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A randomised controlled trial comparing the impact of problem-solving treatment and usual care on wellbeing, functional mobility and quality of life of blind and partially sighted people

Submission date 08/08/2013	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 08/08/2013	**Overall study status** Completed	
Last Edited 06/01/2017	**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
14289

Study information

Scientific Title
A randomised controlled trial comparing the impact of problem-solving treatment and usual care on wellbeing, functional mobility and quality of life of blind and partially sighted people

Acronym
Problem Solving Treatment in Visual Impairment (POSITIVE)

Study objectives
People who lose their vision can have a difficult time adjusting to their condition, especially in the early stages after their diagnosis. This can have an impact on their psychological well-being and their motivation and confidence to continue with their day-to-day activities. It is hoped that helping people to develop their problem-solving skills after their initial diagnosis will increase their level of confidence and wellbeing.

Once problem-solving skills are learnt, they can also be applied to a range of problems that individuals may encounter as a person living with vision loss. The aim of this study is to test an established intervention called Problem-Solving Treatment (PST) among 120 people with an early diagnosis of vision loss.

Ethics approval required
Old ethics approval format

Ethics approval(s)
13/LO/0416

Study design
Randomised; Interventional; Design type: Treatment

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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Topic: Eye; Subtopic: Eye (all Subtopics); Disease: Ophthalmology

Interventions
A trial will be conducted where approximately half of participants will be randomly allocated to receive the intervention, and half will receive usual care. The intervention group will be split into those with severe and those with moderate to slight vision loss. The intervention consists of six sessions of Problem Solving Treatment conducted over 8 weeks, and also a telephone booster session approximately three months after the last session. The study will examine whether the intervention has a positive impact on psychological wellbeing, quality of life and mobility, and if any changes are related to severity of vision loss. If there is evidence that PST is a useful intervention for people with vision loss, the trialists will consider how it can be incorporated into usual care after diagnosis.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Warwick-Edinburgh Mental Well-being Scale; Timepoint(s): Baseline, 3 months, 6 months, 9 months

Secondary outcome measures
1. Generalized Self-efficacy Scale; Timepoint(s): Baseline, 3 months, 6 months, 9 months
2. Hospital Anxiety and Depression Scale; Timepoint(s): Baseline, 3 months, 6 months, 9 months
3. Impact of Vision Impairment Questionnaire; Timepoint(s): Baseline, 3 months, 6 months, 9 months
4. Life Spaces Questionnaire; Timepoint(s): Baseline, 3 months, 6 months, 9 months
5. Self-assessed Instrument for Perceived Visual Ability for Independent Mobility; Timepoint(s): Baseline, 3 months, 6 months, 9 months
6. Social Problem Solving Inventory Revised; Timepoint(s): Baseline, 3 months, 6 months, 9 months
7. Vision Quality of Life Index; Timepoint(s): Baseline, 3 months, 6 months, 9 months

Overall study start date
21/06/2013

Completion date
31/12/2014

Eligibility

Key inclusion criteria
A diagnosis of severe, irreversible sight loss, or registration as blind or partially sighted within the last 3 months
Target Gender: Male & Female ; Lower Age Limit 18 years

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 120; UK Sample Size: 120

Key exclusion criteria
1. Already participating in psychiatric/psychological assessment or intervention within the previous 3 months
2. Having significant cognitive impairment (screened by Six-item Cognitive Impairment Test (6-CIT; Katzman et al., 1983) whereby score of =10 will result in exclusion)
3. Having insufficient proficiency in English to participate
4. Residing in a care home

Date of first enrolment
21/06/2013

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Holloway
Egham Hill
Egham
United Kingdom
TW20 0EX

Sponsor information

Organisation

University of London (UK)

Sponsor details
Royal Holloway
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Sponsor type
University/education

ROR
https://ror.org/04cw6st05

Funder(s)

Funder type
Charity

Funder Name
Guide Dogs for the Blind Association, UK. Ref: RFT056/10

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	01/07/2014		Yes	No
HRA research summary			28/06/2023	No	No