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Randomised Controlled Trial of Low Vision Rehabilitation Services.

Submission date 23/01/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 15/12/2009	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
Primary outcome measures include:
Low vision specific and generic health status questionnaires, and measures of vional 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.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/1997

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
225

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
England

United Kingdom

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)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive North West (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

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	01/01/2001		Yes	No
Results article	results	01/11/2004		Yes	No