville, Bélanger, & Ivers, 2011).

The Pittsburgh Sleep Quality Index (PSQI) (Buysse et al., 1989). This 18-item measure produces seven component scores and one overall global score relating to quality of sleep. Question 10 was omitted from administration as it does not contribute to the PSQI global score. This measure has acceptable internal consistency (Cronbach's α =0.75) (Hinz et al., 2017). Participants who entered ranges for times were allocated a mid-point.

Dysfunctional Beliefs and Attitudes about Sleep (DBAS-16) (Morin, Vallières, & Ivers, 2007). The DBAS-16 evaluates an individual's sleep-disruptive cognitions, many of which become the target of CBTi (Morin et al., 2007). Participants are asked to respond to statements relating to beliefs and attitudes about sleep on a Likert scale ranging from 0 (strongly disagree) to 10 (strongly agree). The DBAS-16 has been shown to have acceptable validity and reliability (Cronbach's α= 0.77-0.79) (Morin et al., 2007).

Sleep Related Behaviours Questionnaire (SRBQ) (Ree and Harvey, 2004). This measures the extent to which an individual engages in sleep-related safety behaviours known to maintain insomnia. Participants respond to 32 statements in regard to how often they engage in each behaviour, rating from 0 (almost never) to 4 (almost always). The psychometric properties of the SRBQ have not been systematically evaluated (Lebrun, Gély-Nargeot, Maudarbocus, & Bayard, 2020). It has been shown to have good sensitivity to detect change in psychological therapy for insomnia (Harvey, Sharpley, Ree, Stinson, & Clark, 2007) so is the best available measure. Cronbach's α= .94 for this sample, indicating excellent internal consistency.

The Sleep Diagnostic Algorithm (Wilson et al., 2010). This brief screen for organic sleep disorders (other than insomnia) consists of five lead questions, relating to Narcolepsy, Sleep Apnoea, Restless Leg Syndrome, Circadian Rhythm Sleep Disorder and Parasomnia. The respondent is asked subsequent questions if 'yes' is answered to the lead question. An algorithm is used to calculate the possibility of an organic sleep disorder based on answers given. The screen is not diagnostic, so no participants were excluded based on their responses.

The Generalised Anxiety Disorder Assessment (GAD-7) (Spitzer, Kroenke, Williams, & Löwe, 2006). This 7-item scale assesses anxiety symptoms over the past two weeks. Participants rate anxiety experiences from 0 (not at all) to 3 (nearly every day). Internal consistency of the GAD-7 is excellent (Cronbach's α = 0.92) and good test-retest reliability (α =0.83) (Spitzer et al., 2006). A score between 11 and 15 reflects moderate anxiety, above 15 indicates severe anxiety.

The Patient Health Questionnaire (PHQ-9) (Kroenke, Spitzer, & Williams, 2001). This 9-item scale assesses depression symptoms over the past two weeks, with respondents rating how much they were bothered by symptoms from 0 (not at all) to 3 (nearly every day). The scale has good internal consistency (Cronbach's alpha = 0.89) and good test-retest reliability (α =0.84). A score between 10 and 14 reflects moderate depression, 15-19 indicates moderately severe depression and above 19 indicates severe depression.

Demographic information. A variety of demographic information was collected including age, gender, ethnicity and shift work, as this is known to impact on sleep and circadian rhythms (Boivin & Boudreau, 2014).

The following measures were *only* completed by those who identified as having tinnitus.

Tinnitus-related distress. Participants were asked to rate how much of a problem their tinnitus was. Respondents chose between 'not a problem', 'minor problem', 'moderate problem', 'considerable problem' or 'severe problem'. Categories were informed by research looking at categories of tinnitus-related distress (Handscomb, 2006).

Tinnitus Handicap Inventory (THI) (Newman, Jacobson, & Spitzer, 1996). This 25-item measure requires participants to respond yes, no or maybe to statements about their tinnitus to assess the severity of its impact on day-to-day life. The THI has been found to have high internal consistency (Cronbach's α = 0.92).

Tinnitus Visual Analogue Scale (VAS). This assesses subjective loudness of tinnitus. Participants selected from 0 (I can't hear my tinnitus, even in quiet) to 100 (my tinnitus is louder than any other noise) where they would currently rate their tinnitus. A Cochrane review of CBT for Tinnitus (Martinez-Devesa, Perera, Theodoulou, & Waddell, 2010) found numeric visual analogue scales used in seven of the eight included studies, though variation in presentation was noted. Single item ratings, though limited, have been found to be more reliable than tinnitus loudness matching (Hall, Mehta, & Fackrell, 2017)

Power analysis

A power calculation was conducted a priori using G*Power. This indicated that 180 participants would be required (45 per group) to find a medium effect size (power = 0.8, α= 0.05) for a one-way ANCOVA with four groups.

Data analysis

Data was analysed using IBM SPSS v.25. Differences in participant demographics and general psychological characteristics (PHQ-9 and GAD-7) were explored across participant groups using one-way ANOVA for continuous variables and chi-squared tests for categorical variables. Differences in anxiety and depression were tested using a non-parametric Kruskal-Wallis H test as both variables were non-normally distributed and no sensible transformations were identified.

ANCOVA's were planned *a priori* to test for differences between groups for insomnia-related cognitions, behaviours and sleep quality when controlling for depression and anxiety. However, the assumption of homogeneity of regression slopes was violated, so linear regression analysis was used to test for participant group differences (while controlling depression and anxiety). For each outcome, models were fitted in hierarchical blocks [Block 1: age and gender (female vs male); Block 2: anxiety and depression; Block 3: participant group (4 levels)] to test the incremental contribution of each set of variables to improvements in model fit (change in F-statistic and R_2). Ethnicity was excluded from all regression models as there were too few non-White participants to make meaningful inferences. Pairwise differences between groups were tested post hoc from a full model including all covariates, with a Bonferroni correction for multiple tests. Differences between the tinnitus-related insomnia and tinnitus good sleepers groups were explored using t-tests and Mann-Whitney U tests depending on the distribution of the outcome.

Results

Participant demographics

Demographic characteristics are presented in Table 3.1. Given small cell sizes for some variables, responses were collapsed such that there were two categories for each characteristic (e.g. Male vs Female, White vs non-White).

The tinnitus-related insomnia group were found to be significantly older than the insomnia and control groups ($F_{(3,176)} = 6.59$, $p < .001$). Significant differences were also observed for marital status, $X_2(3, N=176) = 10.7$, $p = .013$, and ethnicity, $X_2(3, N=176) = 14.7$, $p = .002$, whilst no differences were observed with regard to gender, education level and current employment. Table 3.2 presents summary scores across all measures. A Kruskal-Wallis H test showed significant differences between participant groups for both anxiety, $H(3) = 39.60$, $p < .001$ and depression, $H(3) = 71.7$, $p < .001$. Tinnitus-related insomnia and insomnia groups had significantly greater ($p < .01$ for all) levels of anxiety and depression compared to tinnitus good sleepers and controls. Tinnitus-related insomnia compared with insomnia groups and controls compared with tinnitus good sleepers groups did not differ significantly.

Table 3.1

Demographic characteristics of participants in study exploring cognitive-behavioural factors in tinnitus-related insomnia

Demographics	**Insomnia**	**Tinnitus-related insomnia**	**Tinnitus good sleepers**	**Controls**	**P-value**
Age (N=180) M (SD)	34.97$_b$ (15.29)	48.86$_a$ (11.39)	43.08$_a$ (16.27)	41.53$_b$ (14.19)	<.001
Gender (N=178)					
Male	13 (38.2)	21 (42.9)	17 (44.7)	14 (24.6)	0.14
Female	21 (61.8)	28 (57.1)	21 (55.3)	43 (75.4)	
Marital Status (N=176)					
Married/living with partner	13 (38.2)	25 (52.1)	24 (63.2)	40 (71.4)	0.013
Not married/unpartnered	21 (61.8)	23 (47.9)	14 (36.8)	16 (28.6)	
Ethnicity (N=176)					
White	25 (73.5)	47 (97.9)	35 (92.1)	52 (92.9)	0.002
Non-white	9 (26.5)	1 (2.1)	3 (7.9)	4 (7.1)	
Education (N=176)					
Tertiary/further	22 (64.7)	34 (70.8)	29 (76.3)	44 (78.6)	0.49
Less than tertiary/other	12 (35.3)	14 (29.2)	9 (23.7)	12 (21.4)	
Employment (N=176)					
Full-time	15 (44.1)	24 (50.0)	19 (50.0)	29 (51.8)	0.92
Not full-time	19 (55.9)	24 (50.0)	19 (50.0)	27 (48.2)	

Shift /night work (N=176)					
Yes	3 (8.8)	6 (12.5)	4 (10.5)	2 (3.6)	0.40
No	31 (91.2)	42 (87.5)	34 (89.5)	54 (96.4)	

P-values are derived from chi-squared tests for categorical variables and t-tests for continuous variables. Values in cells are expressed as n (%) unless otherwise specified. a, b values sharing super scripts do not differ (p>.05)

Table 3.2

Summary of measures completed across groups in study exploring cognitive-behavioural factors in tinnitus-related insomnia

Group / Measure	Mean (SD)	Range
Insomnia		
ISI (N=34)	15.68 (3.54)	10-23
DBAS-16 (N=34)	5.77 (1.48)	1.81-8.06
SRBQ (N=34)	64.74 (17.87)	27-91
PSQI (N=34)	11 (2.98)	5-16
GAD-7 (N=34)	10.71(5.32)	0-21
PHQ-9 (N=34)	12.15 (5.92)	3-25
THI (N=12)	26.33 (13.59)	6-48
VAS (N=12)	41.17 (18.93)	11-66
Tinnitus-related insomnia		
ISI (N= 49)	16.63 (4.05)	10-25
DBAS-16 (N= 49)	5.85 (1.51)	2.81-9.63
SRBQ (N= 49)	55.24 (17.56)	12-86
PSQI (N= 49)	10.67 (2.75)	4-17
GAD-7 (N=48)	9.50 (6.00)	0-21
PHQ-9 (N=48)	12.29 (6.79)	1-26
THI (N= 49)	58.16 (22.95)	10-98
VAS (N= 49)	70.51(19.82)	25-100
Tinnitus good sleepers		
ISI (N=38)	4.39 (2.71)	0-9
DBAS-16 (N=38)	3.51 (1.52)	0.63-6.50
SRBQ (N=38)	30.87 (13.80)	4-59
PSQI (N=38)	4.58 (2.14)	2-11
GAD-7 (N=37)	5.62 (4.68)	0-17
PHQ-9 (N=38)	4.77 (4.77)	0-20
THI (N=38)	41.9 (21.62)	6-88
VAS (N=38)	60.45 (19.60)	15-100
Controls		
ISI (N=59)	4.37 (2.65)	0-9
DBAS-16 (N=59)	3.21 (1.48)	0.38-6.69

SRBQ (N=59)	33.75 (19.44)	0-83
PSQI (N=59)	5.07 (2.43)	1-11
GAD-7 (N=58)	4.79 (3.82)	0-19
PHQ-9 (N=57)	4.04 (4.14)	0-23
THI (N=36)	19.50 (16.55)	16-92
VAS (N=36)	43.61 (19.16)	1-74

Table 3.3

F-statistics, R-squared, and change in R-squared values derived from hierarchical linear regression models predicting sleep-related cognitions (DBAS-16) / behaviours (SRBQ) / sleep quality (PSIQ) from age, gender, anxiety, depression and group

Model	**Block**	**Variables**	**F**	**df**	**P**	**R_2**	**ΔR_2**
DBAS-16	1	Age, gender	0.28	2	0.76	0.00	--
(n=172)	2	Anxiety, Depression	64.3	2	<.001	0.44	0.44
	3	Group	10.5	3	<.001	0.53	0.09
SRBQ	1	Age, gender	0.78	2	0.17	0.02	---
(n=174)	2	Anxiety, Depression	71.6	2	<.001	0.47	0.45
	3	Group	9.56	3	<.001	0.55	0.08
PSQI	1	Age, gender	.08	2	0.93	0.00	-
(n=174)	2	Anxiety, Depression	5.72	2	<.001	0.47	0.47
	3	Group	10.43	3	<.001	0.66	0.19

df, degrees of freedom

Table 3.4

Effect estimates, adjusted 95% confidence intervals, and adjusted and unadjusted p-values

Model	Comparison	Estimate	95% CI	P_{adj}	P_{unadj}
DBAS-16	Tinnitus Related Insomnia– Insomnia	-0.04	-0.88 - 0.80	1.00	0.90
	Tinnitus Related Insomnia – Tinnitus Good Sleepers	1.41	0.51 - 2.23	<.001	<.001
	Tinnitus Related Insomnia– Controls	1.45	0.60 -2.31	<.001	<.001
	Insomnia - Tinnitus Good Sleepers	1.46	0.53-2.38	<.001	<.001
	Insomnia – Controls	1.49	0.62-2.37	<.001	<.001
	Tinnitus Good Sleepers – Controls	0.04	-0.72-0.80	1.00	0.90
SRBQ	Tinnitus Related Insomnia– Insomnia	-9.20	-18.60 - 0.21	0.06	0.01
	Tinnitus Related Insomnia – Tinnitus Good Sleepers	11.18	1.13-21.23	0.02	<.001
	Tinnitus Related Insomnia– Controls	6.90	-2.61-16.42	0.33	0.06
	Insomnia - Tinnitus Good Sleepers	20.38	10.01-30.74	<.001	<.001
	Insomnia – Controls	16.10	6.31-25.89	<.001	<.001
	Tinnitus Good Sleepers – Controls	-4.28	-12.77- 4.22	1.00	0.18
PSQI	Tinnitus Related Insomnia– Insomnia	-1.03	-2.52- 0.45	0.40	0.07
	Tinnitus Related Insomnia – Tinnitus Good Sleepers	4.15	2.56- 5.73	<.001	<.001
	Tinnitus Related Insomnia– Controls	3.44	1.94- 4.94	<.001	<.001
	Insomnia - Tinnitus Good Sleepers	5.18	3.54-6.82	<.001	<.001
	Insomnia – Controls	4.47	2.93-6.02	<.001	<.001
	Tinnitus Good Sleepers - Controls	-0.71	-2.05-0.62	0.97	0.16

Note. Model is adjusted for age, gender, anxiety and depression. P_{adj} *are adjusted using the Bonferonni method;* P_{unadj} *are not corrected for multiple comparisons.*

After exclusions for missing data on the outcome or covariates, 174 participants were included in the regression analysis (34 in the insomnia group, 48 in the tinnitus-related insomnia group, 37 in the tinnitus good sleepers group, and 55 controls).

Sleep-related cognitions

Results from a hierarchical regression model of sleep-related cognitions (DBAS-16 score) showed that the addition of anxiety and depression scores to predict sleep-related cognitions (DBAS-16 score) led to a statistically significant increase in R_2 ($\Delta R_2 = 0.44$, $F(2, 170) = 64.3$ $p<.001$, as did the addition of group, $\Delta R_2 = 0.09$, $F(3, 169) = 10.5$ $p<.001$. Post-hoc pairwise comparisons showed that the tinnitus-related insomnia group scored significantly higher on sleep-related cognitions compared to the tinnitus good sleepers, difference = 1.41, 95% CI [0.51, 2.23] and controls, difference = 1.45, 95% CI [0.60, 2.31]. The insomnia group scored significantly higher on sleep-related cognitions compared to the tinnitus good sleepers, difference = 1.46, 95% CI [0.53, 2.38] and controls, difference =1.49, 95% CI [0.62, 2.37]. The insomnia group had higher sleep-related cognitions than the tinnitus-related insomnia group, but this difference was not significant: difference = 0.04, 95% CI [-0.88, 0.80], nor was the difference between the tinnitus good sleepers and controls, difference = 0.04, 95% CI [-0.72, 0.80].

Sleep-related behaviours

Results from a hierarchical regression model of sleep-related behaviours (SRBQ scores) showed that the addition of anxiety and depression led to a statistically significant increase in R_2; $\Delta R_2 = 0.45$, F(2, 172) = 71.6, $p<.001$, as did addition of participant group, $\Delta R_2 = 0.08$, F(3, 171) = 9.56, $p<.001$. Post-hoc pairwise comparisons showed that the insomnia group scored highest on the SRBQ compared to other groups, with the difference between group means being significant for the tinnitus good sleepers, difference = 20.38, 95% CI [10.01, 30.74] and controls, difference = 16.10, 95% CI [6.31, 25.89]. Though the insomnia group scored higher on average than the tinnitus-related insomnia group, the difference between group means was not significant, difference = -9.20, 95% CI [-18.60, 0.21]. The tinnitus-related insomnia group scored significantly higher than the tinnitus good sleepers, difference = 11.18, 95% CI [1.13, 21.23] but not the controls, difference =6.90, 95% CI [-2.61, 16.42]. The tinnitus good sleepers group scored lower than the controls for sleep-related behaviours, but this difference was not significant, -4.28, 95% CI [-12.77, 4.22].

Overall sleep quality

Results from a hierarchical regression model of overall sleep quality scores (PSQI score) showed that the addition of anxiety and depression led to a statistically significant increase in R_2; $\Delta R = 0.47$, F(2, 172) = 5.72, $p<.001$, as did addition of participant group, $\Delta R_2 = 0.19$, F(3, 171) = 10.43, $p<.001$. Post-hoc pairwise comparisons showed that the tinnitus-related insomnia group had significantly worse sleep quality (indicated by higher score) compared to the tinnitus good sleepers, difference = 4.14, 95% CI

[2.56, 5.73] and controls, difference = 3.44, 95% CI [1.94, 4.94]. The insomnia group scored significantly higher on sleep quality compared to the tinnitus good sleepers, difference = 5.18, 95% CI [3.54, 6.82] and controls, difference = 4.47. 95% CI [2.93, 6.02]. The tinnitus-related insomnia group had better sleep quality than the insomnia group, but this difference was not significant, difference = -1.03, 95% CI [-2.52, 0.45], nor was the difference between the tinnitus good sleepers and controls, difference = -0.71, 95% CI [-2.05, 0.62].

Tinnitus loudness and tinnitus distress between tinnitus-related insomnia and tinnitus good sleeper groups

The tinnitus-related insomnia group had greater tinnitus distress (*M*=58.54, *SD*=23.04) compared to the tinnitus good sleepers' group (*M*=41.9, *SD*=21.62). This difference was significant (16.64, 95% CI [6.91, 26.28]). The tinnitus-related insomnia group experienced significantly louder subjective tinnitus volume compared to the tinnitus good sleepers group (Median difference = 10, $U = 626$, $z = -2.61$, $p = 0.09$). As this was unexpected, post-hoc one-way ANCOVA explored whether sleep-related cognitions (DBAS-16) and behaviours (SRBQ) differed between the two groups when controlling for tinnitus loudness (VAS) and distress (THI). The tinnitus-related insomnia group had significantly greater insomnia cognitions, $F(1, 83) = 35$, $p < .001$, partial $\eta_2 = .3$, and behaviours, $F(1, 83) = 33.1$, $p < .001$, partial $\eta_2 = .29$, compared to tinnitus good sleepers when controlling for tinnitus distress and loudness, in line with the findings from the main analysis.

Discussion

This study has found that individuals with tinnitus-related insomnia experience the same level of dysfunctional sleep-related cognitions and behaviours as individuals with insomnia without tinnitus. It also found that such sleep-related cognitions and behaviours are significantly greater in tinnitus-related insomnia than people with distressing tinnitus who sleep well and people with neither insomnia nor distressing tinnitus. Together, these findings support the claim that cognitive behavioural processes known to contribute to the maintenance in insomnia (Harvey, 2002), may also contribute to the maintenance of tinnitus-related insomnia.

This study has developed the evidence for possible maintaining factors that might explain how sleep difficulties and tinnitus are associated. The key hypotheses were upheld: that people with tinnitus-related insomnia reported greater levels of unhelpful sleep-related cognitions, behaviours and sleep quality than those reported by tinnitus good sleepers. Importantly, levels of unhelpful sleep-related cognitions, behaviours and sleep quality were not significantly different between people with tinnitus-related insomnia and the insomnia group. This adds significant weight to the literature regarding shared cognitive characteristics between the two experiences of insomnia, i.e. with and without tinnitus (Crönlein et al., 2016). Considering existing evidence in support of shared biological characteristics between insomnia and tinnitus-related insomnia (Burgos et al., 2005), these findings support a bio-psycho-social model of tinnitus-related insomnia.

As expected, levels of anxiety, depression and tinnitus-related distress were higher in people with tinnitus-related insomnia. This is explained by theory that sleep difficulties lead to greater anxiety and depression symptoms and are likely to be associated with elevated tinnitus distress (Asnis et al., 2018). An unexpected finding in our study was that tinnitus subjective volume was louder for those with tinnitus-related insomnia than for those who sleep well. We had not anticipated this as we know tinnitus distress not to be directly associated with the volume of tinnitus experienced (Basile et al., 2013). Whilst this may represent a novel difference between people with tinnitus-related insomnia and those without insomnia further research is needed to draw firm conclusions. Most importantly, significant differences between sleep cognitions, behaviours and quality reported by tinnitus-related insomnia and tinnitus good sleepers remain even after tinnitus severity and volume are accounted for. This finding suggests that the claim that tinnitus noise could be the key factor that prevents people from sleeping (Izuhara et al., 2013) may be inaccurate.

One unexpected finding was a lack of significant difference in sleep-related behaviours between those with tinnitus-related insomnia and controls. One possible explanation may relate to the recruitment strategy whereby recruitment of tinnitus groups directly focused on sleep whilst recruitment of the control group took a broader approach. However the more important finding here is that the tinnitus-related insomnia group reported sleep-related behaviours equivalent to the insomnia group and greater than tinnitus good sleepers, in line with the cognitive behavioural model of insomnia (Harvey, 2002).

Strengths

This is the first study that has compared insomnia related thoughts and behaviours reported by people with tinnitus to people with insomnia, tinnitus good sleepers and individuals without distressing tinnitus or insomnia. The use of multiple comparators is a key strength as it allows for clarification of similarities and differences across all groups and highlights how similar cognitive behavioural factors in tinnitus-related insomnia are to insomnia without tinnitus. The use of a diagnostic tool to assess for insomnia is scarce within tinnitus literature (Asnis et al., 2018) and the robustness of measures collected across the sample is another strength.

Limitations

The possibility of participants having undiagnosed sleep disorders, besides insomnia is a limiting factor. Although a sleep screen was used to assess for the possibility of undiagnosed sleep disorders, it was brief meaning those who met criteria may not have an undiagnosed sleep disorder. For this reason, no participants were excluded from the study based on this screen. Future studies should aim to conduct more rigorous assessments for the presence of sleep disorders through clinical assessment.

This study is limited by the samples lack of ethnic diversity. The insomnia group had more diverse ethnicity and age, possibly as the primary method of recruitment was via Instagram whilst the tinnitus-related insomnia and tinnitus good sleepers groups were recruited via Twitter. Future studies should set out an a-priori strategy relating to recruiting a more ethnically diverse sample to allow conclusions from studies to be more representative of society.

Some participants allocated to the insomnia or control group also reported tinnitus. This is because allocation of participants to groups was based on participant self-selection of tinnitus distress, rather than score on a tinnitus measure. Interestingly, there was a mismatch, with some self-reported ‘mild’ or ‘no’ tinnitus sufferers meeting criteria for moderate tinnitus on the THI. This could mean that sleep related cognitions and behaviours measured in the controls and insomnia groups are impacted by the presence of tinnitus. This would limit the extent to which comparisons between the tinnitus related insomnia and insomnia groups can be drawn. Using the THI to sort participants into groups would have avoided this limitation. However, this would require every person in the study to complete the 25-item tinnitus questionnaire (THI). Along with increasing questionnaire burden, this could cause confusion for participants who say they experience no tinnitus as they would be asked to respond to statements such as “because of your tinnitus do you feel desperate?”. As there are clearly pros and cons to each method of grouping criteria, future studies should consider the limitations of both methods prior to undertaking their study.

Given the clearly defined hypotheses in this study, the methodology would have been strengthened by the a priori statistical analysis plan setting out planned comparisons to reflect the differences predicted between groups. These would been preferable to an ANCOVA as they would increase the statistical power of the comparisons by reducing the chance of Type I errors. Researchers should be encouraged to consult with statisticians to develop an analytic strategy prior to undertaking their study to ensure a robust analysis plan.

Conclusions and clinical implications

This study demonstrates that insomnia-related cognitive and behavioural processes are very similar in people with insomnia both with and without associated tinnitus, and that these are different from people with tinnitus who sleep well. The study replicates findings that people with both tinnitus and insomnia report greater anxiety, depression and tinnitus-related distress than tinnitus sufferers without insomnia (Asnis et al., 2018) but shows that such insomnia related cognitions and behaviours remain important even when such differences are accounted for. This suggests that difficulties with sleep reported by many tinnitus sufferers can be understood by recognising that they are engaging in key sleep-related thoughts and behaviours that are stopping them from sleeping, as reported by people with insomnia and explained by the Cognitive Behavioural model of insomnia (Harvey, 2002).

CBTi has been shown to work with insomnia co-occurring with other physical health problems, such as chronic pain (Jungquist et al., 2010; Tang et al., 2012) and early evidence has suggested it may also be effective in tinnitus-related insomnia (Marks et al., 2019). The findings from this study supports emerging evidence that people presenting with tinnitus-related insomnia could benefit from treatments already known to work effectively on people with insomnia disorder, such as CBTi, targeting sleep-related cognitions and behaviours.

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4. Executive Summary

Main Research Project

Background. Individuals who experience tinnitus often go on to develop insomnia as a secondary difficulty. Our understanding of the thoughts and behaviours that maintain the insomnia are limited. Given the effectiveness of Cognitive Behavioural Therapy for insomnia (CBTi), it would be useful to discover whether the thoughts and behaviours maintaining insomnia in individuals with tinnitus and individuals in which insomnia is their main concern are shared. This study aimed to explore these maintaining thoughts and behaviours to shed light on potential treatment options that could benefit individuals who experience tinnitus-related insomnia.

What we did. Recruitment took place online. We recruited four groups of people - people who had tinnitus that was at least moderately distressing and insomnia (N=48), people who had tinnitus that was at least moderately distressing and slept well (N=38), people with insomnia without other related difficulties (N=34) and people who did not have distressing tinnitus or insomnia (N=59). All participants gave consent to take part and completed questionnaires relating to insomnia severity, sleep quality, sleep-related thoughts, sleep-related behaviours, anxiety, depression, tinnitus distress and tinnitus volume. We used statistical tests to explore whether being in a certain group was significant in relation to sleep-related thoughts and behaviours. When we found that it was significant, we looked to see how the groups were different to compare them to each other.

What we found. People with tinnitus-related insomnia had more sleep-related thoughts and behaviours, and worse overall sleep quality than people with tinnitus who are good sleepers and those without tinnitus or insomnia. People with tinnitus-related insomnia had similar sleep-related thoughts and behaviours as those who have insomnia without other related difficulties. We also found that sleep quality was worse for people with tinnitus-related insomnia than those who have tinnitus and sleep well. They also had higher anxiety and depression symptoms, greater tinnitus-related distress and louder tinnitus volume than people with tinnitus who slept well.

Why this matters. Our findings suggest that the thoughts and behaviours maintaining insomnia in individuals with tinnitus and individuals in which insomnia is their primary concern are shared. This means they should have access to CBTi to treat their insomnia symptoms.

Service Improvement Project

Background. Hearing voices can be highly distressing and can lead people to experience stigma, isolation and low self-esteem. Feeling more connected to other people who hear voices could have a positive impact on wellbeing. Hearing Voices Groups (HVGs) are increasing in popularity in the NHS and allow voice hearers to connect with others who have shared experiences. This study aimed to evaluate a new HVG that was being run in an NHS mental health service in Gloucestershire. We wanted to hear how group attendees and facilitators experienced the group, to inform how we could improve it in the future and evaluate whether it impacted attendees experience of hearing voices, self-esteem and how connected they felt to others who heard voices.

What we did. We asked the four group participants to complete questionnaires before starting the group and on completing the group to see if it made a difference to their experience of hearing voices, their self-esteem and how connected they felt to others who heard voices. We interviewed the four group attendees and the two group facilitators about their experience of the group, thematic analysis was used to analyse what they said.

What we found. As we had a small number of participants statistical analysis was not possible. The impact of the group on participants self-esteem and experience of hearing voices was varied. All group attendees reported that they felt more connected to others who hear voices post-group compared to pre-group. The thematic analysis found three broad themes captured the experiences of participants and facilitators: 1) making connections, 2) valuing session specifics and 3) the challenges of the HVG. All themes had sub-themes within them.

Why this matters. This study found that the HVG supported individuals to feel more connected to others with shared experiences, suggesting it is beneficial and should be run within the service again. The study yielded a number of recommendations for the running of future HVGs. The small number of participants meant that the findings were limited. Future HVGs should be evaluated for continued development.

Critical Review of the Literature

Background. A small proportion of tinnitus sufferers experience extreme distress. Cognitive Behavioural Therapy (CBT) aimed at reducing tinnitus-related distress has been shown to be successful. Research is beginning to explore the participants' experience of such treatments but their views have not yet been synthesised. This study aimed to synthesise the views of participants who have received CBT for tinnitus-related distress in the hope that it could inform the development of future treatments.

What we did. A systematic review of the literature was completed to identify studies that had explored participants' experience of treatment. This resulted in seven studies being analysed using thematic synthesis.

What we found. Thematic synthesis led to three themes being identified relating to patient experiences of CBT-based interventions for tinnitus-related distress: 1) processes of treatment, 2) engagement with treatment, and 3) the wide-reaching impact of treatment. All themes had sub-themes within them. Across the seven studies, a common experience related to a reduction in tinnitus distress was an acceptance that their tinnitus could not be cured. This led to a changed relationship with the condition. Participants reported perceived improvements in anxiety, depression, sleep and an overall more positive outlook.

Why this matters. This study was able to suggest number of recommendations for the development of future CBT treatments aimed at reducing tinnitus-related distress. Importantly, this study stressed that future researchers should aim to hear the experiences of participants who decide not to complete treatment in full. This could aid understanding about what makes an intervention hard to engage with and how it could be adapted to meet the needs of more tinnitus sufferers.

5. Acknowledgments

My biggest thanks is to all of the participants who have taken part in my research. I am extremely grateful to them for sharing their experiences so openly.

My research supervisors have been immensely supportive throughout the past three years and I am very thankful for how generous they have been with their time and expertise. My biggest thanks is to Dr Liz Marks, who has supervised both my main and literature review projects. Her guidance and thoughtfulness has kept me calm throughout the research challenges I have faced. Her expert knowledge and passion for working with tinnitus has been inspiring and meant that the work has always felt exciting and meaningful. I am particularly appreciative of her willingness to think through decisions collaboratively as it has meant that the research demands have felt less isolating.

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And a final thank you goes to Dan – your patience, kindness, interest and humour has made everything feel achievable.

6. Appendices

Appendix: Critical Review of Literature

Appendix A - Psychological Medicine – instructions to authors

Psychological Medicine is a journal aimed primarily for the publication of original research in clinical
psychiatry and the basic sciences related to it. These include relevant fields of biological, psychological and social sciences. Review articles, editorials and letters to the Editor discussing published papers are also published. Contributions must be in English.

Submission of manuscripts

Manuscripts should be submitted online via our manuscript submission and tracking site, http://www.editorialmanager.com/psm/. Full instructions for electronic submission are available directly from this site. To facilitate rapid reviewing, communications for peer review will be electronic and authors will need to supply a current e-mail address when registering to use the system.

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		structured			
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More information about the nomenclature can be found on the ECNP website here, and in the paper here. The Neuroscience-based Nomenclature (NbN) itself is available free of charge as a mobile app (for both Android and iOS devices).

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One work by two authors	Walker and Allen (2004)	Walker and Alien (2004)	(Walker & Allen, 2004)	(Walker & Alien, 2004)
One work by three authors	Bradley, Ramjrez, and Soo (1999)	Bradley et al. (1999)	(Bradley, Ramirez, & Soo, 1999)	(Bradley et al., 1999)
One work by four authors	Bradley, Ramirez, Soo, and Walsh (2006)	Bradley et al. (2006)	(Bradley, Ramirez, Soo, & Walsh, 2006)	(Bradley et al., 2006)

One work by five authors	Walker, Alien, Bradley, Ramirez, and Soo (2008)	Walker et al. (2008)	(Walker, Allen, Bradley, Ramirez, & Soo, 2008)	(Walker et al., 2008)
One work by six authors or more	Wasserstein et al. (2005)	Wasserstein et al. (2005)	(Wasserstejn et al., 2005)	(Wasserstejn et al., 2005)

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Journal article with DOl

Nevin, A. (1990). The changing of teacher education special education. *Teacher Education and Special Education: The Journal of the Teacher Education Division of the Council for Exceptional Children, 13*(3-4), 147-148. doi:XXX

Light, M. A., & Light, I. H. (2008). The geographic expansion of Mexican immigration in the United States and its implications for local law enforcement. *Law Enforcement Executive Forum Journal*, *8*, 73–82. doi:XXX

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Good, C. D., Johnsrude, I. S., Ashburner, J., Henson, R. N. A., Firston, K. J., & Frackowiak, R. S. J. (2001). A voxel-based morphometric study of ageing in 465 normal adult human brains. *NeuroImage, 14,* 21–36. Retrieved from http://xxxx

No retrieval date is needed.

Journal article with DOl, more than seven authors

Gilbert, D. G., McClernon, F. J., Rabinovich, N. E., Sugai, C., Plath, L. C., Asgaard, G., ... Botros, N. (2004). Effects of quitting smoking on EEG activation and attention last for more than 31 days and are more severe with stress, dependence, DRD2 A1 allele, and depressive traits. *Nicotine and Tobacco Research*, *6*, 249–267. doi:XXX

Journal article without DOl, title translated into English, print version

Guimard, P., & Florin, A. (2007). Las evaluations des enseignants en grande section de maternelle sont-elles predictives des difficultes de lecture au cours préparatoire? [Are teacher ratings in kindergarten predictive of reading difficulties in first grade?]. *Approche Neuropsychologique des Apprentissages chez l'Enfant*, *19*, 5–17.

Journal article with DOI, advance online publication

Von Ledebur, S. C. (2007). Optimizing knowledge transfer by new employees in companies. *Knowledge Management Research & Practice*. Advance online publication. doi: 10.1 057/palgrave.kmrp.8500141

In-press article

Briscoe, R. (in press). Egocentric spatial representation in action and perception. *Philosophy and Phenornenological Research*. Retrieved from http://cogprints.org/5780/l/EC...

Citations for Websites

Author's Last name, F. M. (Year, Month Day published). Title of article or page. Retrieved from URL

Simmons, B. (2015, January 9). The tale of two Flaccos. Retrieved from http://grantland.com/the-trian...

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Appendix B - Full search strategy

Table 6.1
Full search strategy for systematic review.

Embase	Web of Science	APA Psycnet
1. exp ‘Tinnitus’	# 1 TOPIC: (tinnitus) Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC Timespan=All years	1. Any Field: tinnitus *Search Databases:* APA PsycInfo, APA PsycArticles, APA PsycExtra, APA PsycTests, APA PsycBooks
2. exp ‘cognitive therapy’	# 2 TS=(CBT or ACT or MBTR or MBSR or MBTSR or psychoeducation or iACT or iCBT or GCBT or psychotherap*) Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC Timespan=All years	2. Any Field: cbt *OR* Any Field: act *OR* Any Field: mbtr *OR* Any Field: mbct *OR* Any Field: mbsr *OR* Any Field: psychoeducation *OR* Any Field: iact *OR* Any Field: icbt *OR* Any Field: gcbt *OR* Any Field: psychotherap* *Search Databases:* APA PsycInfo, APA PsycArticles, APA PsycExtra, APA PsycTests, APA PsycBooks
3. exp ‘behaviour therapy’	#3 ALL=(cognitive therap*) OR ALL=(behavio* therap*) OR ALL=(acceptance and commitment	3. Any Field: cognitive therap* *OR* Any Field: behavio* therap* *OR* Any Field: acceptance *AND* Any

Embase	Web of Science	APA Psycnet
	therap*) OR ALL=(mindfulness) Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC Timespan=All years	Field: commitment therap* *OR* Any Field: mindfulness *OR* Any Field: tinnitus therapy *Search Databases:* APA PsycInfo, APA PsycArticles, APA PsycExtra, APA PsycTests, APA PsycBooks
4. exp ‘acceptance and commitment therapy’ OR exp ‘cognitive behavioural therapy’ OR ‘mindfulness’	#4 #2 OR #3 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC Timespan=All years	4. 2 OR 3 *Search Databases:* APA PsycInfo, APA PsycArticles, APA PsycExtra, APA PsycTests, APA PsycBooks
5. cbt:ab,ti OR act:ab,ti OR mindful*:ab,ti OR mbtr:ab,ti OR mbct:ab,ti OR mbsr:ab,ti OR mbtsr:ab,ti OR psychoeducation:ab,ti OR iact:ab,ti OR icbt:ab,ti OR gcbt:ab,ti OR psychotherap*:ab,ti	#1 AND #4 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC Timespan=All years	5. 1 AND 4
6. 2 or 3 or 4 or 5 7. 1 and 6		

Appendix C - Inclusion and exclusion criteria

Table 6.2
Inclusion and exclusion criteria for systematic review

Inclusion criteria	Exclusion criteria
Written in English	Studies include only quantitative data.
Original study (not review paper)	Studies focused on pharmacological interventions
Sample participants 18years or older experiencing tinnitus-related distress	Studies focused on technological interventions (such as sound therapy or hearing aids) including Tinnitus Retraining Therapy (as it is not based on cognitive-behavioural principles).
Sample received CBT-based intervention for tinnitus-related distress (including ACT and Mindfulness based interventions)	
Qualitative component included in results	

Appendix D - PRISMA diagram for systematic review

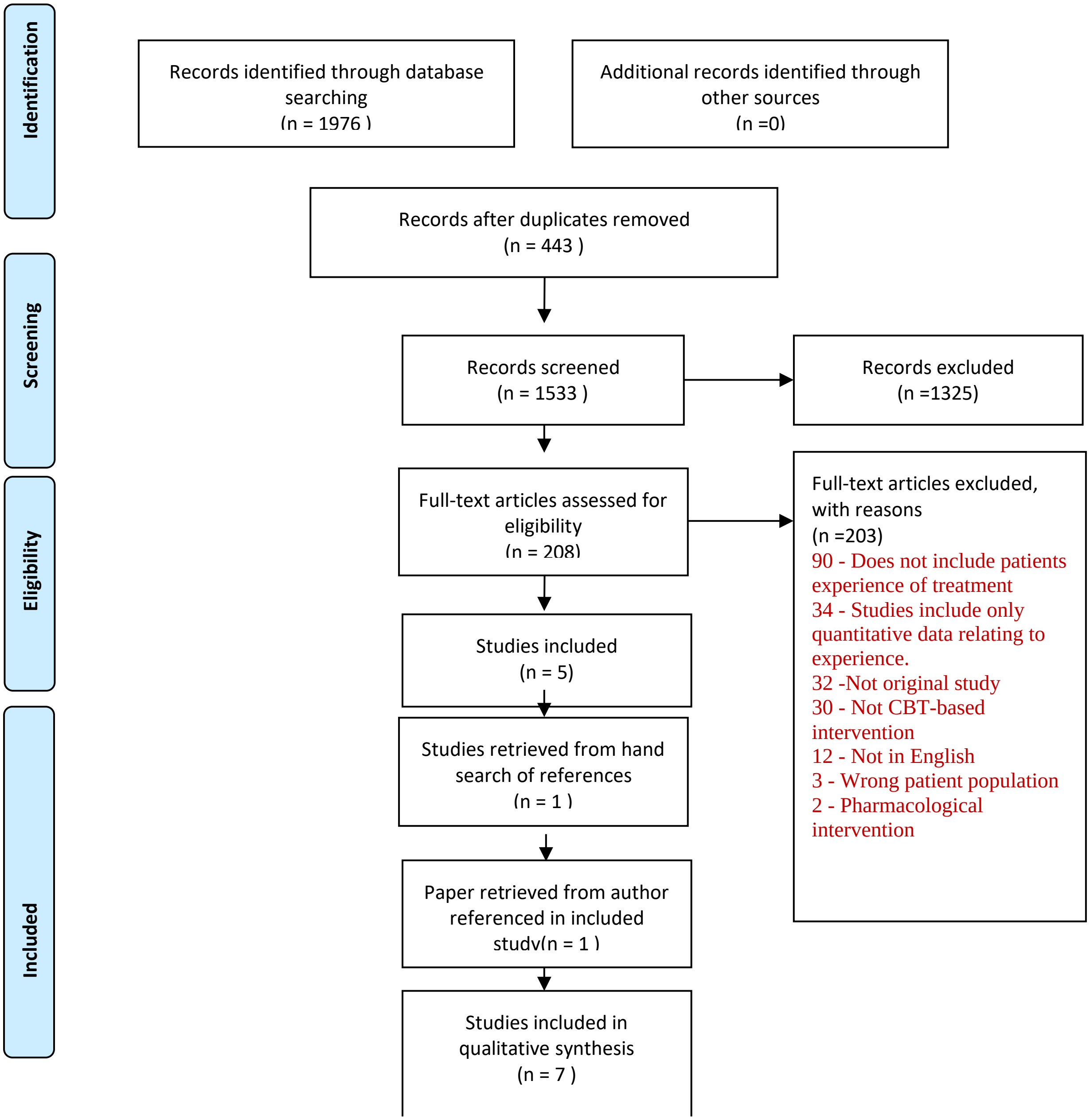

Figure 6.1 PRISMA diagram for systematic search of the literature

Appendix E - Summary of studies for synthesis

Table 6.3

Summary of studies included in synthesis for systematic review.

Authors (year)	Aims	Sample characteristics	Intervention type	Design, data collection and analysis	Key qualitative findings
Andersson & Edvinsson (2009)	Explore participants views of their tinnitus and treatment received.	N= 7 (5 male, 2 female) Age range 22-60 (mean = 47 years) Tinnitus duration range 1.5-8 years (mean 4.6 years)	Cognitive behavioural therapy for tinnitus distress (individual and group).	Qualitative design: semi-structured interviews. Modified grounded theory approach used for analysis.	Three categories reported: 1) consequences, 2) treatment experiences and 3) tinnitus identity. This was summarised in the higher order concept as "mixed feelings about living with tinnitus"
Beukes, Manchaiah, Davies, Allen, Baguley & Andersson (2018)	Explore participants experience of an internet-based cognitive behavioural therapy (iCBT)	N=15 (7 male, 8 female) Age range 52-73 (mean = 58.5 years) Tinnitus durations range 0.4-35 years (mean 9.4 years)	Internet-based cognitive behavioural therapy (iCBT) intervention for tinnitus (individual)	Qualitative design: semi-structured telephone interviews. Thematic Analysis used for analysis.	Results supported the idea of iCBT as an approach for patients struggling with tinnitus-related distress, with the online element being

Authors (year)	Aims	Sample characteristics	Intervention type	Design, data collection and analysis	Key qualitative findings
	intervention for tinnitus.				acceptable to users. Engagement difficulties were highlighted.
Gans, O'Sullivan & Bircheff (2013)	Assess whether a Mindfulness Based Tinnitus Stress Reduction (MBTSR) group was effective at reducing tinnitus-related distress.	N=8 (6 male, 2 female) Age range 38-70 (mean=58 years) Tinnitus duration not listed	MBTSR – 8 weekly sessions of group instruction, 1-day retreat, readings and home-based guided practice	Mixed methods design: qualitative data collected using a post intervention feedback form of open and direct questions. Qualitative data summarised – no methodology described.	Participants reported a shift in the perception of their tinnitus, a reduction in psychological distress and increased mindfulness in daily life.
Greenwell, Sereda, Coulson, & Hoare (2019)	Evaluate user (past and present) reaction to and interaction with the Tinnitus E-Programme using two studies.	**Study 1.** N=27 (13 male, 14 female) Age range (18-24) – (65-74) (no mean) Tinnitus duration <6 months - >10 years **Study 2.** N=13 (7 male, 6 female) Age range 22-79 (mean=54 years)	**Study 1.** Tinnitus E-Programme – 10-week internet based self-management intervention for tinnitus. CBT-based; therapist email contact optional. **Study 2.** As outlined in study	**Study 1.** Mixed methods design: qualitative data collected using online questionnaire. Answers to open questions analysed using Thematic analysis. **Study 2.** Mixed methods design: qualitative data collected via semi-structured telephone	Positive views about the intervention leading to conclusion that the intervention is acceptable to its target population. A number of areas for development / improvement were identified.

Authors (year)	Aims	Sample characteristics	Intervention type	Design, data collection and analysis	Key qualitative findings
		Tinnitus duration range 6 months - >10 years.	1 but with relaxation log as addition.	interview. Analysis using thematic analysis.	
Marks, Smith & McKenna (2019)	Explore the lived experience of people who suffer with chronic and disabling tinnitus who have been through psychological treatment to target distress.	N=9 (7 male, 2 female) Age range 35-67 (mean = 53.2 years) Tinnitus duration - range 1.5-30 years (mean 13.1 years)	Mindfulness Based Cognitive Therapy (MBCT) group to target related distress.	Qualitative design: semi structured interview 6 months following completion of group. Interpretative phenomenological analysis used to analyse the data.	Two themes emerged – 1. 'Living with tinnitus' 2. 'The health care journey' Tinnitus burden could be reduced by developing and disseminating clear information about tinnitus and intervening early.
Marks, Smith & McKenna (2020)	To explore participants experience of MBCT for tinnitus to understand more about what the intervention had changed and how.	N=9 (7 male, 2 female) Age range 35-67 (mean = 53.2 years) Tinnitus duration - range 1.5-30 years (mean 13.1 years)	Mindfulness Based Cognitive Therapy (MBCT) group to target related distress.	Qualitative design: semi structured interview 6 months following completion of group. Interpretative phenomenological analysis used to analyse the data.	Participants experienced change in their relationship with tinnitus. Acceptance of and attending to tinnitus was central. Wide ranging benefits were experienced with the group element being valued.

Authors (year)	Aims	Sample characteristics	Intervention type	Design, data collection and analysis	Key qualitative findings
Thompson, Pryce & Refaie (2011)	To explore what the 'active ingredient' in tinnitus treatment is.	N=8 (4 male, 4 female) Age range 40-83 (mean = 59.5years) Tinnitus duration - range 1-13 years (mean not clear)	Cognitive behavioural therapy for tinnitus distress (individual and group).	Qualitative design: semi-structured interview. Grounded theory approach used to analyse the data.	Group experience creates opportunity to exchange information. Group therapy allows for "upwards social comparison", the opposite is seen in individual therapy.

Appendix F - Critical appraisal of included studies

Table 6.4

Summary of Critical Appraisal Skills Programme for all studies included in synthesis

Paper (Author and year of publication)	Clear aims	Appropriate methodology	Design appropriate for aims	Appropriate recruitment strategy	Appropriate data collected	Researcher participant relationship considered	Ethical issues considered	Rigorous data analysis	Clear statement of findings	Value of research
Andersson & Edvinsson, 2009.	✓	✓	✓	✓	✓	✓	Can’t tell	✓	✓	✓
Beukes et al., 2018	✓	✓	✓	✓	✓	✓	Can’t tell	✓	✓	✓
Gans et al., 2013	✓	✓	×	✓	✓	✓	Can’t tell	×	✓	✓
Greenwell et al., 2019	✓	✓	✓	✓	✓	Can’t tell	✓	Can’t tell	✓	✓
Marks et al., 2019	✓	✓	✓	✓	✓	✓	Can’t tell	✓	✓	✓
Marks et al., 2020	✓	✓	✓	✓	✓	✓	Can’t tell	✓	✓	✓
Thompson et al., 2011	✓	✓	✓	✓	✓	×	Can’t tell	Can’t tell	✓	✓

Appendix: Service Improvement Project

Appendix G – Psychosis Journal instructions for authors

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   This work was supported by the [Funding Agency] under Grant [number xxxx].
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   This work was supported by the [Funding Agency #1] under Grant [number xxxx]; [Funding Agency #2] under Grant [number xxxx]; and [Funding Agency #3] under Grant [number xxxx].
6. **Disclosure statement.** This is to acknowledge any financial interest or benefit that has arisen from the direct applications of your research. Further guidance on what is a conflict of interest and how to disclose it.
7. **Data availability statement.** If there is a data set associated with the paper, please provide information about where the data supporting the results or analyses presented in the paper can be found. Where applicable, this should include the hyperlink, DOI or other persistent identifier associated with the data set(s). Templates are also available to support authors.
8. **Data deposition.** If you choose to share or make the data underlying the study open, please deposit your data in a recognized data repository prior to or at the time of submission. You will be asked to provide the DOI, pre-reserved DOI, or other persistent identifier for the data set.

9. **Supplemental online material.** Supplemental material can be a video, dataset, fileset, sound file or anything which supports (and is pertinent to) your paper. We publish supplemental material online via Figshare. Find out more about supplemental material and how to submit it with your article.
10. **Figures.** Figures should be high quality (1200 dpi for line art, 600 dpi for grayscale and 300 dpi for colour, at the correct size). Figures should be supplied in one of our preferred file formats: EPS, PS, JPEG, TIFF, or Microsoft Word (DOC or DOCX) files are acceptable for figures that have been drawn in Word. For information relating to other file types, please consult our Submission of electronic artwork document.
11. **Tables.** Tables should present new information rather than duplicating what is in the text. Readers should be able to interpret the table without reference to the text. Please supply editable files.
12. **Equations.** If you are submitting your manuscript as a Word document, please ensure that equations are editable. More information about mathematical symbols and equations.
13. **Units.** Please use SI units (non-italicized).

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Disclosure Statement

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Please ensure that all research reported in submitted papers has been conducted in an ethical and responsible manner, and is in full compliance with all relevant codes of experimentation and legislation. All papers which report in vivo experiments or clinical trials on humans or animals must include a written statement in the Methods section. This should explain that all work was conducted with the formal approval of the local human subject or animal care committees (institutional and national), and that clinical trials have been registered as legislation requires. Authors who do not have formal ethics review committees should include a statement that their study follows the principles of the Declaration of Helsinki.

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All authors are required to follow the ICMJE requirements on privacy and informed consent from patients and study participants. Please confirm that any patient, service user, or participant (or that person's parent or legal guardian) in any research, experiment, or clinical trial described in your paper has given written consent to the inclusion of material pertaining to themselves, that they acknowledge that they cannot be identified via the paper; and that you have fully anonymized them. Where someone is deceased, please ensure you have written consent from the family or estate. Authors may use this Patient Consent Form, which should be completed, saved, and sent to the journal if requested.

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Please include all relevant safety precautions; and cite any accepted standard or code of practice. Authors working in animal science may find it useful to consult the International Association of Veterinary Editors' Consensus Author Guidelines on Animal Ethics and Welfare and Guidelines for the Treatment of Animals in Behavioural Research and Teaching. When a product has not yet been approved by an appropriate regulatory body for the use described in your paper, please specify this, or that the product is still investigational.

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Authors are further encouraged to cite any data sets referenced in the article and provide a Data Availability Statement.

At the point of submission, you will be asked if there is a data set associated with the paper. If you reply yes, you will be asked to provide the DOI, pre-registered DOI, hyperlink, or other persistent identifier associated with the data set(s). If you have selected to provide a pre-registered DOI, please be prepared to share the reviewer URL associated with your data deposit, upon request by reviewers.

Where one or multiple data sets are associated with a manuscript, these are not formally peer reviewed as a part of the journal submission process. It is the author’s responsibility to ensure the soundness of data. Any errors in the data rest solely with the producers of the data set(s).

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Appendix H - Service Improvement Project: ethics and R&D approval

2Gether Trust Research and Development approval

Mon 30/07/2018 17:08

Hi Gemma

Re: Hearing Voices Service Evaluation
Ref: 18/011/2GTSE

Sorry, another delay. Yep that is fine – it was all reviewed and it is my fault the approval didn't come through.

My main concern is when we find out about studies that have been completed without ever having heard of them!

You can take this email as confirmation of approval for the study

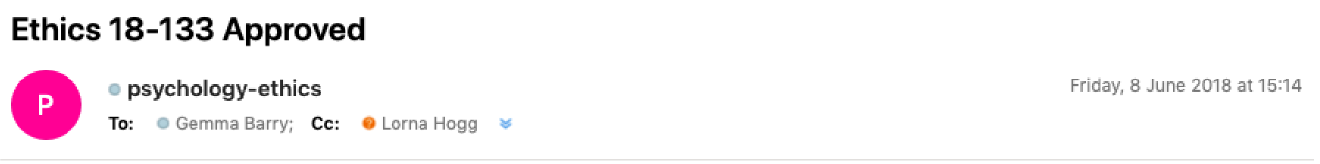
Hope it is all going well!

Cheers

Mark

Mark Walker
Head of Research and Development
Research 2gether

University of Bath Ethical Approval



Ethics 18-133 Approved

P

psychology-ethics

Friday, 8 June 2018 at 15:14

To: Gemma Barry; **Cc:** Lorna Hogg

Dear Gemma,

Ethics 18-133: An evaluation of a pilot Hearing Voices Group within [redacted] Assertive Outreach Team.

The ethics committee have considered your ethics proposal for the study above and have given it full ethical approval.

Best wishes with your research.

Dr Nathalia Gjersoe

Chair, Psychology Research Ethics Committee

****

From: Gemma Barry
Sent: 23 August 2018 16:25
To: psychology-ethics <psychology-ethics@bath.ac.uk>
Cc: Lorna Hogg <L.I.Hogg@bath.ac.uk>
Subject: Request for slight amendment to approved project

Good afternoon,

I am emailing to request an amendment to a project that has been approved by The University of Bath Ethics committee.

My approved application reference is: **EthicS** 18-133: An evaluation of a pilot Hearing Voices Group within the [redacted] Assertive Outreach Team

In my proposal I have said that i will ask for written feedback from service users around improvements for the group. We have now decided that speaking with the service users may gather richer data, which would allow more appropriate recommendations for the service.

I have updated this in my ethics proposal (highlighted in yellow) and included a revised information sheet and consent form detailing that we would like to undertake brief interviews with service users that will be audio recorded.

Thanks for your consideration.

Best wishes,

Gemma

Gemma Barry
Clinical Psychologist in Training
****

Dear Gemma,

Ethics 18-133: An evaluation of a pilot Hearing Voices Group within the [redacted] Assertive Outreach Team

I am happy to confirm that you have received full ethical approval from the University of Bath Department of Psychology Ethics Committee for the amendments to your ethics. Please use the code 18-133 as proof of ethical approval on internal documentation.

Best of luck with your research,
Dr Chris Ashwin
Chair, Psychology Research Ethics Committee

Appendix I - Service Improvement Project: information sheets

An evaluation of a pilot Hearing Voices Group within the [redacted] Assertive Outreach Team (group facilitator)

Before you decide to take part in this study, it is important for you to understand why the research is being done and what it would involve. Please take time to read the following information carefully and discuss it with anyone you wish to. Please ask if there is anything that is not clear or if you would like more information. Please take the time to decide whether or not you wish to take part.

Background
This is a study to evaluate the Hearing Voices Group and the impact it has on how connected participants feel to others who have similar experiences to them. We are also looking to explore how the experiences of those who participated in the group (as service users and facilitators) can inform the running of future groups within the 2Gether NHS Trust.

Procedures
You have been chosen, because you are facilitating the Hearing Voices Group run by the [redacted] Assertive Outreach Team. However, participation in the study is entirely voluntary. It is up to you to decide whether or not to do this. If you do decide to take part, we would ask you to sign a consent form and give you a copy of this information sheet and the consent form to keep. If you decide to take part you are still free to withdraw from the study at any time before the information you provided is anonymised. If you decide not to take part, or to withdraw, you do not have to give a reason, nobody would be upset.

We will ask you to take part in a focus group following the completion of the Hearing Voices Group which will be audio recorded. This focus group will be looking to gather information on your experience of running the group, what you felt worked well and any areas that you think could aid future improvement of such groups within the 2Gether Trust. Following the group, we will inform you in more detail about the hypotheses we are testing, and you will have the opportunity to ask further questions. It is anticipated that the total time for the focus group will be approximately 30 minutes.

What will happen to the information I provide?
Should you decide to take part the focus group will be recorded. These recordings will then be typed up and the files stored on an encrypted password-protected computer. Once the focus group has been typed up, the audio file will immediately be deleted. Any potentially identifying details, including your name, will be removed. These documents will not be linked to any contact details that you provide and will be stored separately so you cannot be identified. You are free to withdraw your data from the study at that point. Once you have given consent, we cannot withdraw your data at a later stage because of the anonymised nature of the study.

If you have any questions at any time about the study, please do not hesitate to contact Gemma Barry at gb258@bath.ac.uk

If you have any concerns related to your participation in this study please direct them to the Department of Psychology Research Ethics Committee, email: psychology-ethics@bath.ac.uk).

An evaluation of a pilot Hearing Voices Group within the [redacted] Assertive Outreach Team (group participant)

Before you decide to take part in this study, it is important for you to understand why the research is being done and what it would involve. Please take time to read the following information carefully and discuss it with anyone you wish to. Please ask if there is anything that is not clear or if you would like more information. Please take the time to decide whether or not you wish to take part.

Background

This is a study to evaluate the Hearing Voices Group and the impact it has on how connected participants feel to others who have similar experiences to them. We are also looking to explore how the experiences of those who participated in the group (as service users and facilitators) can inform the running of future groups within the 2Gether NHS Trust.

Procedures

You have been chosen, because you are attending the Hearing Voices Group run by the [redacted] Assertive Outreach Team. However, participation in the study is entirely voluntary. It is up to you to decide whether or not to do this. If you do decide to take part, we would ask you to sign a consent form and give you a copy of this information sheet and the consent form to keep. If you decide to take part you are still free to withdraw from the study at any time before the information you provided is anonymised. If you decide not to take part, or to withdraw, you do not have to give a reason, nobody would be upset.

We will ask you to complete some brief questionnaires prior to attending the group. Upon completion of the group, we will ask you to complete some more questionnaires along with a free text box. This free text will allow us to gather your views on the group and any recommendations for change that you have. Following the group, we will inform you in more detail about the hypotheses we are testing, and you will have the opportunity to ask further questions. It is anticipated that the total time for these questionnaires will be no more than 45 minutes (15 minutes pre measures, 30 minutes post measures).

Your data

All data collected in this study will be confidential and then anonymised. There is no record that links the data collected from you with personal data from which you could be identified (i.e. the signed consent form). Upon completion of the experiment we ask you to give consent to include your data in further analyses. You are free to withdraw your data from the study at that point. Once you have given consent, we cannot withdraw your data at a later stage because of the anonymised nature of the study.

If you have any questions at any time about the study, please do not hesitate to contact Gemma Barry at gb258@bath.ac.uk

If you have any concerns related to your participation in this study please direct them to the Department of Psychology Research Ethics Committee, email: psychology-ethics@bath.ac.uk).

An evaluation of a pilot Hearing Voices Group within the [redacted] Assertive Outreach Team

Invite to attend feedback interview

Thank you for having taken part in the study so far. In order for us to gather more information about your experiences of attending the group we would like to invite you to take part in a short interview. You have been chosen, because you have attended the Hearing Voices Group run by the [redacted] Assertive Outreach Team and completed the outcome measures. Participation in the interview is entirely voluntary. It is up to you to decide whether or not to do this.

If you do decide to take part, we would ask you to sign a consent form and give you a copy of this information sheet and the consent form to keep. If you decide to take part you are still free to withdraw from the study at any time before the information you provided is anonymised. If you decide not to take part, or to withdraw, you do not have to give a reason, nobody would be upset.

Procedures

You will be invited to attend a brief interview with the main researcher, which will be audio recorded. This interview will be looking to gather information on your experience of attending the group, what you felt worked well and any areas that you think could aid future improvement of such groups within the 2Gether Trust. Following the interview, we will inform you in more detail about the hypotheses we are testing, and you will have the opportunity to ask further questions. It is anticipated that the total time for the interview will be approximately 10 minutes.

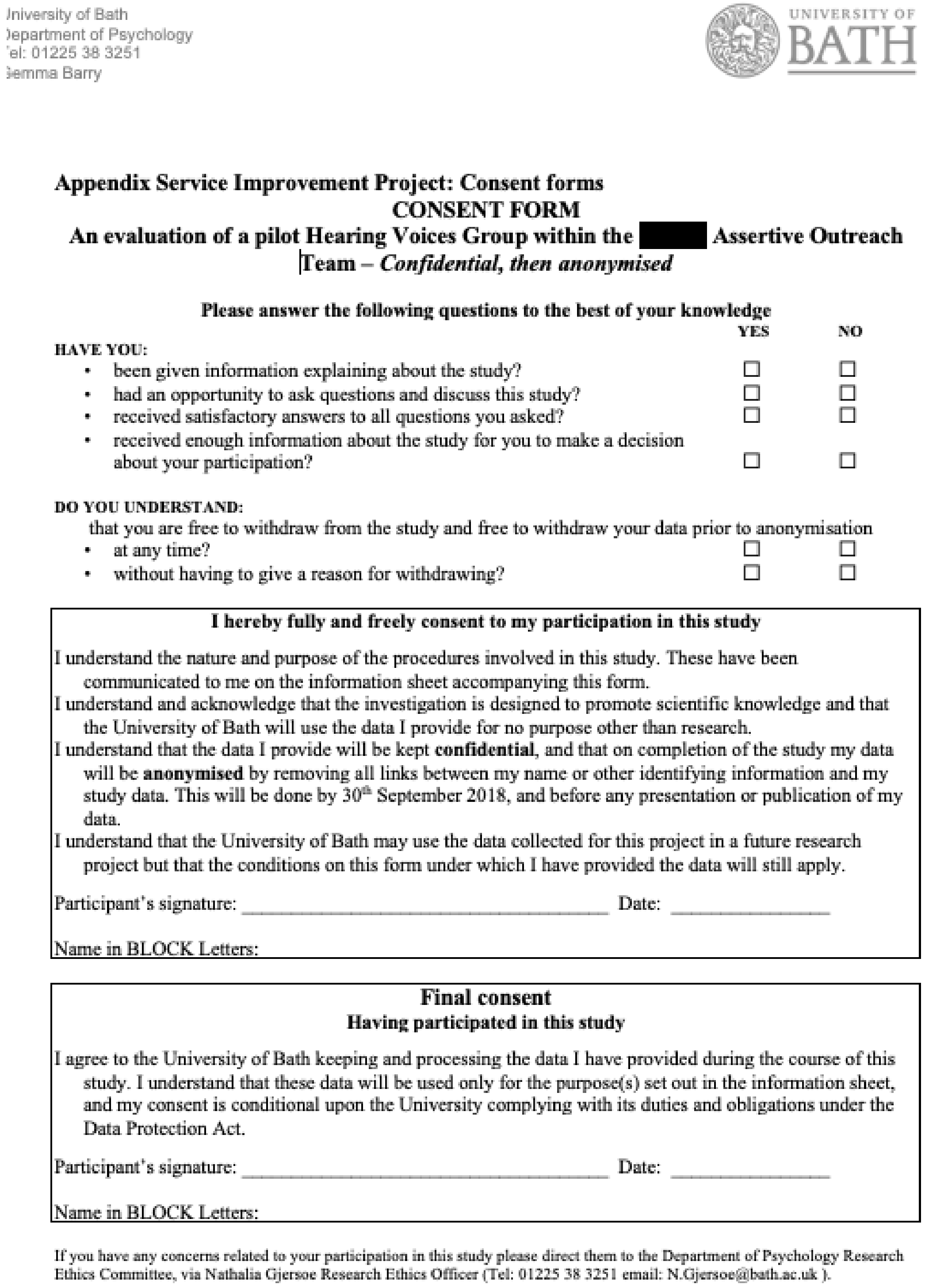
What will happen to the information I provide?

Should you decide to take part the interview will be recorded. This will then be typed up and the files stored on an encrypted password-protected computer. Once the interview has been typed up, the audio file will immediately be deleted. Any potentially identifying details, including your name, will be removed. These documents will not be linked to any contact details that you provide and will be stored separately so you cannot be identified. You are free to withdraw your data from the study at that point. Once you have given consent, we cannot withdraw your data at a later stage because of the anonymised nature of the study.

If you have any questions at any time about the study, please do not hesitate to contact Gemma Barry at gb258@bath.ac.uk

If you have any concerns related to your participation in this study please direct them to the Department of Psychology Research Ethics Committee, email: psychology-ethics@bath.ac.uk).

Appendix J - Service Improvement Project: consent forms



niversity of Bath
epartment of Psychology
el: 01225 38 3251
emma Barry

Appendix Service Improvement Project: Consent forms

CONSENT FORM

An evaluation of a pilot Hearing Voices Group within the [redacted] Assertive Outreach Team – *Confidential, then anonymised*

Please answer the following questions to the best of your knowledge

	YES	NO
HAVE YOU:		
• been given information explaining about the study?	☐	☐
• had an opportunity to ask questions and discuss this study?	☐	☐
• received satisfactory answers to all questions you asked?	☐	☐
• received enough information about the study for you to make a decision about your participation?	☐	☐
DO YOU UNDERSTAND:		
that you are free to withdraw from the study and free to withdraw your data prior to anonymisation		
• at any time?	☐	☐
• without having to give a reason for withdrawing?	☐	☐

I hereby fully and freely consent to my participation in this study

I understand the nature and purpose of the procedures involved in this study. These have been communicated to me on the information sheet accompanying this form.

I understand and acknowledge that the investigation is designed to promote scientific knowledge and that the University of Bath will use the data I provide for no purpose other than research.

I understand that the data I provide will be kept **confidential**, and that on completion of the study my data will be **anonymised** by removing all links between my name or other identifying information and my study data. This will be done by 30th September 2018, and before any presentation or publication of my data.

I understand that the University of Bath may use the data collected for this project in a future research project but that the conditions on this form under which I have provided the data will still apply.

Participant's signature: ____________________________________ Date: _______________

Name in BLOCK Letters:

Final consent

Having participated in this study

I agree to the University of Bath keeping and processing the data I have provided during the course of this study. I understand that these data will be used only for the purpose(s) set out in the information sheet, and my consent is conditional upon the University complying with its duties and obligations under the Data Protection Act.

Participant's signature: ____________________________________ Date: _______________

Name in BLOCK Letters:

If you have any concerns related to your participation in this study please direct them to the Department of Psychology Research Ethics Committee, via Nathalia Gjersoe Research Ethics Officer (Tel: 01225 38 3251 email: N.Gjersoe@bath.ac.uk).

University of Bath
Department of Psychology
Tel: 01225 38 3251
Gemma Barry

UNIVERSITY OF BATH

CONSENT FORM - Interview
An evaluation of a pilot Hearing Voices Group within the Stroud Assertive Outreach Team - Invite to attend feedback interview

Confidential, then anonymised

Please answer the following questions to the best of your knowledge

	YES	NO
HAVE YOU:		
• been given information explaining about the interview?	☐	☐
• had an opportunity to ask questions and discuss this interview?	☐	☐
• received satisfactory answers to all questions you asked?	☐	☐
• received enough information about the interview for you to decide about your participation?	☐	☐
DO YOU UNDERSTAND:		
• that the interview will be audio recorded and securely stored as outlined in the information sheet?	☐	☐
that you are free to withdraw from the study and free to withdraw your data prior to anonymisation		
• at any time?	☐	☐
• without having to give a reason for withdrawing?	☐	☐

I hereby fully and freely consent to my participation in this study

I understand the nature and purpose of the procedures involved in this study. These have been communicated to me on the information sheet accompanying this form.

I understand and acknowledge that the investigation is designed to promote scientific knowledge and that the University of Bath will use the data I provide for no purpose other than research.

I understand that the data I provide will be kept **confidential**, and that on completion of the study my data will be **anonymised** by removing all links between my name or other identifying information and my study data. This will be done by 30th October 2018, and before any presentation or publication of my data.

I understand that the University of Bath may use the data collected for this project in a future research project but that the conditions on this form under which I have provided the data will still apply.

Participant's signature: ______________________________ Date: ______________

Name in BLOCK Letters:

If you have any concerns related to your participation in this study please direct them to the Department of Psychology Research Ethics Committee (Tel: 01225 38 3251).

Appendix K - Service Improvement Project: question to participants

Questionnaires used in the study have not been reproduced as they are not the property of the author. Questions written for the study are below.

Please rank the following statements in order of most useful (1) to least useful (4) when thinking about what you have valued most from the group:

- ☐ The impact that the group has had on how I feel about myself.
- ☐ The opportunity the group provided me to develop connections with those who have had similar experiences to me.
- ☐ Developing skills to help me to think about my experiences in a more helpful way.
- ☐ Exploring new strategies of how to improve coping with distressing experiences.

Please use the space below to let us know what you valued most about the group. This can be with regards to specific sessions, general ideas or anything that you found to be of particular benefit. Please provide as much detail as you are able.

Appendix L - Service Improvement Project: interview schedules

Interview schedule for group facilitator focus group

As this is a focus group, questions will be kept as open as possible to encourage richness in response. The following will be used to elicit more information should they be needed.

- Can you tell me a bit about your overall experiences of running the hearing voices group?
- What do you think worked well within the group and why?
- What do you think could be improved if the group were to run again and why?
- Were there any particular difficulties within the group?
- Has it felt clinically useful to have this style of group running?
- Would you advocate for this group to run again within the Assertive Outreach Team that you work in?

Interview schedule - An evaluation of a pilot Hearing Voices Group within the [redacted] Assertive Outreach Team - Invite to attend feedback interview

Participants who agree to attend the interview will be asked two broad questions:

1) What have you valued most about the group? This can be with regards to specific sessions, general ideas or anything that you found to be of particular benefit.

2) Are there areas of the group that you think could be improved or things that you found to be unhelpful within the group? This can be with regards to specific sessions, general ideas or anything that you think could make future groups more effective.

Appendix M - Service Improvement Project: debrief

Debrief for all participants – verbal

Thank you very much for agreeing to take part in the evaluation of the Hearing Voices Group. The evaluation is looking to explore whether or not the group impacts on participants feelings of connectedness to others who share similar experiences and whether it has an impact on the . We are also looking to see what the most helpful elements of the group have been and how we could improve this in the future.

We have hypothesised that attending the group will lead to improvements in self esteem and feelings of connectedness to other people who hear voices.

Thank you again for participating. If you would like to speak to us about the project please get in touch, please ask one of the group facilitators for my email address.

Appendix: Main Research Project

Appendix N – International Journal of Audiology instructions for authors

COVID-19 impact on peer review

As a result of the significant disruption that is being caused by the COVID-19 pandemic we understand that many authors and peer reviewers will be making adjustments to their professional and personal lives. As a result they may have difficulty in meeting the timelines associated with our peer review process. Please let the journal editorial office know if you need additional time. Our systems will continue to remind you of the original timelines but we intend to be flexible.

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Preparing Your Paper

Structure

Your paper should be compiled in the following order: title page; abstract; keywords; main text introduction, materials and methods, results, discussion; acknowledgments; declaration of interest statement; references; appendices (as appropriate); table(s) with caption(s) (on individual pages); figures; figure captions (as a list).

Word Limits

Please include a word count for your paper.

A typical paper for this journal should be between 1,500 and 7,500 words, inclusive of the abstract, tables, figure captions

A typical Original Article for this journal should be between 6500-7500 words; including the abstract, tables and figure. This also includes 3-5 figures/tables.

Review Articles - several types of review papers are accepted; these articles are usually solicited by the editors, but unsolicited manuscripts are accepted. Because the essence of review papers is the selection and interpretation of relevant literature, it is important for these papers that authors declare no conflicts of interests. Review papers should be between 6500-7500 words with 3-5 figures/tables.

Systematic Reviews -Systematic reviews of topics of current interest are particularly encouraged, and include quantitative, meta-narrative, and qualitative reviews, that have clearly formulated questions and use systematic and explicit methods to identify, select, and critically appraise relevant research, and to collect and analyze data from the studies that are included in the reviews. It is suggested that systematic reviews be accompanied by a completed Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram checklist. Systematic reviews should be between 6500 and 7500 words. If the manuscript is longer than the 7500-word limit, the authors should consider submitting the references and listing of papers reviewed as Supplemental Material which will be placed online and not included in the word count for the manuscript.

Discussion Papers present topics that are controversial or challenging. Reviewer comments follow the published paper and author responses to the review comments follow the reviewer comments (typically 6500-7500 words with 3-5 figures/tables).

Clinical Notes present unique or exceptional clinical cases with important/significant findings in audiology (typically 3000-4000) words with 2-4 figures/tables).

Technical Reports present clinically relevant technical information about new hardware or processing strategies (3000-4000) words with 2-4 figures).

Letters to the Editor are responses to previously published papers, or comments on important topics/issues (typically 1200-1500 words).

Format-Free Submission

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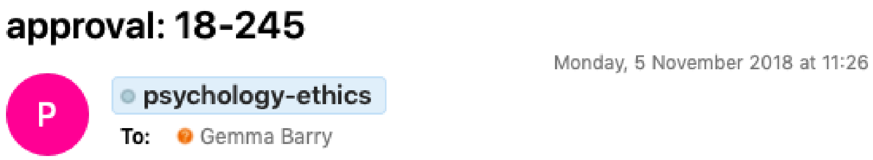
Appendix O – Main Research Project: ethical approval



approval: 18-245

Monday, 5 November 2018 at 11:26

psychology-ethics

To: Gemma Barry

Dear Gemma,

Ethics 18-245: How Thoughts and Behaviours Affect Sleep in People with and without Tinnitus

Thank you for taking the time to make these changes and clarifications. I am happy to confirm that you have received full ethical approval from the University of Bath Department of Psychology Ethics Committee for your application. In light of the fact that this project has no serious ethical concerns, this approval has been granted via Chair's Action. Please use the code 18-245 as proof of ethical approval on internal documentation.

Please be aware that it is your responsibility to let us know as soon as possible if any issues or complaints of an ethical nature arise over the course of your research.

Best of luck with your research,

Jie

Dr. Jie Sui

Chair, Psychology Ethics Committee

Appendix P - Main Research Project: information sheet

How Thoughts and Behaviours Affect Sleep in People with and without Tinnitus

Participant Information Sheet

Before you decide to take part in this study, it is important for you to understand why the research is being done and what it would involve. Please take time to read the following information carefully and take the time to decide whether or not you wish to take part.

Background

Individuals with distressing tinnitus often go on to develop insomnia as a secondary difficulty. Despite being very common, we still do not fully understand why and how tinnitus-related insomnia might begin and persist. Cognitive Behavioural models of insomnia suggest that this might be related to thoughts and behaviours about sleep, but further research is required.

This study aims to look at different groups, including those who do not suffer from tinnitus or insomnia, to explore whether such sleep-specific thoughts and behaviours are central to insomnia-related tinnitus. This could shed light on potential treatment options that could be beneficial to individuals who experience insomnia secondary to tinnitus.

Procedures

Participation in the study is entirely voluntary. If you do decide to take part, we would ask you to confirm of the consent form that you have received enough information about this study and are willing to continue.

We will then ask you some initial questions following which we will ask you to complete some questionnaires that will take approximately 25 minutes.

Your data

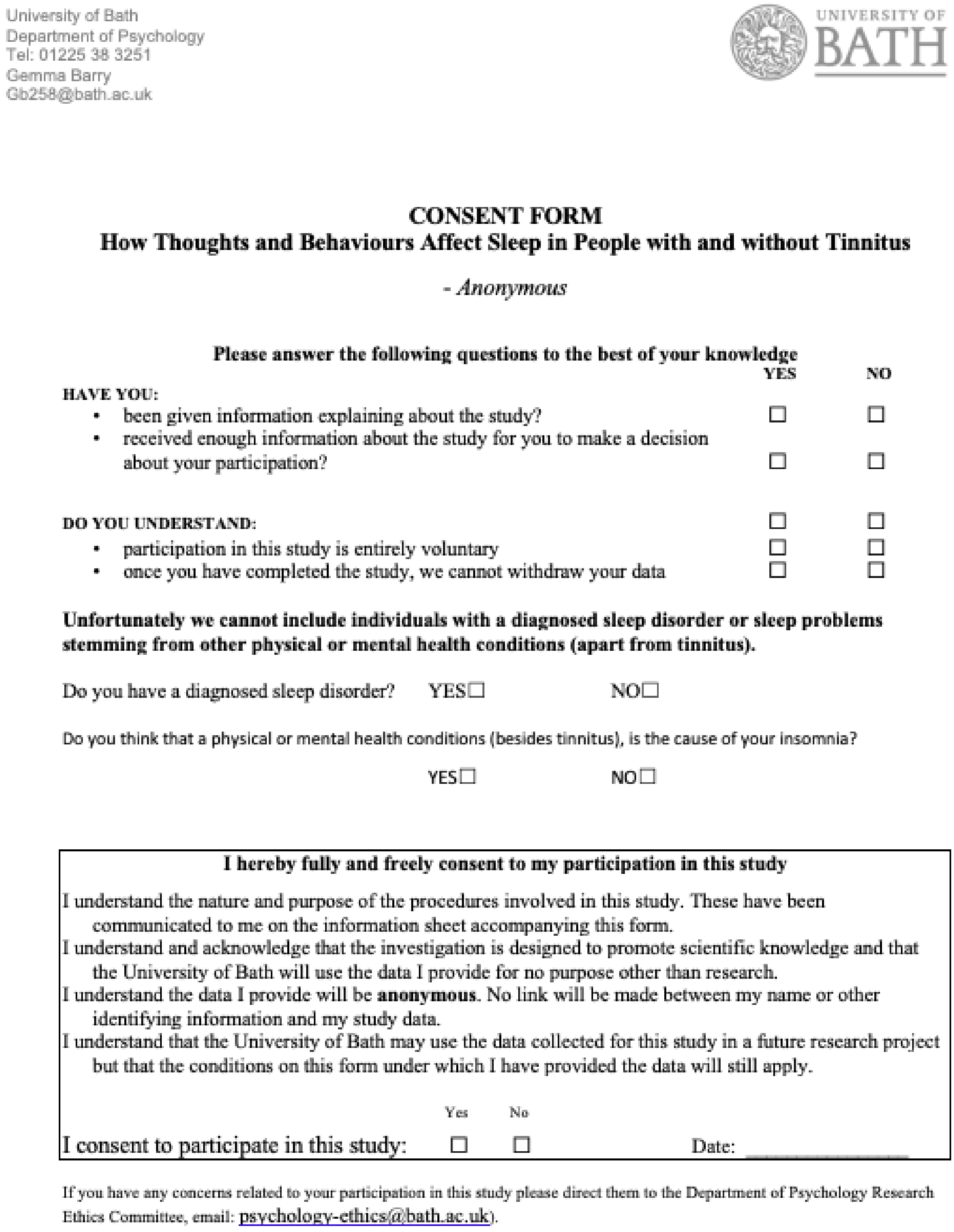
All data collected in this study will be anonymised. There will be no data collected that will allow us to identify your answers in any way. Once you have given consent, we cannot withdraw your data at a later stage because of the anonymised nature of the study.

Questions or Concerns

If you have any questions at any time about the study, please do not hesitate to contact Gemma Barry at gb258@bath.ac.uk
You can also contact the supervisor of this project, Liz Marks, by emailing E.Marks@bath.ac.uk

If you have any concerns about the ethics of this research study, please contact the Bath University Psychology Department (Email: psychology-ethics@bath.ac.uk Phone: 01225 38 4322)

Appendix Q - Main Research Project: consent form



University of Bath
Department of Psychology
Tel: 01225 38 3251
Gemma Barry
Gb258@bath.ac.uk

CONSENT FORM
How Thoughts and Behaviours Affect Sleep in People with and without Tinnitus

- Anonymous

Please answer the following questions to the best of your knowledge

	YES	NO
HAVE YOU:		
• been given information explaining about the study?	☐	☐
• received enough information about the study for you to make a decision about your participation?	☐	☐
DO YOU UNDERSTAND:	☐	☐
• participation in this study is entirely voluntary	☐	☐
• once you have completed the study, we cannot withdraw your data	☐	☐

Unfortunately we cannot include individuals with a diagnosed sleep disorder or sleep problems stemming from other physical or mental health conditions (apart from tinnitus).

Do you have a diagnosed sleep disorder? YES☐ NO☐

Do you think that a physical or mental health conditions (besides tinnitus), is the cause of your insomnia?

YES☐ NO☐

I hereby fully and freely consent to my participation in this study

I understand the nature and purpose of the procedures involved in this study. These have been communicated to me on the information sheet accompanying this form.

I understand and acknowledge that the investigation is designed to promote scientific knowledge and that the University of Bath will use the data I provide for no purpose other than research.

I understand the data I provide will be **anonymous**. No link will be made between my name or other identifying information and my study data.

I understand that the University of Bath may use the data collected for this study in a future research project but that the conditions on this form under which I have provided the data will still apply.

I consent to participate in this study: Yes ☐ No ☐ Date: _______________

If you have any concerns related to your participation in this study please direct them to the Department of Psychology Research Ethics Committee, email: psychology-ethics@bath.ac.uk).

Appendix R - Main Research Project: qualtrics questionnaire (excluding measures)

Questionnaires used in the study have not been reproduced as they are not the property of the author. Other information collected via Qualtrics is below.

Demographic Information
Please read the questions carefully and answer as best applies to you.

Please write your age in the box below

☐☐

Which gender do you best identify as?
- ☐ Male
- ☐ Female
- ☐ Other
- ☐ Prefer not to say

Initial Screening Questions

1. Do you have tinnitus? YES☐ NO☐

2. How much of a problem is your tinnitus?

Not a problem	Minor Problem	Moderate Problem	Considerable Problem	Severe Problem
1	2	3	4	5

3. Do you have any sleep problems? YES☐ NO☐

Individuals who identified as having at least moderately distressing tinnitus were asked the following:

How long have you had tinnitus?

- ☐ Less than 6 months
- ☐ 6 months to 1 year
- ☐ 1-2 years
- ☐ 3-5 years
- ☐ 5-10 years
- ☐ Over 10 years
- ☐ n/a

Have you ever had your tinnitus assessed by a doctor?

- ☐ Yes
- ☐ No
- ☐ n/a

Tinnitus Handicap Inventory Questionnaire (not included in portfolio)

Visual Analogue Scale

Please draw a cross on the line below to show how loud your tinnitus is at the moment.

Individuals who identified as having sleep problems were asked the following:

1. **How long have you had a sleep problem?**
    a. Less than 6 months
    b. 6 months to 1 year
    c. 1-2 years
    d. 3-5 years
    e. 5-10 years

    f. Over 10 years
    g. n/a

2. **Have you ever had your sleep problem assessed by a doctor?**
    a. Yes
    b. No
    c. n/a

All participants completed the following measures

Insomnia Severity Index (not included in portfolio)
Pittsburgh Sleep Quality Index (PSQI) (not included in portfolio)

Dysfunctional Beliefs and Attitudes about Sleep-16 (DBAS-16) (not included in portfolio)

Sleep-Related Behaviours Questionnaire (SRBQ) (not included in portfolio)

Generalised Anxiety Disorder – 7 (not included in portfolio)

Patient Health Questionnaire – 9 (not included in portfolio)

Further Demographic Information

Please read the questions carefully and click the answer that most applies to you.

1. **Marital status:**
    - ☐ Single
    - ☐ Have a partner but not living together
    - ☐ Married / living with a partner
    - ☐ Divorced / Separated
    - ☐ Widow / Widower
    - ☐ Prefer not to say

2. **What is your ethnic group?**
    - ☐ White
    - ☐ Black or Black British
    - ☐ Asian or Asian British
    - ☐ Mixed ethnicity
    - ☐ Other (please state) ………………………

☐ Prefer not to say

3. What is your highest level of education?

☐ Primary education or less
☐ Secondary Education
☐ Tertiary / Further education
☐ Other general education
☐ prefer not to say

4. What is your current employment status?

☐ Full-time
☐ Part-time
☐ Self employed
☐ Retired
☐ Unemployed

5. Do you work shifts or night-time hours?

☐ Yes
☐ No

Appendix S - Main Research Project: debrief

How Thoughts and Behaviours Affect Sleep in People with and without Tinnitus

Participant Debrief Form

Thank you very much for agreeing to take part in this research exploring how thoughts and behaviours may affect sleep for people with and without tinnitus.
This study aims to explore whether thoughts and behaviours related to sleep are similar in people who have insomnia both with and without related tinnitus. It also explores if such thoughts and behaviours are different in people without sleep problems, whether or not they have distressing tinnitus. We hope that this information will improve our understanding of tinnitus-related insomnia and lead to the development of more effective treatments.

Further Reading
If you are interested in other research that has been conducted around tinnitus-related insomnia the following articles are recommended:
Crönlein, T., Langguth, B., Pregler, M., Kreuzer, P. M., Wetter, T. C., & Schecklmann, M. (2016). Insomnia in patients with chronic tinnitus: Cognitive and emotional distress as moderator variables. Journal of Psychosomatic Research, 83, 65–68.
Miguel, G. S., Yaremchuk, K., Roth, T., & Peterson, E. (2014). The effect of insomnia on tinnitus. Annals of Otology, Rhinology and Laryngology, 123(10),696–700.

Looking for more help?
Sleep difficulties and tinnitus can be distressing conditions that affect people's wellbeing. Please note, since this survey is anonymous we are not able to offer follow up support. If you feel that you are in need of more support or would like more help with tinnitus or your sleep, we advise that you contact your GP.
You may also find the following organisations helpful:
If you are struggling with difficult feelings, you can talk to The Samaritans in confidence at any time on ***116 123.*** You can also email them at ***jo@samaritans.org*** *or get more information at their website:* https://www.samaritans.org/
The British Tinnitus Association has some very helpful information as well as a telephone support helpline, and you can find out more here - https://www.tinnitus.org.uk/
For more information about insomnia and sleep problems, there is good information on the NHS website here: https://www.nhs.uk/conditions/insomnia/