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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	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 16/02/2009	**Overall study status** Completed	
Last Edited 05/10/2018	**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

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised delayed-intervention controlled trial

Study type(s)
Treatment

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(s)

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

Key secondary outcome(s)
No secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

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)

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

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