Bold exposure or safe masking? A fear-conditioning approach to chronic tinnitus suffering

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27634

Source
Nationaal Trial Register

Health condition

Tinnitus, Cognitive behavioural treatment, Masking-therapy, fear-avoidance

Sponsors and support

Primary sponsor: Maastricht University | Dept. of Clinical Psychological Science
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Source(s) of monetary or material Support: NWO - Veni grant
Dossier nummer 016.165.105

Intervention

Outcome measures

Primary outcome

1. Tinnitus-disability: Tinnitus Handicap Inventory, (TFI; Tinnitus Functional Index)

2. Tinnitus-severity: Tinnitus questionnaire (TQ)

3. Health related QoL: HUI, SF36

Secondary outcome

4. Tinnitus-fear: FTQ; Fear of Tinnitus Questionaire (FTQ)

5. Catastrophic thoughts: Tinnitus Catasstrophising Scale (TCS)

6. Tinnitus variability

7. Threat expectancies

8. Negative emotional status

9. Avoidance behaviour (safety-seeing) (behavioural task/Inventory of Tinnitus Avoidance Behaviours (ITAB)

10. Daily diaries (including 3 weeks pre- and post intervention)

a. Tinnitus loudness & maskability Questionnaire (LMI)

b. Tinnitus-related fear-responding and tinnitus-intensity

Study description

Background summary

Does exposure to tinnitus decrease fear and tinnitus-disability, as opposed to masking tinnitus?
Method: In a RCT, 250 tinnitus-patients (including 15% loss to follow-up) recently diagnosed with tinnitus will be randomized (stratified on severity) in a masking or exposure condition, with tinnitus-disability and severity as independents and tinnitus-related fear, threat-appraisal, avoidance/safety behaviour, and psychoacoustic measures [41] as dependent variables, at baseline, pre-/post-treatment, and follow-up at 3 and 6 months after intervention. Tinnitus-related fear-responding and tinnitus-intensity (using self-report diaries) during masking-exposure procedures during 12 weeks (6 weeks masking-exposure procedures; 3 weeks pre-/post-measurements) will be assessed daily.
Exclusion: severe hearing-loss (cut-off point at a pure-tone average of 45dB hearing-level in worst ear). Masking- and exposure-procedures will follow previously developed guidelines [32, 42, 43]. Only masking and exposure elements will be extracted from the formal

guidelines for test-purposes

Hypotheses: (a) Tinnitus-fear, threat-appraisal, and tinnitus-related avoidance/safety behaviour decrease in the exposure-condition, not in the masking-condition. (b) Changes in tinnitus-related fear mediate changes in tinnitus-disability.

Study objective

Does exposure-treatment decrease tinnitus-related fear, tinnitus-severity and recovery, when compared to a masking-therapy with use of personalised on-ear masking-devices, or vice versa? Can we identify different sub-groups of patients who benefit more from one approach over the other?

Study design

1. baseline,

2. pretreatment

3. post treatment

4. 6 months (after baseline)

5. 9 months (after baseline)

Intervention

CBT for tinnitus
Masking-therapy for tinnitus

Contacts

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Eligibility criteria

Inclusion criteria

- Score on Tinnitus questionnaire of TQ>30

- No previous masking or exposure therapy of minimally 5 years before inclusion

- Aged 18 plus

Exclusion criteria

- Hearing loss of more than 40 dB in either/both ears

- Limited knowledge: reading and writing skills in Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-05-2017
Enrollment:	250
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	24-04-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44287
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6235
NTR-old	NTR6415
CCMO	NL61673.015.17
OMON	NL-OMON44287

Study results

Summary results

1. Fuller, Thomas, Cima, R.F.F., Langguth, Berthold, Mazurek, Birgit, Waddell, Angus, Hoare, Derek J., & Vlaeyen, Johan W. S. (2017). Cognitive behavioural therapy for tinnitus. Cochrane Database of Systematic Reviews(4). doi: 10.1002/14651858.CD012614
2. Fuller, T. E., Haider, H. F., Kikidis, D., Lapira, A., Mazurek, B., Norena, A., . . . Cima, R. F. F.(2017). Different Teams, Same Conclusions? A Systematic Review of Existing Clinical

Guidelines for the Assessment and Treatment of Tinnitus in Adults. Front Psychol, 8, 206. doi: 10.3389/fpsyg.2017.00206
3. Hall, D. A. Haider, H. Szczepek, A. J.Lau, P.Rabau, S.Jones-Diette, J.Londero, A.Edvall, N. K.Cederroth, C. R.Mielczarek, M.Fuller, T.Batuecas-Caletrio, A.Brueggemen, P.Thompson, D. M.Norena, A. Cima, R. F. F..Mehta, R. L.Mazurek, B.. (2016). Systematic review of outcome domains and instruments used in clinical trials of tinnitus treatments in adults. Trials, 17(1), 270. doi: 10.1186/s13063-016-1399-9
4. Lopez-Escamez, J. A., Bibas, T., Cima, R. F.F. Van de Heyning, P., Knipper, M., Mazurek, B., . . . Cederroth, C. R. (2016). Genetics of Tinnitus: An Emerging Area for Molecular Diagnosis and Drug Development. Front Neurosci, 10, 377. doi: 10.3389/fnins.2016.00377
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7. Maes, I.H., Cima, R. F. F., Vlaeyen, J. W. S., Anteunis, L., Baguley, D., El Refaie, A., & Joore, M.A. (2014). Cost-effectiveness of multidisciplinary management of Tinnitus at a specialized Tinnitus centre. Otology & Neurotology 35(5): 787-795. Impact Factor: 1.44
8. Maes, I. H., Cima, R. F. F., Vlaeyen, J. W., Anteunis, L. J., & Joore, M. A. (2013). Tinnitus: a cost study. Ear and Hearing, 34(4), 508-514. Impact Factor: 2.06
9. Andersson, G., Hesser, H., Cima, R. F. F., & Weise, C. (2013). Autobiographical memory specificity in patients with tinnitus versus patients with depression and normal controls. Cognitive behaviour therapy, 42(2), 116-126. Impact Factor: 0.86
10. Cima, R. F. F., Maes, I. H., Joore, M. A., Scheyen, D. J. W. M., El Refaie, A., Baguley, D. M., Anteunis, L. J.C., van Breukelen, G. J. P., & Vlaeyen, J.W.S. (2012). Specialised treatment based on cognitive behaviour therapy versus usual care for tinnitus: a randomised controlled trial. The Lancet, 379(9830), 1951-1959. Impact Factor: 39.06
11. Maes, I. H., Joore, M. A., Cima, R. F. F., Vlaeyen, J. W. S., & Anteunis, L. J. (2011). Assessment of health state in patients with tinnitus: a comparison of the EQ-5D and HUI mark III. Ear and Hearing, 32(4), 428-435. Impact Factor: 2.06
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13. Cima, R. F. F., Crombez, G., & Vlaeyen, J. W. S. (2011). Catastrophizing and Fear of Tinnitus Predict Quality of Life in Patients With Chronic Tinnitus. Ear and Hearing, 32(5), 634-641. Impact Factor: 2.06
14. Cima, R. F. F., Joore, M.A., Maes, I.H., Scheyen, D.J.W.S., Refaie, A. E., Baguley, D. M., Vlaeyen, J. W. S., Anteunis, L.J.C. (2009). Cost-effectiveness of multidisciplinary management of Tinnitus at a specialized Tinnitus centre. BMC Health Services Research, 9, 29. Impact Factor: 1.77
15. Maes, I. H., Joore, M. A., Cima, R. F. F., Vlaeyen, J. W. S., & Anteunis, L. J. (2008). QL5 comparison of EQ-5D and HUI3 in patients with tinnitus. Value in Health 01/2008; 11(6). Impact Factor: 2.19