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A systematic review and meta-analysis exploring effects of third-wave psychological therapies on hearing-related distress, depression, anxiety and quality of life in people with audiological problems

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25 **ABSTRACT**

26 *Purpose:*

27 There is growing evidence supporting the use of third-wave psychological therapies, such as
28 mindfulness-based interventions (MBIs) and acceptance and commitment therapy (ACT), for people
29 with long-term or chronic physical health conditions. We conducted a systematic review and meta-
30 analysis to critically evaluate the effectiveness of third-wave interventions for improving hearing-
31 related distress and psychological wellbeing in people with audiological problems.

32 *Method:*

33 We searched online bibliographic databases and assessed study quality. We conducted random-
34 effects meta-analyses if at least two randomized controlled trials (RCTs) examined hearing-related
35 distress, depression, anxiety or quality of life in people with audiological problems. Findings of pre-
36 post studies were summarized narratively.

37 *Results:*

38 We identified 15 studies: 6 RCTs and 9 pre-post studies. The methodological quality of studies was
39 mostly poor-to-moderate and sample sizes were typically small (overall n=750). Most studies focused
40 on tinnitus (n=12), MBIs (n=8) and ACT (n=6). Statistically significant improvements in hearing-related
41 distress were found with ACT and MBIs vs. controls and other treatments at post-intervention in
42 people with tinnitus, while improvements in depression and anxiety were only found for ACT vs.
43 controls at post-intervention. However, gains were either not maintained or not examined at follow-
44 up and there was no evidence for improvements in quality of life.

45 *Conclusions:*

46 At present, there is insufficient evidence to recommend the use of third-wave interventions for
47 improving hearing-related distress or psychological wellbeing in people with audiological problems.
48 There is some evidence that ACT and MBIs may be useful in addressing hearing-related distress in
49 people with tinnitus, but only in the short-term. However, findings should be interpreted with caution
50 given the small number of studies with generally small sample sizes and mostly poor-to-moderate

51 methodological quality. More high quality, adequately powered, double-blind RCTs, particularly in
52 audiological problems other than tinnitus, are needed to draw firm conclusions and meaningful clinical
53 recommendations.

54 **Word count:** 298

55

56 **KEYWORDS:** third-wave therapies; audiology; systematic review; meta-analysis;

57 **INTRODUCTION**

58 Audiological problems, such as hearing loss and tinnitus, are common in the population and represent a
59 significant public health concern. Over 1.5 billion people today are living with hearing loss, defined as having
60 an average hearing threshold of 20 decibels or greater in hearing level at 0.5, 1, 2 and 4 kilohertz, and the
61 prevalence is expected to rise to 2.5 billion by 2050 (World Health Organization [WHO], 2021). Tinnitus is a
62 subjective symptom characterized by a perception of sound (e.g. ringing, buzzing) in the absence of an external
63 stimulus (Tunkel et al., 2014). Studies have reported a wide range of prevalence rates from 5.1% to 42.7%
64 (McCormack et al., 2016), which may be partially explained by the fact that different methods have been used
65 to diagnose tinnitus, which in turn may be an effect of the lack of a universal definition of tinnitus.

66
67 Hearing loss and tinnitus are associated with a range of negative outcomes, including increased risk of falls
68 and dementia (Lin & Ferrucci, 2012; Livingston et al., 2017), reduced physical health (Genther et al., 2013),
69 increased psychological distress (Genther et al., 2013; Marks et al., 2019; Tambs, 2004), increased suicidal
70 ideation (Marks et al., 2019), poorer quality of life (Preminger & Meeks, 2010) and impairments in everyday
71 functioning (Genther et al., 2014; Tambs, 2004). Moreover, problems in working life, for instance, stigma and
72 discrimination, communication difficulties, reduced productivity and relatively low earnings, are often
73 encountered as a result of audiological impairments (Shield, 2019). Unsurprisingly, symptoms of anxiety have
74 been reported in 31.3% and 10.2-95% of those with hearing loss and tinnitus, respectively, while symptoms of
75 depression have been reported in 22.5% and 9.8-80%, respectively (Carlsson et al., 2014; Ziai et al., 2017).
76 These prevalence rates are much higher than reported in the global population (anxiety: 3.6%, depression:
77 4.4%; WHO, 2017).

78
79 Although hearing aids are an effective treatment for alleviating hearing handicap, there is mixed or limited
80 evidence of efficacy of hearing aids for reducing anxiety and depression in people with hearing problems
81 (Cieśła et al., 2016; Lawrence et al., 2020). Both the American Psychiatric Association (APA) and the National
82 Institute for Health and Clinical Excellence (NICE) guidelines recommend cognitive behavioral therapy (CBT)

83 for common mental health problems such as depression and anxiety (APA, 2010; NICE, 2011). Conventional
84 CBT is focused on alleviating distress or symptoms and aims to change how one thinks, feels and behaves in
85 emotional situations (Beck & Beck, 2011). It does this through techniques such as challenging the validity of
86 negative thoughts or trying to eliminate or solve problems. Although a systematic review and meta-analysis
87 of randomized controlled trials (RCTs) reported that CBT significantly decreased tinnitus distress (Hesser et al.,
88 2011), there is low certainty to support its use for depression and anxiety in people with tinnitus due to the
89 methodological quality of evidence (Fuller et al., 2020). Furthermore, there is little research on CBT for other
90 audiological problems.

91

92 In contrast to CBT, third-wave psychological therapies such as mindfulness-based cognitive therapy (MBCT),
93 mindfulness-based stress reduction (MBSR), acceptance and commitment therapy (ACT), dialectical behavior
94 therapy (DBT), compassion-focused therapy (CFT) and meta-cognitive therapy (MT) aim to change how a
95 person relates to their internal experiences such as thoughts, feelings and bodily sensations (Hayes, 2004; see
96 supplemental table for a fuller description of each therapy). Although third-wave therapies differ conceptually
97 and methodologically, the approaches share three common components and processes: to produce greater
98 psychological openness to one's experiences, to become more aware of the present moment, and to motivate
99 meaningful action (Hayes et al., 2011). These types of therapies have been argued to be more befitting for
100 improving outcomes in objectively difficult or immutable situations, such as living with long-term health
101 conditions like chronic pain, neurological conditions and acquired brain injuries (Hughes et al. 2017; Kangas &
102 McDonald, 2011; Robinson et al., 2019). There is currently no curative treatment for most forms of hearing
103 loss or tinnitus (Hurley & Walczak, 2020), and psychological therapies cannot directly treat such physiological
104 conditions. Therefore, equipping individuals with skills to accept and adapt to their audiological impairment
105 and find ways to live life as best as they can alongside these difficulties may be a more pragmatic approach
106 than trying to control or get rid of distressing and difficult experiences.

107

108 In support of the potential effectiveness of third-wave therapies for people with audiological problems,
109 individual studies have reported evidence for therapies such as ACT for reducing hearing-related distress in
110 those with hearing problems (Molander et al., 2018) and MT for reducing tinnitus distress (Ferraro et al., 2019).
111 Furthermore, a recent systematic review reported preliminary evidence for the effectiveness of mindfulness-
112 based interventions (MBIs) for reducing tinnitus distress (Rademaker et al., 2019). However, relatively little is
113 known about the effectiveness of MBIs for audiological problems other than tinnitus (e.g. hearing loss and
114 deafness) or other types of third-wave therapies for tinnitus and other audiological conditions.

115

116 Therefore, this systematic review aimed to: (1) critically evaluate the evidence for third-wave therapies for
117 improving hearing-related distress and psychological wellbeing in people with audiological problems; (2)
118 assess the clinical effectiveness of third-wave therapies compared to active or non-active controls and other
119 treatments at post-intervention; and (3) examine the maintenance of any effects at follow-up.

120

121 **MATERIAL AND METHODS**

122 This review was conducted and reported according to PRISMA guidelines (Page et al., 2021; see Appendix A
123 for the PRISMA checklist) and was registered with Open Science Framework (OSF; ref: osf.io/cqte7).

124

125 **Search strategy**

126 Searches were conducted on the following databases from date of inception to 23 March 2020: Embase,
127 PsychINFO, Web of Science, PubMed and CINAHL. The search terms are shown in Appendix B. Grey literature,
128 specifically Open Grey, was also searched using the same keywords. References of relevant published reviews
129 and studies were also manually searched.

130

131 **Inclusion/exclusion criteria**

132 Studies were included based on the following criteria:

- 133 • Involved adults (aged ≥ 18 years) with any audiological problem, as defined by Oh and Lee (2016),
134 including issues with tinnitus, balance and hearing (see full list in Appendix B);
- 135 • Involved a common third-wave psychological therapy, as defined by O'Connor et al. (2018), including
136 ACT, DBT, MBCT, MBSR and MT (see full list in Appendix B);
- 137 • Used either an RCT, observational cohort study (i.e. pre-post), case-control study or single-case
138 experimental design;
- 139 • Reported data on validated hearing-related distress, depression, anxiety or quality of life outcomes;
- 140 • Reported in English.

141

142 Interventions including a small component of a third-wave therapy (e.g. yoga or tai chi), behavioral activation
143 without third-wave therapy components or where most of the intervention content was not consistent with
144 common third-wave therapies were not included in the review. RCT protocols, qualitative studies, systematic
145 reviews, meta-analyses, meeting abstracts, conference reports or case studies with no control (or not using a
146 single case experimental design) were also excluded.

147

148 **Study selection**

149 After removal of duplicates, titles and abstracts were independently screened to identify potentially eligible
150 studies for retrieval. Full texts of retrieved articles were then screened for eligibility against the inclusion and
151 exclusion criteria. These processes were completed by two independent reviewers (BW and PK, BT or LP).
152 Where there was uncertainty, disagreements were resolved through discussion with a third reviewer (RG).

153

154 **Assessment of study quality**

155 The methodological quality of RCTs was evaluated using the Cochrane Collaboration Risk of Bias tool 2 (RoB 2;
156 Sterne et al., 2019), which assesses five known domains of bias: bias arising from the randomization process,
157 bias due to deviations from intended intervention, bias due to missing outcome data, bias in measurement of
158 outcome and bias in selection of the reported results. Each domain was rated as low or high risk of bias, or

159 some concerns. The Effective Public Health Practice Project (EPHPP) Quality Assessment Tool for Quantitative
160 Studies (EPHPP, 2009) was used to assess the methodological quality of non-RCTs. Each study was rated as
161 weak, moderate or strong for the first six components of the tool (selection bias, study design, confounders,
162 blinding, data collection methods and withdrawal and drop-outs), which determined the global rating for the
163 study. Descriptive information was provided for the last two components of the tool (integrity of study
164 intervention and analyses), though they do not contribute to the global rating. In addition to the above tools,
165 factors that may confound or influence the interpretation or generalizability of results were also identified.
166 The quality of studies was completed by two independent reviewers and disagreements were resolved
167 through discussion with a third reviewer, as described previously.

168

169 **Data extraction and data synthesis**

170 Study, demographic and intervention characteristics, as well as study results (including means, standard
171 deviations, etc.) were independently extracted by two reviewers and disagreements were resolved through
172 discussion with a third reviewer, as described previously. Following previous guidance (Cochrane Consumers
173 and Communication Review Group, 2016; Valentine et al., 2010) random-effects meta-analyses were
174 performed where two or more RCTs reported on the same type of audiological condition, third-wave therapy
175 and category of outcome: hearing-related distress, depression, anxiety and quality of life. Studies that did not
176 use validated tools to measure the abovementioned outcomes were not included in the meta-analyses. Means
177 and standard deviations (or standard errors) for each outcome, in each condition, and at each timepoint (post-
178 intervention, 1-5 month, 6-12 month and >12 month follow-up) were extracted and data were submitted to
179 separate meta-analyses with respect to outcome and timepoint using Review Manager software (version 5.4;
180 The Cochrane Collaboration, 2020). Random-effects meta-analyses using a DerSimonian and Laird estimator
181 based on inverse variance weights were conducted due to anticipated heterogeneity in treatment effects as a
182 result of between-study variations in clinical and study factors. Pooled effect sizes were calculated using
183 Hedges' g , whereby standardized mean differences were adjusted for small sample bias (Hedges & Olkin,
184 1985). The I^2 statistic was used to quantify heterogeneity, with values of 25%, 50% or 75% suggesting low,

185 moderate or high level of heterogeneity, respectively (Higgins et al., 2003). Subgroup analyses were used to
186 explore causes of significant heterogeneity, where possible. Publication bias was estimated using funnel plots
187 (test of asymmetry) for meta-analyses that included at least ten studies, as previously recommended (Higgins
188 & Green, 2011). As it is not recommended to analyze pre-post standardized mean differences within a meta-
189 analysis (Cuijpers et al., 2017), the findings of pre-post studies were summarized in a narrative synthesis.

190

191 **RESULTS**

192 **Study characteristics**

193 The search identified 1,827 records: 18 publications relating to 15 separate studies are included in the review
194 after screening for inclusion criteria (see Figure 1). Three studies reported two publications each, in the form
195 of the main publication and secondary data analyses (Hesser et al., 2012, 2014; Husain et al., 2019 and
196 Zimmerman et al., 2019) or follow-up data (Gans et al., 2014, 2015). No potentially eligible studies reported
197 in non-English were found. Table 1 presents study characteristics. Of the fifteen included studies, six adopted
198 an RCT design, while the rest (n=9) were pre-post studies. Among the six RCTs, two included a non-active
199 waitlist control, one included an active control of an online discussion forum and five included another form
200 of treatment as the comparator: relaxation therapy/training, CBT, tinnitus retraining therapy. Sample sizes
201 ranged from 7 to 205, with a combined total of 750 participants at enrolment. Studies were most frequently
202 conducted in the USA (n=4), Sweden (n=4) and the UK (n=3). All studies used self-report questionnaires as
203 their primary outcome measure and outcome assessments were conducted pre-intervention and immediately
204 post-intervention. Most studies (n=11) included longer-term follow up assessments, with follow-ups ranging
205 from 4 weeks post-intervention to 18 months post-baseline (or 15.5 months post-intervention).

206

207 **Participant characteristics**

208 The majority of studies (n=10) used self-referral to recruit their participants and most studies (n=13) did not
209 select participants on the basis of psychological distress or psychiatric comorbidities. Only one study selected
210 participants who reported significant psychological distress (McKenna et al., 2017), while another included

211 participants with psychiatric comorbidities (Hassinen & Lappalainen, 2018). The most commonly examined
212 audiological problem was tinnitus (n=12), followed by Deaf/deafness (n=2) and hearing problems (n=1). The
213 manner in which audiological problems were diagnosed varied among the studies: some requested formal
214 evidence of diagnosis by a specialist (n=6), others required participants to score over a specified value on self-
215 report questionnaires (n=5) and a few conducted a pure-tone threshold assessment (n=3). Four studies did
216 not explicitly state the diagnostic criteria for audiological problems, though participants were recruited from
217 audiology-related services in three of these studies. In most studies, participants were typically male (range=
218 31-100%, median= 55.0%, IQR= 14.5%) and in their early 50s (range= 20-83, mean= 52.2, SD= 7.1). Very few
219 studies reported ethnicity data (n=2) and those that did reported sample comprising >70% Caucasian
220 participants.

221

222 **Intervention characteristics**

223 Table 2 presents a summary of intervention characteristics. A wide variety of third-wave therapies was
224 examined, with ACT being the most frequently assessed intervention (n=6), followed by MBCT (n=4) and MBSR
225 or variants (n=3). On average, interventions consisted of eight sessions (SD= 1.3, range= 4-9), with each
226 session, on average, lasting approximately 95 minutes (SD= 35.1, range= 40-150 mins). With the exception of
227 one study which did not report the mode of therapy (Roland et al., 2015), interventions were most typically
228 delivered in groups (n=7) or a combination of group and individual delivery (n=1). Most therapies were
229 adequately manualized (n=11), while manualization in the remaining studies was partially adequate or
230 unclear. All interventions, except one (Dehnabi et al., 2017), were delivered by professional therapists or
231 postgraduate students with experience in delivering the third-wave intervention(s), though specialists with
232 hearing-related experience were only included in three studies (Gans et al., 2014; Hassinen & Lappalainen,
233 2018; McKenna et al., 2018).

234

235 **Meta-analysis**

236 The meta-analytic results for the outcomes listed below are presented for tinnitus alone as there are
237 insufficient studies to perform an analysis for other audiological conditions.

238

239 **Hearing-related distress**

240 As shown in Figure 2, there was a large statistically significant pooled effect size of -1.10 (95% confidence
241 interval [95% CI]= -1.51 to -0.70) at post-intervention, favoring ACT over controls for hearing-related distress.

242 When ACT was compared to other treatments, a smaller but statistically significant pooled effect size of -0.55
243 (95% CI= -0.94 to -0.15) in favor of ACT was observed at post-intervention. However, these gains were not
244 maintained at 6-12 month follow-up (Hedges' g =-0.19, 95% CI= -0.95 to 0.56), and there was evidence of
245 moderate heterogeneity in effect sizes.

246

247 There was a statistically significant benefit of MBIs over other treatments for hearing-related distress at post-
248 intervention (Hedges' g = -0.39; 95% CI= -0.74 to -0.04). It was not possible to examine whether gains were
249 maintained at follow-up as this was only assessed in one study (McKenna et al., 2017).

250

251 **Depression**

252 As shown in Figure 3, there was a statistically significant benefit of ACT over controls for depression at post-
253 intervention (Hedges' g = -0.50; 95% CI= -0.88 to -0.11). However, this benefit was not seen when compared
254 to other treatments at post-intervention (Hedges' g = -0.31; 95% CI= -1.03 to 0.42) or at 6-12 month follow-up
255 (Hedges' g = 0.05; 95% CI= -1.06 to 1.17), with moderate to high heterogeneity in effect sizes being found in
256 both analyses.

257

258 There was a small, non-significant pooled effect size in favor of MBIs compared to other treatments for
259 depression at post-intervention (Hedges' g = -0.28; 95% CI= -0.60 to 0.04) and at 1-5 month follow-up (Hedges'
260 g = -0.28; 95% CI= -0.60 to 0.04).

261

262 **Anxiety**

263 As shown in Figure 4, there was a statistically significant benefit of ACT over controls for anxiety at post-
264 intervention (Hedges' $g = -0.79$; 95% CI= -1.18 to -0.40). However, this benefit was not seen when compared
265 to other treatments at post-intervention (Hedges' $g = -0.50$; 95% CI= -1.23 to 0.22) or at 6-12 month follow-up
266 (Hedges' $g = 0.00$; 95% CI= -0.77 to 0.77). There was also evidence of moderate heterogeneity in effect sizes in
267 both analyses.

268

269 There was a small, non-significant pooled effect size in favor of MBIs in comparison to other treatments for
270 anxiety at post-intervention (Hedges' $g = -0.29$; 95% CI= -0.61 to 0.02) and at 1-5 month follow-up (Hedges' $g =$
271 -0.17 ; 95% CI= -0.58 to 0.24).

272

273 **Quality of life**

274 Quality of life was only examined in RCTs of ACT for people with tinnitus (see Figure 5). Minimal to small, non-
275 significant pooled effect sizes were found when ACT was compared to controls at post-intervention (Hedges'
276 $g = 0.18$; 95% CI= -0.42 to 0.677), other treatments at post-intervention (Hedges' $g = -0.08$; 95% CI= -0.52 to
277 0.37) and other treatments at 6-12 month follow-up (Hedges' $g = -0.22$; 95% CI= -1.10 to 0.65). There was
278 evidence of moderate to high heterogeneity in effect sizes in these analyses. There was evidence of moderate
279 to high heterogeneity in effect sizes in these analyses.

280

281 **Causes of heterogeneity**

282 It was not possible to explore the causes of heterogeneity due to the low number of studies.

283

284 **Publication bias**

285 No tests of publication bias were conducted as these are not recommended for meta-analyses that include
286 less than ten studies (Higgins & Green, 2011).

287

288 **Narrative synthesis of pre-post studies**

289 **Hearing-related distress**

290 As shown in Table 3, the effectiveness of third-wave therapies on measures of hearing-related distress was
291 examined in seven pre-post studies. All seven studies reported statistically significant pre-post changes in
292 hearing-related distress measures: four of these examined MBIs (Gans et al., 2014; Husain et al., 2019;
293 McKenna et al., 2018; Roland et al., 2019), two examined ACT (Drey, 2017; Hesser et al., 2009), and one
294 examined MT (Ferraro et al., 2019). Four out of six studies reported maintenance of treatment gains at follow-
295 up: three examined MBIs (Gans et al., 2015; McKenna et al., 2018; Roland et al., 2015) and one examined MT
296 (Ferraro et al., 2019).

297

298 **Depression and anxiety**

299 Depression and anxiety were examined in six pre-post studies. Four reported statistically significant pre-post
300 changes in depression and/or anxiety: two examined ACT (Drey, 2017; Hassinen & Lappalainen, 2018), one
301 examined MT (Ferraro et al., 2019), and one examined MBI (Dehnabi et al., 2017), though the reporting of
302 main findings was poor in the latter study. One study examining MBI chose to report effect sizes instead of
303 significance levels due to small sample size and found moderate to large improvements for both depression
304 and anxiety (Gans et al., 2014). Two studies included follow-up assessments and only one of these reported
305 maintenance of treatment benefits for anxiety but not depression at 3 months post-intervention (Ferraro et
306 al., 2019).

307

308 **Quality of life**

309 Quality of life was examined in two pre-post studies. Findings were mixed: one study examining ACT reported
310 no significant pre-post changes (Drey, 2017), while the other study of MBI reported moderate to large
311 improvements (based on effect size as significance levels were not reported due to small sample size; Gans et
312 al., 2014). Neither of these studies conducted follow-up assessments.

313

314 **Clinically Significant Changes, Reliable Deterioration and Adverse Events**

315 Clinically significant changes for measures of hearing-related distress, indicated by reliable change indices or
316 minimum clinically important differences, were examined in three RCTs and three pre-post studies. Only one
317 RCT with an active control group examined clinically significant changes and found a significant between-group
318 difference in the proportion of participants showing reliable changes at post-intervention (ACT: 60%, 21/35;
319 control: 16%, 5/32; Hesser et al., 2012). When compared to other treatments, only one out of three RCTs
320 reported a significant difference in the proportion of participants showing reliable changes at 6 months of
321 intervention (ACT: 55%, 12/22; tinnitus retraining therapy: 20%, 4/20; Westin et al., 2011). No significant
322 differences between the third-wave therapy condition and other treatments were reported in the remaining
323 two RCTs (Hesser et al., 2012; McKenna et al., 2017). Clinically significant changes at post-intervention were
324 seen for both pre-post studies of MBIs: 60% (9/15) and 50% (91/182) of participants (Husain et al., 2019;
325 McKenna et al., 2018, respectively). All three pre-post studies of MBIs that included a follow-up assessment
326 reported that 58% (7/12), 52.8% (96/182) and 62% (8/13) of participants showed reliable improvements at
327 follow-ups (Husain et al., 2019; McKenna et al., 2018; Roland et al, 2015).

328
329 Reliable deterioration was reported in two studies, with reported rates being low. Three out of 39 in MBI and
330 3/36 participants in relaxation therapy (McKenna et al., 2017), along with 1/22 participants in ACT and 2/20
331 participants in tinnitus retraining therapy (Westin et al., 2011) showed reliable deterioration on hearing-
332 related distress. Adverse events were only reported two studies: no adverse events were reported in one
333 study (Gans et al., 2014), while two events were reported in the other study, though these were considered
334 to be unrelated to the intervention (McKenna et al., 2017).

335

336 **Quality assessment and critical appraisal**

337 As shown in Table 4, all six studies were judged to be at an overall high risk of bias. With the exception of one
338 RCT (Arif et al., 2019), risk of bias due to missing outcome data was mostly low. In contrast, risk of bias due to
339 measurement of the outcome was judged to be high in all six studies. The methodological quality of pre-post

340 studies was generally moderate (see Table 5), with the exception of one study rated as weak (Dehnabi et al.,
341 2017) and one study rated as strong (McKenna et al., 2018). For most studies, good reliability and validity of
342 data collection methods were reported (n=7), while selection bias was rated as weak since self-referral was
343 often used (n=7). No study provided information regarding blinding of outcome assessors, leading to a rating
344 of moderate according to the EPHPP tool.

345

346 Factors that may influence or confound the generalizability and interpretation of results are presented in Table
347 6. Self-referral was allowed in most studies (n=10), while it was unclear for three. The majority of studies did
348 not provide details about ethnicity (n=13). Six studies did not indicate whether a formal assessment of
349 audiological problems was conducted (i.e. a formal diagnosis by a clinician and/or audiogram assessment with
350 threshold criteria detailed). It was unclear for the majority of studies if concurrent psychotherapy was allowed
351 (n=11) or if participants received psychotherapy in the 3 months prior to study commencement (n=15). Only
352 two studies reported screening of cognitive impairment. Finally, sample sizes were small in ten studies (n<15
353 participants per condition), while only four out of the fifteen studies performed a sample size calculation.

354

355 **DISCUSSION**

356 In summary, our meta-analysis found no differences between ACT and controls and/or other treatments for
357 quality of life in people with tinnitus, while there were insufficient studies to examine the effects of MBIs for
358 this outcome. There was some evidence that both ACT and MBIs improved hearing-related distress in
359 comparison to controls and other comparators in people with tinnitus at post-intervention, but the effects
360 were either not maintained at follow-up or not examined in enough studies to permit a meta-analysis. ACT,
361 but not MBIs, improved depression and anxiety in this population when compared to controls at post-
362 intervention. However, again, these effects were not maintained at follow-up or were not observed when ACT
363 was compared to other treatments at post-intervention. Reports of reliable improvements on measures of
364 hearing-related distress in 50%-60% participants from pre-post studies of ACT and MBIs support the meta-

365 analytic findings. However, findings should be interpreted with caution given the small number of included
366 studies with relatively small sample sizes and the mostly poor-to-moderate methodological quality.

367

368 Overall, the findings of the current review are consistent with previous meta-analysis and systematic reviews
369 of third-wave therapies for tinnitus (Rademaker et al., 2019), chronic pain (Hughes et al., 2017) and
370 neurological conditions (Robinson et al., 2019). Third-wave therapies may be particularly beneficial to those
371 with physical health conditions as they can equip individuals with skills to accept and adapt to their new
372 situation in life and their current abilities, and help them to live their lives in important and meaningful ways
373 alongside their physical health condition. Possible theoretical frameworks for improvements in outcomes
374 include: (1) re-constructing the individual's identity with the focus of 'here-and-now' actual self, rather than
375 the 'hoped-for' self; (2) setting realistic and measurable goals; and (3) re-engaging in activities that individuals
376 can still do with their loved ones (Kangas & McDonald, 2011). In keeping with our findings, a recent meta-
377 analysis of ACT for chronic pain did not find significant difference in quality of life (Hughes et al., 2017).
378 Measures of quality of life are praised to be multi-dimensional and broadly applicable, but are often criticized
379 for not being sensitive to specific aspects of quality of life for different health conditions (Pequeno et al., 2020).
380 Other similarities between Hughes et al. (2017) and the current review include effect sizes for maintenance of
381 treatment gains were generally smaller than the effect sizes at post-intervention and the strength of evidence
382 was weaker at follow-ups. This could be due to loss of efficacy over time, but could also be due to
383 methodological difficulties in the available evidence, including: small number of studies including a follow-up
384 assessment, moderate-to-high heterogeneity, as well as studies being inadequately powered to account for
385 the dropout rate. The quality of studies of the current review was mostly consistent with other reviews, with
386 the exception of Rademaker et al. (2019) which reported moderate to high quality, while an overall poor-to-
387 moderate quality was reported here. This discrepancy may reflect differences in the use of methodological
388 quality assessment tools and the inclusion of studies (n=7 in Rademaker et al. and n=15 in the current review).

389

390 **Future research**

391 There is a need for more high quality, large-scale, double-blind RCTs with active comparators to examine short-
392 and long-term effects of third-wave therapies, with validated diagnostic criteria of the audiological problem
393 being examined. Several of the reviewed studies omitted details regarding diagnosis, particularly studies
394 involving participants from audiology clinics. Therefore, the tools and thresholds used for diagnosis of
395 audiological problem should be clearly defined in order that more meaningful recommendations can be made
396 with respect to clinical and/or research practice. Future RCTs should also recruit sufficient participants to be
397 adequately powered to detect minimal clinically important differences between third-wave therapies and
398 control conditions and other treatment comparators. A non-inferiority trial design could be considered to
399 suggest whether third-wave therapies provide at least the same benefit to patients as other treatment
400 comparators such as CBT, which would permit patient choice with respect to interventions (Wang et al., 2017).
401 In addition, future studies should include active controls that control for attention and social support in order
402 to adequately address this issue (Serfaty et al., 2011; Williams et al., 2014). Finally, the cost-effectiveness of
403 third-wave therapies for people with audiological problems should be explored in future studies as little has
404 been reported in this area.

405

406 With regards to interventions, the majority of studies focused on MBIs and ACT. Future studies should examine
407 the effectiveness of other types of third-wave therapies such as CFT, DBT and MT in audiological problems. In
408 addition, previous research has suggested the usefulness of ACT-informed physiotherapy for adults with
409 chronic pain (Godfrey et al., 2020; Jacobs et al., 2016). Future studies could similarly examine whether third-
410 wave informed treatments led by professionals with hearing-related experience could be beneficial for people
411 with audiological problems. Furthermore, a minority of studies in this review examined adverse events and/or
412 reliable deterioration (n=3), highlighting another under-researched area. This area requires further
413 investigation as adverse effects of mindfulness-based approaches, including exacerbated psychological
414 problems, have been reported (Farias & Wikholm, 2016). Future studies could examine for whom and under
415 what circumstances third-wave therapies are useful and when they may be contraindicated.

416

417 **Limitations**

418 To the authors' knowledge, this systematic review and meta-analysis is the first to evaluate the effectiveness
419 of third-wave therapies in people with audiological problems. However, there are a number of limitations of
420 the review. First, as meta-analytic findings only applied to ACT and MBIs in people with tinnitus, findings
421 cannot be generalized to other third-wave therapies or other audiological problems. This represents a large
422 knowledge gap which future research should address. Second, generalizability of findings is further restricted
423 due to a number of demographic and clinical issues. Participants were typically self-referred, hence may have
424 been self-motivated to engage in treatment, and were mostly males in their early 50s with tinnitus, with
425 ethnicity being rarely reported. Furthermore, some participants may not have had clinically significant
426 audiological problems as a formal assessment of audiological problems was not required in some studies. As
427 a result, the findings of the review may not generalize to broader or ethnically diverse populations, those who
428 might be less self-motivated to engage in treatment, and those with clinically significant audiological
429 problems. Third, publication bias and causes of heterogeneity could not be assessed due to the small number
430 of studies included in the meta-analyses. In line with this, the grey literature search was limited to Open Grey
431 and more unpublished studies may have been identified if this search had extended beyond this. We chose
432 not to do this as this may have introduced further bias as studies that are hard to locate tend to have lower
433 methodological quality (Egger et al., 2003). Fourth, our random-effects meta-analyses were performed with
434 two or more studies, following guidance (e.g. Cochrane Consumers and Communication Review Group, 2016;
435 Valentine et al., 2010), and some have argued that at least five studies are required for such analyses (Tufanaru
436 et al., 2015). Fifth, the small sample sizes in the majority of studies means that they might have been
437 underpowered to detect differences in study outcomes, particularly when comparing third-wave therapies to
438 other forms of treatment. Finally, the small number of studies precluded direct, sub-group exploration of
439 which type of third-wave intervention was effective for which type of audiological problem and their effects
440 at different assessment points.

441

442 **Conclusion**

443 At present, there is insufficient evidence to recommend the use of third-wave interventions for improving
444 hearing-related distress or psychological wellbeing in people with audiological problems. Some evidence
445 tentatively suggests that ACT and MBIs may be useful in addressing hearing-related distress in people with
446 tinnitus, but only in the short term. However, there is insufficient evidence at present to suggest that these
447 treatment gains are maintained at follow-up, or that ACT and MBIs are superior to other treatments in
448 addressing these outcomes. Furthermore, these findings should be interpreted with caution as the
449 methodological quality of studies was generally poor-to-moderate, the number of studies was small, with
450 generally small sample sizes, and many studies were not adequately powered. Whether ACT and MBIs are
451 beneficial in people with audiological problems other than tinnitus, or indeed whether other forms of third-
452 wave therapies are beneficial for audiological conditions remains unclear. This represents a significant
453 knowledge gap and future research should aim to address this. High quality, double-blind RCTs with active
454 comparators and long-term follow-up, that are adequately powered to detect clinically meaningful differences
455 need to be conducted before firm conclusions can be drawn about the efficacy of third-wave therapies for
456 people with audiological problems.

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463

464 **DISCLOSURE OF INTERESTS**

465 None.

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Legends of Tables and Figures

Figure 1: PRISMA flow chart of identification and selection of studies.

Figure 2: Forest plots of third-wave therapies versus controls and other treatments for hearing-related distress at post-intervention and follow-up.

Figure 3: Forest plots of third-wave therapies versus controls and other treatments for depression at post-intervention and follow-up.

Figure 4: Forest plots of third-wave therapies versus controls and other treatments for anxiety at post-intervention and follow-up.

Figure 5: Forest plots of third-wave therapies versus controls and other treatments for quality of life at post-intervention and follow-up.

Table 1: Study, demographic and clinical characteristics of studies included in the review.

Table 2: Intervention characteristics of studies included in the review.

Table 3: Results of studies included in the systematic review.

Table 4: Potential sources of bias in studies included in the systematic review assessed by Cochrane's Risk of Bias.

Table 5: Potential sources of bias in studies included in the systematic review assessed by EPHPP.

Table 6: Further critical appraisal of studies included in the systematic review.

Appendix A: PRISMA 2020 Checklist

Appendix B: Search terms

Supplemental table: Characteristics of third-wave therapies

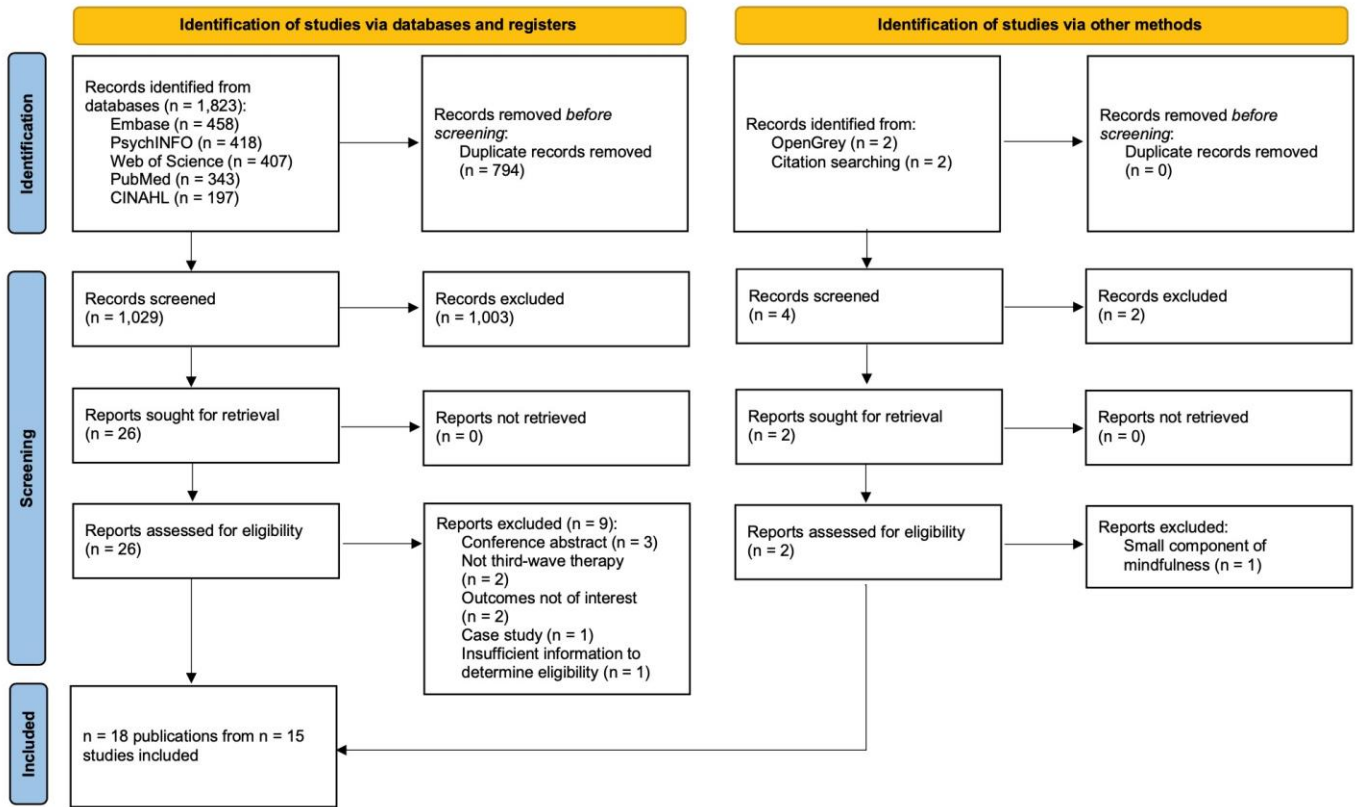
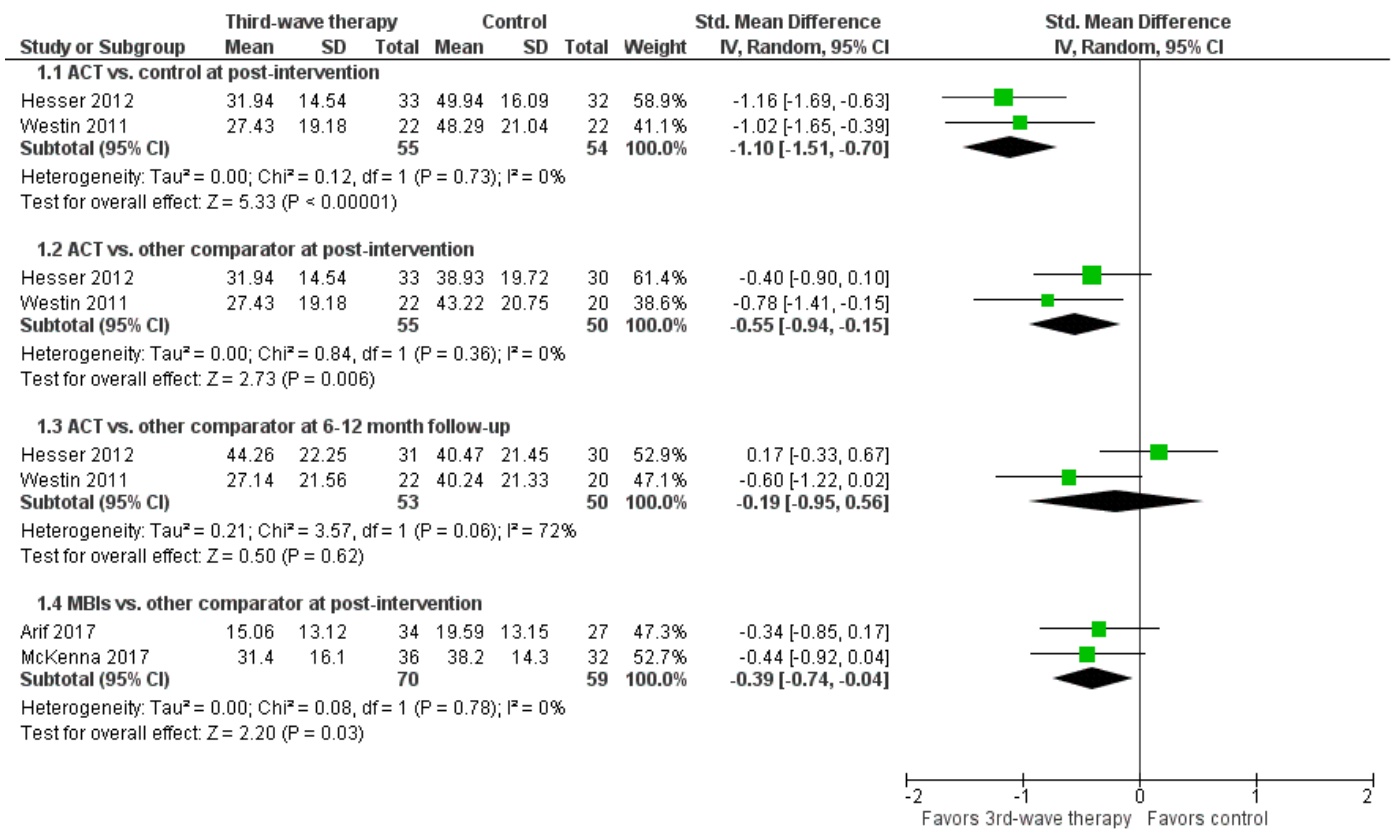
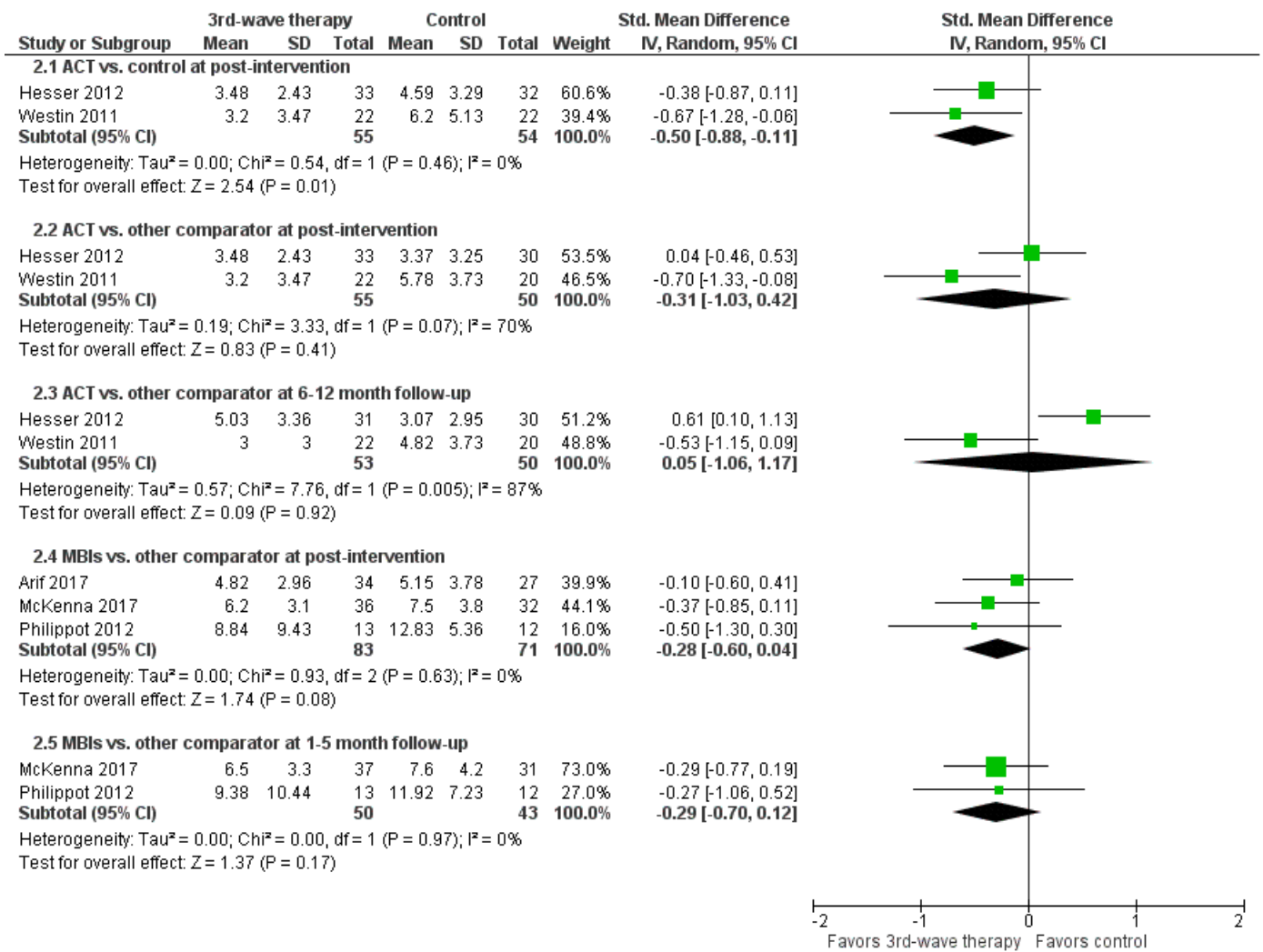


Figure 1: PRISMA flow chart of identification and selection of studies.



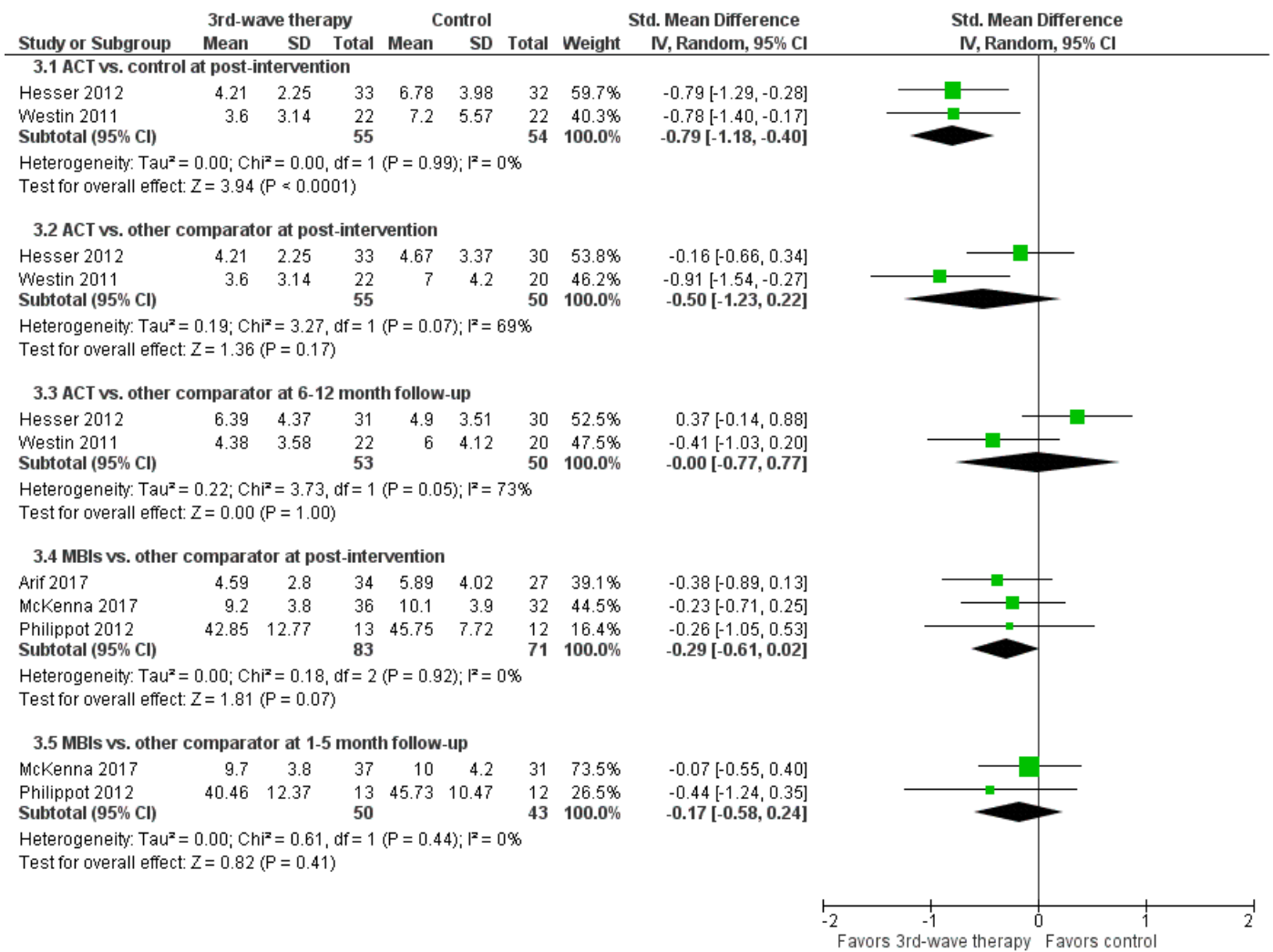
Notes: ACT= Acceptance and Commitment Therapy; Chi²= chi-squared statistic; CI= confidence interval; df= degrees of freedom; I²= I-squared heterogeneity statistic; IV= inverse variance; MBIs= Mindfulness-Based Interventions; P= p-value; SD= standard deviation; std.= standardized; Tau²= tau-squared statistic; Z= Z statistic.

Figure 2: Forest plots of third-wave therapies versus controls and other treatments for hearing-related distress at post-intervention and follow-up.



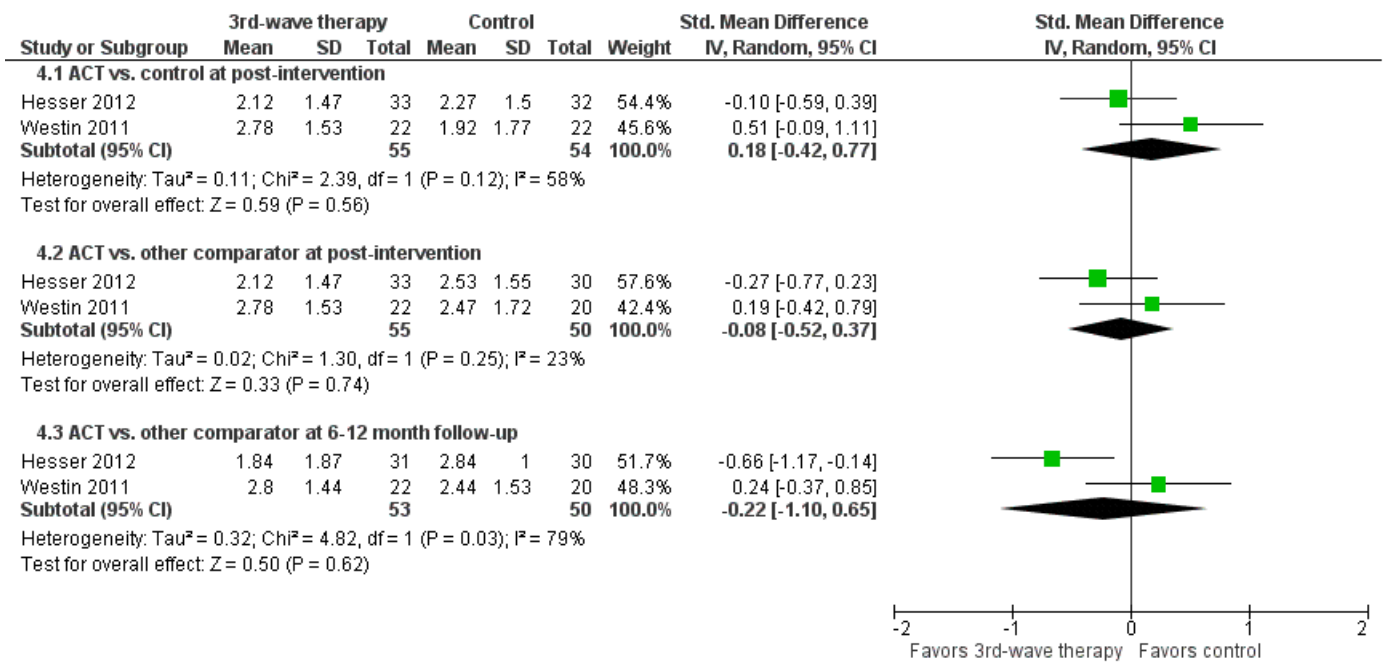
Notes: ACT= Acceptance and Commitment Therapy; Chi²= chi-squared statistic; CI= confidence interval; df= degrees of freedom; I²= I-squared heterogeneity statistic; IV= inverse variance; MBIs= Mindfulness-Based Interventions; P= p-value; SD= standard deviation; std.= standardized; Tau²= tau-squared statistic; Z= Z statistic.

Figure 3: Forest plots of third-wave therapies versus controls and other treatments for depression at post-intervention and follow-up.



Notes: ACT= Acceptance and Commitment Therapy; Chi²= chi-squared statistic; CI= confidence interval; df= degrees of freedom; I²= I-squared heterogeneity statistic; IV= inverse variance; MBIs= Mindfulness-Based Interventions; P= p-value; SD= standard deviation; std.= standardized; Tau²= tau-squared statistic; Z= Z statistic.

Figure 4: Forest plots of third-wave therapies versus controls and other treatments for anxiety at post-intervention and follow-up.



Notes: ACT= Acceptance and Commitment Therapy; Chi²= chi-squared statistic; CI= confidence interval; df= degrees of freedom; I²= I-squared heterogeneity statistic; IV= inverse variance; MBIs= Mindfulness-Based Interventions; P= p-value; SD= standard deviation; std.= standardized; Tau²= tau-squared statistic; Z= Z statistic.

Figure 5: Forest plots of third-wave therapies versus controls and other treatments for quality of life at post-intervention and follow-up.

Table 1: Study, demographic and clinical characteristics of studies included in the review.

| Authors (year) | Country | Type of study | Referral setting | Audiological problem | Diagnostic inclusion criteria | Third-wave Intervention | Tx comparators | n allocated (n of completers) | | Mean age (range) | % male |
|----------------------------|---------|----------------------|----------------------------|----------------------|---|-------------------------|------------------------------|-------------------------------|------------------|---------------------|--------|
| | | | | | | | | Intervention | Comparators | | |
| Arif et al (2017) | UK | RCT | Clinical and self-referral | Tinnitus | Conducted a pure-tone audiogram and tympanogram | Mindfulness meditation | RT | 42 (34) | 44 (27) | 55.8 (25-80) | 45 |
| Hesser et al (2012) (2014) | Sweden | RCT | Self-referral | Tinnitus | Formal proof of tinnitus dated >6 months | ACT | CBT, online discussion forum | 35 (32) | 32 (25), 32 (32) | 48.5 (NS) | 57 |
| McKenna et al (2017) | UK | RCT | Clinical | Tinnitus | Completed medical investigations for tinnitus, tinnitus present >6 months | MBCT | RT | 39 (37) | 36 (32) | Median age: 50 (NS) | 55 |
| Molander et al (2018) | Sweden | RCT | Self-referral | Hearing problems | Score >8 on HHIE-S | ACT | WLC | 31 (27) | 30 (29) | 59.0 (25-83) | 33 |
| Philippot et al (2012) | Belgium | RCT | Self-referral | Tinnitus | Medical check-up by hearing-related specialist, tinnitus experienced within past 6 months | MBCT | RT | 15 (13) | 15 (12) | 60.0 (35-79) | 60 |
| Westin et al (2011) | Sweden | RCT | Clinical and self-referral | Tinnitus | Pure-tone threshold \leq 30dB HL up to 2kHz testing frequency, score \geq 28 on THI | ACT | TRT, WLC | 22 (21) | 20 (18), 22 (22) | 50.9 (20-72) | 53 |
| Dehnabi et al (2017) | Iran | Observational cohort | Unclear | Deafness | NS | MBSR | Control ^a | 12 (NS) | 12 (NS) | NS | 67 |
| Drey (2017) | USA | Observational cohort | Self-referral | Tinnitus | Formal proof of tinnitus dated >6 months prior treatment | ACT | NA | 7 (7) | NA | 32.6 (27-39) | 100 |
| Ferraro et al (2019) | Italy | Observational cohort | Clinical and self-referral | Tinnitus | NS (patients were from Audiology Unit) | Metacognitive therapy | NA | 12 (9) | NA | 49.1 (NS) | 56 |
| Gans et al (2014) (2015) | USA | Observational cohort | Clinical and self-referral | Tinnitus | Medical check-up by audiologist, score \geq 20 on THI | MBTSR | NA | 10 (8) | NA | 58.0 (38-70) | 75 |

| Authors (year) | Country | Type of study | Referral setting | Audiological problem | Diagnostic inclusion criteria | Third-wave Intervention | Tx comparators | n allocated (n of completers) | | Mean age (range) | % male |
|---|---------|----------------------|---|----------------------|--|-------------------------|----------------|-------------------------------|-------------|------------------|--------|
| | | | | | | | | Intervention | Comparators | | |
| Hassinen & Lappalainen (2018) | Finland | Observational cohort | Community (Service Centre for the Deaf) | Deaf | NS (participants were from service centre) | ACT | NA | 16 (NS) | NA | 43.8 (20-60) | 56 |
| Hesser et al (2009) | Sweden | Observational cohort | Unclear | Tinnitus | score ≥ 30 on THI | ACT | NA | 24 (NS) | NA | 52.7 (34-72) | 33 |
| Husain et al (2019) Zimmerman et al (2019) | USA | Observational cohort | Self-referral | Tinnitus | Pure-tone threshold ≤ 30 dB HL up to 2kHz testing frequency, score ≥ 28 on THI | MBCT | NA | 21 (15) | NA | 55.5 (25-72) | 47 |
| McKenna et al (2018) | UK | Observational cohort | Clinical | Tinnitus | Medically and audiotologically assessed, tinnitus present >3 months | MBCT | NA | 205 (182) | NA | 59.0 (27-83) | 43 |
| Roland et al (2015) | USA | Observational cohort | Clinical and self-referral | Tinnitus | NS (patients were from clinic) | MBSR | NA | 16 (13) | NA | 55.0 (32-65) | 31 |

Notes:

^aNo information on the type of control group.

ACT: Acceptance and Commitment Therapy; CBT: Cognitive Behavioral Therapy; HHIE-S: Hearing Handicap Inventory for the Elderly – screening version; MBCT: Mindfulness-Based Cognitive Therapy; MBSR: Mindfulness-Based Stress Reduction; MBTSR: Mindfulness-Based Tinnitus Stress Reduction; n: number; NA: not applicable; NS: not specified; RCT: randomized controlled trial; RT: Relaxation Therapy/Training; THI: Tinnitus Handicap Inventory; TRT: Tinnitus Retraining Therapy; Tx: treatment; WLC: wait-list control.

Table 2. Intervention characteristics of studies included in the review.

| Study (year) | Intervention arm | Control arm | Mode of intervention | Number of sessions | Duration of session (in mins) | Manualized therapy? | Therapist(s) professional background | Therapist(s) training to deliver intervention | Supervision of therapist(s) to deliver intervention |
|-------------------------------|------------------------|------------------------------|----------------------|--------------------|-------------------------------|---------------------------------|--|---|---|
| Arif et al (2017) | Mindfulness meditation | RT | Individual | 5 | 40 | Partially adequate ^a | 1 experienced therapist | NS | NS |
| Hesser et al (2012) (2014) | ACT | CBT; online discussion forum | Online | 8 | NA | Adequate | 1 licensed psychologist and 4 Master's students in clinical psychology | Yes | Yes |
| McKenna et al (2017) | MBCT | RT | Group | 8 | 120 | Adequate | 2 clinical psychologists (experience in CBT and RT) | Yes | Yes |
| Molander et al (2018) | ACT | WLC | Online | 8 | NS | Adequate | 4 Master's students; 1 licensed psychologist (experience in CBT and ACT) | Yes | Yes |
| Philippot et al (2012) | MBCT | RT | Group | 7 | 135 | Adequate | 2 PhD level psychotherapists (experience in mindfulness and RT) | Yes | Yes |
| Westin et al (2011) | ACT | TRT; WLC | Individual | 5 – 10 | 60 | Adequate | 6 Master's students in clinical psychology; 2 clinical psychologists | Yes | Yes |
| Dehnabi et al (2017) | MBSR | Unclear | Group | 8 | NS | Unclear | NS | NS | NS |
| Drey (2017) | ACT | NA | Individual | 4 | 60 | Partially adequate ^b | PhD student (theoretical knowledge of ACT) | Yes | Yes |
| Ferraro et al (2019) | Metacognitive therapy | NA | Group | 8 | 90 | Unclear | 4 trained psychotherapists | NS | NS |
| Gans et al (2014) (2015) | MBTSR | NA | Group | 8 | 150 | Adequate | 1 licensed clinical psychologist (trained in MBSR and psychological impact of deafness and hearing difficulty) | Yes | Yes |
| Hassinen & Lappalainen (2018) | ACT | NA | Individual and group | 7 – 11 | 65 | Adequate | 9 voluntary counsellors (have been working with deaf or deaf-blind clients for >3 years) | Yes | Yes |

| Study (year) | Intervention arm | Control arm | Mode of intervention | Number of sessions | Duration of session (in mins) | Manualized therapy? | Therapist(s) professional background | Therapist(s) training to deliver intervention | Supervision of therapist(s) to deliver intervention |
|---|------------------|-------------|----------------------|--------------------|-------------------------------|---------------------|---|---|---|
| Hesser et al (2009) | ACT | NA | Individual | Average 8.7 | 45 – 75 | Adequate | 6 Master's students in clinical psychology; 2 clinical psychologists | NS | Yes |
| Husain et al (2019) Zimmerman et al (2019) | MBCT | NA | Group | 8 | 120 | Adequate | Clinical psychology graduate students (had experience leading MBCT groups) | Yes | Yes |
| McKenna et al (2018) | MBCT | NA | Group | 8 | 120 | Adequate | 3 clinical psychologists (experience in MBCT, CBT and in working with tinnitus) | Yes | Yes |
| Roland et al (2015) | MBSR | NA | NS | 8 | 120 | Adequate | Certified MBSR instructor | Yes | NS |

Notes:

^aThe control group was adequately manualized whereas the manual for mindfulness meditation was not stated.

^bOnly one supporting statement was provided in the appendix which is not referenced in-text.

ACT: Acceptance and Commitment Therapy; CBT: Cognitive Behavioral Therapy; MBCT: Mindfulness-Based Cognitive Therapy; MBSR: Mindfulness-Based Stress Reduction; MBTSR: Mindfulness-Based Tinnitus Stress Reduction; NA: not applicable; NS: not specified; RT: Relaxation Therapy/Training; TRT: Tinnitus Retraining Therapy; WLC: wait-list control.

Table 3. Results of studies included in the systematic review.

| Study (year) | Ax periods | Statistical analyses | Primary and secondary outcome measures | Main results | Total sample enrolled (N=) Analyzed sample (n=) | Additional information |
|-------------------------------|-----------------------------------|---|--|--|--|--|
| Arif et al (2017) | Pre, post | Paired sample t-tests | Primary: TRQ Secondary: HADS | Significant between-group differences for TRQ, where greater differences in mindfulness meditation. Improvements in both groups for all OMs. | N = 86 n = 61 | Analyses comparing between- and within-group differences were not stated. |
| Hesser et al (2012) (2014) | Pre, post, 12-M FU | Linear mixed-effect models with maximum likelihood estimation | Primary: THI Secondary: HADS, QoLI | Significant between-group difference for THI, where lower scores in intervention conditions vs control (ACT Cohen's d=0.68). Significant differences between CBT vs control for HADS-A and QoLI. Significant differences between ACT vs control for HADS-A and HADS-D. No significant differences between CBT and ACT for all OMs. Reliable change for THI reported for 60% in ACT vs 44% in CBT vs 16% in control at post-intervention and 44% in CBT vs 29% in ACT at FU. No significant between group differences between CBT vs ACT for reliable changes. | N = 99 n = 99 | 2014 publication reported secondary data analyses. |
| McKenna et al (2017) | Pre, post, 1-M FU, 6-M FU | Linear mixed model | Primary: TQ Secondary: TFI, HADS | Significant reduction from pre-post in both groups for TQ, where lower scores in MBCT vs RT (Cohen's d=0.49). Scores for TQ were not significantly different at 1-M FU, but significantly lower in MBCT vs RT at 6-M FU. Significant reduction from pre-post for HADS in both groups but no significant between-group differences at any other timepoints. Significant reductions for TFI scores in both groups, but group-difference only at 6-M FU (lower in MBCT vs RT; Cohen's d=0.56). Reliable change for TQ reported for 59% in MBCT vs 44% in RT at post-intervention and 62% in MBCT vs 53% in RT at 6-M FU. No significant between group differences for reliable changes. | N = 75 n = 75 | Difference between treatments was adjusted for pre-intervention score in each group. |
| Molander et al (2018) | Pre, post | Linear mixed effect models with maximum likelihood-estimation | Primary: HHIE Secondary: GAD-7, PHQ-9, QoLI | Significant group x time interaction for HHIE (Cohen's d=0.93), PHQ and QoLI, in favor of intervention vs control. No significant group differences for GAD-7. | N = 61 n = 61 | — |
| Philippot et al (2012) | Baseline, pre, post, 3-M FU | 2 x 2 ANOVAs | Primary: QIPA Secondary: BDI, STAI | No significant time or group effects for any other OM at pre-post. Significant time x group interaction for cognitive control at pre vs 3-M FU (decreases in MBCT while increases in RT) and not at other time points indicate treatment benefits of MBCT. | N = 30 n = 25 | Period between baseline and pre involved psychoeducation. |

| Study (year) | Ax periods | Statistical analyses | Primary and secondary outcome measures | Main results | Total sample enrolled (N=) Analyzed sample (n=) | Additional information |
|-------------------------------|---|---|---|---|--|--|
| Westin et al (2011) | Pre, 10-W, 6-M, 18-M | Linear mixed effect models with maximum-likelihood estimation | Primary: THI Secondary: QoLI, HADS | Significant time (pre vs 10-W) x group (ACT vs WLC) interaction for THI (Cohen's d=1.04) and HADS-anxiety, where lower scores in ACT. Significant time (all ax points) x group (ACT vs TRT) interaction for THI (Cohen's d=0.75), where lower scores in ACT. No significant effects of time or treatment for remaining OMs. Treatment gains maintained in ACT for all OMs at 6- and 18-M vs 10W. Reliable change for THI reported for 54.5% in ACT vs 20% in TRT at 6-M FU. | N = 64 n = 62 | 10-week (i.e. post-intervention in ACT). 18-M (i.e. post-intervention in TRT). |
| Dehnabi et al (2017) | Pre, post | Analysis of Covariance (ANCOVA) | Primary: Social Phobia Inventory (SPIN): avoidance, fear, physiological | According to the study, it was concluded that intervention leads to a reduction in the total score of social anxiety and its physiological component. | N = 24 n = NS | Poor reporting of findings. |
| Drey (2017) | Pre, post | Paired sample t-tests | Primary: PHQ-9, STAI-Y, TFI, WHO Overall QoL | Significant pre-post differences for TFI, STAI-Y and PHQ-9. No significant pre-post differences for WWHO Overall QoL. | N = 7 n = 7 | — |
| Ferraro et al (2019) | Pre, post, 3-M FU | Friedman test | Primary: THI, HADS | Significant differences for THI in post and FU vs pre and post vs FU. Significant decreases over time in anxiety subscale but not depression subscale. | N = 12 n = 9 | — |
| Gans et al (2014) | Pre, post | Paired sample t-tests | Primary: THI Secondary: SCL-90-R | Moderate to large improvements seen for THI and the depression and anxiety subscale of SCL-90-R. | N = 10 n = 8 | Reported effect size (Cohen's d) rather significance levels due to small sample size. No analyses reported for 2015 publication. |
| (2015) | 12-M FU | NS | | Reported sustained and continued reduction in THI 12 months after participation in intervention. | n=7 | |
| Hassinen & Lappalainen (2018) | Pre, post, 6-M FU | Repeated measure design | Primary: BDI, SCL-90 | Significant effect for time on anxiety subscales of SCL-90. A non-significant difference for the depression subscale of SCL-90. A non-significant trend was observed for BDI. | N = 16 n = 16 | — |
| Hesser et al (2009) | Pre, before each therapy session, 1-W post-, 6-M FU | NS | Primary: THI | Significant pre vs 6-M FU differences. Decrease from pre vs Session 2 was not significant, but significant difference seen between pre vs Session 3. | N = 24 n = 19 | Paper primarily explored mediators of treatment effects. |

| Study (year) | Ax periods | Statistical analyses | Primary and secondary outcome measures | Main results | Total sample enrolled (N=) Analyzed sample (n=) | Additional information |
|--|-------------------|-------------------------------------|---|--|--|---|
| Husain et al. (2019) Zimmerman et al (2019) | Pre, post, 8-W FU | Friedman tests | Primary: THI, TPFQ, TFI | Significant reduction in TFI between pre vs post, but a non-significant increase from post vs FU. Significant declines in THI and TPFQ between pre vs FU, but non-significant difference between pre vs post. | N = 21 Analyzed sample (n=) | Zimmerman et al. (2019) reported secondary data analyses. |
| McKenna et al (2018) | Pre, post, 6-M FU | Paired sample t-tests | Primary: TQ | Significant pre-post and pre-FU differences for TQ. | N = 205 n = 182 | – |
| Roland et al (2015) | Pre, post, 4-W FU | Friedman tests, seed-based analyses | Primary: THI, TFI Secondary: PHQ-9, PROMIS-A | Significant pre-post, pre-FU and post-FU differences for THI and TFI. A non-significant pre-post change for PHQ-9. No significant pre-post difference for remaining OMs. Reliable change in THI reported for 62% at post-intervention and 77% at FU. | N = 16 n = 13 | Only primary outcomes included a FU assessment. |

Notes:

Significance of findings is defined as $p < 0.05$.

Ax: assessment; BDI: Beck Depression Inventory; CBT: Cognitive Behavioral Therapy; FU: follow-up; GAD: Generalized Anxiety Disorder; HADS: Hospital Anxiety and Depression Scale; HHIE: Hearing Handicap Inventory for the Elderly; m: month; MBCT: Mindfulness-Based Cognitive Therapy; NS: not specified; OM: outcome measure; PHQ-9: Patient Health Questionnaire – 9; PROMIS-A: Patient-Reported Outcomes Measurement Information System – Anxiety; QoLI: Quality of Life Inventory; QIPA: Tinnitus Psychological Impact Questionnaire; RT: Relaxation Therapy/Training; SCL-90(-R): Symptom Checklist- 90 (Revised); SSTAI: State-Trait Anxiety Inventory; TFI: Tinnitus Functional Index; THI: Tinnitus Handicap Inventory; TPFQ: Tinnitus Primary Function Questionnaire; TQ: Tinnitus Questionnaire; TRQ: Tinnitus Reaction Questionnaire; TRT: Tinnitus Retraining Therapy; w: week; WHO Overall QoL: World Health Organization Overall Quality of Life; WLC: wait-list control.

Table 4. Potential sources of bias in studies included in the systematic review assessed by Cochrane’s Risk of Bias.

| Study (year) | Cochrane Collaboration Risk of Bias Tool | | | | | Overall |
|-------------------------------|---|---|----------------------------------|------------------------------------|--|-----------|
| | Bias arising from the randomization process | Bias due to deviations from intended intervention | Bias due to missing outcome data | Bias in measurement of the outcome | Bias in selection of the reported result | |
| Arif et al (2017) | Low | Some concerns | Some concerns | High | Some concerns | High risk |
| Hesser et al (2012) (2014) | Low | Low | Low | High | Some concerns | High risk |
| McKenna et al (2017) | Low | Low | Low | High | Low | High risk |
| Molander et al (2018) | Some concerns | Low | Low | High | Low | High risk |
| Philippot et al (2012) | Some concerns | Some concerns | Low | High | Some concerns | High risk |
| Westin et al (2011) | Some concerns | Low | Low | High | Some concerns | High risk |

Notes:

An overall risk of bias was rated as follows: low risk = all domains rated as low risk; some concerns = at least one domain rated as some concerns; high risk = at least one domain rated as high risk or multiple domains rated as some concerns.

Table 5. Potential sources of bias in studies included in the systematic review assessed by EPHPP.

| Study (year) | EPHPP | | | | | | | | Global rating | Further information |
|---|----------------|--------------|-------------|----------|-------------------------|--------------------------|---|--|---------------|---|
| | Selection bias | Study design | Confounders | Blinding | Data collection methods | Withdrawals and dropouts | Intervention integrity | Analyses | | |
| Dehnabi et al (2017) | Weak | Moderate | Weak | Moderate | Strong | Weak | (Q1) Can't tell (Q2) Can't tell (Q3) Can't tell | (Q1) Individual (Q2) Individual (Q3) Can't tell (Q4) Can't tell | Weak | No information about blinding |
| Drey (2017) | Weak | Moderate | Strong | Moderate | Strong | Strong | (Q1) 80-100% (Q2) Yes (Q3) No | (Q1) Individual (Q2) Individual (Q3) Yes (Q4) Can't tell | Moderate | No information about blinding |
| Ferraro et al (2019) | Weak | Moderate | Strong | Moderate | Strong | Moderate | (Q1) 80-100% (Q2) Can't tell (Q3) No | (Q1) Individual (Q2) Individual (Q3) Yes (Q4) Can't tell | Moderate | No information about blinding |
| Gans et al (2014) (2015) | Weak | Moderate | Strong | Moderate | Strong | Strong | (Q1) 80-100% (Q2) Can't tell (Q3) No | (Q1) Individual (Q2) Individual (Q3) Yes (Q4) Can't tell | Moderate | No information about blinding; no analysis reported for FU (2015 study) |
| Hassinen & Lappalainen (2018) | Moderate | Moderate | Strong | Moderate | Weak | Strong | (Q1) 80-100% (Q2) Can't tell (Q3) No | (Q1) Individual (Q2) Individual (Q3) Yes (Q4) Can't tell | Moderate | No information about blinding |
| Hesser et al (2009) | Weak | Moderate | Strong | Moderate | Moderate | Strong | (Q1) 80-100% (Q2) Yes (Q3) No | (Q1) Individual (Q2) Individual (Q3) Can't tell (Q4) Can't tell | Moderate | No information about blinding; no data or explanation for absence of data for 1-week post-treatment |
| Husain et al (2019) Zimmerman et al (2019) | Weak | Moderate | Strong | Moderate | Strong | Moderate | (Q1) 80-100% (Q2) Can't tell (Q3) No | (Q1) Individual (Q2) Individual (Q3) Yes (Q4) Can't tell | Moderate | No information about blinding |
| McKenna et al (2018) | Moderate | Moderate | Strong | Moderate | Strong | Strong | (Q1) 80-100% (Q2) Can't tell (Q3) No | (Q1) Individual (Q2) Individual (Q3) Yes (Q4) Can't tell | Strong | No information about blinding |

| Study (year) | EPHPP | | | | | | | | Global rating | Further information |
|---------------------|----------------|--------------|-------------|----------|-------------------------|--------------------------|--|---|---------------|-------------------------------|
| | Selection bias | Study design | Confounders | Blinding | Data collection methods | Withdrawals and dropouts | Intervention integrity | Analyses | | |
| Roland et al (2015) | Weak | Moderate | Strong | Moderate | Strong | Moderate | (Q1) 80-100% (Q2) Can't tell (Q3) No | (Q1) Individual (Q2) Individual (Q3) Yes (Q4) Can't tell | Moderate | No information about blinding |

Notes:

Questions under Intervention Integrity: (Q1) What percentage of participants received the allocated intervention; (Q2) Was consistency of intervention measured; (Q3) Is it likely that subjects received an unintended intervention that may influence the results.

Questions under Analyses: (Q1) Indicate unit of allocation; (Q2) Indicate unit of analysis; (Q3) Are the statistical methods appropriate for the study design; (Q4) Is the analysis performed by intervention allocation status (i.e. intention to treat) rather than actual intervention received.

Table 6: Further critical appraisal of studies included in the systematic review.

| Study (year) | Unrepresentative sample as self-referral was allowed | Unrepresentative sample due to demographic characteristics | Formal ax of hearing problems | Concurrent psychotherapy allowed | Received psychotherapy 3 months previously | Concurrent psychotropic pharmacotherapy allowed | Screening for cognitive impairment | Treatment adherence checks | Small sample size (n < 15 per group) | Other factors |
|----------------------------|--|--|-------------------------------|----------------------------------|--|---|------------------------------------|----------------------------|--------------------------------------|--|
| Arif et al (2017) | Yes | Unclear | Yes | Unclear | Unclear | Unclear | Unclear | Unclear | No | No imputation of missing values |
| Hesser et al (2012) (2014) | Yes | Unclear | Yes | No | Unclear | Unclear | Unclear | Unclear | No | – |
| McKenna et al (2017) | No | Yes (80% white) | Yes | Unclear | Unclear | Unclear | Unclear | Yes | No | Selected participants for the presence of significant psychological distress (score >10 on the Clinical Outcomes in Routine Evaluation – Non-Risk) |
| Molander et al (2018) | Yes | Yes (33% men) | No | Unclear | Unclear | Unclear | Unclear | No | No | – |
| Philippot et al (2012) | Yes | Unclear | Yes | No | Unclear | Unclear | Unclear | Yes | Yes | No imputation of missing values |
| Westin et al (2011) | Yes | Unclear | Yes | Unclear | No | Yes | Unclear | Yes | No | Treatment and control conditions differed in duration (ACT for 10 weeks, TRT for 18 months; WLC for 10 weeks) |
| Dehnabi et al (2017) | Unclear | Yes (67% men) | Unclear | Unclear | Unclear | Unclear | Unclear | Unclear | Yes | No analysis examining or controlling for group differences at baseline (a cohort study) |
| Drey (2017) | Yes | Yes (100% men; 71% white) | Yes | Unclear | No | Yes | Unclear | Yes | Yes | – |
| Ferraro et al (2019) | Yes | Unclear | Unclear | No | Unclear | No | Unclear | Unclear | Yes | No imputation of missing values |
| Gans et al (2014) (2015) | Yes | Yes (75% men) | Yes | No | Unclear | Unclear | Unclear | Unclear | Yes | No imputation of missing values |

| Study (year) | Unrepresentative sample as self-referral was allowed | Unrepresentative sample due to demographic characteristics | Formal ax of hearing problems | Concurrent psychotherapy allowed | Received psychotherapy 3 months previously | Concurrent psychotropic pharmacotherapy allowed | Screening for cognitive impairment | Treatment adherence checks | Small sample size (n < 15 per group) | Other factors |
|-------------------------------|--|--|-------------------------------|----------------------------------|--|---|------------------------------------|----------------------------|--------------------------------------|--|
| Hassinen & Lappalainen (2018) | Unclear | Unclear | Unclear | No | Unclear | Yes | Unclear | Unclear | Yes | Included participants with psychiatric comorbidities |
| Hesser et al (2009) | Unclear | Yes (33% men) | Unclear | Unclear | No | Unclear | Unclear | Yes | No | – |
| Husain et al (2019) | Yes | Unclear | Yes | Unclear | Unclear | Unclear | Yes | Unclear | Yes | No imputation of missing values |
| Zimmerman et al (2019) | | | | | | | | | | |
| McKenna et al (2018) | No | Unclear | Yes | Unclear | Unclear | Unclear | Unclear | Yes | No | – |
| Roland et al (2015) | Yes | Yes (31% men) | Unclear | Unclear | Unclear | No | Yes | Unclear | Yes | No information about imputation of missing values |

Notes:

Ax: assessment.

Appendix A
PRISMA 2020 Checklist

| Section and Topic | Item # | Checklist item | Location where item is reported |
|-------------------------------|--------|--|---------------------------------|
| TITLE | | | |
| Title | 1 | Identify the report as a systematic review. | p.1 |
| ABSTRACT | | | |
| Abstract | 2 | See the PRISMA 2020 for Abstracts checklist. | p.2-3 |
| INTRODUCTION | | | |
| Rationale | 3 | Describe the rationale for the review in the context of existing knowledge. | p.4-6 |
| Objectives | 4 | Provide an explicit statement of the objective(s) or question(s) the review addresses. | p.6 |
| METHODS | | | |
| Eligibility criteria | 5 | Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses. | p.6-9 |
| Information sources | 6 | Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted. | p.6-7 |
| Search strategy | 7 | Present the full search strategies for all databases, registers and websites, including any filters and limits used. | p.6-7 |
| Selection process | 8 | Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process. | p.7 |
| Data collection process | 9 | Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process. | p.7-9 |
| Data items | 10a | List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect. | p.6-9 |
| | 10b | List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information. | p.6-9 |
| Study risk of bias assessment | 11 | Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process. | p.7-8 |
| Effect measures | 12 | Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results. | p.8-9 |
| Synthesis methods | 13a | Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)). | p.8-9 |
| | 13b | Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions. | p.8-9 |
| | 13c | Describe any methods used to tabulate or visually display results of individual studies and syntheses. | p.8-9 |
| | 13d | Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used. | p.8-9 |
| | 13e | Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression). | p.8-9 |

| Section and Topic | Item # | Checklist item | Location where item is reported |
|--|--------|--|---------------------------------|
| | 13f | Describe any sensitivity analyses conducted to assess robustness of the synthesized results. | N/A |
| Reporting bias assessment | 14 | Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases). | p.8-9 |
| Certainty assessment | 15 | Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome. | N/A |
| RESULTS | | | |
| Study selection | 16a | Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram. | Figure 1 |
| | 16b | Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded. | Figure 1 |
| Study characteristics | 17 | Cite each included study and present its characteristics. | Table 1, 2 |
| Risk of bias in studies | 18 | Present assessments of risk of bias for each included study. | Table 4, 5 |
| Results of individual studies | 19 | For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots. | Figure 2-5 |
| Results of syntheses | 20a | For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies. | N/A |
| | 20b | Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect. | p.10-12, Figure 2-5 |
| | 20c | Present results of all investigations of possible causes of heterogeneity among study results. | p.12 |
| | 20d | Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results. | N/A |
| Reporting biases | 21 | Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed. | N/A |
| Certainty of evidence | 22 | Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed. | N/A |
| DISCUSSION | | | |
| Discussion | 23a | Provide a general interpretation of the results in the context of other evidence. | p.15-16 |
| | 23b | Discuss any limitations of the evidence included in the review. | p.18 |
| | 23c | Discuss any limitations of the review processes used. | p.18 |
| | 23d | Discuss implications of the results for practice, policy, and future research. | p.16-17 |
| OTHER INFORMATION | | | |
| Registration and protocol | 24a | Provide registration information for the review, including register name and registration number, or state that the review was not registered. | p.6 |
| | 24b | Indicate where the review protocol can be accessed, or state that a protocol was not prepared. | p.6 |
| | 24c | Describe and explain any amendments to information provided at registration or in the protocol. | N/A |
| Support | 25 | Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review. | p.20 |
| Competing interests | 26 | Declare any competing interests of review authors. | p.20 |
| Availability of data, code and other materials | 27 | Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review. | N/A |

Appendix B
Search terms

((mindfulness-based OR acceptance-based OR "third wave" OR "third-wave therapy" OR "third-wave therapies" OR "mindfulness-based cognitive therapy" OR "mindfulness-based stress reduction" OR "compassion-focused therapy" OR "compassion focused therapy" OR "compassionate mind training" OR "behavioral activation" OR "behaviour activation" OR "behavioural activation" OR "behaviour activation" OR "dialectical behavior therapy" OR "dialectical behavioral therapy" OR "dialectical behaviour therapy" OR "dialectical behavioural therapy" OR "metacognitive therapy" OR "cognitive behavioral analysis system of psychotherapy" OR "cognitive behavioural analysis system of psychotherapy" OR "functional analytic psychotherapy" OR "integrative behavioral couple therapy" OR "integrative behavioural couple therapy" OR "acceptance and commitment therapy" OR "acceptance commitment therapy" OR "acceptance commitment training" OR "acceptance and commitment training") AND (tinnitus* OR hearing* OR balance* OR "sound sensitivity" OR hyperacus* OR hypoacus* OR distortion OR diplacusis OR deaf* OR "communication disorder" OR cochlea* OR vestibular OR auditory OR audiolog* OR acoustic OR aural OR ear OR sensory OR otolog* OR otoacoustic)

Supplemental Table 1: Characteristics of third-wave therapies

| Name | Mindfulness-based Cognitive Therapy (MBCT) | Mindfulness-based Stress Reduction (MBSR) | Acceptance and Commitment Therapy (ACT) | Dialectical Behaviour Therapy (DBT) | Compassion-Focused Therapy (CFT) | Meta-cognitive Therapy (MT) |
|--|--|--|--|--|--|---|
| Key references | Segal et al. (2002) | Kabat-Zinn (1990) | Hayes et al. (1999) | Linehan (1993a,b) | Gilbert (2009) | Wells (2009) |
| Goals of therapy | To cultivate non-judgmental, present-focused awareness of one's thoughts, emotions and physical sensations, with an attitude of acceptance and self-compassion | To cultivate non-judgmental, present-focused awareness of one's thoughts, emotions and physical sensations, with an attitude of acceptance and self-compassion | To be more open to and accepting of one's internal experiences (e.g. thoughts, emotions and physical sensations), to become more aware of one's internal experiences in the here-and-now, and to commit to doing things guided by what really matters to oneself | To help oneself engage in functional, meaningful behavior in the presence of intense emotions (e.g. by encouraging acceptance and tolerance of distressing internal experiences) | To foster a compassionate relationship with oneself and others, and to experience inner warmth, safeness and soothing through the development of self-compassion and compassion skills | To modify thoughts and beliefs about one's thinking processes rather than the content of one's thoughts, and to develop skills in attentional control and mindfulness |
| Mode of delivery | Group | Group | Individual or group | Both individual and group | Individual or group | Individual or group |
| Who typically provides the therapy* | Psychologists, psychotherapists, CBT therapists and counsellors | Psychologists, psychotherapists, CBT therapists and counsellors | Psychologists, psychotherapists, CBT therapists and counsellors | Psychologists, psychotherapists, CBT therapists and counsellors | Psychologists, psychotherapists, CBT therapists and counsellors | Psychologists, psychotherapists, CBT therapists and counsellors |
| Average number of sessions | 8 (with or without a 1-day retreat) | 8 (with or without a 1-day retreat) | 6-12 | 6-12 | 4-6 | 8-12 |
| Average duration of each session (mins) | 120 | 120-150 | 60 | 60 | 60 – 120 | 60-90 |

Note: * Although psychologists, psychotherapists, CBT therapists and counsellors may typically provide these therapies, audiologists who are trained in these interventions can also deliver them.

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