‘Vocational Rehabilitation for employees with hearing impairment: A cost-effectiveness study’.

No registrations found.

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

Summary

ID

NL-OMON25626

Source
Nationaal Trial Register

Brief title
VEP

Health condition

slechthorendheid, gehoorverlies, hearing impairment, hearingloss

Sponsors and support

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Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

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

1. 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);

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

3. 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);

4. 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;

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

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

7. Direct and indirect costs will be measured with questionnaires:

A. Costs for sick leave will be measured subjective and objective;

B. 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;

C. The health care costs will be measured with the questionnaire for Costs associated with psychiatric illness (TIC-P).

8. 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

A randomized controlled trial will be performed with 80 participants in the control (care as usual) and 80 participants in the treatment group (VEP). KLM, Corus and VU university have confirmed their participation in this study. Also patients of the ENT doctors 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.

Country of recruitment: The Netherlands.

Study objective

The hypothesis is that the Vocational Enablement Protocol (VEP) is effective and cost-effective compared with usual care from a societal perspective.

Study design

Baseline measurement and after 3, 6, 9 and 12 months after randomization.

Intervention

People in the intervention group get the VEP. 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.

People in the control group get the usual care of the general practitioner, Ear-, Nose and Throat doctor or the occupational physician.

Contacts

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Eligibility criteria

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:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2011
Enrollment:	160
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-02-2011
Application type:	First submission

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
NTR-new	NL2654
NTR-old	NTR2782
Other	ZonMw / VUmc : 50-51415-98-015 / 2011/054;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A