

Randomised Controlled Trial of Low Vision Rehabilitation Services.

Submission date 23/01/2004	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 23/01/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 15/12/2009	Condition category Eye Diseases	☐ Individual participant data

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
RHC18039

Study information

Scientific Title

Study objectives

The proposed study is a 3-arm randomised controlled trial, comparing the effectiveness of a conventional hospital based optometric low vision service and an integrated low vision service for patients with age related macular degeneration (ARMD).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Three-arm randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Eye diseases: age-related macular degeneration

Interventions

Plan of Investigation

ARM 1 : Patients will receive conventional optometric low vision care in Hospital Eye Service.

ARM 2 : Patients will receive integrated low vision care. In addition to conventional optometric management, these patients will be seen three times by a trained low vision rehabilitation officer. The officer will give specific rehabilitation training.

ARM 3 : Patients in arm 3 will receive conventional optometric management and will be seen three times by a community care worker - specific rehabilitation training will not be given by the community care worker (age concern).

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Primary outcome measures include:

Low vision specific and generic health status questionnaires, and measures of visual function. In addition, the study aims to estimate and compare the costs of these models of low vision care.

Main study outcomes include :

Visual Functions - near and distance logMAR visual acuity, contrast sensitivity, reading speed.

Low vision symptoms - MREH low vision questionnaire.

Quality of Life - SF36 questionnaire, Nottingham Adjustment Scale.

Health and Welfare Service usage - including hospital visits, contacts with GP's, other members of the Primary Care Team, Social Services and voluntary organisations.

Key secondary outcome(s))

Not provided at time of registration

Completion date

01/10/2001

Eligibility

Key inclusion criteria

We propose to recruit 225 new patients (75 in each group) on the basis of a recent audit of the low vision service at MREH.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/06/1997

Date of final enrolment

01/10/2001

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Central Manchester Healthcare NHS Trust

Manchester

United Kingdom

M13 9WH

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

NHS Executive North West (UK)

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?
Results article	results	01/11/2004		Yes	No
Protocol article	protocol	01/01/2001		Yes	No