Counselling, prescription and instruction-effects of closed circuit television systems in rehabilitation of visually impaired adults.

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

Summary

ID

NL-OMON31146

Source
ToetsingOnline

Brief title
CCTV instruction-effects

Condition

- Vision disorders

Synonym
visually impaired; vision loss; blind

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: CCTV, low vision, randomised controlled trial, visually impaired adults

Outcome measures

Primary outcome

The development of an optimal rehabilitation protocol for the instructions of the use of CCTVs for visually impaired adults. It will focus on several specific objectives:

- To study the present process of counselling, prescribing and delivering a CCTV to visually impaired patients.

- To develop a standardized method to instruct and train visually impaired patients in using a CCTV.

- To study the effectiveness of this instruction and training program in the use of a CCTV.

- To study the feasibility of this instruction and training program.

Secondary outcome

- Reading speed (LEO test)

- Understanding of texts (Aarnoutse test)

- Activity Inventory

- Frequency, nature and time of the use of a CCTV

Special attention will be given to several other aspects which can interfere with the study:

- Visual acuity

- Competence to use the CCTV (such as stroke and arthritis)

- Living alone or with a partner (care giver)

- Previous reading habits

- Previous use of other low vision aids and electronic devices (acceptance)

- Prevalence of co-morbidity (since this can have a negative effect on the

outcome)

Study description

Background summary

One of the major problems of visually impaired people is the inability to read. These reading problems are a major threat to the social functioning and independency. Important goals of rehabilitation processes are counselling, to prescribe reading aids and to give instructions how to use these aids. A closed-circuit television system (CCTV) offers the highest level of magnification of all low vision aids and is therefore prescribed to those patients who have profound or severe low vision. For many patients it takes effort to actually use the device and sometimes the prescribed CCTV will not be used at all. Studies on the process of counselling, prescribing CCTVs and on the effects of instructions on the use are scarce and standardized protocols are lacking. Also, those studies regarding the use of CCTVs performed in the past mainly focus on reading speed and are hard to compare. Other aspects of outcome such as the benefits and problems of CCTVs are virtually unknown. This study will examine the whole process of counselling and prescribing CCTVs and the outcomes of the use of CCTVs.

Study objective

The most important objectives in this study are: (1) the development of a standardized method to instruct and train patients how to use a CCTV; (2) the effectiveness of this instruction and training program in the use of a CCTV and (3) the feasibility of this instruction and training program.

Study design

The design of the study is a two group pragmatic randomised controlled trial. One group will receive the CCTV as soon as possible after the prescription and will receive only the usual delivery instructions by the distributor of the

aid; this group will serve as control group. The other group will follow our newly developed and standardised training program on how to use the CCTV. Before entering the randomisation process, the first measurements will be performed (baseline); immediately after receiving the CCTV (before entering the training program) and three months later when the program is finished data will be collected during a home visit. To make objective measurements possible, videotapes will be used. We will videotape the use of the CCTV in the participants own house. These tapes will be rated by independent investigators, who are not aware which patients received training, using a rating protocol. We will investigate several outcomes. First, we will use reading speed of both a standardised text and the participant*s own texts but we will also focus on the participants usual reading activities and needs. To assess if the participant understands the texts, Aarnoutse tests combined with quiz questions will be used. Second, we will use several measures such as visual acuity, age, gender, years of education, former reading activities and co-morbidity as co-variables. Third, we will
ask participants to register the use of the CCTV and ask them in a semi-structured way to the use as well. Finally, to study the feasibility, we will discus the effects of the process of counselling, prescribing the CCTV and delivery instructions and training with both patients and rehabilitation workers. After finishing the study we will inform rehabilitation workers in the field of low vision on the outcomes of our study.

Intervention

The intervention will consist of the newly developed standardized training program in the use of the CCTV for those persons who were counselled for this use in the three national Dutch rehabilitation centres.

Study burden and risks

To minimize the respondent burden, the baseline questionnaires will be taken during the client intake at the MRCs. Participants will receive the delivery instructions or the training program on the use of CCTVs in their own environment so there will not be the extra effort of an other visit to the MRCs. In the data collection phase of the study, participants will be videotaped during two home visits, to register the use of the CCTV. The videotapes will only be viewed by the investigators and will be kept safe. This will take roughly one hour, in which they will perform all the tests and questionnaires needed. We realize this is an extra effort for the participants. Though, we feel that the relevance of the study indicates this can be asked of them. The voluntary nature of participation will be emphasized on every occasion. Moreover, in former research by de Boer et al. (2005) with visually impaired elderly, we have experienced that many participants were enthusiastic about participating in scientific research. A possibility in this study is the harm we do to the control group by abstaining them from the training program,

therefore the training program will be offered to this group after the study as well.

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 according to the Dutch guidelines
Acceptance of the conditions of the study (informed consent)
Above age of 18 years
Sufficient understanding of the Dutch language
Competence to understand the questions of the questionnaires

Exclusion criteria

Patient stays (or stayed before) in a psychogeriatric institution.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2007
Enrollment:	120
Type:	Anticipated

Medical products/devices used

Generic name:	closed circuit television system
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Application type:	First submission
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
ISRCTN	ISRCTN80599264
CCMO	NL19092.029.07