Online nurse-assisted eye-screening in home healthcare; implementation study and economic evaluation, from an individual, healthcare and socio-political perspective [iSCREEN-study]

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Cost-utility and cost-effectiveness of eye-screening in home healthcare in reducing eye complaints from a societal perspective and its health consequences will be investigated over 1 year. A cluster randomized controlled trial (RCT), including an...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Vision disorders
Study type	Interventional

Summary

ID

NL-OMON54100

Source
ToetsingOnline

Brief title
iSCREEN-study

Condition

- Vision disorders

Synonym
Visual impairment

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Eye screening, Home healthcare, Implementation, RCT

Outcome measures

Primary outcome

Primary outcome is incidence in clinically relevant progress of 10 letters (2 lines, exceeding measurement error) or more on the Colenbrander-1M visual acuity chart between baseline and 12 months follow-up. Measurements are performed in participants' homes by research assistants from Amsterdam UMC at baseline, after 6 and after 12 months.

Secondary outcome

• Vision-related measures:

- Average visual acuity change in letters per participant and eye between baseline and 12 months follow-up, including stenopeic visual acuity.

- Number of participants and eyes with baseline visual impairment (visual acuity 8/24 or lower) with clinically relevant progress of 10 letters or more.

- Optometric status 12 months after baseline. This measurement will be used for diagnostic purposes indicating whether we may have missed (latent) pathology in both groups, but also to make sure that all participants will receive eye care after the study, if necessary.

- Vision-related quality of life: CAT-EyeQ

• Health-related measures:

- Falling accidents and bone fractures: A shortened version of the *fall and fracture calendar* will be used. Questions are about the number of falls and fractures in the previous 6 months.

- Depressive symptomatology will be measured with the Patient Health Questionnaire (PHQ-9) with nine questions corresponding to the Diagnostic Statistical Manual symptoms for major depressive disorder during the past 2 weeks.

- Health-related quality of life will be investigated with the EuroQol 5-Dimension 5-Level questionnaire (EQ-5D-5L) which covers the dimensions mobility, self-care, daily activities, pain and discomfort, and anxiety and depression.

- Wellbeing: The ICEpop CAPability measure for Older people (ICECAP-O) is a measure of capability in older people for use in economic evaluations.

- Health literacy will be measured with the European Health Literacy Survey Questionnaire (HLS-EU-Q16).

• Healthcare utilization and cost-effectiveness from a societal perspective:

The institute for Medical Technology Assessment (iMTA) Medical Cost Questionnaire (iMCQ) will be used to measure health care utilization at baseline, 6 and 12 months.

• Process evaluation:

Participants from the intervention group, nurses, professionals from home

healthcare services and professionals that participants were referred to after

eye-screening, will be involved in the process evaluation.

Study description

Background summary

Having a severe visual impairment or blindness has a significant impact on the quality of life and social participation of older adults. Visual impairment in older age can lead to depressive symptoms, falls and fractures, including second contralateral hip fractures. Visual impairment is one of the barriers to access health information and an important reason for low health literacy in older adults, whereas low health literacy is associated with high hospitalization and emergency room access rates and mortality. A recent cross-sectional pilot study with one of the largest home healthcare organizations in the Netherlands (i.e. Buurtzorg Nederland) showed that simple eye-screening by community nurses helps to detect eye complaints among elderly people living independently. Of all patients, 20% had a severe visual impairment with a visual acuity lower than 8/24 of the best eye. In addition, of all patients who were referred to a general practitioner (GP), optician, optometrist or ophthalmologist based on this screening (also 20% of the total group), it was found that almost half had a severe visual impairment whereas others had eye complaints that had affected acuity to a smaller extent. In most cases, eye complaints could be treated with spectacles or cataract surgery, but also untreatable eye diseases were found. These complaints may not have been detected without eye-screening and treatment would not have been offered. The number of falls was considerably higher for people with visual impairment (52% vs. 38%), however, the potential beneficial outcomes of screening on visual outcomes or quality of life were not investigated.

Study objective

Cost-utility and cost-effectiveness of eye-screening in home healthcare in reducing eye complaints from a societal perspective and its health consequences will be investigated over 1 year. A cluster randomized controlled trial (RCT), including an extensive process evaluation will be combined with an economic evaluation. This will provide insight into the incremental costs per additional patient with relevant progress in visual outcomes (i.e. cost-effectiveness analysis, CEA) versus incremental costs per QALY gained (cost-utility analysis, CUA) in case of eye-screening plus care as usual versus care as usual only.

Study design

To gain insight into the public support for eye-screening, cost-utility and cost-effectiveness of nurse-assisted online eye-screening in home healthcare in reducing eye complaints will be studied from a societal perspective, including the impact on physical and mental health over 1 years* time. A cluster-RCT comparing the effects of online screening guided by community nurses in patients* homes compared to care as usual, and in which both healthcare costs and societal costs are mapped, will be performed in collaboration with two large home healthcare organizations. The study will also encompass a process evaluation to evaluate the online eye-screening from the perspectives of patients, nurses and home healthcare organizations and referral partners who will be taking part in the online eye-screening and subsequent intervention uptake.

Intervention

On top of usual care, nurse-assisted eye-screening takes place with the Easee app, which is implemented on the tablet or laptop of the community nurse. Participants will be referred if necessary and after assessment by a contracted optometrist.

Study burden and risks

Negligible risk. Participants constitute a vulnerable population (65+ who receive home care for health problems) for whom an intervention is applied (eye screening via the Easee app, assisted by the nurse). They may be referred to an optician, optometrist or ophthalmologist based on the results of this eye screening. If necessary, pupil dilating eye drops will be used at the 12 month optometric exam. This can blurry the vision of the participants and they can be extra sensitive to bright light. The effects of dilating eye drops last a few to several hours.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

- Patients receive home healthcare for health problems
- 65 years or older (query)
- Understanding of the Dutch language (telephone assessment)
- Cognitive ability to participate in research (telephone assessment: six-item Mini Mental State Examination score >3)

Exclusion criteria

- Very serious health condition of the patient (query: e.g. terminal illness, receiving palliative home care)
- Cognitively unable to participate in research (query: e.g. late stage Alzheimer's, Parkinson's)
- Having received an optometric or ophthalmic consultation within the last 6 months (query and telephone assessment)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

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

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-03-2023
Enrollment:	240
Type:	Actual

Medical products/devices used

Generic name:	Visual function analysers easee digital eye lab (NL-CA002-2021-58717)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	20-12-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-02-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-04-2023
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	NL78386.018.22