Study on the effect of innovative Electronic Mobility Aids (EMA) on participation of visual impaired and blind persons - A Randomized Controlled Trial (RCT) on the effectiveness of navigation systems in supporting mobility and societal participation of person who are visually impaired

Published: 29-11-2010
Last updated: 03-05-2024

To assess the effectiveness of an individually selected navigation system on mobility and societal participation of persons who are visually impaired.

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

Summary

ID

NL-OMON34413

Source
ToetsingOnline

Brief title
RCT on the effectiveness of EMA on participation

Condition

- Other condition

Synonym

blindness, severe low vision

Health condition

visuele beperkingen

Research involving
Human

Sponsors and support

Primary sponsor: Hogeschool Zuyd
Source(s) of monetary or material Support: ZonMw;programma InZicht

Intervention

Keyword: - (Societal) participation, - Orientation and Mobility, - Self-Help Devices (Assistive Technology), - Visually Impaired Persons

Outcome measures

Primary outcome

- participation (sub-scores USER-P)

- perceived added value of the assistive device on problems of daily living

(IPPA)

Secondary outcome

- independent mobility and orientation (*Independent Mobility Questionnaire*)

- number and kind of traveled routes outdoors (travel habits / travel patterns)

(activity diary and GPS data logger)

- number and kind of activities performed outdoors (activity diary)

Study description

Background summary

The number of persons who are visually impaired will grow considerably in the near future, due to the ageing of the population. Persons who are blind or have

low vision experience problems while moving around or travelling, which frequently decrease their mobility. This in turn results in difficulty in arriving at a desired level of societal participation. Assistive devices can provide a significant contribution to the functioning, social participation and wellbeing of (visually) impaired persons. Innovative Electronic Mobility Aids (EMA) integrate technologies as GPS, infrared or sonar sensors, which developed fast and successfully in the consumer market domain and are expected to have promising potential for persons who are visually impaired, concerning enhancement of mobility and participation. However, it is yet unclear what their functional capacities and abilities are in daily life.

Study objective

To assess the effectiveness of an individually selected navigation system on mobility and societal participation of persons who are visually impaired.

Study design

This phase of the research project will be performed as a randomized controlled trial (RCT), followed by a quasi-experimental part. In sum, 90 volunteers will be included. Subsequent to screening for the eligibility criteria, informed consent and measurement of the outcome parameters to establish a baseline, they will be allocated randomly to one of the two different groups / conditions. Members of the experimental group will receive instruction and training with one individually selected EMA. Measurement of the relevant outcome variables will be performed after two and six months. Members of the control group will receive instruction and training with an individually selected EMA after six month. Two additional measurements of the relevant outcome variables will be performed after 8 and 12 months (after 2 and 6 months of device use).

Intervention

Instruction, training and use of an Electronic Mobility Aid (EMA). Measurement to establish a baseline, after the training the participants will be followed during 6 month, there will be measurements after 2 and 6 months. These measurements comprise that participants will fill in an e-mailed questionnaire in accessible format, they will be asked to keep an activity diary on daily basis three times for two weeks and to use a GPS data logger while moving around and traveling outside the home three times for two weeks. In the control group 2 additional measurements after 8 and 12 months will be performed (after 2 and 6 months of device use).

Study burden and risks

After a short telephone interview for the screening of eligibility criteria and informed consent, participants will be asked to travel to the nearest care

provider (a regional centre of Bartiméus or Royal Visio) for selection of, instruction and training with the navigation system. An accessible questionnaire will be administered by e-mail three times (in the control group: five times) and participants will be asked to keep an activity diary on daily basis three times (in the control group: five times) for two weeks, and to make use of a GPS data logger at the same time for validation. The duration of instruction and training will be tailored to the specific needs of the individual participant. Participants decide themselves by means of their travel behaviour on frequency, manner and time they want to make use of the navigation system (time spent). Participants are self-reliant / responsible for their own safety while traveling outdoors. It is assumed that participants do not run any risks concerning independent outdoor mobility and that they are well informed about the (im)possibilities of the navigation system they use.

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

- persons must have a moderate to severe visual impairment (blindness or very low vision), defined by visual acuity below 0.3 (6/18) and/or a visual field less than 30 degrees; resulting functional consequences in daily live could be described as that persons are
o in need of mobility devices such as the long (white) cane or a dog guide and/or
o not able to make use of common signposting
- persons need to have good orientation and mobility skills (which is operationally defined as being able to travel outdoors without the assistance of a human guide)
- persons need to be able to travel safe (being able to cross a street safely, being able to assess possible risks and to react adequately etc.)
- persons have to be aged 18 years or older
- persons have to be capacitated
- persons need to have a computer with Internet and e-mail at their disposal and they need to have basic computer skills
- persons need to be able to keep an activity diary in accessible format
- persons need to be willing to wear a GPS data logger while travelling or moving around outside the home during the defined periods (6 weeks in sum; for participants in the control group 10 weeks in sum)

Exclusion criteria

- intellectual disabilities
- additional motor / physical mobility impairments
- (long-term) use of a navigation EMA prior to inclusion into the study
- completely satisfied with the own level of (societal) participation
- completely satisfied with the own frequency and / or quality of outdoor mobility / travel
- no sufficient comprehension of the Dutch language

Study design

Design

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

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-07-2011
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO

Date:	29-11-2010
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL34258.096.10