# The impact of orientation and mobility training on mobility, participation and quality of life in older adults with visual impairments: a randomized controlled trial

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Vision disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON31341

**Source**
ToetsingOnline

**Brief title**
Surely InSight

### Condition

- Vision disorders

**Synonym**
low vision, visual impairments

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Universiteit Maastricht
**Source(s) of monetary or material Support:** ZonMw - Programma InZicht

## Intervention

**Keyword:** low vision, mobility, quality of life, randomised controlled trial

## Outcome measures

### Primary outcome

The primary outcomes of the study are mobility and restrictions with regard to ADL activities. Three assessments are planned: before randomization, directly after the orientation and mobility instruction and three months after the instruction.

### Secondary outcome

The secondary outcomes of the study are, among others, participation (social interaction, indoor and outdoor activities, and work and leisure activities), quality of life, loneliness, falls and fear of falling. For these outcomes three assessments are planned as well: before randomization, directly after the orientation and mobility instruction and three months after the instruction.

# Study description

### Background summary

During the next decades the number of older people with visual impairment will increase substantially. Visual impairments are associated with mobility problems and limitations in physical and social functioning and may threaten independent functioning. To improve functioning and promote independent living orientation and mobility instruction is offered to older persons with visual impairments.

Yet, up until now no thorough and systematic study has been performed to evaluate the effects of orientation and mobility instruction with respect to using an identification cane in this population. In addition, in the Netherlands a standardized format of this instruction is lacking, despite a nationally organized orientation and mobility training for facilitators of this instruction. A standardized orientation and mobility instruction might improve functioning in older people with visual impairments as well as the implementation of this instruction by the facilitators.

## Study objective

In light of the aforementioned the current study has three objectives:
1) to standardize orientation and mobility instruction for older people with visual impairments who use the identification cane;
2) to evaluate the effects of this standardized orientation and mobility instruction on mobility, participation and quality of life;
3) to evaluate the feasibility and acceptability of the standardized orientation and mobility instruction.

## Study design

A randomized controlled trial with random allocation to the intervention or control group will be conducted. The intervention group will receive the standardized orientation and mobility training while the control group receives the regular orientation and mobility training (that is care as usual). To avoid contamination, facilitators who provide the standardized instruction and consequently receive training to perform this instruction will solely provide instruction to people in the intervention group; facilitators of people allocated to the control group will receive no additional training.

## Intervention

The intervention consists of a standardized orientation and mobility instruction that is based on the regular instruction and information obtained from the manual of the national orientation mobility training for facilitators and in-depth interviews with facilitators. The standardized instruction comprises two individual sessions of approximately 2 hours each on using the identification cane, applying the cane in daily life and goal setting with regard to applying the cane. The number and duration of the sessions is comparable to the regular instruction that is also individually conducted.

## Study burden and risks

The burden and risks associated with participating in the study are considered small as a standardized version of a regular instruction will be evaluated. In addition to four extra questions during the intake procedure, the additional

burden for the study population consists solely of the assessments, which comprise three to four telephone interviews of about 30 minutes. To this end, the fact that the study population consists of visually impaired people aged 55 years or older is taken into account.

# 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

Visually impaired people aged 55 years or older who request instruction with regard to improving mobility while using the identification cane

### Exclusion criteria

People living in nursing homes, mentally disabled people, people suffering from hearing impairments or cognitive problems

## Study design

### Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Active |
| Primary purpose: | Treatment |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 29-11-2007 |
| Enrollment: | 190 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 13-08-2007 |
| Application type: | First submission |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 09-11-2009 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |

# 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 | NL17601.068.07 |