Online treatment for older dizzy patients in general practice

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Stand-alone internet-based Vestibular Rehabilitation (VR) and internet-based VR with physiotherapeutic support is more (cost-)effective than usual care when treating dizziness in older patients in general practice.

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

Samenvatting

ID

NL-OMON22573

Bron
Nationaal Trial Register

Verkorte titel
VERTIGO (VEstibular Rehabiliation Therapy: Internet-based treatment in General Practice for Older adults)

Aandoening

Dizziness / Duizeligheid

Ondersteuning

Primaire sponsor: VU University Medical Center/EMGO+
Overige ondersteuning: ZonMw (The Netherlands Organisation for Health Research and Development)/SBOH.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Dizziness symptoms at six months -> Vertigo Symptoms Scale-Short Form (VSS-SF)
2. Health economic outcomes -> iMTA Medical Consumption Questionnaire (iMCQ)

Toelichting onderzoek

Achtergrond van het onderzoek

INTRODUCTION:

Dizziness is a common symptom in general practice with a high prevalence among older adults. The most common cause of dizziness in general practice is peripheral vestibular disease. Vestibular rehabilitation (VR) is a safe and effective treatment for peripheral vestibular disease that entails specific exercises to maximise the central nervous system compensation for the effects of vestibular pathology. An internet-based VR intervention has recently been shown to be safe and effective. Online interventions are low cost and easily accessible, but prone to attrition and non-adherence. A combination of online and face-to-face therapy, known as blended care, may balance these advantages and disadvantages.

METHODS AND ANALYSIS:

A single-blind, three-arm, randomised controlled trial among patients aged 50 years and over presenting with dizziness of vestibular origin in general practice will be performed. In this study, we will compare the clinical and cost-effectiveness of stand-alone internet-based VR and internet-based VR with physiotherapeutic support ('blended care') with usual care during 6 months of follow-up. We will use a translated Dutch version of a British online VR intervention. Randomisation will be stratified by dizziness severity. The primary outcome measure is the Vertigo Symptoms Scale-Short Form. Intention-to-treat analysis will be performed, adjusting for confounders. The economic evaluation will be conducted from a societal perspective. We will perform an additional analysis on the data to identify predictors of successful treatment in the same population to develop a clinical decision rule for general practitioners.

Doel van het onderzoek

Stand-alone internet-based Vestibular Rehabilitation (VR) and internet-based VR with physiotherapeutic support is more (cost-)effective than usual care when treating dizziness in older patients in general practice.

Onderzoeksopzet

Inclusion: June 2017 -May 2018.
Follow-up: September 2017 - November 2018.
Measurements: at baseline, 3 months, and 6 months follow-up.

Onderzoeksproduct en/of interventie

We will compare stand-alone internet-based VR (trial arm 1, N=100) and internet-based VR with physiotherapeutic support (trial arm 2, N=100) with usual care (trial arm 3, N=100). The internet-based VR intervention closely resembles on the effective booklet-based VR by Yardley et al (BMJ 2012).
VR entails specific exercises with the aim of maximising central nervous system compensation for vestibular pathology. Recently, specific components have been defined, namely compensation (using motion to habituate or reduce responsiveness to repetitive stimuli and to re-balance tonic activity within the vestibular nuclei), adaptation (using repetitive and provocative movements of the head and/or eyes to reduce error and restore vestibule-ocular reflex gain), substitution (promoting the use of individual or combinations of sensory inputs), and motor learning principles (changing movement behaviour).

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

a. Aged 50 years and over.
b. Reported symptoms of dizziness.
c. Head movements increase the dizziness.
d. Acces to internet and an email account.
e. Ability to speak, read and write Dutch.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

a. An identifiable non-vestibular cause of dizziness in the electronic record of the patient.
b. Medical contraindications for making the required head movements (for example, severe cervical arthrosis).
c. Serious comorbid conditions that preclude participation in an exercise programme.
d. Current enrolment in another – interfering – study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2016
Aantal proefpersonen:	300
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	07-04-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5606
NTR-old	NTR5712
Ander register	METc Amsterdam UMC, location VUmc : 2016.226

Resultaten

Samenvatting resultaten

1. Van Vugt VA, van der Horst HE, Payne RA, Maarsingh OR. Chronic vertigo: treat with exercise, not drugs. BMJ. 2017 Aug 23;358:j3727. doi: 10.1136/bmj.j3727.

2. Van Vugt VA, Diaz Nerio PM, van der Wouden JC, van der Horst HE, Maarsingh OR. Use of canalith repositioning manoeuvres and vestibular rehabilitation: a GP survey. Scand J Prim Health Care. 2017 Mar;35(1):19-26. doi:10.1080/02813432.2017.1288683.

3. Van Vugt VA, van der Wouden JC, Bosmans JE, Smalbrugge M, van Diest W, Essery R, Yardley L, van der Horst HE, Maarsingh OR. Guided and unguided internet-based vestibular rehabilitation versus usual care for dizzy adults of 50 years and older: a protocol for a three-armed randomised trial. BMJ Open. 2017 Jan 20;7(1):e015479. doi:

10.1136/bmjopen-2016-015479.