

Effect of low vision rehabilitation on self-reported visual disability for people with diabetic eye disease

Submission date 10/02/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 16/02/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 05/10/2018	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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
08/H0716/70

Study information

Scientific Title

Effect of low vision rehabilitation on self-reported visual disability for people with diabetic eye disease: a randomised controlled trial.

Study objectives

This study aims to determine the efficacy of low vision rehabilitation on people with diabetic eye disease using a delayed intervention randomised controlled trial.

Ethics approval required

Old ethics approval format

Ethics approval(s)

National Hospital for Neurology and Neurosurgery and Institute of Neurology Joint REC, 16/10/2008, ref: 08/H0716/70

Study design

Randomised delayed-intervention controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Diabetic eye disease

Interventions

The intervention is a Low Vision Assessment (LVA) and will conform to the standard care provided to all low vision patients at Moorfields Eye Hospital.

This includes:

1. Check patient's understanding of their eye condition
2. Discuss needs/visual requirements and set initial goals
3. Assess distance and near vision
4. Determine appropriate levels of magnification required
5. Demonstrate selected low vision aids based on the results of the vision assessment and patient goals

6. Determine which visual aids are to be prescribed and review their use and handling
7. Discuss lighting and other methods of enhancing vision as appropriate
8. Discuss other services that may be available to the patient (e.g., social services, charities)
9. Dispense prescribed low vision aids on loan
10. Arrange for follow-ups as necessary

The intervention arm will receive LVA assessment at month 0. The control arm will receive delayed intervention at month 3. Both groups will be followed up for 6 months from study enrolment.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Self-reported visual disability as measured by the Massof Activity Inventory questionnaire at 0, 3 and 6 months

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/04/2009

Completion date

30/09/2011

Eligibility**Key inclusion criteria**

1. Both males and females
2. Patients with diabetes mellitus attending Moorfields Diabetic Clinics
3. Patients with diabetic eye disease as defined by an ophthalmologist

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

100

Key exclusion criteria

1. Patients under the age of 18
2. Patients who are not fluent in English
3. Patients with serious hearing impairment
4. Patients with concomitant eye disease (other than mild cataract)
5. Patients who have previously attended a Low Vision Clinic
6. Patients with poor mobility or in poor general health
7. Patients who are hospital inpatients, living in nursing homes or who are otherwise non-independent

Date of first enrolment

01/04/2009

Date of final enrolment

30/09/2011

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University College London (UCL) Institute of Ophthalmology

London

United Kingdom

EC1V 9EL

Sponsor information

Organisation

Moorfields Eye Hospital NHS Foundation Trust (UK)

Sponsor details

c/o Ms Sue Lydeard

Research and Development Department

162 City Road

London

England

United Kingdom

EC1V 2PD

Sponsor type

Hospital/treatment centre

Website

<http://www.moorfields.nhs.uk>

ROR

<https://ror.org/03zaddr67>

Funder(s)

Funder type

Charity

Funder Name

Fight for Sight (UK) - Clinical Fellowship Grant (ref: 1775/76)

Results and Publications

Publication and dissemination plan

2013 results published in thesis <http://discovery.ucl.ac.uk/1393954/>

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	01/07/2012		Yes	No