Effectiveness of Autonomy Enhancing Therapy in hearing-impaired adults with psychosocial problems and/or mental disorders

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The study aims to determine the effectiveness of the application of AET in decreasing self-reported deficits in autonomy-connectedness / self-reported symptoms of anxiety and depression in HI adults.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON51554

Source
ToetsingOnline

Brief title
Autonomy in hearing-impaired adults

Condition

- Other condition
- Hearing disorders

Synonym
Selfdetermination, selfgouvernance

Health condition

psycho-social disorder (autonomy deficit)

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: VCVGZ stichting tot steun

Intervention

Keyword: autonomy, hearing impairment, rehabilitation

Outcome measures

Primary outcome

The main study parameters /endpoints, outcomes in the psychosocial and mental health domain are evaluated at the end of the experimental phase (T2) with standardized questionnaires. A questionnaire of autonomy-connectedness (Autonomy- Connectedness Scale-30, ACS-30) and questionnaires for anxiety disorder (Symptom Checklist 90-R, SCL-90-R) and depression (Beck Depression Inventory, BDI-II-NL).

Secondary outcome

In the secondary phase for clinical-therapeutical purposes the AET is provided to the control group. T3 assessment with standardized questionnaires of autonomy-connectedness and mental disorders is performed to verify effect of therapy for the control group. In case of persisting autonomy-connectedness or mental health disorders these assessments are necessary for referral for further psychological care.

In the experimental group T3 the Autonomy-Connectedness scale-30 (ACS-30) is used to assess the retention effect of AET in the experimental group.

Study description

Background summary

In scientific literature psychosocial problems and mental disorders such as anxiety or depression are frequently reported in hearing-impaired (HI) adults who use hearing aids/cochlear implants. A recent pilot in HI adults with CI in which the Autonomy-Connectedness Scale (ACS-30) was used, has shown deficits in autonomy-connectedness in 72% of the patients. Low autonomy-connectedness has been acknowledged as a known risk factor for anxiety and depression. In HI adults these problems are not only a consequence of the hearing loss itself, but also of the communication problems and the social isolation that result from it. In addition, within the HI group, low help-seeking behavior for this type of problems is reported. Systematic evidence-based training for prevention and treatment of mental disorders in adults with HI is currently not available. Therefore, the present project focuses on the determination of the effectiveness of Autonomy Enhancing Therapy (AET), a certified therapy in Geestelijke Gezondheidszorg (GGZ- Mental Health Services) that is developed supplementary to the ACS-30. AET has proven to be both effective and cost-effective in normal-hearing adults with an autonomy deficit / anxiety disorder, in a recent large-scale national RCT, when compared to cognitive behavioral therapy.

Study objective

The study aims to determine the effectiveness of the application of AET in decreasing self-reported deficits in autonomy-connectedness / self-reported symptoms of anxiety and depression in HI adults.

Study design

This study is set up as a prospective longitudinal repeated measures randomized control study, which measures the effectiveness of the application of AET in HI adults compared to *Standard Audiological Support*.

Intervention

In the experimental phase of the study the experimental group receives Autonomy Enhancing Therapy and the control group receives standard audiological support.
- The experimental treatment, Autonomy Enhancing Therapy, a certified GGZ therapy which has proven cost-effective in hearing adults, will be carried out according to the standardized procedure of 15 weeks of group therapy in which eight persons receive two hours of weekly training. The intervention treatment will be carried out by psychologists and social workers, who are certified AET trainers and in addition, have ample experience in guidance of adults with

hearing loss.
- The control condition treatment consists of standard audiological support during a timeframe that is similar to that of the AET. Standard audiological support entails the general medical-technical aural rehabilitation services provided at audiological centers and cochlear implant centers.
For clinical-therapeutical purposes the control group receives the AET in a *Secondary phase* of the study.

Study burden and risks

No medical tests or medical treatments are involved in the study.
Participation benefits for the patient group are diagnosis and treatment of psychosocial problems / mental health disorders that are frequently present in the patient group but often undiagnosed.
The negative effect of the risk of an unexpected diagnosis of mental health problems is minimized by the subsequent participation in the Autonomy Enhancing Therapy study. These problems would otherwise remain untreated.
The burden consists of participation in the Autonomy Enhancing (group)Therapy which entails 15 weeks with 2-hours group therapy sessions by experienced therapists. Furthermore, linguistic assessment of 30 minutes duration is carried out prior to one of these therapy visits.
In addition, at 3 moments (inclusion and pre and post treatment phase) completion of three standardized mental health questionnaires has to be carried out at home.
No risks are expected as a result of the treatment. Individual patients are expected to benefit more from the AET on the psychosocial or mental health domain, than from standard audiological support. The control group that receives the proven effective AET after the experimental phase, in the secondary phase, is not disadvantaged as compared to the experimental group that receives AET in the experimental phase, because standard GGZ waiting list times are not exceeded after diagnoses of mental health problems.
For both the experimental and the control group the mental health status is expected to improve in this study and may prevent more severe problems.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Hearing loss in the best ear >= 35 dB
and a clinically deviant score on at least one subscale ot the AGS-30 (below average score)

Exclusion criteria

Receiving treatment for psychiatric problems or tinnitus.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	05-09-2022
Enrollment:	64
Type:	Anticipated

Ethics review

Approved WMO

Date:	19-07-2022
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL80114.058.22