ISRCTN44807874 https://doi.org/10.1186/ISRCTN44807874

Does rehabilitation officer input improve quality of life in individuals with low vision?

Submission date
27/02/2015

Recruitment status
No longer recruiting

Registration date
09/03/2015

Overall study status
Completed

Last Edited
20/12/2016

Condition category
Eye Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
There are many causes of low vision including age-related macular degeneration, diabetic retinopathy and glaucoma. People with low vision can suffer from depression, reduced quality of life and reduced mobility. When people lose some or all of their sight, they may be offered the services of a Rehabilitation Officer for the Vision Impaired. This person can look at things that are more difficult for someone with low vision – such as using magnifiers, or using lights to enhance remaining vision or finding aids that make everyday tasks safer. The Rehabilitation Officer works with you in your own home or office to help you come to terms with your sight loss. There is some evidence of improved quality of life following visual rehabilitation, but there is a need for high-quality evidence regarding the effectiveness of low vision rehabilitation services. This study will consider whether support from a Rehabilitation Officer for the Vision Impaired makes a difference on the quality of life of individuals experiencing vision loss.

Who can participate?
People aged over 18 in the Cardiff area with low vision who have a requirement for low vision rehabilitation

What does the study involve?
There is one visit to the Cardiff School of Optometry which involves answering some general questions about your health and measuring your vision using a letter chart. After that, an appointment will be made for a telephone interview. This involves going through some questionnaires, which include questions about how well you are able to do vision-related activities such as reading and driving, and questions about your health and how you are feeling. You would then be randomly allocated to either receive immediate support from a Rehabilitation Officer for the Vision Impaired, or to the Sight Cymru waiting list to receive rehabilitation support. Six months after the initial telephone interview there is a second phone appointment going through the same questions.

What are the possible benefits and risks of participating?
If you agree to take part in the study you will receive support from a Rehabilitation Officer for the Vision Impaired within 6 months. The results of the study will help identify the impact of rehabilitation work and will influence the support for this work in future. There are no direct

risks of participating. One of the questionnaires that is being used in the study may identify depressive symptoms, which may result in being referred to the GP.

Where is the study run from?
This study is being organised by Cardiff University in collaboration with Sight Cymru. Low vision rehabilitation consists of home visits by a Rehabilitation Officer for the Vision Impaired.

When is the study starting and how long is it expected to run for?
October 2014 to October 2015

Who is funding the study?
Cardiff Council and Sight Cymru (UK)

Who is the main contact?
Dr Jennifer Acton
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Contact information

Type(s)
Scientific

Contact name
Dr Jennifer Acton

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Contact details
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CF24 4HQ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1377

Study information

Scientific Title
Does rehabilitation officer input improve quality of life in individuals with low vision? A pilot study

Study objectives
The principal question is to determine whether a low vision rehabilitation officer has an impact on quality of life outcome in individuals with low vision.

Ethics approval required
Old ethics approval format

Ethics approval(s)
School of Optometry and Vision Sciences Research Ethics Audit Committee, Cardiff University, 01/10/2014, ref: 1377

Study design
Exploratory single-masked randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Low vision

Interventions
The intervention is input from a low vision rehabilitation officer. Low vision rehabilitation is defined as an amelioration of the lives of individuals with sight loss by improving functional ability, and other general aspects, e.g. quality of life and psychosocial status.

There will be two arms:
1. Intervention arm: individuals with low vision who receive low vision rehabilitation
2. Control arm: individuals with low vision who are on a waiting list to receive low vision rehabilitation i.e. they have not yet received low vision rehabilitation

Intervention Type
Other

Primary outcome measure

Questionnaire outcomes will be recorded at baseline and after 6 months by telephone interview:
1. 48-item Veterans Affairs Low Vision Visual Functioning Questionnaire (VA LV VFQ-48)

Secondary outcome measures
Questionnaire outcomes will be recorded at baseline and after 6 months by telephone interview:
1. Patient Health Questionnaire (PHQ9)
2. The Warwick-Edinburgh Mental Well-being Scale (WEMWBS)
3. Adjustment to age-related visual loss scale (AVL-12)
4. Standardised health-related quality of life questionnaire (EQ-5D)
5. UCLA loneliness scale

Overall study start date
01/06/2014

Completion date
01/10/2016

Eligibility

Key inclusion criteria
1. A requirement for low vision rehabilitation
2. Distance visual acuity of 6/12 or worse; and/or near acuity of N6 or worse; or significant contraction of the visual field
3. Age 18 years or over

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
70

Key exclusion criteria
1. Live in area outside catchment of rehab officer
2. Ineligible for rehab officer
3. Those with significant need (fast track waiting list)
4. A score of <27/30 on the MMSE
5. Unable to use telephone e.g. caused by very poor hearing
6. Unable to understand English
7. Unable to take part in 6-month study

8. Unable to provide informed consent
9. Previous recipient of low vision rehabilitation via a rehabilitation officer within the last 12 months and no relevant change in circumstances

Date of first enrolment
16/10/2014

Date of final enrolment
16/10/2015

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Cardiff Centre for Vision Sciences
College of Biomedical and Life Sciences
Cardiff University
Maindy Road
Cardiff
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CF24 4HQ

Sponsor information

Organisation
Cardiff University

Sponsor details
Research and Innovation Services
30-36 Newport Road
Cardiff
Wales
United Kingdom
CF24 0DE

Sponsor type
University/education

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name
Sight Cymru

Funder Name
Cardiff Council

Funder Name
Welsh Government

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	24/02/2016		Yes	No
Results article	results	01/12/2016		Yes	No