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

Gepubliceerd: 24-04-2017 Laatst bijgewerkt: 19-03-2025

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27634

Bron
Nationaal Trial Register

Aandoening

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

Ondersteuning

Primaire sponsor: Maastricht University | Dept. of Clinical Psychological Science
P.O. Box 616 | 6200 MD Maastricht
E-mail: r.cima@maastrichtuniversity.nl
Adelante| Centre of expertise in Rehabilitation & Audiology
Zandbergsweg 111 | 6432 CC Hoensbroek
Tel (mob): +31 6 17 900 161| Fax: +31 45 5282348
Overige ondersteuning: NWO - Veni grant
Dossier nummer 016.165.105

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Tinnitus-disability: Tinnitus Handicap Inventory, (TFI; Tinnitus Functional Index)
2. Tinnitus-severity: Tinnitus questionnaire (TQ)
3. Health related QoL: HUI, SF36

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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?

Onderzoeksopzet

1. baseline,

2. pretreatment

3. post treatment

4. 6 months (after baseline)

5. 9 months (after baseline)

Onderzoeksproduct en/of interventie

CBT for tinnitus
Masking-therapy for tinnitus

Contactpersonen

Publiek

P.O. Box 616, Dept. of Clinical Psychological Science

Rilana Cima
Maastricht 6200 MD
The Netherlands
0031 433881460

Wetenschappelijk

P.O. Box 616, Dept. of Clinical Psychological Science

Rilana Cima
Maastricht 6200 MD
The Netherlands
0031 433881460

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Score on Tinnitus questionnaire of TQ>30

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

- Aged 18 plus

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

- Limited knowledge: reading and writing skills in Dutch language

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	22-05-2017
Aantal proefpersonen:	250
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	24-04-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44287
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

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
5. Muller, K., Edvall, N. K., Idrizbegovic, E., Huhn, R., Cima, R. F.F.., Persson, V., . . . Cederroth, C. R. (2016). Validation of Online Versions of Tinnitus Questionnaires Translated into Swedish. Front Aging Neurosci, 8, 272. doi: 10.3389/fnagi.2016.00272

6. Cima, R. F. F., Andersson, G. J., Schmidt, C. J., & Henry, J. (2014). Cognitive-behavioral therapy for Tinnitus: A review of literature. Journal of the American Academy of Audiology. 25(1): 29-61. Impact Factor: 1.63
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
12. Cima, R. F. F., Vlaeyen, J. W. S., Maes, I. H. L., Joore, M. A., & Anteunis, L. J. C. (2011). Tinnitus Interferes With Daily Life Activities: A Psychometric Examination of the Tinnitus Disability Index. Ear and Hearing, 32(5), 623-633. Impact Factor: 2.06
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