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Cognitive behavioural factors in tinnitus-related insomnia

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8 **Keywords:** tinnitus₁, insomnia₂, CBT₃, cognitive, behavioural₅, sleep, sleep disorder (Min.5-
9 Max. 8)

10 Abstract

11 **Background:** A significant proportion of individuals with distressing tinnitus also report insomnia.
12 Limited but emerging evidence suggests tinnitus-related insomnia cannot be explained purely by the
13 presence of tinnitus, and that that sleep-related cognitive behavioural processes may also play a key
14 role in exacerbating tinnitus-related insomnia.

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

17 **Methods:** This between-groups study recruited 180 participants online for four groups: tinnitus-
18 related insomnia (N=49), insomnia disorder without tinnitus (N=34), tinnitus sufferers who are good
19 sleepers (N=38) and controls (N=59). They completed questionnaires assessing insomnia severity,
20 sleep-related cognitions and behaviours, sleep quality, anxiety and depression. People with tinnitus
21 completed a measure of tinnitus severity and rated the loudness of their tinnitus on a subjective
22 measure.

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

29 **Conclusion:** Findings suggest that tinnitus-related insomnia may be maintained by cognitive
30 behavioural processes similar to those found in insomnia disorder, and such processes are more
31 important than tinnitus severity when understanding sleep disturbance. People with tinnitus-related
32 insomnia may benefit from treatments such as Cognitive Behavioural Therapy for insomnia.

33 1 Introduction

34 Tinnitus is defined by the experience of hearing sound, commonly ringing or buzzing, in
35 the absence of external stimuli (Beukes et al., 2017). Estimates vary, some suggesting it may

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36 affect 30% of the population (McCormack, Edmondson-Jones, Somerset, & Hall, 2016). Common
37 impacts of distressing tinnitus include emotional distress, anxiety (Laurikainen, Johansson,
38 Akaan-Penttila, & Haapaniemi, 2000), difficulties in sleep, relationships, work functioning and
39 concentration (Asnis et al., 2018). A systematic review looking at the co-occurrence of
40 depression and tinnitus suggested a 33% prevalence of depression amongst people who suffer
41 with tinnitus (Salazar et al., 2019). It is likely that this co-occurrence is bidirectional, for
42 example tinnitus fueling depression and depression possibly making tinnitus harder to cope
43 with, thus making tinnitus worse. A UK survey estimated societal costs of £2.7bn annually
44 (Stockdale et al., 2017).

45 Those suffering with tinnitus commonly complain of sleep disturbance (Hébert, Fullum, &
46 Carrier, 2011; Miguel, Yaremchuk, Roth, & Peterson, 2014), though our understanding of the
47 comorbidity rates of insomnia and tinnitus is incomplete. A review examining the relationship
48 between the two disorders (Asnis et al., 2018) found that 15 of 16 studies included in the
49 review used variable and often inadequate assessment techniques and criteria to define
50 insomnia. Most reported prevalence of insomnia above 40% in their tinnitus sample (Asnis et
51 al., 2018). The remaining study used diagnostic assessment (Miguel et al., 2014) and reported
52 an insomnia prevalence of 27%. This review led to predictions that individuals who suffer with
53 both disorders will experience greater tinnitus distress than those with only tinnitus and
54 highlighted that higher tinnitus-related distress is associated with greater levels of anxiety and
55 depression. Research has found that men who experience insomnia associated with tinnitus
56 have higher depression scores than women, indicating potential gender differences to consider
57 in treatment (Richter et al., 2021).

58 Our understanding about why sleep disturbance is common in tinnitus is limited. One
59 hypothesis suggests insomnia in tinnitus be understood through the association between noise
60 and difficulty sleeping (Izuhara et al., 2013). Izuhara and colleagues (2013) suggested that
61 sleep disturbance associated with tinnitus could be similar to residents in a noisy
62 neighborhood experiencing difficulties falling asleep, suggesting that tinnitus volume alone
63 maintains insomnia. However, other research has indicated that interpretation of tinnitus
64 causes greater distress than its volume alone (Basile, Fournier, Hutchins, & Hébert, 2013). A
65 further study looked at the relationship between the loudness of tinnitus and insomnia (Aazh
66 and Moore, 2019). The researchers found that the relationship was mediated by depression,
67 tinnitus handicap and tinnitus annoyance as opposed to insomnia being directly related to the
68 loudness of tinnitus. It remains unclear if the experience of tinnitus can be compared to an
69 external sound, particularly as there are different types and possible causes of tinnitus.

70 Insomnia disorder is commonly comorbid with psychological disorders such as anxiety
71 and depression (Harvey, 2001), however evidence indicates that it is not just a 'symptom' of
72 other psychological disorders (Harvey, 2001). This is because it can be treated independently
73 from comorbidities and it can both precede and follow on from comorbidities. The cognitive
74 model of insomnia (Harvey, 2002) outlines many processes that an individual experiences
75 during the night and day which maintain insomnia. In summary, it proposes that insomnia
76 arises from worry about sleep and the consequential impact on day-to-day life. This causes
77 increased emotional and physiological arousal leading to selective attention and monitoring
78 and distorted perceptions (i.e. underestimating sleep and functioning). Worries also lead to
79 safety-seeking behaviours intended to reduce insomnia and its impact (e.g. cancelling plans)
80 but which paradoxically exacerbate sleep difficulties. This leads to escalating anxiety and
81 further insomnia.

82 Cognitive Behavioural Therapy for insomnia (CBTi) was developed as a brief
83 psychological intervention for insomnia. Though it does not address all processes put forward
84 in the cognitive model of insomnia (Harvey, 2002) it aims to target unhelpful thoughts and
85 behaviours around sleep using psychoeducation, behavioural experiments, sleep restriction,
86 stimulus control and cognitive restructuring (Pigeon et al., 2012). Research shows that
87 specifically targeting distorted perception of sleep leads to reduced sleep-related anxiety (Tang
88 & Harvey, 2004) whilst challenging insomnia-related thoughts and behaviours enables
89 individuals to establish healthier sleep patterns and improve quality of life (Okajima, Komada,
90 & Inoue, 2011). A high-quality meta-analysis of RCTs using CBTi in insomnia (Okajima et al.,
91 2011) found it to be effective, with medium to large effect sizes. Improvement on measures of
92 dysfunctional sleep-related cognitions was a significant change following CBTi, suggesting
93 these are central to maintaining insomnia and crucial to target in treatment.

94 It is argued that the same cognitive and behavioural processes maintain insomnia,
95 regardless of comorbidities such as chronic pain (Tang, Goodchild, & Salkovskis, 2012). CBTi is
96 proven to successfully treat insomnia where such comorbidities exist (Jungquist et al., 2010).
97 Of note, chronic pain shares many similarities with tinnitus (Moller, 2000); both being sensory
98 perceptual disorders associated with hypersensitivity (Rauschecker, May, Maudoux, & Ploner,
99 2015) and related psychological difficulties (Rauschecker et al., 2015).

100 Evidence has shown that people with insomnia and people with tinnitus share similar sleep
101 processes, including physiological characteristics of sleep disturbance (Burgos et al., 2005).
102 Polysomnography (PSG), the 'gold standard' objective assessment for sleep disorders, has
103 shown that tinnitus patients experience more awakenings and greater difficulty with sleep
104 onset compared to healthy controls (Burgos et al., 2005). This finding is similar to that reported
105 when comparing people with insomnia to healthy controls. A systematic review of studies of
106 polysomnography applied to patients with tinnitus found that few have assessed tinnitus
107 sufferers sleep using this technique, instead opting for self-report questionnaires (Teixeira,
108 Granjeiro, De Oliveira & Júnior, 2017), highlighting the need for future studies to use
109 polysomnography as an objective evaluation method.
110

111 Crönlein et al., (2016) assessed sleep and psychological difficulties in samples with and
112 without tinnitus, using the Regensburg Insomnia Scale (RIS). People with tinnitus reported
113 more difficulties with and greater worries about sleep, supporting the theory that insomnia in
114 tinnitus may be maintained by the insomnia process outlined above. However, this study is
115 limited by the use of the RIS, a brief outcome measure rather than a tool designed to assess
116 insomnia-specific cognitions and behaviours. It also did not offer comparison with an insomnia
117 group without tinnitus, and the authors suggested that anxiety and depression could be
118 confounding factors that were not accounted for in their study.

119 Few tinnitus studies include measures of improved sleep as a primary or secondary
120 outcome and few consider severity of sleep impairment in recruitment or analysis (Hesser,
121 Weise, Westin, & Andersson, 2011). However, a clinic-based study evaluated outcomes from
122 CBTi for tinnitus-related insomnia (Marks, McKenna, & Vogt, 2019) and found that 66.7% of
123 participants showed reliable improvement on the Insomnia Severity Index (ISI). Participants
124 reported reduced tinnitus severity and psychological distress. Though limited by the small
125 sample size and lack of a control group, it was the first of its kind to evidence the efficacy of
126 CBTi as a treatment for tinnitus-related insomnia. A more recent randomised controlled study
127 looked at the benefits of CBTi for people with tinnitus-related insomnia and found it to be more

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128 effective in reducing tinnitus distress and improving sleep quality compared with audiology-
129 based care or a sleep support group (Marks, Hallsworth, Vogt, Klein & McKenna, 2022). These
130 studies offer tentative evidence that tinnitus-related insomnia is maintained by cognitive and
131 behavioural processes similar to those seen in insomnia without comorbidities or insomnia
132 disorder (Harvey 2002).

133 In summary, evidences shows that the physiological characteristics of insomnia are
134 similar in populations with and without tinnitus (Burgos et al., 2005), both experiencing
135 decreased sleep efficiency, sleep time and a higher number of awakenings compared to healthy
136 controls (Burgos et al., 2005). Limited evidence indicates that the psychological processes that
137 may underpin the experience of insomnia in tinnitus could be equivalent to the psychological
138 processes that underpin insomnia without tinnitus (Crönlein et al., 2016; Marks et al., 2019).
139 An example of this would be dysfunctional sleep related cognitions, which are beliefs about
140 people's expectations and attitudes about the causes and consequences of poor sleep e.g. "when
141 I sleep poorly one night, I know it will disturb my sleep schedule for the whole week". Our
142 understanding in this area is hampered by a lack of consistency across the field regarding the
143 outcome measures used to assess sleep quality, the presence of insomnia, and sleep related
144 thoughts and behaviours. It is vital to clarify how psychological factors are associated with
145 tinnitus-related insomnia to improve understanding of patient experiences and effective
146 treatment of tinnitus-related insomnia.

147 This study aimed to examine whether cognitive and behavioural factors believed to commonly
148 maintain insomnia (Harvey, 2002) are equally important factors that contribute to insomnia in
149 people who have tinnitus. It was hypothesized that levels of dysfunctional sleep-related
150 cognitions, behaviours and sleep quality would be similar in individuals reporting insomnia,
151 regardless of tinnitus presence, and greater than people who do not report insomnia (both with
152 and without distressing tinnitus). As research has suggested that those with tinnitus and
153 insomnia experience higher levels of anxiety, depression and tinnitus distress than individuals
154 who have tinnitus without insomnia (Asnis et al., 2018) it was hypothesised that tinnitus
155 distress, anxiety and depression will be significantly higher in tinnitus-related insomnia
156 compared with tinnitus good sleepers. A final hypothesis was that subjective tinnitus volume
157 will not differ significantly between tinnitus-related insomnia and tinnitus good sleepers, to
158 add weight to the argument that it is not the noise of the tinnitus that keeps people who have
159 insomnia awake.

160

161 2 Materials and Methods

162 2.1 Design

163 This cross-sectional study used a between-groups design in which four groups were
164 compared: 1) tinnitus-related insomnia; 2) insomnia; 3) tinnitus good sleepers and 4) controls.
165 All responses were collected via the online platform Qualtrics, questionnaires were presented
166 in the same order to participants. Inclusion criteria was a minimum age of 18. Exclusion criteria
167 were existing diagnosis of a sleep disorder other than insomnia, or belief that their insomnia
168 was explained by a physical or mental health condition besides tinnitus. Recruitment was
169 conducted via social media, with relevant charities agreeing to share the study on their
170 websites.

171 2.2 Participants and Procedures

172 A total of 773 participants initiated the study, of which 266 did not consent, and 73 exited
173 the survey before completion. Significantly more (N=253) met criteria for the controls and
174 tinnitus-related insomnia group than planned and were prevented from taking part. One
175 participant was excluded as they wrote “333” in all free-text boxes. The final sample consisted
176 of 180 participants who had completed all questionnaires (all but the GAD-7 and PHQ-9 were
177 counted as complete data sets). Participants were asked whether or not they had tinnitus and a
178 further question to assess how much of a problem it was for them. Participants then completed
179 The Insomnia Severity Index (ISI; Morin, 1993). This information was then used to sort
180 participants into one of the four groups (Figure 1 in supplementary material shows the study
181 flow). The final groups were as follows: insomnia (N=34); tinnitus-related insomnia (N=49);
182 tinnitus good sleepers (N=38); and controls (N=59). See Table 1.1 for demographic
183 characteristics of the sample.

184 2.3 Measurement

185 All participants completed the following self-report questionnaires:

186 2.3.1 The Insomnia Severity Index (ISI; Morin, 1993)

187 This 7-item measure was used to screen participants for insomnia. The measure uses a five-point
188 Likert scale, ranging from 0 to 4 and offers a clinically-relevant tool for assessing insomnia.
189 Participants were allocated to a certain group depending on their score on this measure. The ISI has
190 good reliability and validity (Bastien, Vallières, & Morin, 2001). A score of 10 or above is deemed
191 appropriate for identifying clinically-relevant insomnia in a community sample (Morin, Belleville,
192 Bélanger, & Ivers, 2011). The ISI has been shown to have excellent internal consistency (Cronbach’s
193 $\alpha = 0.75$) when used to assess insomnia in a community sample (Morin et al., 2011).

194 2.3.2 The Pittsburgh Sleep Quality Index (PSQI) (Buysse et al., 1989)

195 This was used to assess participants sleep quality. The 18-item measure produces seven
196 component scores and one overall global score relating to quality of sleep. Question 10 was
197 omitted from administration as it does not contribute to the PSQI global score. This measure
198 has acceptable internal consistency (Cronbach’s $\alpha = 0.75$) (Hinz et al., 2017). Participants who
199 entered time ranges, for example answering 9-11pm when asked what time they have usually
200 gone to bed in the past month, were allocated a mid-point. This measure was used to assess
201 sleep quality instead of the ISI as it includes both quantitative aspects of sleep, such as sleep
202 duration, along with more subjective constructs, such as “restfulness” (Buysse et al., 1989).

203 2.3.3 Dysfunctional Beliefs and Attitudes about Sleep (DBAS-16) (Morin, Vallières, & Ivers, 204 2007)

205 The DBAS-16 was used to assess participants sleep related beliefs, many of which become the
206 target of CBTi (Morin et al., 2007). Participants are asked to respond to statements relating to
207 beliefs and attitudes about sleep on a Likert scale ranging from 0 (strongly disagree) to 10
208 (strongly agree). Examples of dysfunctional beliefs participants are asked to respond to are
209 “without an adequate nights sleep, I can hardly function the next day” and “I am worried that I
210 may lose control over my sleep abilities”. The DBAS-16 has been shown to have acceptable
211 validity and reliability (Cronbach’s $\alpha = 0.77-0.79$) (Morin et al., 2007).

212 **2.3.4 Sleep Related Behaviours Questionnaire (SRBQ) (Ree and Harvey, 2004)**

213 This measures the extent to which an individual engages in sleep-related safety behaviours thought
214 to maintain insomnia. Participants respond to 32 statements about how often they engage in each
215 behaviour, rating from 0 (almost never) to 4 (almost always). Examples of sleep related safety
216 behaviours are “I catch up on sleep by napping” and “I try to stop all thinking when trying to sleep”.
217 The psychometric properties of the SRBQ have not been systematically evaluated (Lebrun, Gély-
218 Nargeot, Maudarbocus, & Bayard, 2020). It has been shown to have good sensitivity to detect change
219 in psychological therapy for insomnia (Harvey, Sharpley, Ree, Stinson, & Clark, 2007) so is the best
220 available measure. Cronbach’s $\alpha = .94$ for this sample, indicating excellent internal consistency.

221 **2.3.5 The Generalised Anxiety Disorder Assessment (GAD-7) (Spitzer, Kroenke, Williams, & 222 Löwe, 2006)**

223 This 7-item scale assesses anxiety symptoms over the past two weeks. Participants rate anxiety
224 experiences from 0 (not at all) to 3 (nearly every day). Internal consistency of the GAD-7 is
225 excellent (Cronbach’s $\alpha = 0.92$) and good test-retest reliability ($\alpha = 0.83$) (Spitzer et al., 2006). A
226 score between 11 and 15 reflects moderate anxiety, above 15 indicates severe anxiety.

227 **2.3.6 The Patient Health Questionnaire (PHQ-9) (Kroenke, Spitzer, & Williams, 2001)**

228 This 9-item scale assesses depression symptoms over the past two weeks, with respondents rating
229 how much they were bothered by symptoms from 0 (not at all) to 3 (nearly every day). The scale has
230 good internal consistency (Cronbach’s $\alpha = 0.89$) and good test-retest reliability ($\alpha = 0.84$). A
231 score between 10 and 14 reflects moderate depression, 15-19 indicates moderately severe depression
232 and above 19 indicates severe depression.

233 **2.3.7 Demographic information**

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

236

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

238 **2.3.8 Tinnitus Handicap Inventory (THI) (Newman, Jacobson, & Spitzer, 1996)**

239 This 25-item measure was used to assess the severity of impact of participants tinnitus on
240 their daily lives. The THI requires participants to respond yes, no or maybe to statements about
241 their tinnitus. The THI has been found to have high internal consistency (Cronbach’s $\alpha = 0.92$).
242 This measure was chosen as it focuses less on sleep impairment than other tinnitus
243 questionnaires, which reduced the risk of redundant questions.

244 **2.3.9 Tinnitus-related distress**

245 This was a single question that asked participants to rate how much of a problem their tinnitus was.
246 Respondents chose between ‘not a problem’, ‘minor problem’, ‘moderate problem’, ‘considerable
247 problem’ or ‘severe problem’. Categories were informed by research looking at categories of
248 tinnitus-related distress (Handscorn, 2006). This, along with the ISI, was used to inform which
249 group participants were sorted into. This was used instead of the THI to insure the tinnitus groups
250 both contained participants with at least moderate distress.

251 2.3.10 Tinnitus Visual Analogue Scale (VAS)

252 This assesses subjective loudness of tinnitus. Participants selected from 0 (I can't hear my tinnitus,
253 even in quiet) to 100 (my tinnitus is louder than any other noise) where they would currently rate
254 their tinnitus. A Cochrane review of CBT for Tinnitus (Martinez-Devesa, Perera, Theodoulou, &
255 Waddell, 2010) found numeric visual analogue scales used in seven of the eight included studies,
256 though variation in presentation was noted. Single item ratings, though limited, have been found to
257 be more reliable than tinnitus loudness matching (Hall, Mehta, & Fackrell, 2017), this was included
258 in addition to the THI due to literature suggesting tinnitus loudness may be independent from tinnitus
259 distress.

260 2.4 Data analysis

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

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

280 3 Results

281 3.1 Participant demographics

282 Demographic characteristics are presented in Table 1.1. Given small cell sizes for some
283 variables, responses were collapsed such that there were two categories for each characteristic
284 (e.g. Male vs Female, White vs non-White).

285 The tinnitus-related insomnia group were found to be significantly older than the insomnia and
286 control groups ($F_{(3,176)} = 6.59, p < .001$). Significant differences were also observed for marital
287 status, $X^2(3, N=176) = 10.7, p = .013$, and ethnicity, $X^2(3, N=176) = 14.7, p = .002$, whilst no
288 differences were observed with regard to gender, education level and current employment.
289 Table 1.2 presents summary scores across all measures. A Kruskal-Wallis H test showed
290 significant differences between participant groups for both anxiety, $H(3) = 39.60, p < .001$ and
291 depression, $H(3) = 71.7, p < .001$. Tinnitus-related insomnia and insomnia groups had
292 significantly greater ($p < .01$ for all) levels of anxiety and depression compared to tinnitus good

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293 sleepers and controls. Tinnitus-related insomnia compared with insomnia groups and controls
294 compared with tinnitus good sleepers groups did not differ significantly.

295 After exclusions for missing data on the outcome or covariates, 174 participants were included in the
296 regression analysis (34 in the insomnia group, 48 in the tinnitus-related insomnia group, 37 in the
297 tinnitus good sleepers group, and 55 controls) (Table 1.3).

298 The results of the pairwise differences between groups, which were tested post hoc from a full model
299 can be seen in Table 1.4

300 3.2 Sleep-related cognitions

301 Results from a hierarchical regression model of sleep-related cognitions (DBAS-16 score) showed
302 that the addition of anxiety and depression scores to predict sleep-related cognitions (DBAS-16
303 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
304 addition of group, $\Delta R^2 = 0.09$, $F(3, 169) = 10.5$ $p < .001$. Post-hoc pairwise comparisons showed that
305 the tinnitus-related insomnia group scored significantly higher on sleep-related cognitions
306 compared to the tinnitus good sleepers, difference = 1.41, 95% CI [0.51, 2.23] and controls,
307 difference = 1.45, 95% CI [0.60, 2.31]. The insomnia group scored significantly higher on sleep-
308 related cognitions compared to the tinnitus good sleepers, difference = 1.46, 95% CI [0.53,
309 2.38] and controls, difference = 1.49, 95% CI [0.62, 2.37]. The insomnia group had higher sleep-
310 related cognitions than the tinnitus-related insomnia group, but this difference was not
311 significant: difference = 0.04, 95% CI [-0.88, 0.80], nor was the difference between the tinnitus
312 good sleepers and controls, difference = 0.04, 95% CI [-0.72, 0.80].

313 3.3 Sleep-related behaviours

314 Results from a hierarchical regression model of sleep-related behaviours (SRBQ scores)
315 showed that the addition of anxiety and depression led to a statistically significant increase in R^2 ; ΔR^2
316 = 0.45, $F(2, 172) = 71.6$, $p < .001$, as did addition of participant group, $\Delta R^2 = 0.08$, $F(3, 171) = 9.56$,
317 $p < .001$. Post-hoc pairwise comparisons showed that the insomnia group scored highest on the
318 SRBQ compared to other groups, with the difference between group means being significant for
319 the tinnitus good sleepers, difference = 20.38, 95% CI [10.01, 30.74] and controls, difference =
320 16.10, 95% CI [6.31, 25.89]. Though the insomnia group scored higher on average than the
321 tinnitus-related insomnia group, the difference between group means was not significant,
322 difference = -9.20, 95% CI [-18.60, 0.21]. The tinnitus-related insomnia group scored
323 significantly higher than the tinnitus good sleepers, difference = 11.18, 95% CI [1.13, 21.23] but
324 not the controls, difference = 6.90, 95% CI [-2.61, 16.42]. The tinnitus good sleepers group
325 scored lower than the controls for sleep-related behaviours, but this difference was not
326 significant, -4.28, 95% CI [-12.77, 4.22].

327 3.4 Overall sleep quality

328 Results from a hierarchical regression model of overall sleep quality scores (PSQI score)
329 showed that the addition of anxiety and depression led to a statistically significant increase in R^2 ; ΔR^2
330 = 0.47, $F(2, 172) = 5.72$, $p < .001$, as did addition of participant group, $\Delta R^2 = 0.19$, $F(3, 171) = 10.43$,
331 $p < .001$. Post-hoc pairwise comparisons showed that the tinnitus-related insomnia group had
332 significantly worse sleep quality (indicated by higher score) compared to the tinnitus good
333 sleepers, difference = 4.14, 95% CI [2.56, 5.73] and controls, difference = 3.44, 95% CI [1.94,
334 4.94]. The insomnia group scored significantly higher on sleep quality compared to the tinnitus
335 good sleepers, difference = 5.18, 95% CI [3.54, 6.82] and controls, difference = 4.47. 95% CI

336 [2.93, 6.02]. The tinnitus-related insomnia group had better sleep quality than the insomnia
 337 group, but this difference was not significant, difference = -1.03, 95% CI [-2.52, 0.45], nor was
 338 the difference between the tinnitus good sleepers and controls, difference = -0.71, 95% CI [-
 339 2.05, 0.62].

340 **3.5 Tinnitus loudness and tinnitus distress between tinnitus-related insomnia and tinnitus** 341 **good sleeper groups**

342 The tinnitus-related insomnia group had greater tinnitus distress ($M=58.54$, $SD=23.04$)
 343 compared to the tinnitus good sleepers' group ($M=41.9$, $SD=21.62$). This difference was
 344 significant (16.64, 95% CI [6.91, 26.28]). The tinnitus-related insomnia group experienced
 345 significantly louder subjective tinnitus volume compared to the tinnitus good sleepers' group
 346 (Median difference = 10, $U = 626$, $z = -2.61$, $p = 0.09$). As this was unexpected, post-hoc one-
 347 way ANCOVA explored whether sleep-related cognitions (DBAS-16) and behaviours (SRBQ)
 348 differed between the two groups when controlling for tinnitus loudness (VAS) and distress
 349 (THI). The tinnitus-related insomnia group had significantly greater insomnia cognitions, $F(1,$
 350 $83) = 35$, $p < .001$, partial $\eta^2 = .3$, and behaviours, $F(1, 83) = 33.1$, $p < .001$, partial $\eta^2 = .29$,
 351 compared to tinnitus good sleepers when controlling for tinnitus distress and loudness, in line
 352 with the findings from the main analysis.

353 **4 Discussion**

354 In line with hypotheses, this novel study found that individuals with tinnitus-related insomnia
 355 report the same level of dysfunctional sleep-related cognitions and behaviours as individuals
 356 with insomnia without tinnitus. For example, catastrophic cognitions about having inadequate
 357 sleep, which fuels anxiety and worry, hypervigilance to nighttime wakefulness and daytime
 358 sleepiness, and unhelpful behaviours such as spending too long in bed or taking day-time naps.
 359 These sleep-related cognitions and behaviours were significantly more prevalent in tinnitus-
 360 related insomnia than people with distressing tinnitus who sleep well and in people with
 361 neither insomnia nor distressing tinnitus. Such findings support the claim that cognitive
 362 behavioural processes hypothesised to contribute to the maintenance in insomnia (Harvey,
 363 2002), also maintain insomnia in people with tinnitus. This aligns with recent findings from a
 364 RCT which found that CBTi targeting specifically sleep-related behaviours and cognitions (e.g.
 365 through time-in-bed restriction, psychoeducation about sleep, anxiety and worry management,
 366 etc) led to large, clinically significant improvements in sleep and tinnitus (Marks et al., 2022).
 367 Together, these studies suggest that insomnia in tinnitus patients may involve the same
 368 processes that are found in people who have insomnia without tinnitus. Of course, tinnitus may
 369 add an additional layer of complexity and challenge for the patient, but this similarity across
 370 groups indicates how tinnitus and insomnia patients can benefit from existing insomnia
 371 therapies.

372 One possible explanation could have been that anxiety and depression symptoms contributed
 373 to the impaired sleep and dysfunctional cognitive-behaviours related to sleep, as such
 374 symptoms were significantly higher both groups with insomnia. However, the fact that the
 375 differences in sleep remained after controlling for anxiety and depression demonstrates that sleep-
 376 related cognitive behavioural factors in fact explain unique variance in the experience of insomnia
 377 both with and without tinnitus.

378 This study offers new insight into possible maintaining factors for sleep difficulties reported by
 379 people with distressing tinnitus. The finding that people with tinnitus-related insomnia

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380 reported greater levels of unhelpful sleep-related cognitions, behaviours and sleep quality than
381 tinnitus good sleepers indicates that the factors differentiating these two groups relate to
382 insomnia-relevant processes (cognitions and behaviours) rather than tinnitus-relevant
383 processes. Furthermore, there were equivalent levels of sleep-related cognitions, behaviours
384 and quality in the insomnia-only and tinnitus-related insomnia groups. This adds significant
385 weight to the literature regarding shared cognitive-behavioural characteristics between the
386 two experiences of insomnia, i.e. with and without tinnitus (Crönlein et al., 2016). Considering
387 existing evidence in support of shared biological characteristics between insomnia and
388 tinnitus-related insomnia (Burgos et al., 2005), these findings support a biopsychosocial model
389 of tinnitus-related insomnia.

390 Unexpectedly, tinnitus subjective volume was louder for those with tinnitus-related insomnia than for
391 those who sleep well, counter to evidence that tinnitus distress is not directly associated with tinnitus
392 volume (Basile et al., 2013). Whilst this may represent a novel difference between people with
393 tinnitus-related insomnia and those without insomnia further research is needed to draw firm
394 conclusions and explain why this may be the case. The findings from the main analyses did not
395 change when controlling for tinnitus severity and volume, supporting the argument that sleep-
396 related cognitive behavioural factors maintain tinnitus related insomnia, and countering the
397 hypothesis that tinnitus volume fuels insomnia (Izuhara et al., 2013; Aazh and Moore, 2019).

398 Another unexpected finding was a lack of significant difference in sleep-related behaviours
399 between those with tinnitus-related insomnia and controls. One possible explanation may
400 relate to the recruitment strategy whereby recruitment of tinnitus groups directly focused on
401 sleep whilst recruitment of the control group took a broader approach, which may have led to a
402 tinnitus sample with greater concerns about sleep than the controls.

403 4.1 Strengths

404 This is the first study that has compared insomnia related thoughts and behaviours reported by people
405 with tinnitus to people with insomnia, people with tinnitus who sleep well and individuals without
406 distressing tinnitus or insomnia. The use of multiple comparators is a key strength as it allows for
407 clarification of similarities and differences across all groups and highlights how similar cognitive
408 behavioural factors in tinnitus-related insomnia are to insomnia without tinnitus. The use of the ISI
409 (Morin, 1993) to assess for the presence of insomnia, which is a validated outcome measure for
410 insomnia research (Bastien, Vallières & Morin, 2001), is scarce within tinnitus literature (Asnis et al.,
411 2018) and the robustness of measures collected across the sample is another strength.

412 4.2 Limitations

413 The possibility of participants having undiagnosed sleep disorders, besides insomnia is a limiting
414 factor in this study. The researchers collected an outcome measure intended to screen for the
415 possibility of undiagnosed sleep disorders (The Sleep Diagnostic Algorithm, Wilson, 2010) but its
416 brevity meant that no participants were excluded based on responses. Sleep disorders are diagnosed
417 using thorough clinical assessments, which future research in this field should aim to include.

418 Some participants allocated to the insomnia or control group also reported tinnitus. This is because
419 allocation of participants to groups was based on participant self-selection of tinnitus distress, rather
420 than score on a tinnitus measure. Interestingly, there was a mismatch, with some self-reported 'mild'
421 or 'no' tinnitus sufferers meeting criteria for moderate tinnitus on the THI. This could mean that
422 sleep related cognitions and behaviours measured in the controls and insomnia groups are impacted

423 by the presence of tinnitus. This would limit the extent to which comparisons between the tinnitus
424 related insomnia and insomnia groups can be drawn. Using the THI to sort participants into groups
425 would have avoided this limitation. However, this would require every person in the study to
426 complete the 25-item tinnitus questionnaire (THI). Along with increasing questionnaire burden, this
427 could cause confusion for participants who say they experience no tinnitus as they would be asked to
428 respond to statements such as “because of your tinnitus do you feel desperate?”. As there are clearly
429 pros and cons to each method of grouping criteria, future studies should consider the limitations of
430 both methods prior to undertaking their study. The study is further limited by the questionnaires not
431 being counterbalanced and solely using self-report measures and cut offs to classify people as having
432 insomnia, tinnitus, or both. Future studies should consider more robust assessments, that are more in
433 line with the clinical diagnostic process for each condition and administered in a randomised way.
434 Additionally, the field would benefit from future studies using consistent standardised
435 measures to compare outcomes more easily.

436 This study is limited by the samples lack of ethnic diversity. The study did not collect any
437 information about participants socio-economic status, which may mean we are missing information
438 about the prevalence of tinnitus and insomnia in different fractions of society. A large proportion of
439 the sample reported to have further education experience, which can improve cognitive flexibility
440 and lead to better coping strategies. Future studies should set out an a-priori strategy to recruit a more
441 diverse sample, and to set hypotheses around potential differences between groups, such as gender
442 differences (Richter et al., 2021). This will allow conclusions to be more representative of society
443 and could lead to new insights into risk and protective factors.

444 **4.3 Conclusions and clinical implications**

445 This study demonstrates that insomnia-related cognitive and behavioural processes are very similar in
446 people with insomnia both with and without associated tinnitus, and that these are different from
447 people with tinnitus who sleep well. The study replicates findings that people with both tinnitus and
448 insomnia report greater anxiety, depression and tinnitus-related distress than tinnitus sufferers
449 without insomnia (Asnis et al., 2018) but shows that such insomnia related cognitions and behaviours
450 remain important even when such differences are accounted for. This suggests that difficulties with
451 sleep reported by many tinnitus sufferers can be understood by recognising that they are engaging in
452 key sleep-related thoughts and behaviours that are stopping them from sleeping, as reported by
453 people with insomnia and explained by the Cognitive Behavioural model of insomnia (Harvey,
454 2002).

455 CBTi has been shown to work with insomnia co-occurring with other physical health problems, such
456 as chronic pain (Jungquist et al., 2010; Tang et al., 2012) and evidence has indicated it is also
457 effective in tinnitus-related insomnia (Marks et al., 2019; Marks et al., 2022). The findings from
458 this study supports emerging evidence that people presenting with tinnitus-related insomnia could
459 benefit from treatments already shown to work effectively on people with insomnia disorder, such as
460 CBTi, targeting sleep-related cognitions and behaviours.

461 **5 Conflict of Interest**

462 *The authors declare that the research was conducted in the absence of any commercial or financial*
463 *relationships that could be construed as a potential conflict of interest.*

464 **6 Author Contributions**

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465 EM and GB designed the study. GB collected the data for the study, analysed the data and wrote the
466 manuscript. EM contributed substantially to the reviewing and editing of the manuscript. EM
467 supervised the study. Both authors contributed to the reviewing of the article and approved it for
468 submission.

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475 Association. An earlier version study has been published online as part of the second authors thesis.

476 9 Supplementary Material

477 Supplementary Material should be uploaded separately on submission, if there are Supplementary
478 Figures, please include the caption in the same file as the figure. Supplementary Material templates
479 can be found in the Frontiers Word Templates file.

480 Please see the [Supplementary Material section of the Author guidelines](#) for details on the different
481 file types accepted.

482 10 Data Availability Statement

483 The fully anonymised data supporting the conclusions of this article will be made available to any
484 qualified researcher on request.

485 11 Ethics Statement

486 The study received ethical approval from The University of Bath. Participants provided their
487 informed consent and were provided with debrief information following participation. This
488 included websites for further support.

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- 628
- 629

630 12 Tables

631 Table 1.1

632 *Demographic characteristics of participants in study exploring cognitive-behavioural factors in tinnitus-*
633 *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)					

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634	Yes	3 (8.8)	6 (12.5)	4 (10.5)	2 (3.6)	0.40
635	No	31 (91.2)	42 (87.5)	34 (89.5)	54 (96.4)	
636	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)					
637						
638						
639						

Table 1.2 *Summary of measures completed across groups in study exploring cognitive-behavioural factors in tinnitus-related insomnia*

	Insomnia group (N=34)	Tinnitus-related insomnia group (N=48)	Tinnitus good sleeper groups (N=37)	Controls (N=55)
ISI- Mean (SD), range	15.68 (3.54), 10-23	16.63 (4.05), 10-25	4.39 (2.71), 0-9	4.37 (2.65), 0-9
DBAS-16 - Mean (SD), range	5.77 (1.48), 1.81-8.06	5.85 (1.51), 2.81-9.63	3.51 (1.52), 0.63-6.50	3.21 (1.48), 0.38-6.69
SRBQ - Mean (SD), range	64.74 (17.87), 27-91	55.24 (17.56), 12-86	30.87 (13.80), 4-59	33.75 (19.44), 0-83
PSQI - Mean (SD), range	11 (2.98), 5-16	10.67 (2.75), 4-17	4.58 (2.14), 2-11	5.07 (2.43), 1-11
GAD-7 - Mean (SD), range	10.71(5.32), 0-21	9.50 (6.00), 0-21	5.62 (4.68), 0-17	4.79 (3.82), 0-19
PHQ-9 - Mean (SD), range	12.15 (5.92), 3-25	12.29 (6.79), 1-26	4.77 (4.77), 0-20	4.04 (4.14), 0-23
THI - Mean (SD), range	26.33 (13.59), 6-48	58.16 (22.95), 10-98	41.9 (21.62), 6-88	19.50 (16.55), 16-92
VAS - Mean (SD), range	41.17 (18.93), 11-66	70.51(19.82), 25-100	60.45 (19.60), 15-100	43.61 (19.16), 1-74

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ISI Insomnia Severity Index; DBAS-16 Dysfunctional Beliefs and Attitudes about Sleep; SRBQ Sleep Related Behaviours Questionnaire; PSQI The Pittsburg Sleep Quality Index; GAD-7 The Generalised Anxiety Disorder Assessment; PHQ-9 The Patient Health Questionnaire; THI Tinnitus Handicap Inventory; VAS Tinnitus Visual Analogue Scale

646 Table 1.3
 647 *F*-statistics, *R*-squared, and change in *R*-squared values derived from hierarchical linear regression models
 648 predicting sleep-related cognitions (DBAS-16) / behaviours (SRBQ) / sleep quality (PSQI) from age, gender,
 649 anxiety, depression and group
 650

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

DBAS-16 Dysfunctional Beliefs and Attitudes about Sleep; SRBQ Sleep Related Behaviours Questionnaire; PSQI The Pittsburg Sleep Quality Index

651 Table 1.4 *Effect estimates, adjusted 95% confidence intervals, and adjusted and unadjusted p-values*

Model	Comparison	Estimate	95% CI	P _{adj}	P _{unadj} ⁶⁵²
DBAS-16	Tinnitus Related Insomnia– Insomnia	-0.04	-0.88 - 0.80	1.00	0.90 ⁶⁵³ 654
	Tinnitus Related Insomnia – Tinnitus Good Sleepers	1.41	0.51 - 2.23	<.001	<.001 ⁶⁵⁵ 656
	Tinnitus Related Insomnia– Controls	1.45	0.60 -2.31	<.001	<.001 ⁶⁵⁷ 658
	Insomnia - Tinnitus Good Sleepers	1.46	0.53-2.38	<.001	<.001 ⁶⁵⁹ 660
	Insomnia – Controls	1.49	0.62-2.37	<.001	<.001 ⁶⁶¹ 662
	Tinnitus Good Sleepers – Controls	0.04	-0.72-0.80	1.00	0.90 ⁶⁶³ 664
SRBQ	Tinnitus Related Insomnia– Insomnia	-9.20	-18.60 - 0.21	0.06	0.06 ⁶⁶⁵ 666
	Tinnitus Related Insomnia – Tinnitus Good Sleepers	11.18	1.13-21.23	0.02	<.001 ⁶⁶⁶ 667
	Tinnitus Related Insomnia– Controls	6.90	-2.61-16.42	0.33	0.33 ⁶⁶⁸ 669
	Insomnia - Tinnitus Good Sleepers	20.38	10.01-30.74	<.001	<.001 ⁶⁶⁹ 670
	Insomnia – Controls	16.10	6.31-25.89	<.001	<.001 ⁶⁷⁰ 671
	Tinnitus Good Sleepers – Controls	-4.28	-12.77- 4.22	1.00	0.18 ⁶⁷¹ 672
PSQI	Tinnitus Related Insomnia– Insomnia	-1.03	-2.52- 0.45	0.40	0.40 ⁶⁷³ 674
	Tinnitus Related Insomnia – Tinnitus Good Sleepers	4.15	2.56- 5.73	<.001	<.001 ⁶⁷⁴ 675
	Tinnitus Related Insomnia– Controls	3.44	1.94- 4.94	<.001	<.001 ⁶⁷⁵ 676
	Insomnia - Tinnitus Good Sleepers	5.18	3.54-6.82	<.001	<.001 ⁶⁷⁶ 677
	Insomnia – Controls	4.47	2.93-6.02	<.001	<.001 ⁶⁷⁷ 678
	Tinnitus Good Sleepers - Controls	-0.71	-2.05-0.62	0.97	0.16 ⁶⁷⁸ 679 680

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

683 DBAS-16 *Dysfunctional Beliefs and Attitudes about Sleep*; SRBQ *Sleep Related Behaviours Questionnaire*; PSQI *The*
684 *Pittsburg Sleep Quality Index*