Vocational Rehabilitation for employees with hearing impairment: a cost-effectiveness study.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hearing disorders
Study type	Interventional

Summary

ID

NL-OMON38003

Source
ToetsingOnline

Brief title
Evaluation of the vocational rehabilitation for employees.

Condition

- Hearing disorders

Synonym
hearing impairment, hearingloss

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Economic evaluation, Employees, Need for recovery, Vocational Enablement protocol

Outcome measures

Primary outcome

1. Need for recovery after work (NFR) scale comprised 11 dichotmized items assessing the short term effects of fatigue caused by work activities (Meijman en Van Veldhoven, 1994) .

Secondary outcome

Coping of people with a hearing impairment will be measured by the Communication Profile for the Hearing Impaired (CPHI) (Kramer et al., 1995; Mokkink et al., 2008).

With the 4-Dimensional Symptom Questionnaire (4DSQ) we measured the distress of the participants (Terluin et al., 2004; Terluin et al., 2006).

The subscales 'decision latitude' (skill dicretion' and 'decison authority'), 'phychological job demands', 'physical job demands', 'supevisor social support' and 'coworker social support' of the Job Control Questionnaire (JCQ) to measure the psychosocial work characteristics (Karasek et al., 1998).

ASE-determinants (attitude, social influence, self-efficacy) will be measured with questionnaires based on studies of Driessen et al., 2008 and Vyth et al., 2011.

Quality of life will be measured by EQ-5D and VAS.

General Self Efficacy Scale (Bosscher et al., 1998) to measure the self efficacy.

Direct and indirect costs will be measured with questionnaires:
Costs for sick leave will be measured subjective and objective.
PROductivity and DISease Questionnaire (PRODISQ) (Koopmanschap 2005) and the Health and work Performance Questionnaire (HPQ) (Kessler et al., 2004) to measure productivity and sick leave. We also measured the sick leave data as registered by the company.
The health care costs will be measured with the questionnaire for Costs associated with psychiatric illness (TIC-P).

Patient satisfaction of the participants of the intervention group will be measured by the Patient Satisfaction with Occupational Health Services (PSOHQ) (Verbeek et al., 2005).

Study description

Background summary

Hearing impairment is one of the most prevalence chronic disabilities. It has significant negative effects on work performance and is associated with high levels of need for recovery after work, sick leave and early retirement. These consequences are related to high costs. Care as usual is insufficiently equipped to effectively address the vocational difficulties of employees with hearing problems. The Vocational Enablement Protocol (VEP) is a transmural

multidisciplinary care protocol aimend at maintaining, facilitating, or improving the employment situation for people with hearing loss.

Study objective

The first aim of this study is to determine the effectiveness of the VEP program on the primary and secondary outcomes: Need for Recovery after work (NFR), sick leave, Communication Profile for the Hearing Impaired (CPHI), distress, work productivity, self-efficacy, job content and general health status.
The second aim is to determine whether the VEP program is cost-effective for reducing Need for Recovery after work (NFR) compared with usual care.
The purpose of this study includes a description of the study protocol (design article) as well as a process evaluation.

Study design

A randomized controlled trial will be performed with 80 participants in the control (care as usual) and 80 participants in the treatment group (VEP). Employees of 365/Arboned (e.g. Tata Steel) and KLM and VU university/ VU medical center can participate in this study. Also patients of the ENT doctors, hearing aid specialist and occupational physician will recruited in the study. All participants give their informed consent. Outcomes will be measured at baseline and after 3, 6, 9 and 12 months en consist of questionnaires. The participants in the intervention group have to visit the Audiological center of the VUmc.

Intervention

The VEP comprise a half-day assessment of complex problems at the Audiological Center conducted by a team of professionals from different disciplines: E.N.T. physician, audiologist, occupational physician, social worker, psychologist, speech therapist. The patient's hearing status is assessed using an extensive battery of audiotry tests, including pure-tone and speech audiometry, various Speech-Reception-Treshold (SRT) tests (in quiet, in steady state noise and in fluctuating noise) and -if indicated- a test for localization. To examine aided hearing, a free-field version of the SRT in noise test is also performed. Furthermore, a semi-structured interview is conducted by the psychologist evaluating the psychosocial history of the person, their specific needs, attitude and expectations and an evaluation of the problems at work from the patient's perspective. Refferal information is taken into account. The interview is attended by the occupational physician of the team to specifically evaluate the work-related problems and to discuss the patient's view on possible solutions and legal issues.
If indicated, the workplace itself is visited and is accoustically examined by conducting a Speech-Transmission-Index (STI) measurement. The STI provides an

assessment of the intelligibility of speech in the workplace and verifies whether speech is intelligible for the employee, given the hearing impairment and the acousical conditions. The STI measures the combined effects of background noise and reverberation.
At the end of the session, all test results are examined and considered by the psychologist, specialized occupational physician, and the audiologist and explained to the patient. Here, we identify the (mis)match between the audiotry capacities of the employee and the audiotory demands at the workplace. Possibilities of technical, speech-therapeutic and/or psychosocial interventions are then discussed. We argue that a patient-centered approach (i.e. involving the patient in the problem solving process) is crucial.

Study burden and risks

The intervention study will take three hours. In this time the participant will do a audiological tests (non-invasive) and have some conversations in the multidisciplinary team.
In addition participants will fill out some forms at 4 measuring moments. This will take 30 minutes of each measuring moment.

The research is of no risk for the participants.

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

1. Diagnosis with hearing impairment (i.e. mean pure-tone hearing loss at 1, 2 and 4 kHZ in best ear >25 dB HL) or a score of *insufficient* or *poor* on the National Hearing Test
2. Age above 18 years
3. Able to complete questionnaires written in Dutch language and capable of giving informed consent
4. Working for at least 8 hours a week
5. Available for the study for the following 12 months

Exclusion criteria

1. Not willing or unable to comply with the study protocol
2. Those who have already been referred to or passed a VEP in the last year
3. Those for whom tinnitus is the primary condition affecting the individual
4. Those who were pregnant

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-07-2011

Enrollment:	160
Type:	Actual

Ethics review

Approved WMO Date:	20-04-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-12-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL34597.029.11