1   **Intervention planning for the Tinnitus E-Programme 2.0, an internet-based cognitive**

2   **behavioural intervention for tinnitus**

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ABSTRACT

Purpose: To comprehensively describe the intervention planning process for the Tinnitus E-Programme 2.0, an internet-based cognitive behavioural intervention for tinnitus.

Method: Theory-, evidence-, and person-based approaches to intervention development were used. In Phase 1, quantitative systematic reviews were used to identify potentially effective intervention techniques and design features. Primary mixed-methods research involving adults with tinnitus explored the acceptability of the first version of the intervention. In Phase 2, person-based guiding principles highlighted key intervention design objectives and features to address needs of the intervention's target group (identified in Phase 1) to maximise its acceptability, feasibility of delivery, and effectiveness. Theory-based 'behavioural analysis' and 'logic modelling' comprehensively described intervention content and potential mechanisms of action. From this planning work, a prototype intervention was developed.

Results: The intervention design objectives outlined in the guiding principles were to (1) normalise tinnitus; (2) support users to maintain a regular relaxation practice; (3) minimise the worsening of users' tinnitus sensation; and (4) ensure the intervention is accessible to those with hearing loss. Behavioural analysis and logic modelling identified intervention processes (e.g. illness perceptions, beliefs about consequences, skills, goals) and purported mediators (acceptance of tinnitus, negative thinking, use of the cognitive skills tools for managing negative thoughts, and practicing regular relaxation) hypothesised to facilitate reductions in tinnitus symptom severity.

Conclusions: The guiding principles highlight key design objectives and features to consider when developing interventions for tinnitus. The logic model offers hypothesised mechanisms of action that can be tested in future process analyses.

INTRODUCTION

52   Tinnitus (often described as ringing in the ears) is a common condition, affecting an

53   estimated 12-30% of the population (McCormack et al., 2016). Tinnitus can significantly

54   affect an individual's quality of life, leading to sleep disturbances, hearing difficulties,

55   difficulties with concentration, disruption to work activities, social life, and relationships, and

56   emotional difficulties such as anxiety, depression, irritation, and inability to relax (Hall,

57   Fackrell, et al., 2018; Marks et al., 2019). In the absence of a cure, tinnitus management

58   focuses on reducing tinnitus symptom severity. This typically involves reducing the tinnitus

59   percept through sound therapy (e.g. wearable sound generators, hearing aids) and/or reducing

60   the negative emotional impact of tinnitus through education or psychological therapy (e.g.

61   cognitive behaviour therapy [CBT], client-centred counselling)(Cima et al., 2019; Lewis et

62   al., 2000; NICE, 2020; Tunkel et al., 2014). Sound therapy options are commonly offered.

63   However, evidence for the effectiveness of these options is limited. Such evidence includes

64   lower quality non-randomised studies that report varied outcomes, and randomised controlled

65   trials comparing two different sound therapy options and finding them equivalent in terms of

66   outcome (Cima et al., 2019; Hoare et al., 2013, 2014; Sereda et al., 2018).

67   Evidence for the effectiveness of psychological therapies is stronger, and particularly so for

68   CBT (Fuller et al., 2020). However, access to psychological therapies is limited, with therapy

69   being reserved for those most in need (McFerran et al., 2018). A recent survey of people with

70   tinnitus found that the psychological support offered in tinnitus services in the UK is variable,

71   including written information (66.7%), relaxation (23.0%), CBT (10.7%), mindfulness

72   meditation (8.9%), or group education (7.0%) (McFerran et al., 2018). Only 10.7% of

73   respondents reported receiving information about tinnitus from their GP and 2.6% reported

74   seeing a psychologist. One fifth of respondents reported that the GP took no action at their

75   first appointment; two thirds of those referred to secondary care were discharged without any

76   therapeutic intervention; and one third of the total discharged returned to primary care about

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77   their tinnitus (McFerran et al., 2018). Similar surveys in the US have also highlighted

78   considerable variability among tinnitus services regarding the provision of psychological

79   support (Schmidt et al., 2017). Digital interventions may provide a relatively low-cost way of

80   improving access to psychological support.

81   The Tinnitus E-Programme, described in detail by Greenwell et al. (2015), is an internet-

82   based cognitive behavioural intervention initially developed as a resource for clinicians, but

83   can also be accessed and completed independently by people with tinnitus seeking to improve

84   tinnitus symptom severity. One advantage of self-guided internet-based interventions is that

85   they can be delivered at scale with minimal staff resources and are therefore suitable for

86   delivery in a primary care context and for those without complex mental health needs. Self-

87   guided internet-based interventions can also be used by patients at home at a time that is

88   convenient to them. Other available internet-based tinnitus interventions are relatively

89   resource-intensive, requiring input from trained audiologists or psychological therapists

90   (Beukes et al., 2016; Beukes, Baguley, et al., 2018; Nyenhuis, Zastrutzki, Weise, et al.,

91   2013).

92   The 10-week Tinnitus E-Programme supports self-management by providing education about

93   tinnitus to help people develop realistic tinnitus beliefs; cognitive skills training (e.g.

94   cognitive restructuring) to develop effective and adaptive ways of thinking and feeling; and

95   relaxation skills training to support people to develop a regular relaxation practice to reduce

96   their physiological arousal and emotional distress (Greenwell et al., 2015). It has been argued

97   that negative thinking, tinnitus beliefs, and physiological arousal are key determinants of

98   tinnitus symptom severity (McKenna et al., 2014). Moreover, CBT that focuses on tackling

99   negative thoughts, relaxation therapy, and group education have all been shown to improve

100   tinnitus symptom severity, specifically tinnitus-related distress, depression, and quality of life

101   (Fuller et al., 2020).

102 Unique to the Tinnitus E-Programme is the inclusion of a moderated online support forum

103 that allows users to communicate with each other and gain social support. A questionnaire

104 (the Tinnitus Handicap Inventory; THI) (Newman et al., 1996) is provided to facilitate self-

105 monitoring of tinnitus-related distress. Through self-monitoring, users can track their

106 intervention progress, evaluate its success, and gain insight into how their tinnitus affects

107 them.

108 The Tinnitus E-Programme had been available online since 2009, but had not undergone any

109 formal evaluation. Following the Medical Research Council guidance on developing and

110 evaluating complex interventions (Craig et al., 2008; Moore et al., 2014), a research team not

111 involved in the development of the Tinnitus E-Programme carried out a mixed-methods

112 process evaluation with users of the intervention to explore intervention acceptability.

113 Findings suggested that the Tinnitus E-Programme was acceptable to its target group, but

114 also highlighted some barriers to engagement that need to be addressed before additional

115 evaluation work can be carried out (Greenwell et al., 2019). For example, users experienced

116 difficulties with meeting the intervention's relaxation goals and reported several barriers to

117 practicing relaxation (e.g. finding the time to practice, forgetting). Users also held negative

118 views about some intervention components (THI, online support forum) and use of these

119 components was lower.

120 The aim of this paper is to comprehensively describe the intervention planning process for

121 the Tinnitus E-Programme 2.0, and optimised version of the Tinnitus E-Programme (referred

122 to now as 'the Tinnitus E-Programme 1.0'). Specifically, we explain how we used the

123 findings from the mixed-methods process evaluation and other evidence synthesised in

124 systematic reviews to maximise the intervention's acceptability, feasibility of delivery, and

125 likely effectiveness. This paper also provides a description of the intervention content and its

126 potential mechanisms of change (i.e. how it is hypothesised to work). Previously published

127   descriptions of interventions are often inadequate, but are important for planning process

128   evaluations, replication in research and practice, and data extraction in systematic reviews

129   (Craig et al., 2008; Michie & Abraham, 2004, 2008; Moore et al., 2014).

130   **METHODS**

131   **Intervention Planning Methodology**

132   Theory-, evidence-, and person-based approaches to intervention development (Band et al.,

133   2017; Greenwell et al., 2018) were used to guide the development of the Tinnitus E-

134   Programme 2.0. The person-based approach to intervention development emphasises the

135   importance of gaining an in-depth understanding of the perspectives of the intervention's

136   target group (Yardley et al., 2015). It proposes that understanding and accommodating these

137   perspectives is essential for maximising intervention uptake, adherence, and outcomes.

138   Guidelines for developing complex interventions recommend creating a 'programme theory'

139   for an intervention that describes the key intervention components (i.e. content and delivery),

140   its mechanisms of action (i.e. how an intervention is expected to lead to its effects), and its

141   outcomes (O'Cathain et al., 2019). Two theory-based methods - 'behavioural analysis' and

142   'logic modelling' – were used to comprehensively describe the intervention's content,

143   outcomes, and potential mechanisms of action (i.e. communicate the intervention's

144   programme theory). Guidelines also recommend drawing on reviews of published evidence

145   to inform intervention development (O'Cathain et al., 2019).

146   Intervention planning was carried out in two sequential phases. Following an evidence-based

147   approach, phase 1 collated and analysed evidence from previous studies to identify potential

148   areas for improvement, and design features acceptable to target users and feasible to

149   implement in a digital intervention. This paper focuses on Phase 2, which used the evidence-

150   base from Phase 1 to inform the development of an intervention plan. A prototype

151 intervention was then created from this intervention plan. The complete intervention planning

152 process for the Tinnitus E-Programme 2.0 is illustrated in Figure 1.

Phase 1: Collating and Analysing Evidence

154 In Phase 1, we drew upon two existing quantitative systematic reviews that assessed the

155 effectiveness of self-help interventions for adults with chronic tinnitus. Nyenhuis, Golm, et

156 al. (2013) reviewed the evidence for CBT-based self-help interventions for tinnitus delivered

157 with minimal or no therapist contact. To supplement this work, we carried out a systematic

158 review focused on the techniques and effects of self-guided interventions, not limited to

159 CBT-based interventions (Greenwell, Sereda, Coulson, El Refaie, et al., 2016). Both

160 systematic reviews compared self-help interventions to passive controls (e.g. waiting list

161 control) and active controls (i.e. face-to-face therapies or therapist-guided self-help

162 interventions). Taken together, the review findings provided promising evidence that use of

163 self-help interventions can lead to improvements in tinnitus symptom severity. Our review

164 also identified additional feasible and potentially effective intervention techniques, using

165 Michie et al.'s Behaviour Change Techniques Taxonomy (Michie et al., 2013) to code

166 intervention content. The aim of the taxonomy is to standardise the classification and

167 description of complex behavioural interventions. Such standardisation provides a common

168 language to reliably report intervention techniques and behavioural determinants (Michie et

169 al., 2015).

170 These reviews were supplemented with primary mixed-method research with adults with

171 tinnitus to explore the acceptability of the Tinnitus E-Programme 1.0 (Greenwell et al., 2019;

172 Greenwell, Sereda, Coulson, & Hoare, 2016) and highlight the key issues, needs, and

173 behavioural challenges of the target group the Tinnitus E-Programme 2.0 must address. Two

174 mixed-methods studies were carried out to explore users' views and usage of the Tinnitus E-

175 Programme 1.0. In the first study, an online survey explored the views of past and current

176 users, including adults with tinnitus (*n*=25) and health professionals (*n*=2). In the second

177 study, adults with tinnitus (*n*=13), who were resident in the UK and had not previously used

178 the intervention, completed the intervention and took part in semi-structured interviews.

179 Participants in the second study completed a relaxation log to assess the extent to which they

180 met pre-specified relaxation goals. Detailed methods and findings are published elsewhere

181 (Greenwell et al., 2019; Greenwell, Sereda, Coulson, & Hoare, 2016).

182 The key findings from Phase 1 that influenced intervention planning are presented in the

183 results.

184 **Phase 2: Creating the intervention plan**

185 Deciding on the intervention components and design features

186 Phase 1 findings were used to inform decisions regarding which intervention components

187 and design features from the Tinnitus E-Programme 1.0 will be included in the Tinnitus E-

188 Programme 2.0. Specifically, the findings from the systematic reviews and primary mixed-

189 methods research guided decisions around whether the intervention would remain self-guided

190 or be delivered with therapist support. This evidence also helped to identify additional

191 behaviour change techniques and design features that should be added to improve

192 intervention acceptability or effectiveness. The mixed-methods evaluation of the Tinnitus E-

193 Programme 1.0 also highlighted intervention content that were not deemed acceptable by the

194 target group and should subsequently be removed.

195 Guiding principles

196 Consistent with a person-based approach, the intervention plan included a set of guiding

197 principles (Yardley et al., 2015). These were created at the outset of Phase 2 and were

198 consulted and refined throughout this phase and when writing intervention content for the

199 intervention prototype. The guiding principles consisted of 'intervention design objectives' to

200 address the key issues, needs and behavioural challenges of the target group identified in the

9

201 primary mixed-methods research, and the key 'intervention features' that will achieve these

202 objectives. Development was also informed by Yardley et al.'s (2015)common person-based

203 guiding principles that are important for maximising acceptability and engagement with

204 digital interventions. The common guiding principles were informed by Yardley et al.'s

205 experience of intervention development and the self-determination theory which proposes

206 that people are more likely to engage in behaviour (e.g. practicing relaxation) if they have the

207 intrinsic motivation to do so (Ryan & Deci, 2000).

208 Behavioural analysis

209 Theory-based behavioural analysis was used to comprehensively describe the intervention

210 content and identify potential determinants of behaviour (i.e. what needs to change for a

211 behaviour to occur) using behaviour change theory (Band et al., 2017). Following the

212 recommended approach by Band et al., we used a behavioural analysis table to map out the

213 behavioural content of the Tinnitus E-Programme 2.0, linking the behaviour change

214 techniques to key behaviours the intervention is trying to change (e.g. practicing relaxation)

215 and its behavioural determinants.

216 Several theory-based frameworks were used to ensure behavioural content was reported in

217 the behavioural analysis table using standardised terminology. As was done in our systematic

218 review (Phase 1), each behaviour change technique was coded using the Behaviour Change

219 Techniques Taxonomy. The Behaviour Change Wheel (Michie et al., 2011, 2014) is based on

220 a model of behaviour change that argues that 'Behaviour' arises from an individual's

221 'Capability', 'Opportunity', and 'Motivation' to enact it (the COM-B model; Michie et al.,

222 2011). The Behaviour Change Wheel includes a list of nine intervention functions (that ways

223 by which an intervention can change behaviour, such as education or training) and six

224 sources of behaviour intervention may target (e.g. psychological capability, physical

225 opportunity, and reflective motivation). The Theoretical Domains Framework (Cane et al.,

226   2012) helps to further pin down the behaviour determinants. It is an integrative framework

227   that brings together 14 of the key behavioural determinants ('theoretical domains') used in

228   behaviour change theories (e.g. knowledge, skills). Using these two frameworks, individual

229   or sets of behaviour change techniques were mapped to their corresponding intervention

230   function, source of behaviour (Behaviour Change Wheel), and theoretical domain

231   (Theoretical Domains Framework). All three frameworks and the list of behaviour change

232   techniques identified from the tinnitus self-help interventions included in our systematic

233   review (Phase 1) were reviewed to identify additional intervention content suitable for

234   inclusion in the Tinnitus E-Programme 2.0.

235   The behavioural analysis focused solely on intervention techniques that target behaviour

236   change and behavioural determinants. The techniques and processes that target non-

237   behavioural outcomes (e.g. education about tinnitus) were considered when developing the

238   logic model.

239   Logic modelling

240   Logic modelling was used to illustrate the hypothesised causal relationships proposed to

241   mediate the intervention outcome (i.e. how the intervention is thought to work) (Band et al.,

242   2017; Baxter et al., 2014; Greenwell et al., 2018; Moore et al., 2014). Logic models are

243   diagrams that outline how the intervention's techniques are hypothesised to impact on

244   intervention processes (short-term outcomes the techniques are hypothesised to affect, such

245   as beliefs and skills) and mediators (cognitive and behavioural factors hypothesised to

246   directly affect the intervention outcome, such as regular relaxation practice) to ultimately

247   affect the intervention outcome (tinnitus symptom severity). They do not inform intervention

248   development, rather they are outputs of the planning process that make explicit the key

249   intervention components, processes and outcomes, and can inform future process evaluations

250 whereby the hypothesised causal relationships are tested. The different components of the

251 logic model are described in the results section.

RESULTS

Deciding on the intervention components and design features

254 Should we offer therapist support?

255 In the Tinnitus E-Programme 1.0, although the intervention was largely self-guided, users

256 were able to contact the intervention developer (a psychotherapist/hearing therapist) for

257 support if they wished. We drew upon the systematic reviews and mixed methods research to

258 help us decide whether we should offer therapist support alongside the Tinnitus E-

259 Programme 2.0. In their meta-analysis, Nyenhuis, Golm, et al. (2013) observed no difference

260 in outcomes between self-help interventions and active controls. That is, the involvement of a

261 therapist in the intervention did not amount to greater reductions in tinnitus symptom

262 severity. This suggested that purely self-directed interventions are a credible option.

263 In the mixed-methods evaluation, there were contradictory views on the value of therapist

264 support. Some users valued this form of support. However, others valued the user autonomy

265 (i.e. it was less pressurised and they did not have to talk about their tinnitus with others) and

266 convenience provided by the self-guided intervention. When new users were asked whether

267 they contacted the intervention therapist, none reported doing so. Moreover, providing

268 therapist support may not be feasible for all UK tinnitus patients given that access to

269 psychological therapy is limited, with less than half of audiology staff claiming to have

270 access to an individual trained in psychological therapy as part of their multidisciplinary team

271 or the option to directly refer patients to such services (Gander et al., 2011; Hoare et al.,

272 2015). Taken together, it was concluded that the intervention should be self-guided.

273 Which intervention components from the Tinnitus E-Programme 1.0 should we keep or

274 deliver in a different way?

275   We drew upon the mixed-methods evaluation to help us decide which intervention

276   components from the Tinnitus E-Programme 1.0 should be included in version 2.0. Overall,

277   participants in this research expressed positive views of the Tinnitus E-Programme 1.0

278   content and design features, particularly valuing education about tinnitus and its

279   management, and relaxation skills training. Use of these components was high. Therefore,

280   these components were also incorporated in the Tinnitus E-Programme 2.0, along with the

281   cognitive skills training.

282   This study also highlighted issues affecting intervention acceptability and barriers to

283   engagement. Participants' views on the THI were mixed. Users saw potential benefits of self-

284   monitoring using the THI, but some found its response scale, scoring, feedback system, and

285   some of its items confusing. Given this and concerns over the suitability of the THI as a

286   sensitive outcome measure (Fackrell et al., 2014), it was not included in the Tinnitus E-

287   Programme 2.0. Instead, other intervention techniques were added to help facilitate users'

288   confidence in the intervention and its ability to improve their tinnitus severity. First, the

289   educational content provided users with an explanation of the role of stress and negative

290   thoughts in tinnitus and presented lay summarises of the research evidence on the

291   effectiveness of education, cognitive skills training, and relaxation skills training. Second, in

292   the relaxation module, users were provided with a printable relaxation log that allowed them

293   to record how they felt after practicing relaxation to help them evaluate the benefits they

294   gained from relaxation.

295   Views on the online support forum were mixed and use of this component was low. Some users

296   disliked talking to people they could not see or perceived forum posts as negative. Therefore,

297   the online support forum was also removed due to its low use and lack of acceptability among

298   users. Instead, the Tinnitus E-Programme 2.0 included user stories and testimonials to facilitate

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299   perceptions of social context and support (Morrison et al., 2012). The remaining acceptability

300   issues were addressed by the guiding principles.

301   Table 1 provides an overview of the final Tinnitus E-Programme 2.0 content, including aims,

302   components, and individual intervention techniques.

303   **Guiding principles**

304   We created four guiding principles specific to the Tinnitus E-Programme 2.0 to address the

305   key acceptability issues identified by the mixed-methods research. These issues and their

306   associated guiding principles are summarised in Table 2.

307   An important intervention design objective from the guiding principles was 'to support users

308   to maintain a regular relaxation practice', which was created to address the challenges users

309   of the Tinnitus E-Programme 1.0 were having with maintaining a regular relaxation practice.

310   We used our systematic review (Greenwell, Sereda, Coulson, El Refaie, et al., 2016) to help

311   identify which behaviour change techniques we could add to the Tinnitus E-Programme 2.0

312   to support users with their relaxation practices. The systematic review identified 15 behaviour

313   change techniques across the self-help interventions in five studies. From this list, five of

314   these behaviour change techniques were present in the Tinnitus E-Programme 1.0 (Appendix

315   1). Six additional behaviour change techniques were considered relevant and feasible and

316   were, therefore, included in the Tinnitus E-Programme 2.0 (Appendix 1). 'Self-monitoring of

317   behaviour', 'habit formation', 'social support (practical)' and 'prompts/cues' were chosen to

318   remind users to practice and to help build a relaxation habit. 'Self-monitoring of outcome of

319   behaviour' and 'information about emotional consequences' were deemed useful for

320   persuading users that the relaxation is beneficial (see Appendix 2 for more information on

321   these behaviour change techniques).

322 Appendix 3 outlines how Yardley et al.'s common guiding principles were addressed in the

323 Tinnitus E-Programme 2.0. These common guiding principles were helpful for addressing

324 acceptability issues relating to the structure of the Tinnitus E-Programme 1.0. In the mixed

325 methods research, users valued the 10-week structure of the Tinnitus E-Programme 1.0

326 because it broke the content into manageable stages. However, some users commented that

327 they would prefer a different intensity (time between sessions) and duration (length of

328 intervention). The common guiding principles recommend promoting user autonomy by

329 offering users choice where possible. Therefore, in the Tinnitus E-Programme 2.0, we

330 decided to provide users with a recommended course structure, but allow them to choose

331 which modules to use and when to start each module.

332 **Behavioural analysis**

333 The full behavioural analysis table is presented in Appendix 2. The behavioural analysis was

334 carried out on the two key behaviours targeted by the Tinnitus E-Programme 2.0: use of the

335 cognitive skills tools for managing negative thoughts, and practicing regular relaxation. The

336 behavioural analysis identified that the intervention aims to target four of the six potential

337 behavioural sources listed in the Behaviour Change Wheel (psychological capability,

338 reflective motivation, physical opportunity, and social opportunity) and six of the 14

339 theoretical domains listed in the Theoretical Domains Framework (beliefs about

340 consequences, skills, environmental context and resources, goals, behavioural regulation, and

341 social influences). The behavioural content was mapped onto six of the nine intervention

342 functions (education, persuasion, training, enablement, environmental restructuring, and

343 modelling) in the Behaviour Change Wheel and 16 different behaviour change techniques in

344 the Behaviour Change Techniques Taxonomy, including information about health

345 consequences, self-monitoring of behaviour, habit formation, and action planning.

346   No additional intervention content was identified through reviewing the Behaviour Change

347   Techniques Taxonomy, Theoretical Domains Framework, or Behaviour Change Wheel.

348   **Logic modelling**

349   The final logic model is presented in Figure 2. It comprised four components. *Intervention*

350   *techniques* summarised the behaviour change techniques outlined in the behavioural analysis,

351   as well as the educational techniques intended to help users develop realistic tinnitus beliefs.

352   *Intervention processes* included seven processes or short-term outcomes that these techniques

353   are hypothesised to affect. Six of these processes were theoretical domains identified in the

354   behavioural analysis and influenced one or both target behaviours (regular relaxation

355   practice, use of cognitive skills training). We also identified one additional process (not listed

356   in any of the behaviour change frameworks), illness perceptions, that the educational

357   techniques were likely to affect. Illness perceptions are cognitive representations or beliefs

358   that individuals have about their illness (Weinman et al., 1996), and have been shown to be

359   associated with tinnitus outcomes (Vollmann et al., 2014), and a key mediator in CBT

360   interventions in severe functional somatic syndromes (Christensen et al., 2015).

361   *Purported mediators* are the cognitive and behavioural factors hypothesised to directly affect

362   the intervention outcome. In addition to the two target behaviours outlined in the behavioural

363   analysis, two cognitive mediators were identified: acceptance of tinnitus, and negative

364   thinking. These factors have been identified as mediators of tinnitus symptom severity in

365   internet intervention studies (Hesser et al., 2014), are core components of cognitive

366   behavioural models of tinnitus (Handscomb, 2018; McKenna et al., 2014), and have been

367   recommended for inclusion in a core outcome set for psychology-based tinnitus intervention

368   (Hall, Smith, et al., 2018). *Outcome* outlined the outcome that the intervention is ultimately

369   trying to change (tinnitus symptom severity).

370   **DISCUSSION**

16

371   This paper describes the use of theory-, evidence- and person-based approaches to develop

372   the Tinnitus E-Programme 2.0, an internet-based cognitive behavioural intervention for

373   tinnitus. These different approaches provided complementary insights to maximise the

374   intervention's acceptability, feasibility of delivery, and likely effectiveness. This article

375   provides a comprehensive description of the intervention planning process to allow other

376   researchers to easily understand how this methodology could be applied to different

377   intervention contexts. The comprehensive intervention description will also facilitate

378   intervention replication and evaluation, and comparison with different tinnitus interventions.

379   The frameworks used in the behavioural analysis provided a systematic way of classifying

380   behaviour change techniques and identifying potential behavioural determinants that may

381   explain how these techniques exert their effects. Beukes et al. reported the use of behaviour

382   change theory (Behaviour Change Model for Internet Interventions)(Ritterband et al., 2009)

383   and behaviour change techniques in their published description of the development an

384   internet-based CBT intervention for tinnitus (Beukes et al., 2016). However, details on how

385   theory was used were not provided and the specific techniques used were not explicitly listed.

386   Another strength of the development of the Tinnitus E-Programme 2.0 was the use of the

387   person-based approach to understand and accommodate the perspectives of its target users.

388   Other intervention studies have explored users' views, however, this tends to be limited to the

389   evaluation stage to assess user satisfaction or preferences, or to make general

390   recommendations for how to improving user engagement in internet interventions (Beukes,

391   Manchaiah, Baguley, et al., 2018; Beukes, Manchaiah, Davies, et al., 2018; Jasper et al.,

392   2014; Nyenhuis, Zastrutzki, Jäger, et al., 2013). One study explored user views during the

393   intervention development stage, but the findings were used only for suggesting minor

394   technical or usability improvements (Beukes et al., 2016). Some studies have drawn upon the

395   expertise of multidisciplinary professionals and public and patient involvement (PPI)

396 representatives when developing their interventions (Andersson et al., 2008; Beukes et al.,

397 2016). The person-based approach advocates that PPI and clinical expertise should be used in

398 combination with in-depth qualitative research (Yardley, 2018). PPI representatives tend to

399 be particularly motivated, educated, and knowledgeable (Learmonth et al., 2009; Renedo &

400 Marston, 2015; Thompson et al., 2014). Using qualitative research alongside PPI allows

401 intervention developers to capture a more diverse set of views and experiences that they need

402 to address.

403 This tinnitus intervention development was the first to use theory-based behavioural analysis

404 and logic modelling to describe the intervention's hypothesised mechanisms of action that

405 can be tested in future process analyses. Several studies have examined single mediators of

406 the effects of psychological treatments for tinnitus, such as tinnitus-related fear and

407 acceptance of tinnitus (Cima et al., 2018; Hesser et al., 2014; Hesser & Andersson, 2009).

408 Logic models can guide such mediation work by identifying all potential mechanisms of

409 action within an intervention and illustrating potential links between each mediator or

410 intervention process to the key intervention components.

411 There were some limitations of the mixed-methods research informing the intervention plan.

412 As registration to the Tinnitus E-Programme 1.0 was voluntary, it was not possible to track

413 past and current users who did not register to invite them to take part in the survey study.

414 This resulted in a small sample size (*n*=27) and may have introduced a self-selection bias.

415 Moreover, we used the Behaviour Change Techniques Taxonomy (Michie et al., 2013) to

416 systematically classify the behaviour change techniques used. The lack of an equivalent

417 framework to classify the cognitive and emotional management techniques (e.g. cognitive

418 restructuring, education about tinnitus), meant that the description of these specific

419 techniques was not as comprehensive as it could have been.

420 **Clinical implications and future directions**

421 Four guiding principles were created to address the key needs, issues, and challenges of the

422 target group, highlighting key design objectives and features that other intervention

423 developers may consider when developing interventions for adults with tinnitus. The

424 developed logic model hypothesises that the Tinnitus E-Programme 2.0 will target six

425 intervention processes, with two cognitive mediators and two behavioural mediators

426 hypothesised to directly affect tinnitus symptom severity. These hypothesised mechanisms of

427 action can be tested in future process analyses. Consistent with a person-based approach, the

428 Tinnitus E-Programme 2.0 has been evaluated using think aloud interviews to explore users'

429 reactions to and expectations of the Tinnitus E-Programme 2.0 in order to test and refine the

430 intervention (Greenwell et al., 2020). Before the intervention can be implemented in clinical

431 practice, its effectiveness must be established through a definitive randomised controlled

432 trial.

433 **ACKNOWLEDGMENTS**

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661

662 **FIGURE LEGENDS**

663 **Figure 1** Tinnitus E-Programme planning process **Key:** PBA = Person-Based Approach;

664 EBA = Evidence-Based Approach; TBA = Theory-Based Approach. **Note:** The findings from

665 Phase 1 are reported in detail elsewhere.

666 **Figure 2** Logic model of the Tinnitus E-Programme 2.0 (Modified from Greenwell et al.,

667 2020)

668   **TABLES**

669   **Table 1 Outline of intervention content of the Tinnitus E-Programme 2.0, including intervention aims, intervention components, module names, and**

670   **individual techniques**

Intervention aims	Intervention component to address these aims	Individual techniques
To develop realistic tinnitus-related illness beliefs	Education about tinnitus	• Provide information that targets specific illness cognitions (e.g. causes, timeline, curability/controllability) • Provide lay-friendly explanations of adaptive models of illness explaining how tinnitus is created and maintained in the brain.
To develop effective and adaptive ways of thinking and feeling	Cognitive skills training	• Monitoring thoughts • Thought record • Cognitive defusion • Cognitive restructuring (challenging thoughts and beliefs) • Gratitude diary
To reduce physiological arousal and emotional distress	Relaxation skills training	• Breathing exercise • Muscle relaxation • Guided relaxation • Relaxation challenge

671   **Note:** This table is modified from Greenwell et al. (2020)

Table 2 Guiding Principles for the Tinnitus E-Programme 2.0

Issues identified in the mixed-methods evaluation of the Tinnitus E-Programme 1.0	Intervention design objectives	Key features of the Tinnitus E-Programme 2.0
• Users reported that the Tinnitus E-Programme 1.0 helped them to normalise and accept their tinnitus. • They found it comforting to know there were other people with tinnitus; this made them feel less alone.	1. To normalise tinnitus	• Provide users with adaptive models of illness explaining how tinnitus is created and maintained in the brain, informed by theories of medically unexplained symptoms that have been used in practice to explain tinnitus to patients (van Ravenzwaaij et al., 2010). • Provide information to normalise the experience of tinnitus (e.g. acknowledge how common tinnitus is, that you may not know what caused your tinnitus, that it is normal for tinnitus to vary, quotes from other people with tinnitus).
• Although most participants believed that the relaxation goals were achievable, users experienced difficulties meeting them. • The relaxation log data demonstrated that users met less than half of the set relaxation goals. • Users reported several barriers to practicing relaxation, including finding a suitable environment, finding the time to practice, fatigue, and forgetting.	2. To support users to maintain a regular relaxation practice	• Facilitate behavioural habituation (e.g. 2-week relaxation challenge, suggest practicing relaxation at the same time each day, provide relaxation diary to log daily relaxation practice). • Provide advice on setting up relaxation reminders (e.g. set an alarm, put a marker somewhere eye catching), how to make your environment conducive to relaxation practice (e.g. avoid distractions and falling asleep, creating a comfortable environment), goal setting, and action planning. • Provide downloadable audio exercises for offline use.

• Some users were concerned that engaging with the intervention or its components (mainly the online support forum) might negatively affect their tinnitus by making them focus on it too much.	3. To minimise the worsening of users' tinnitus sensation	• Address people's concerns about their tinnitus getting worse when engaging in the intervention (e.g. reassure users that a temporary increase in perceived loudness is normal when starting a relaxation practice). • Emphasise the aim to reduce the impact that tinnitus has on users' everyday lives, rather than reduce tinnitus loudness. • Recommend course structure reduced from 10 to 7 weeks. • Keep modules short and specify how long each one takes. • Provide offline materials that people can use without logging onto the intervention.
• The audio guided relaxation exercises were not accessible to people with more severe hearing losses, which prevented them from achieving their relaxation goals.	4. To ensure the intervention is accessible to those with hearing loss	• Provide written guided relaxation exercises for those with hearing loss.

673