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

Submission date 05/09/2007	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 05/09/2007	**Overall study status** Completed	
Last Edited 16/08/2010	**Condition category** Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR1031; 94305005

Study information

Scientific Title

Study objectives
The most important objectives in this study are:
1. The actual process of counselling, prescribing and delivering a Closed Circuit Television (CCTV) to visually impaired adults
2. The development of a standardised method to instruct and train patients how to use a CCTV
3. The effectiveness of this instruction and training program in the use of a CCTV, and
4. The feasibility of this instruction and training program

It is to be expected that a standardised instruction program on how to use a CCTV will improve acceptance and that the frequency and time and number of tasks this aid is used by visually impaired people as well as reading speed, compared to those who only get the usual delivery instruction will be higher.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Medical Ethics Committee of the VU University Medical Center, Amsterdam

Study design
Multicentre single blinded randomised active controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Eye conditions, Visual impairment

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

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
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:
1. To study the present process of counselling, prescribing and delivering a CCTV to visually impaired patients
2. To develop a standardized method to instruct and train visually impaired patients in using a CCTV
3. To study the effectiveness of this instruction and training program in the use of a CCTV
4. To study the feasibility of this instruction and training program

Secondary outcome measures
1. Reading speed (LEO test)
2. Understanding of texts (Aarnoutse test)
3. Activity inventory, frequency, nature and time of the use of a CCTV

Overall study start date
01/12/2007

Completion date
01/10/2009

Eligibility

Key inclusion criteria
1. Visually impaired according to the Dutch guidelines
2. Acceptance of the conditions of the study (informed consent)
3. Above age of 18 years
4. Sufficient understanding of the Dutch language (Cito-NT2 level higher than or equal to 3)
5. Competence to understand the questions of the questionnaires (adequate cognitive ability)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120

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

Date of first enrolment
01/12/2007

Date of final enrolment
01/10/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
Vrije University Medical Centre
Amsterdam
Netherlands
1007 MB

Sponsor information

Organisation
Vrije University Medical Centre (VUMC) (Netherlands)

Sponsor details
Department of Ophthalmology
Amsterdam
Netherlands
1081 BT

Sponsor type
Hospital/treatment centre

Website
http://www.vumc.nl/english/

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type

Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/03/2010		Yes	No