

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 08/08/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/01/2017	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

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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Egham
England
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TW20 0EX

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