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A randomised controlled study to assess the emotional needs and efficacy of a service to meet identified emotional needs of individuals with macular disease

Submission date 24/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 06/11/2007	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 05/04/2013	**Condition category** Eye Diseases	[_] Individual participant data [_] 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

Version 1, 27th July 2007

Study information

Scientific Title

Study objectives
To compare the emotional wellbeing of individuals newly registered as sight impaired with macular disease who have access to an emotional support package of care together with current standard care, with those who only receive the current standard care. The hypothesis is that the additional care group will experience less psychological pathology (anxiety and depression) and higher quality of life compared to the 'standard care' group.

Primary objective is to assess the efficacy of an emotional support service for individuals who are visually impaired.

Secondary objectives include:
1. To assess the emotional needs of individuals with macular disease over the 12 months following registration as sight impaired
2. To identify factors that predict individuals who are experiencing emotional difficulties adjusting to registration
3. To use the findings of the study to inform an update of the Certificate of Visual Impairment (CVI) form

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval pending from the Devon and Torbay Research Ethics Committee as of 24/09 /2007.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Age related macular disease

Interventions
All patients (both intervention and control groups) will have current standard care plus an initial assessment via completion of questionnaires and an interview administered via the psychology service.

Each of the participants in the intervention group will be allocated to a volunteer who also has a macular disease. The participants will then receive a telephone call from the volunteers they are assigned to, inviting them to attend a 'newly diagnosed' group meeting run by volunteers with macular disease.

Key activities of the newly diagnosed group:
The group aims to:
1. Provide information:
1.1. Answer questions about macular disease from volunteers' own experiences
1.2. Distribute information (leaflets, audio tapes, etc.,) regarding macular disease, the low vision clinic, support services, benefits, etc.,
1.3. Describe, invite to and answer questions about the Macular Disease Support Group
2. Screen individuals for evidence of unmet needs:
2.1. Those who are in low mood, extremely anxious
2.2. Those who need but are not obtaining available social service support
2.3. Those not accessing appropriate medical services, e.g., low vision clinic
3. Provide a link between newly diagnosed individuals and the professional and voluntary services:
3.1. Relay questions that they could not answer to the ophthalmologist, social services, clinical psychology, etc., as relevant and ensure that the answer is fed back to the questioner
3.2. Relay details of those requiring additional support to either the ophthalmology service, social services or clinical health psychology service as appropriate

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Psychological pathology, measured at baseline, 4 and 12 months:
1. Psychiatric status, assessed by the 28-item General Health Questionnaire (GHQ-28)
2. Hospital Anxiety and Depression Scale (HADS)
3. Risk of deliberate self-harm, assessed by Beck Hopelessness Scale (BHS)

Secondary outcome measures
The following secondary outcomes will be measured at baseline, 4 and 12 months:
1. Quality of Life, assessed by the Macular Disease-dependent Quality of Life (MacDQoL) scale
2. Adjustment, assessed by the Impact of Events Scale (IES)
3. Coping strategies, assessed by the COPE questionnaire
4. Social support, assessed by the Social Support Questionnaire (SSQ)
5. Knowledge, support and satisfaction questionnaire

Overall study start date

01/10/2007

Completion date
31/01/2011

Eligibility

Key inclusion criteria
1. Patients who are experiencing sight impairment through Age related Macular Disease (AMD) that requires initial registration as sight impaired
2. Voluntary informed consent given

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
128

Key exclusion criteria
1. Limited understanding of English
2. Diagnosis of dementia
3. Have severe learning disabilities
4. Have a current severe psychiatric illness
5. Sight impairment for reasons other than macular disease
6. Unable to give voluntary informed consent

Date of first enrolment
01/10/2007

Date of final enrolment
31/01/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Clinical Psychology
Torquay

United Kingdom
TQ2 7AA

Sponsor information

Organisation
South Devon Healthcare NHS Foundation Trust (UK)

Sponsor details
Torbay Hospital
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Sponsor type
Hospital/treatment centre

Website
http://www.sdhct.nhs.uk/

ROR
https://ror.org/05374b979

Funder(s)

Funder type
Charity

Funder Name
Torbay Medical Research Fund (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