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Characterization of problems associated with vision impairment and utility of the current interventions

Submission date	Recruitment status	[_] Prospectively registered
18/12/2018	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/01/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/11/2022	Eye Diseases	

Plain English summary of protocol

Background and study aims
The burden caused by vision loss can be reduced using targeted vision rehabilitation. Vision rehabilitation is intended to promote the best possible functional ability and the individual's ability to maintain their skills. However, there is still a lack of knowledge regarding the “value-for-money” of vision rehabilitation not only for people with impaired vision but also for the society. The aim of this study is to estimate the cost-effectiveness (value-for-money) of vision rehabilitation by measuring the consequences of rehabilitation for visual ability (visual ability is defined as the overall ability to perform activities that depends on vision).

Who can participate?
Adults diagnosed with diabetic retinopathy (DR) or age-related macular degeneration (AMD) with visual acuity between 0.4 - 0.1 (decimal scale) in the better-seeing eye. Participants must live in the community (not in nursing homes or other types of institution).

What does the study involve?
The study intervention consists of dispensing new glasses and magnifiers, defined as "vision aids" with minimal training. Instructions are provided in clinical settings with emphasis on reading tasks. Participants randomly allocated to the immediate intervention group receive the device in the first visit. Participants in the delayed intervention group receive the device after 3 months, in the second visit. All participants have a follow-up assessment at 3 month and at 9 months after receiving vision aids. During visits participants also need to response to questionnaires and to perform vision tests (none of them are invasive).

What are the possible benefits and risks of participating?
This study brings benefits to all participants because they will receive a basic vision rehabilitation intervention which includes new glasses and/or magnifiers with minimal training and instructions provided in clinical settings with emphasis on reading tasks. With the intervention procedures the patients won’t be exposed to any risk.

Where is the study run from?
The study is being run by the University of Minho and takes place in a single centre, a public hospital in Barcelos, Portugal

When is the study starting and how long is it expected to run for?
September 2016 to December 2021

Who is funding the study?
The ophthalmic lenses and part of the magnifiers are supported by Essilor Portugal

Who is the main contact?
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2. Laura Moreno
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Cost-effectiveness of basic vision rehabilitation services (the basic VRS-effect study): a cross-over randomised controlled trial

Acronym
The basic VRS-effect study

Study objectives
The aim of the trial is to compare the effects and costs of “usual low vision care” with a “basic vision rehabilitation service (basic VRS)” on self-reported visual ability.

Hypothesis: A basic low vision intervention, consisting of prescription of new glasses, magnifiers and instructions, improves visual ability more than usual care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Life Sciences and Health of the University of Minho, 02/05/2017, ref: SECVS 147/2016

CEUM/SECVS – Secretariado
Att: Isabel Monteiro
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Registered in the Portuguese data protection authority, ref: 7012/ 2017

Study design
Randomised cross-over controlled trial

Primary study design

Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, pelase use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Vision impairment caused by diabetic retinopathy or age-related macular degeneration

Interventions
To perform a cost-effectiveness analysis (CEA) of basic VRS the trialists designed a randomised, cross-over controlled trial (AB/BA structure), comparing the effects and costs of “usual low vision care” (which is not yet systematised in Portugal) with a “basic-VRS intervention” on self-reported visual ability.

Participants will be allocated to the immediate intervention group (IMI), which is represented by group A or to a delayed intervention group (DEI) represented by group B. Participants are allocated to the IMI or DEI to create the best possible match between the groups according to age and visual acuity. The sequence of randomization is done blocks of 4 to guarantee two participants for each group using four similar envelopes. Each envelope will contain the code of the group, two envelopes for IMI and two for DEI group. The study takes place in a single-centre.

The intervention consists of dispensing new glasses and magnifiers, defined as "vision aids", with minimal training and instructions provided in clinical settings with emphasis on reading tasks. Participants allocated to the immediate intervention group will receive the device in the first visit. Participants in the delayed intervention group will receive the device after 3 months, in the second visit. All participants will have a follow-up assessment at 3 months and at 9 months after receiving vision aids.

Intervention Type
Device

Primary outcome measure
Measured at baseline, 12 weeks and 36 weeks:
1. Visual ability, measured using Massof Activity Inventory (AI)
2. Health-related quality of life, measured using EQ-5D-5L

Secondary outcome measures
Measured at baseline, 12 weeks and 36 weeks:
1. Reading ability, measured using Portuguese version of Minnesota Low-Vision Reading Test (MNread test)
2. Depression and anxiety, measured using Hospital Anxiety and Depression Scale (HADS)

Overall study start date
02/09/2016

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Visual acuity between 0.4 - 1.0 logMAR (0.4 - 0.1 decimal) in the better-seeing eye
2. Primary diagnosis (cause of vision loss) diabetic retinopathy or age-related macular degeneration
3. 18 years of age or older
4. Resident in the community (not in nursing homes or other types of institution)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
88 participants (44 per group).

Total final enrolment
47

Key exclusion criteria
1. Cognitive impairment based on scores on mini-mental examination test
2. Communication problems due to, for example, hearing impairment, or unable to speak Portuguese
3. Unable to read in Portuguese due to low level of education
4. Unable to attend the requested appointments at the study setting

Date of first enrolment
03/03/2017

Date of final enrolment
30/03/2020

Locations

Countries of recruitment

Portugal

Study participating centre
University of Minho
Campus de Gualtar
Braga
Portugal
4710-057

Sponsor information

Organisation
University of Minho

Sponsor details
Department of Physics
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Sponsor type
University/education

Website
https://www.uminho.pt/PT

ROR
https://ror.org/037wpkx04

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication:
Protocol: 29/03/2019
Results: 2019, 2020, 2021

Intention to publish date
01/03/2022

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/05/2020	14/02/2020	Yes	No
Interim results article	Association between social support and depression and anxiety	03/03/2021	07/09/2021	Yes	No
Interim results article	Association between depression and anxiety and health-related quality of life	10/02/2022	25/07/2022	Yes	No
Results article		11/11/2022	14/11/2022	Yes	No