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Usefulness of self-report questionnaires for psychological assessment of patients with
tinnitus and hyperacusis and patients' views of the questionnaires

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12 Short title
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13 Acceptability of psychological questionnaires for tinnitus/hyperacusis patients

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20 Abbreviations

21	CBT	Cognitive behavioural therapy
22	CI	Confidence Interval
23	ENT	Ear, nose, and throat
24	GAD	Generalised Anxiety Disorders questionnaire
25	GP	General Practitioner
26	HADS	Hospital Anxiety and Depression Scale
27	HAI	Health Anxiety Inventory
28	HQ	Hyperacusis questionnaire
29	IAPT	Improving Access to Psychological Therapies
30	ISI	Insomnia severity index
31	NHS	National Health Service
32	OCI	Obsessive Compulsive Inventory
33	PDSS	Panic Disorder Severity Scale
34	PFQ	Patient Feedback Questionnaire
35	PHQ	Patient Health Questionnaire
36	PSWQ	Penn State Worry Questionnaire
37	PTA	Pure tone average
38	RRR	Relative risk ratio
39	SD	Standard deviation
40	SHAI	Short Health Anxiety Inventory
41	SPIN	Social Phobia Inventory
42	THI	Tinnitus Handicap Inventory
43	THTSC	Tinnitus and Hyperacusis Therapy Specialist Clinic
44	ULL	Uncomfortable Loudness Level
45	VAS	Visual Analogue Scale
46		

48 *Objective:* The objective was to determine the relevance and applicability of psychological 49 questionnaires to patients seeking help for tinnitus and/or hyperacusis. Design: This was a 50 questionnaire-based survey. The following questionnaires were administered: Generalized Anxiety Disorder (GAD-7), Short Health Anxiety Inventory (SHAI), Mini-Social Phobia 51 52 Inventory (Mini-SPIN), Obsessive Compulsive Inventory-Revised (OCI-R), Panic Disorder 53 Severity Scale-Self Report (PDSS-SR), Patient Health Questionnaire (PHQ-9), and Penn 54 State Worry Questionnaire-Abbreviated version (PSWQ-A). In addition, a patient feedback 55 questionnaire was completed asking about the extent to which each questionnaire was relevant to them and how strongly they would recommend its use in the assessment of 56 57 patients with tinnitus and hyperacusis. Study Sample: A total of 150/402 consecutive patients 58 seen in a one-year period completed the questionnaires. Results: 65% of patients had 59 abnormal scores for one or more of the questionnaires. All questionnaires except the PDSS-60 SR were rated as relevant and recommended for use. Conclusions: The GAD-7, SHAI, Mini-61 SPIN, OCI-R, PSWQ-A, and PHQ-9 are recommended for evaluation of psychological 62 problems for patients seeking help for tinnitus and/or hyperacusis. Abnormal results on these 63 questionnaires may indicate the need for referral for possible treatment of psychological 64 problems. 65

Key Words: Tinnitus; Hyperacusis; Psychological assessment; Mental health; Patients'
views

69 Tinnitus is the sensation of sound without any external sound source. Hyperacusis is 70 intolerance of everyday sounds that causes significant distress and impairment in social, 71 occupational, recreational, and other day-to-day activities (Aazh et al, 2016). The sounds may be perceived as uncomfortably loud, unpleasant, frightening, or painful (Tyler et al, 2014). 72 73 There are several reports suggesting a high prevalence of psychological disturbances 74 in patients suffering from tinnitus and hyperacusis (Pinto et al, 2014; Juris et al, 2013; Schecklmann et al, 2014; Andersson et al, 2004; Pattyn et al, 2016; Paulin et al, 2016; Aazh 75 76 et al, 2016; Aazh & Allott, 2016). The prevalence of psychological disorders in the tinnitus 77 population is estimated to be between 10% (Bartels et al, 2008) and 69% (Andersson et al, 78 2004) for depression, 40% for panic disorder (Mathias et al, 2011), between 10% (Bartels et 79 al, 2008) and 23% (Adoga et al, 2008) for anxiety, 83% for obsessive compulsive disorder 80 (OCD) (Andersson et al, 2004), and 63% for social phobia (Andersson et al, 2004). For 81 patients whose main complaint is hyperacusis, prevalence percentages are 47% for anxiety 82 disorder (Juris et al, 2013) and 52% for OCD (Juris et al, 2013). Schroder et al (2013) 83 reported that 52% of patients with hyperacusis were diagnosed with obsessive compulsive 84 personality disorder. Schecklmann et al (2014) reported that 20% of patients with hyperacusis combined with tinnitus were receiving psychiatric care. Paulin et al (2016) reported that 85 86 among 30 patients with self-reported hyperacusis, 5% had generalised anxiety disorder, 17% 87 had depression and 3.5% had panic disorder.

There is no recent report about the extent to which tinnitus and hyperacusis patients seen in UK National Health Service (NHS) audiology outpatient services suffer from psychological disturbances. McKenna et al (1991) reported that 45% of 44 consecutive patients with tinnitus seen in a neuro-otology NHS outpatient clinic were in need of psychological help. However, their study was conducted at a center that receives secondary and tertiary referrals. The prevalence of psychological disorders may have been higher in their population than in typical audiology outpatient clinics.

Audiology departments play a major role in offering therapy and support for patients
experiencing tinnitus and hyperacusis (Thompson et al, 2016). In the UK, 82% of tinnitus
patients follow a referral path to Audiology for management and therapy either via their

98 General Practitioners (GPs) or via Ear-Nose-Throat (ENT) departments (Gander et al, 2011). 99 In tinnitus and hyperacusis clinics, it is important to screen for psychological co-morbidities 100 in order to make appropriate onward referrals to mental health services when needed (Department of Health, 2009; McKenna et al, 1991). In the UK mental health services, the 101 initial treatment for people suffering from anxiety disorders and depression is mainly 102 103 provided under the Improving Access to Psychological Therapies programme (IAPT, 2011a). 104 Several validated self-report psychological questionnaires are used routinely in the 105 assessment of patients in the IAPT. These include the Patient Health Questionnaire (PHQ-9; Kroenke et al, 2001), the Generalized Anxiety Disorder questionnaire (GAD-7; Spitzer et al, 106 107 2006), the Short Health Anxiety Inventory (SHAI; Salkovskis et al, 2002), the Panic Disorder Severity Scale – Self Report form (PDSS-SR; Houck et al, 2002), the Social Phobia 108 109 Inventory (SPIN) (Connor et al, 2000), the Obsessive–Compulsive Inventory (OCI; Foa et al, 110 1998), and the Penn State Worry Questionnaire (PSWQ; Meyer et al, 1990).

Some of the above-mentioned questionnaires, or shorter versions of them, can be used in tinnitus and hyperacusis clinics to screen for co-morbid psychological disorders. However, it is not clear whether these questionnaires are relevant to the problems faced by patients experiencing tinnitus and hyperacusis and whether patients seen in NHS audiology clinics find completing such questionnaires relevant to them and applicable generally to people with tinnitus and/or hyperacusis.

117 The aims of this study were to assess for each psychological questionnaire: (1) the proportion of patients seeking treatment for tinnitus and hyperacusis under the UK NHS who 118 give abnormal scores; (2) whether high scores for tinnitus handicap are associated with an 119 120 increased likelihood of an abnormal score; (3) whether high scores for hyperacusis handicap 121 are associated with an increased likelihood of an abnormal score; (4) patients' views as to 122 personal relevance and general applicability of the questionnaire. The results were intended 123 to inform audiologists in selecting the appropriate questionnaires to be used in screening for psychological co-morbidities and in deciding whether to make onward referrals. 124 125

126 Methods

127 Study design

128 This was a questionnaire-based service evaluation survey designed to improve the assessment 129 and onward referral procedures in routine NHS care at the Tinnitus and Hyperacusis Therapy 130 Specialist Clinic (THTSC), Royal Surrey County Hospital, Guildford, UK. All patients who 131 attended the THTSC for therapy sessions from 15th March 2015 to 15th March 2016 were 132 asked in person by their audiologist to complete the psychological questionnaires and provide 133 their feedback. They were informed that their participation was completely voluntary and 134 some patients did not complete all of the questionnaires. Demographic data for the patients 135 and the outcomes of their latest audiological investigations and their routine self-report 136 questionnaires were imported from records held at the Audiology department. These 137 comprised: (1) pure tone audiogram measured using the procedure described by the British Society of Audiology (BSA, 2004); (2) uncomfortable loudness levels (ULLs) measured 138 139 following the BSA recommended procedure (BSA, 2011); (3) a wide range of self-report 140 questionnaires comprising the Tinnitus Handicap Inventory (THI; Newman et al, 1996), the 141 Hyperacusis Questionnaire (HQ; Khalfa et al, 2002), the Insomnia Severity index (ISI; 142 Bastien et al, 2001), the Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 143 1983), and the Visual Analogue Scale (VAS; Maxwell, 1978) of tinnitus loudness, annoyance

144 and effect on life; (4) Age.

145

146 Ethical approval

147 This study was initially registered as a service evaluation with the Clinical Audit, Patient 148 Safety and Quality department at the Royal Surrey County Hospital. Further analysis of the 149 data was approved by the South West-Cornwall and Plymouth Research Ethics Committee 150 and the Research and Development department at the Royal Surrey County Hospital. 151

152 Study population

153 The total number of patients who attended the THTSC in the one-year period was 402.

154 According to local service agreements, all patients who need tinnitus or hyperacusis therapy

155 should be referred via their GPs. However, most of the patients attending the THTSC had

156 seen an ENT specialist who recommended tinnitus and hyperacusis rehabilitation. The

- 157 average age of the patients was 57 years (standard deviation, SD = 15 years, range 16 to 95
- 158 years). The mean pure-tone average (PTA) audiometric threshold at the frequencies 0.25, 0.5,
- 159 1, 2, and 4 kHz was 25 dB HL (SD =19 dB) for the right ears and 25 dB HL (SD =18 dB) for

160	the left ears. The mean uncomfortable loudness level (ULL) at the frequencies 0.25, 0.5, 1, 2,
161	4 and 8 kHz was 83 dB HL (SD =14 dB) for the right ears and 83 dB HL (SD =15 dB) for the
162	left ears. The mean scores on the THI, VAS, HADS, ISI, and HQ are shown in Table 1.
163	
164	Table 1
165	
166	Routine questionnaires
167	The questionnaires listed in this section are those that are routinely given to all
168	patients attending the THTSC for tinnitus or hyperacusis therapy.
169	
170	THI
171	The THI has 25 items, and response choices are "no" (0 points), "sometimes" (2 points) and
172	"yes" (4 points). The overall score ranges from 0 to 100. Scores from 0–16 indicate no
173	handicap, scores from 18-36 indicate mild handicap, scores from 38-56 indicate moderate
174	handicap, and scores from 58-100 indicate severe handicap (Newman et al, 1996).
175	
176	HQ
177	The HQ comprises 14 items and the response choices are "no" (0 points), "yes, a little" (1
178	points), "yes, quite a lot" (2 points), and "yes, a lot" (3 points). The overall score ranges from
179	0 to 42. Scores above 26 indicate strong auditory hypersensitivity (Meeus et al, 2010).
180	
181	ISI
182	The ISI comprises seven items that assess the severity of sleep difficulties and their effect on
183	the patient's life. Each item is rated on a scale from 0 to 4 and the total score ranges from 0 to
184	28. Scores from 0-7 indicate no clinically significant insomnia, scores from 8-14 indicate
185	minimal insomnia, scores from 15-21 indicate moderate insomnia, and scores from 22-28
186	indicate severe insomnia (Bastien et al, 2001).
187	
188	HADS
189	The HADS consists of 14 items each rated from 0 to 3 according to the severity of difficulty
190	experienced. Eight items require reversed scoring, after which depression (HADS-D) and
191	anxiety (HADS-A) subscale totals are calculated. Total scores for each subscale range from 0
192	to 21. Scores from 0-7 are classified as normal, scores from 8-10 are classified as borderline
193	abnormal, and scores from 11-21 are classified as abnormal (Zigmond & Snaith, 1983).

194	
195	VAS
196	VAS scores are ratings on a scale from 0 to 10. The VAS score for loudness of tinnitus was
197	assessed by asking the patient to rate the loudness of tinnitus during their waking hours over
198	the last month (It was explained that 0 corresponds to no tinnitus being heard and 10 is the
199	loudest sound that they can imagine). The VAS score for annoyance induced by the tinnitus
200	was assessed by asking the patient to rate their subjective perception of annoyance on average
201	during the last month (It was explained that 0 corresponds to no annoyance and 10 is the most
202	annoying thing that can possibly happen). The VAS score for the impact of tinnitus on their
203	life was assessed by asking the patient to rate the effect of tinnitus on their life during the last
204	month (It was explained that 0 corresponds to no effect and 10 is an extreme effect).
205	
206	Additional questionnaires examining psychological factors
207	The questionnaires listed in this section are not used in the routine assessment of patients
208	attending the THTSC for tinnitus or hyperacusis therapy, but were used here to assess
209	psychological factors that might be associated with tinnitus or hyperacusis.
210	
211	GAD-7
212	This is a 7-item questionnaire for assessment of anxiety symptoms (Spitzer et al, 2006).
213	Patients are asked how often during the last 2 weeks they had been bothered by each
214	symptom. Response options are not at all (0), several days (1), more than half the days (2),
215	and nearly every day (3). The total score ranges from 0 to 21. Cronbach's alpha for the GAD-
216	7 is 0.92 and its test-retest reliability (intraclass correlation) is $r = 0.83$ (Spitzer et al, 2006). A
217	score of 10 or above is suggested as indicating anxiety disorder (Spitzer et al, 2006).
218	However, the recommended cut-off score for general anxiety in the UK mental health system
219	is a score of 8 or above (IAPT, 2011b). This is referred to as meeting "caseness".
220	
221	SHAI

Health anxiety is excessive fear of having a serious illness based on the misinterpretation of

bodily sensations (American Psychiatric Association, 2000). The SHAI has 18 items. Each

item consists of four statements in which the individual is instructed to select the statement

that best describes their feelings over the past two weeks. Item scores are weighted 0–3 and

are summed to obtain a total score between 0 and 54. Cronbach's alpha for this questionnaire

is between 0.74 and 0.96 (Alberts et al, 2013). Test-retest reliability was found to be good (*r*

- 228 = 0.87) (Olatunji et al, 2011). A score of 27 or above indicates the likely presence of health
- anxiety (Alberts et al, 2013). However, a less conservative score of 18 or above was
- suggested by Rode et al (2006). The score that is used in mental health services in the UK to
- indicate caseness is 18 or above (IAPT, 2011b).
- 232

233 MINI-SPIN

- The Mini-SPIN (Connor et al, 2001) is the short version of the SPIN (Connor et al, 2000)
- 235 questionnaire, which is designed to assess social anxiety disorder. Cronbach's alpha for the
- SPIN is 0.94 and its test-retest reliability is r = 0.89 (Connor et al, 2000). Unlike the 17-item
- full version used in the IAPT, the Mini-SPIN consists of only 3 items. Each item has 5
- possible answers with scores from 0 to 4. The total score is between 0 and 12. Total scores of
- 6 or higher on the Mini-SPIN indicate possible problems with social anxiety (Weeks et al,
- 240 2007). The recommended cut-off for caseness for social phobia in the UK mental health
- system is a score of 19 or above on the full version of the SPIN (IAPT, 2011b). Scores of 6 or
 higher on the Mini-SPIN indicate possible problems with social anxiety (Connor et al, 2001).
- 243

244 OCI-R

The OCI–R (Foa et al, 2002) is the short version of the OCI (Foa et al, 1998) and is a selfreport questionnaire to assess symptoms of obsessive compulsive disorder (OCD). While the full version used in the IAPT contains 42 items, the OCI-R contains only 18 items. Items are rated on 5-point Likert-type scale (0-4) giving total scores between 0 and 72. Patients are instructed to circle the number that best describes how much that experience has distressed or bothered them during the past month. This questionnaire has 6 subscales: Checking, Washing, Obsessing, Mental Neutralizing, Ordering, and Hoarding (Foa et al, 2002).

- 252 Cronbach's alpha for the total score is 0.81 and test-retest reliability is 0.82, both of which
- are good (Foa et al, 2002). The recommended cut-off for caseness for OCD in the UK mental
- health system is scores of 40 or above on the full version of the OCI (IAPT, 2011b). Scores
- of 21 or above indicate the likely presence of OCD for the OCI-R (Foa et al, 2002).
- 256
- 257 PDSS-SR
- 258 This is a 7-item questionnaire for assessment of panic disorder. Each item has 5 possible
- answers weighted from 0 to 4 (0= none, higher ratings reflecting more severe symptoms).
- 260 Patients are instructed to choose the answer that best reflects how they have felt over the past

261 week. For this questionnaire, a panic attack is defined as a sudden rush of fear or discomfort accompanied by at least four of the following panic symptoms: rapid or pounding heartbeat, 262 263 chest pain or discomfort, chills or hot flushes, sweating, nausea, fear of losing control or going crazy, trembling or shaking, dizziness or faintness, breathlessness, feelings of unreality, 264 265 fear of dying, feeling of choking, numbress or tingling. The total score is between 0 and 28. 266 Cronbach's alpha for this questionnaire is 0.92 and it has good test-retest reliability (r = 0.81) 267 (Houck et al, 2002). Yamamoto et al (2004) suggested that total scores up to 10 correspond to 268 mild, 11-15 to moderate, and 16 or above to severe panic disorder. Furukawa et al (2009) suggested a cut off score of 8 to identify people with panic disorder. The recommended cut-269 270 off for caseness in the UK mental health system is a score of 8 or above (IAPT, 2011b).

271

272 PHQ-9

This is a 9-item questionnaire for assessment of depression. The total score ranges from 0 to 274 27. A score less than 5 indicates no depression, while 5-9 indicates mild depression, 10-14 275 indicates moderate depression, 15-19 indicates moderately severe depression, and a score 276 over 19 indicates severe depression (Kroenke et al, 2001). Cronbach's alpha for the PHQ-9 is 277 0.89 and its test-retest reliability is r= 0.84 (Kroenke et al, 2001). The recommended cut-off 278 for caseness for depression in the UK mental health system is a score of 10 or above (IAPT,

279

280

281 PSWQ-A

2011b).

282 The PSWQ-A (Hopko et al, 2003) is a short version of the PSWQ used for assessment of 283 generalised anxiety disorder. The full version used in the IAPT has 16 items while the 284 PSWQ-A contains only 8 items. Each item has 5 possible answers with scores from 1 (not at all typical of me) to 5 (very typical of me). The total score for the PSWO-A is between 8 and 285 40. Cronbach's alpha was 0.89 and test-retest reliability was r = 0.87 (Crittendon & Hopko, 286 287 2006). The recommended cut-off for caseness for generalised anxiety disorder in the UK 288 mental health system is a score of 45 or above on the full version of the PSWQ (IAPT, 2011b). A score of 23 or more on the PSWQ-A indicates the presence of generalised anxiety 289 290 disorder (Wuthrich et al, 2014).

292	Additional questionnaire assessing patients' views of the psychological questionnaires
293	After completing each questionnaire assessing psychological factors, patients were asked to
294	complete a form, the patient feedback questionnaire (PFQ), assessing their views of the
295	psychological questionnaire. The PFQ included two items:
296	1- Was this questionnaire relevant to you?
297	Patients were asked to rate the relevance of the questionnaire on a scale from 1 to 5 $(1 = not)$
298	at all, 5 = very relevant).
299	2- Would you recommend the use of this questionnaire for assessment of patients with
300	tinnitus and/or hyperacusis?
301	Patients were asked to rate whether they would recommend the questionnaire on a scale from
302	1 to 5 (1 = not at all, 5 = definitely).
303	
304	Order of administration of the questionnaires
305	The questionnaires were administered in the following order: GAD-7, PFQ, SHAI, PFQ,
306	MINI-SPIN, PFQ, OCI-R, PFQ, PDSS-SR, PFQ, PHQ-9, PFQ, PSWQ-A, PFQ
307	
308	Data analysis
309	The data were anonymised prior to statistical analysis. Descriptive statistics (means, SDs, and
310	95% confidence intervals, CI) for the characteristics of the patients and scores for the self-
311	report questionnaires and the feedback form for each questionnaire, were calculated. Group
312	differences between responders and non-responders were assessed using t-tests. The p value
313	required for statistical significance was set at $p < 0.05$. Multinomial logistic regression was
314	used to assess whether higher scores on the THI and HQ were associated with abnormal
315	scores on the psychological questionnaires. These analyses yielded a relative risk ratio (RRR)
316	of an abnormal score on each questionnaire based on scores for the THI and HQ. Some of
317	those who responded did not complete all of the questionnaires. The analyses were restricted
318	to responders with complete data on all variables required for a particular analysis. The
319	number of patients included in each analysis (n) is reported. The STATA programme (version
320	13) was used for statistical analyses.
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- 324 A total of 150/402 of patients completed the additional questionnaires assessing
- 325 psychological factors, a response rate of 37%. All of these patients were referred via their

326 GPs. However, 85% of the responders had also been seen by an ENT specialist who made a 327 recommendation to their GP for a referral to the THTSC for tinnitus or hyperacusis 328 rehabilitation. 329 As shown in Table 2, there were no significant differences between the responders 330 and non-responders in age, PTA of the better and worse ear, ULLs of the worse ear (the ear 331 with smaller ULL values between 0.25 and 8 kHz), and, with one exception, scores for the questionnaires. The exception was that the mean VAS for tinnitus loudness was slightly 332 333 higher (worse) for responders than for non-responders (p=0.04). 334 335 Table 2 here 336 337 Based on the PTA of the worse ear (n=139 for the responders with available audiograms), 1.5% had profound hearing loss, 3.6% had severe hearing loss, 17% had 338 339 moderate hearing loss, and 40% had mild hearing loss; the remainder had no hearing loss. 340 Based on scores for the THI, 11% (16/144) had no tinnitus handicap, 22% (32/144) had a 341 mild tinnitus handicap. 29% (42/144) had a moderate tinnitus handicap and 55% (54/144) had 342 a severe tinnitus handicap. The average ULL (averaged across 0.25, 0.5, 1, 2, 4, and 8 kHz 343 was 84 dB HL (SD =14 dB) for both the right and left ears. Based on the average ULLs in the 344 worse ear (the ear with lower sound tolerance thresholds), 31% (29/95) of patients were 345 considered as having abnormally low ULLs (below 80 dB HL), which might be an indication of hyperacusis. Based on scores for the HQ, 26% (37/145) of the responders experienced 346 347 significant hyperacusis handicap. Twenty two percent (14/65) of the responders had both 348 abnormally reduced ULLs and significant hyperacusis handicap. 349 Based on scores for the ISI, 27% (38/142) of the responders did not have insomnia, 350 30% (42/142) had sub-threshold insomnia, 30% (42/142) had moderate insomnia, and 14% 351 (20/142) had severe insomnia. Based on scores for the anxiety subscale of the HADS, 38% 352 (56/147) of the responders had normal scores, 21% (31/147) had borderline abnormal scores, 353 and 41% (60/147) had abnormal scores. Based on scores for the depression subscale of the 354 HADS, 64% (94/146) of the responders had normal scores, 20% (29/146) had borderline 355 abnormal scores, and 16% (23/146) had abnormal scores. 356

357 *Responses on the PFQ*

358 Table 3 shows the responses on the PFQ regarding whether the patients found the

359 psychological questionnaires to be relevant to their problems and whether they would

360 recommend their use in the assessment of patients with tinnitus and/or hyperacusis. With the exception of the PDSS-SR, which only 45% of respondents thought was relevant for them 361 362 (giving scores of 3, 4 or 5), all questionnaires were thought to be personally relevant by 60% 363 or more of respondents. Similarly, with the exception of the PDSS-SR, which only 61% of 364 respondents recommended for use in the evaluation of patients with tinnitus and/or 365 hyperacusis, all questionnaires were recommended by 69% or more of respondents. The 366 highest ratings for both personal relevance and recommended use were given to the GAD-7. PHQ-9, and PSWQ-A questionnaires, for which over 79% of the patients recommended their 367 368 use. 369 370 Table 3 here 371 372 Prevalence of psychological disorders and relationship to severity of tinnitus and 373 hyperacusis handicap 374 Table 4 shows the means and SDs of the total scores on the questionnaires concerned with 375 psychological problems. Sixty five percent of the patients met the caseness criteria for at least 376 one psychological test. Over 10% of patients with mild tinnitus handicap had abnormal scores for the GAD-7, SHAI, Mini-SPIN, OCI-R, PDSS-SR, and PSWQ-A (Table 5). Over 20% of 377 patients with moderate tinnitus handicap and over 30% of patient with hyperacusis handicap 378 379 (score =>26 on HQ) had abnormal scores for the GAD-7, SHAI, Mini-SPIN, OCI-R, PDSS-380 SR, PSWO-A, and PHO-9 (Table 5).

381 The outcomes of the multinomial logistic regression model are shown in Table 5. The 382 RRR values in relation to tinnitus handicap are expressed relative to the values for patients 383 with no tinnitus handicap except for two questionnaires that were not completed by any patients with no tinnitus handicap, namely the PDSS-SR and the PHO-9. For these two 384 385 questionnaires, RRR values in relation to tinnitus handicap are expressed relative to the 386 values for patients with mild tinnitus handicap. There were significant relationships between 387 tinnitus handicap category and responses on the GAD-7, SHAI and PHQ-9, which assess 388 generalised anxiety, health anxiety and depression. The RRR of abnormal scores on the 389 GAD-7 increased by factors of 12.7 (95% CI: 1.5-107) and 18 (95% CI: 2.2-151) for patients with moderate and severe tinnitus handicap, respectively, relative to those with no tinnitus 390 391 handicap. The RRR of abnormal scores on the PHQ-9 increased by a factor of 4.3 (95% CI: 392 1.1-16.9) for patients with severe tinnitus handicap relative to those with mild handicap. The

393 RRR of abnormal scores on the SHAI increased by a factor of 9.05 (95% CI: 1.05-78) for
394 patients with severe tinnitus handicap relative to those with no tinnitus handicap.

395 There were significant relationships between hyperacusis handicap and responses on

the PHQ-9, SHAI, Mini-SPIN, PDSS-SR, and PSWQ. The RRR of abnormal scores on the

397 PHQ-9, SHAI, Mini-SPIN, PDSS-SR and PSWQ increased by factors of 2.7 (95% CI: 1.04-

398 7.13), 4.05 (95% CI: 1.59-10.3), 3.4 (95% CI: 1.4-8.09), 4.4 (95% CI: 1.5-12.8), and 2.5

399 (95% CI: 1.2-7.3), respectively, for patients with HQ scores above 26 relative to scores for

400 those with scores below 26. Scores on the OCI-R were not related to tinnitus or hyperacusis401 handicap.

402

403 **Discussion**

404 Study limitations

405 In this study we assessed the viewpoint of patients who were referred for tinnitus or 406 hyperacusis rehabilitation to an Audiology outpatient clinic in the UK regarding a wide range 407 of psychological self-report questionnaires. Specifically, the patients were asked to rate the 408 relevance of each questionnaire to themselves and to rate how strongly they would 409 recommend the general use of each questionnaire in the evaluation of patients with tinnitus 410 and/or hyperacusis. Although the self-report questionnaires under examination were validated 411 instruments, the PFQ that was used in order to assess them was specifically designed for local 412 service evaluation at the RSCH and no data with regard to its psychometric properties are available (e.g., test-retest reliability). Therefore, the results obtained using the PFQ need to be 413 414 interpreted with caution.

415 The response rate was 37%, which is not as high as the average response rate of 55% 416 for surveys conducted by primary health care services in the NHS (Grol et al, 1999). This 417 indicates a risk of selection bias (Pannucci & Wilkins, 2010). The outcomes of this study may 418 not be representative of the whole sample of tinnitus and hyperacusis patients seen at the 419 THTSC. Nevertheless, there was no significant difference between responders and non-420 responders in any of the measures obtained during their standard evaluation for tinnitus and hyperacusis, except for a difference in the VAS scores for tinnitus loudness (6.5 for 421 422 responders and 6.0 for non-responders). Therefore, it seems unlikely that selection bias had a strong influence on the outcomes. 423

In this study, 85% of the responders had been seen by an ENT specialist and 100%
had been seen by their GP prior to being referred to the THTSC. Our results may not be
representative of patients who self-refer for treatment for tinnitus and hyperacusis. Although,

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427 most people who are bothered by tinnitus seek medical help, once they are informed that 428 there is no definitive cure, they often choose to self-manage their symptoms and do not seek 429 further professional help. One study showed that only 42% of the patients who were seen by 430 an ENT department wished to undertake further tinnitus counselling (Aazh et al, 2009). It is 431 plausible that patients who choose to receive professional help for tinnitus or hyperacusis 432 experience greater distress than those who choose to self-manage. Therefore, the tinnitus-433 related and/or hyperacusis-related distress in our sample may be more severe than for a typical sample of tinnitus/hyperacusis patients who seek help for the first time. Nevertheless 434 435 our data are relevant to Audiology services offering rehabilitative interventions for patients 436 with troublesome tinnitus or hyperacusis who seek professional help in the management of 437 their tinnitus or hyperacusis. Such patients form the typical case load of audiologists who 438 specialise in tinnitus and hyperacusis rehabilitation.

- As the questionnaires were administered in a fixed order, it is possible that patients
 felt tired when completing the later questionnaires, which could have led to a response bias.
- 441 However, a meta-analysis showed that the association between the length of questionnaires
- 442 and response pattern is weak, and the quality and relevance of the content of the
- 443 questionnaires from the patient's point of view is the main factor influencing completion rate
- 444 and data quality (Rolstad et al, 2011). In the present study, the questionnaires were well
- 445 researched standardised questionnaires that are widely used in mental health services in the
- 446 UK, and the majority of the responders found them to be relevant. Hence, it is unlikely that
- 447 there was any substantial response bias due to fatigue.
- 448

449 Acceptability of the questionnaires

450 The questionnaires that were assessed in this study were the GAD-7, SHAI, Mini-SPIN, OCI-

451 R, PDSS-SR, PHQ-9, and PSWQ-A. All except the PDSS-SR were rated as personally

452 relevant (scores of 3, 4, or 5 on the PFQ) by 61% or more of patients. It seems that symptoms

- 453 of panic (as assessed by the PDSS-SR) are not regarded as personally relevant by most
- 454 patients seeking help for tinnitus and/or hyperacusis, but anxiety (as assessed by the GAD-7

455 and PSWQ-A) is especially relevant. Our results also showed that abnormal scores on PDSS-

- 456 SR in our sample were less prevalent than for other questionnaires. This is consistent with
- 457 general population surveys that suggest that panic disorder is less prevalent than other anxiety
- disorders and depression (Bandelow & Michaelis, 2015). A similar pattern emerged for
- 459 patients' recommendations for general use, with the GAD-7 and PSWQ-A receiving the
- 460 highest overall ratings. However, for general use even the PDSS-SR was recommended by

61% of patients and the PHQ-9 was recommended by 79% of patients, indicating that panic
disorder and depression are also regarded as relevant by most patients seeking help for
tinnitus and/or hyperacusis.

464

465 *Clinical applicability of the psychological questionnaires*

466 Sixty five percent of patients met the caseness criteria for at least one of the psychological 467 questionnaires. This highlights the need for screening for psychological disorders among 468 patients seen for tinnitus and hyperacusis rehabilitation at audiology departments and for 469 onward referral for further assessment and management of the co-morbid psychological 470 disorder(s) by mental health services. The highest incidence of caseness (44%) occurred for 471 the GAD-7, which assesses anxiety. Caseness was above 29% for two other questionnaires 472 that assess anxiety, namely the SHAI (which assesses health anxiety) and the PSWQ-A 473 (which assesses generalised anxiety). These incidence values are somewhat higher than the 474 incidence values for anxiety of 10% (Bartels et al, 2008) and 23% (Adoga et al, 2008) 475 reported for patients whose primary complaint is tinnitus, but are comparable to the incidence 476 of 47% reported for patients whose primary complaint is hyperacusis (Juris et al. 2013). Note 477 that 26% of the patients in our sample suffered from both tinnitus and hyperacusis. The high 478 incidence of caseness for the GAD-7 is consistent with the finding that the GAD-7 was rated 479 highly both for personal relevance (79% of patients giving ratings of 3, 4, or 5) and for 480 general use (85% of patients giving ratings of 3, 4, or 5).

The incidence of caseness was 26% for the PHQ-9, which assesses depression. This value is within the incidence range for depression of 10% (Bartels et al, 2008) to 69% (Andersson et al, 2004) reported for patients whose primary complaint was tinnitus, and slightly above the incidence of depression of 17% reported for patients whose primary complaint was hyperacusis (Paulin et al, 2016). Seventy percent of our patients thought that the PHQ-9 was relevant to them, and 79% recommended it for general use in assessing patients with tinnitus and/or hyperacusis.

The incidence of caseness was 23% for the OCI-R, which assesses OCD. This contrasts with the finding of Andersson et al (2004) that 83% of tinnitus sufferers had OCD. However, theirs was an internet-based survey using a relatively small (n = 44) sample of selfselected tinnitus sufferers and their criteria for diagnosis of psychiatric disorders were relatively lax, being described as "probable case". In fact, the incidences of many psychiatric disorders found in their study were much higher than have been found in other studies of

494 tinnitus sufferers. The authors themselves concluded that "diagnostic criteria need to be495 adjusted for Internet use".

496 Our data show that over 20% of patients with moderate tinnitus handicap (THI scores 497 \geq 36/100) and over 30% of patient with hyperacusis (HQ scores \geq 26) had abnormal scores for 498 the GAD-7, SHAI, Mini-SPIN, OCI-R, PDSS-SR, PSWO-A, and PHO-9. Therefore, 499 application of these questionnaires may be useful in the assessment of such patients, as they 500 might need a referral to mental health services. However, due to the time constraints in 501 audiology clinics, audiologists may have to limit the number of questionnaires uses. The 502 outcome of our risk ratio analysis maybe used to select appropriate questionnaires based on 503 the patient's initial THI or HQ scores. Patients with THI scores \geq 36 are at higher risk of 504 abnormal scores on the GAD-7, SHAI, or PHQ-9. Hence, application of these questionnaires 505 is recommended for such patients. Patients with HQ scores ≥ 26 are at higher risk of 506 abnormal scores on the SHAI, Mini-SPIN, PDSS-SR, PHQ-9, and PSWQ-A. The value of 507 the PDSS-SR remains in some doubt.

508 It should be emphasised that application of these questionnaires is not a replacement 509 for psychological/psychiatric evaluation; instead these questionnaires could be used to 510 identify tinnitus and hyperacusis patients who need to be referred for

511 psychological/psychiatric evaluations and possible treatment. Many patients who give

512 abnormal scores on these questionnaires will, on further evaluation, not be considered as

513 having a mental health problem that needs treating, but some will go on to receive treatment.

514 More research is needed to determine the proportion of patients referred from 515 tinnitus/hyperacusis clinics for psychological/psychiatric evaluation who go on to receive 516 treatment for mental health problems. Some patients may be reluctant to see a psychologist or 517 psychiatrist, believing that their problems are to do with the auditory system rather than being 518 psychological in nature. However, the likelihood of such patient reluctance appears to be low, 519 as 70% or more of the patients in our sample thought that the GAD-7, PSWO-A, SHAI, and 520 PHQ-9 were relevant to them personally, and 70% or more thought that these questionnaires 521 were appropriate for general use in evaluating patients seeking help for tinnitus and/or 522 hyperacusis.

523

524 Conclusions

525 Sixty five percent of patients met the caseness criteria for at least one of the psychological 526 questionnaires. At least 20% of patients with THI scores \geq 36 and 30% of patients with HQ

527	scores \geq 26 had abnormal scores for the GAD-7, SHAI, Mini-SPIN, OCI-R, PDSS-SR,
528	PSWQ-A, and PHQ-9. Based on responses to the PFQ, all questionnaires except the PDSS-
529	SR were relevant to the patients and were recommended by them for assessment of patients
530	with tinnitus and/or hyperacusis. The psychological questionnaires, excluding the PDSS-R,
531	may be considered for use as a part of the assessment package for patients with tinnitus and
532	hyperacusis.
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