

**A pilot randomised controlled trial of  
Problem-Solving Treatment for Visual Impairment (POSITIVE): protocol paper**

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**Short title:** Problem-Solving Treatment for Visual Impairment

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## **Abstract**

### **Purpose**

For visually impaired individuals, motivation to be mobile and the individual's emotional states are predetermining factors of functioning. In addition, loss of confidence at the time of diagnosis could inhibit the ability to make progress. The aims of this study are to evaluate whether Problem-Solving Treatment (PST), a brief, structured psychological intervention, leads to better psychological well-being, in people who have been recently diagnosed as blind or partially sighted.

### **Methods**

A pilot randomised controlled trial. The trial aims to recruit 120 individuals who have either: 1) been diagnosed with severe, irreversible sight loss, or 2) registered as blind or partially sighted within the last 3 months. Individuals will be randomly allocated to either the intervention or control group with randomisation stratified by severity of vision loss. Those in the intervention arm will receive PST, an established intervention that addresses individual's confidence, motivation and psychological well-being by undertaking specific tasks to help individuals work through their problems, and recognising steps to problem resolution. Both groups will continue to receive routine care, such as mobility training.

### **Study outcomes**

The primary outcome is psychological well-being measured at 3, 6, and 9 months after recruitment and assignment to intervention or control group. Secondary outcomes include symptoms of distress, mobility and quality of life.

## **Background**

Visual impairment is associated with high levels of disability, including loss of mobility and reduced ability to perform activities of daily living.<sup>1,2</sup> Further, for visually impaired individuals, individual motivation to be mobile and their emotional states are predetermining factors of functioning.<sup>3</sup> The link between vision loss and symptoms of depression is well-documented.<sup>4</sup> Epidemiological data in the UK indicates incidence of depression amongst older adults with visual impairment to be 13.5%, compared to 4.6% among older adults with normal vision.<sup>5</sup> However, major depression is not a normal and expected outcome of vision loss in older adults. Most older adults with low vision do not become clinically depressed.<sup>4,6</sup> Instead, throughout the process of losing their vision, older adults may experience distress around perceived control, fear of dependency, and perceived loss of ability to maintain meaningful personal connections and social roles.<sup>7</sup> This may in turn affect motivation and confidence to continue with their day-to-day activities, and overall functioning. Hence interventions to promote psychological well-being, especially within the early stages after the diagnosis of vision loss, are warranted.

Within the UK social care system, those registered as blind or partially sighted are generally assessed either by social services or local not for profit organisations to determine the type and extent of services required. These typically focus on mobility training, as well as through the provision of devices designed to aid activities of daily living such as low vision aids. Such rehabilitation services have been shown to be associated with improvements in functional status.<sup>8</sup> However, these services do not routinely target psychological needs per se, and the impact of these services on quality of life (QoL) has been found to be modest.<sup>8</sup>

Several studies have looked at the effectiveness of psychological interventions for vision loss. An intervention comprising several components including health education, group discussion, and training in behavioural and cognitive skills aimed at reducing barriers to independence, was effective in reducing psychological distress and improving self-efficacy in elderly individuals with age-related macular degeneration.<sup>9</sup> Similarly, a self-management program involving health education and cognitive and behavioural training which included training in problem solving skills was found to be effective in increasing self-efficacy and reducing depressive symptoms at 6 month follow up in people with age-related macular degeneration.<sup>10</sup> Although in one of the studies<sup>9</sup> participants in the intervention group increased their use of vision aids, the impact on other aspects of functioning, such as mobility, is far from clear.

The Problem-solving Treatment for Visual Impairment trial (POSITIVE) will examine the impact of problem-solving treatment (PST),<sup>11</sup> on psychological well-being, for newly diagnosed visually impaired individuals - approximately 76% of whom are likely to be 65 years of age or older<sup>12</sup>. PST is an established intervention which can specifically address individuals' confidence, motivation and psychological well-being.<sup>11</sup> It is a brief, structured psychological treatment, which focuses on the "here and now" by teaching a rational and systematic approach to problem solving and addressing negative perceptions that may interfere with finding solutions.<sup>11</sup> The behavioural component includes setting specific tasks to help individuals work through their problems. The cognitive component demonstrates that they need not be overwhelmed by their problems, but that there are practical and effective steps to problem resolution. The skills are used to develop practical compensatory strategies to achieve valued functional goals thereby promoting better psychological functioning and prevention of depression.<sup>13</sup>

PST has been used successfully in people with anxiety and depression within primary care.<sup>11,14</sup> Interventions based on problem-solving skills training, has been demonstrated in various samples (e.g. <sup>15-19</sup>), including those with macular degeneration.<sup>13</sup> PST is likely to be an effective tool in coping with the diagnosis of vision loss. Focusing on the present may allow individuals to continue managing day-to-day responsibilities, and create situations that appear more manageable. PST will offer a clear structure within which to breakdown problems into manageable components, establishing achievable goals, and generating solutions, with the expectation that their psychological well-being will improve as their problems resolve. It has been suggested that PST-treated individuals with macular degeneration were able to develop compensatory strategies to continue to pursue valued activities, resulting in reduced levels of depression.<sup>13</sup>

The POSITIVE trial expands upon the research conducted by Rovner and colleagues <sup>13</sup> in four primary ways. Firstly, the main aim of the Rovner study was to examine the impact of PST in preventing cases of major depression. We are interested in promoting psychological well-being, and our primary outcome measure is psychological well-being. In the British National Survey of Psychiatric Morbidity at least half of all neurotic disorders were mixed anxiety and depressive disorders,<sup>20</sup> where the full criteria for major depression and anxiety were not met, and there is evidence that this group untreated have persistently lower quality of life.<sup>21</sup> Especially within the group of people with visual impairment, there are likely to be many who do not necessarily meet the clinical criteria for depression, who may nevertheless report reduced well-being and may have sub-threshold symptoms of depression or anxiety. PST may operate quite differently for prevention of depression in comparison to promotion of psychological well-being by raising self-esteem and increasing problem-solving ability in the context of newly diagnosed visual impairment. PST may maintain or improve

psychological well-being at follow-up in this group of people, and this has yet to be tested. Second, our study includes a booster session at 3 months after completion of PST training. Rovner and colleagues<sup>13</sup> suggest that such booster sessions may prolong the beneficial effects of PST, which in their study had diminished by 6-month follow up. Third, we will be examining mobility as one of our outcome measures. PST should help individuals to recognise the realistic limitations of their visual disabilities, and to come up with alternative strategies so that their valued activities can still be performed. The intervention may foster the development of problem-solving skills to enable individuals to compensate for their mobility through identifying barriers to change for mobility problems, and in-depth solution-focussed work to overcome these barriers. Fourth, the population of interest is different. While Rovner and colleagues<sup>13</sup> and another recent study comparing the efficacy of PST with supportive therapy on vision function<sup>22</sup> have targeted a group of elderly individuals with age-related macular degeneration, the present study includes participants from all adult age groups with vision loss from all causes. However, we anticipate the majority of participants to be older adults.

#### Primary objective

- To determine whether blind and partially sighted people who undertake Problem-Solving Treatment (PST) demonstrate better psychological well-being (as measured by Warwick Edinburgh Mental Well-being Scale), symptoms of distress, mobility and quality of life than those undergoing usual care.

## Secondary objectives

- To assess the acceptability of PST from the perspective of participants using in-depth interviews and qualitative analysis to elicit their experiences of the intervention, and aspects that were helpful or unhelpful
- To evaluate changes in health services resource use
- To explore whether changes in self-efficacy and problem-solving ability act as a mediator of change in the main outcome measure
- To explore whether participants' response to treatment is moderated by the degree of vision loss.

## Methods/design

### Design

This trial is a pilot, multicentre, individually randomised controlled trial. Consenting participants who meet the eligibility criteria will be randomised to receive either problem solving therapy or care as usual. The trial design and CONSORT (Consolidating Standards of Reporting Trials) flow diagram<sup>23</sup> of participants are summarised in Figure 1.

### Participants

#### Sample size calculations

Approximately 120 patients will be entered into the study, 60 in the Problem-solving Treatment arm and 60 in the control arm. With this sample size the study will have 80% power to detect a statistically significant treatment difference between the groups on the Warwick-Edinburgh Mental Well-being Scale at the 5% significance level, assuming a true difference of 5 points, a standard deviation of 8.8 (a conservative estimate derived from a Scottish population survey<sup>24</sup>), and a 15% rate of attrition.



We aim to recruit for 12 months, equating to a pool of approximately 875 for recruitment based on eligible number of people being recently diagnosed within our planned recruitment sites. This is a conservative estimate based on approximate number of diagnoses from previous years. Estimates suggests around 70% of individuals would fit our eligibility criteria (N=612). Previous research<sup>13</sup> indicates that only around 50% of individuals will be interested in taking part (N=306). Of these, we estimate that only 70% of responders will be eligible for the trial, and that a further 10% may drop out at the time of eligibility interviews, which will roughly equate to 193 participants who will be eligible for randomisation. The consent rate is likely to be around 65%<sup>25</sup>, allowing for 120 participants required for the trial.

## **Eligibility criteria**

### *Inclusion criteria*

Inclusion criteria: adults ( $\geq 18$  years of age); community-dwelling (i.e. not living in a care home); and diagnosed with severe, irreversible sight loss, or registered as sight impaired (partially sighted) or severely sight impaired (blind) within the previous 3 months.

### *Exclusion criteria*

Exclusion criteria: participation in psychiatric or psychological assessment or intervention within the previous 3 months; have severe cognitive impairment (screened by the Six Item Cognitive Impairment Test<sup>26</sup>; whereby a score of  $\geq 10$  will result in exclusion); are severely hearing impaired (to a level that makes participation impractical); and/or have insufficient proficiency in English to participate.

## **Sources of participants**

Participants will be recruited through two methods:

*1) Community recruitment via County Council and London Borough Sensory Needs Services*

Information packs containing the Information sheet (both paper and audio copy), a large-font reply slip and a pre-paid reply envelope will be sent by the Sensory Needs Service team approximately a week after the newly diagnosed individuals receive the Certificate of Visual Impairment (CVI). The Information Sheet will clearly outline the number and duration of contact with study personnel in both the intervention and control groups. Those interested in participating can contact the Study Coordinator either by phone, or by completing and returning the reply slip. Participants will be recruited from 5 Sensory Needs Services across South-East England.

*2) NHS Eye Hospitals/ Eye Units*

Potential participants will also be identified via 6 NHS Eye Hospitals/Eye Units across London, South East and Central England. They will be provided with an Information pack (as above) by one of the following: an NHS-based Vision Support Officer (VSO), an ophthalmologist, or a research nurse. Individuals are then offered the option of discussing the study with the Study Coordinator, with no obligation to participate. If the participant wishes to take up the opportunity of the Study Coordinator phoning them, they will be asked to sign a sheet indicating permission for their contact details to be passed to the study team.

**Telephone screening**

Potential participants will be screened on the telephone to determine whether they meet the above inclusion/exclusion criteria. Following telephone screening, the Study Coordinator will inform potential participants whether they are eligible to participate in the trial. The Study

Coordinator will then arrange a home visit for eligible participants to talk through and sign the consent form, and to complete baseline measures. At this visit, the Study Coordinator will also request access to the participant's CVI, in order to note the severity and cause of visual impairment. Should a participant not have access to their CVI or a CVI has not been issued for the patient, the Study Coordinator will relay the signed consent form to the relevant service, which will then release details of cause and severity of visual impairment.

### **Outcome measures**

Participants in both the problem-solving and control groups will be asked to complete the full set of outcome measures at baseline and at 9 months. Outcomes of well-being, symptoms of distress, mobility, and quality of life only will additionally be completed at 3 and 6 months in order to reduce participant burden so that participants will not be completing measures of problem-solving, self-efficacy and health resource use at these time points. The study coordinator will visit participants at their home to conduct baseline outcome measures. Subsequent follow-up assessments using the same questionnaires will be conducted over the phone.

### **Main outcomes:**

Our primary outcome measure is psychological well-being, measured by the Warwick-Edinburgh Mental Well-being Scale (WEMWBS)<sup>27</sup>. The WEMWBS is a scale for assessing positive mental health (mental well-being), including 14 positively-worded items with five response categories. It covers most aspects of positive mental health (positive thoughts and feelings) currently in the literature, including both hedonic and eudaimonic perspectives.

### **Secondary outcomes:**

Secondary outcomes are as follows: psychological distress, as measured by the Hospital Anxiety and Depression Scale<sup>28</sup>; functional mobility, measured by the Self-assessed Instrument for Perceived Visual Ability for Independent Mobility<sup>29</sup> and Life Spaces Questionnaire<sup>30</sup>; quality of life, measured by the Impact of Vision Impairment Questionnaire<sup>31</sup> and the VISQOL<sup>32</sup>; problem-solving ability, measured by the Social Problem Solving Inventory – Revised: Short,<sup>33</sup> and self-efficacy, measured by the Generalized Self-efficacy Scale.<sup>34</sup> Self-reported information on health resource use over the previous 4 weeks will also be gathered by a health resource use questionnaire developed for a previous study.<sup>14</sup>

### **Randomisation**

Randomisation will take place after CVI details have been received. Stratified randomisation will be employed to balance severe/moderate vision loss across the intervention/control groups. Blocking will be used within strata with random block sizes. Participants will be randomised using web-based randomisation. In order to ensure the Study Coordinator (who is the outcome assessor) is masked to treatment group, participant data (initials, participant identification number and level of impairment) will be entered by the study therapist, who will then be notified of the randomisation result. After randomisation the study therapist will inform participants as to whether they are in the intervention or control group of the study, and will arrange appointments with those allocated to the intervention group.

### **Trial conditions**

#### **Problem Solving Treatment.**

Six Problem Solving Treatment sessions of 45-60 minutes duration will be conducted over an eight week period by a study therapist trained in PST by Dr. Mynors-Wallis, developer of PST. The first 4 sessions will take place weekly, and the last 2 sessions every two weeks. All

PST sessions will take place at the participant's home. For quality assurance, all PST sessions will be digitally recorded. An independent rater will score randomly selected sessions for the standard of delivery and any deviations from protocol. If there are deviations to protocol, these will be noted and the extent of any deviations from protocol will be reported in any articles or reports presenting the results of the study.

The structure of PST involves a series of seven stages, with core elements of the structure present in all sessions. These stages represent discrete steps in either the treatment process (i.e. explanation of the treatment and its rationale, and evaluation of progress) or in the problem-solving process itself (i.e. identifying and defining problems, establishing achievable goals, generating solutions, evaluating and choosing the solution and applying the chosen solution).<sup>35</sup>

The first PST session will provide an overview of the problem-solving steps. Participants will then be assisted to identify current problems in their lives and use the problem-solving framework to work through solutions to one or two problems in a session, finishing the session by agreeing homework tasks to be completed by the second session. The second and subsequent sessions will begin with an evaluation of progress and then follow the problem-solving structure. In the final session the study therapist will again review problem-solving principles and techniques. The ability of the participants to be effective problem solvers, the importance of maintaining a positive orientation, and the usefulness of intervention principles as coping tools will be stressed.

Three months after completing the final PST session, the study therapist will conduct a follow-up telephone booster session to review knowledge and skills of problem-solving. A

subsample of participants will be interviewed by a researcher using open-ended questions to identify aspects of the intervention they found helpful or unhelpful and to identify any changes they experienced. This will take place after the 9 months follow-up.

### **Control group**

Both the intervention and the control group will continue to receive routine medical care (such as further eye examinations) and rehabilitation (such as mobility training) depending on individual needs, although no psychological intervention will be offered to the control group.

### **Independent monitoring**

This trial is being conducted with support from PRIMENT UK-CRC Registered Clinical Trials Unit<sup>36</sup>, and will adhere to their Standardised Operating Procedures (SOPs), including trial monitoring and quality assurance. A Trial Steering Committee will be established to monitor the conduct of the trial. The committee will meet once every 6 months to monitor that the study is being conducted to the standards set out in the Medical Research Council's (MRC) Guidelines for Good Clinical Practice.<sup>37</sup> They will assess progress of the trial, adherence to protocol, and patient safety.

### **Quantitative Analysis**

The primary analysis will be a comparison of the primary outcome measure, WEMWBS, across treatment groups using an analysis of covariance (ANCOVA) approach via a mixed model to adjust for baseline scores and stratification factor and measurements at multiple time-points. Analysis will be conducted once the outcome measures have been transformed to interval-level measurement using Rasch analysis.<sup>38</sup>

Baseline comparability of the two groups, acceptance of and adherence to treatment, and descriptive statistics for all outcome measures will be presented. Analyses will be carried out using all randomised patients using the principle of Intention-To-Treat (ITT). Effect sizes will be reported with confidence intervals. If sufficient numbers are not collected then only descriptive statistics will be presented, rather than *p*-values. Secondary analyses will adjust for covariates including age, gender, cause and degree of visual impairment. Additional secondary analyses will explore whether there are any subgroup effects such as between those who have severe or moderate/slight vision loss. Supplementary, exploratory analyses will be carried out to determine predictors of response to treatment. These will include: 1) dichotomous variables e.g. whether the individual has severe or moderate/slight vision loss; and 2) continuous variables e.g. scores on baseline questionnaires. Preliminary mediation analyses will be conducted to examine self-efficacy as a possible mediator of the treatment effect. Further exploratory analyses to examine the extent of vision loss, as a potential moderator of response to treatment, will also be conducted. The impact of missing data will be investigated via imputation and sensitivity analyses.

### **Qualitative analysis**

The post session interview data will be analysed using a constant comparative approach.<sup>39</sup> This involves dividing each interview into units, identifying each discrete area through extracting significant statements and highlighting of text in the transcripts. The units will then be grouped into categories and coded based on similarities and differences. After further reflection in comparing and integrating the units, they will be categorised into themes. The themes will describe the units of meaning contained within. The clusters of themes will then be referred back to the original descriptions for validation.

## **Discussion**

This pilot RCT will establish the feasibility of using PST to improve well-being following a diagnosis of visual impairment or severe visual impairment. It will evaluate if those who undergo PST demonstrate better outcomes compared to those who undergo ‘care as usual’. As we are focusing on the promotion of psychological well-being following a new diagnosis of vision loss, our trial has inclusive eligibility criteria. Thus we are offering a psychological intervention to a group of people who would not otherwise receive any therapy but are nonetheless undergoing significant challenges and may have reduced psychological well-being and sub-threshold symptoms of depression. We will perform exploratory analyses with the results of the present study to explore whether treatment effects depend on baseline values of psychological well-being.

This pilot trial will assess whether PST has potential to impact on psychological well-being of newly diagnosed people with visual impairment, as well as a number of secondary outcomes. It has a relatively long follow-up period (9 months), which will allow for the measurement of both the short and long-term effects of the intervention. The inclusion of the telephone booster session at 3 months after the completion of the intervention will demonstrate whether the PST has sustained impact with fairly minimum costs and resources involved for the booster session. By assessing potential mediators of change (self-efficacy and problem-solving) with the intervention, the trial can also shed light on the process of change in psychological well-being.

The advantages of PST are that it is relatively brief and already well-established. Therefore, if found to be an effective therapy, PST could be implemented as part of the usual care package provided for people with visual impairment post diagnosis. For example, rehabilitation



workers can potentially be trained to deliver PST. Other health care professionals, such as nurses who come into contact with newly diagnosed individuals could also potentially be trained to deliver PST. Such support would be in line with recommendations from National Low Vision Services Consensus Group<sup>40</sup> that emotional and practical support should be provided within the core rehabilitation service.

PST has the advantage that staff other than mental health specialists can be trained to teach problem-solving skills, with evidence that health care professionals such as practice nurses can be successfully trained to use PST.<sup>41</sup> This contrasts to other psychological interventions, such as CBT, where there is negative evidence of its use in routine care by non-mental health specialist.<sup>42</sup> Thus, compared to other psychological interventions that can only be delivered by mental health specialists, there is a wider scope for adoption of PST. PST delivered over a few treatment sessions by less highly trained therapists may be advantageous in instances when there may be insufficient numbers of mental health specialist therapists, or insufficient resources, to provide more intensive treatments to all newly diagnosed people with visual impairment.

The trial is set up to be methodologically robust and to conform to best practise for RCTs. There is independent web-based randomisation and outcome assessors will be blind to the intervention status. Statistical analysis will be conducted using a detailed analysis plan developed prior to the first un-blinded data analysis. As an additional check on blinding, the study coordinator will record which trial group they think each participant is assigned to, and this will be compared to the actual groups to determine if the probability of guessing correctly is greater than chance.

There will be one study therapist who has been trained by the developer of PST who will conduct all the PST sessions, and therapy fidelity will be assessed by an independent rater. The outcome measures are self-reported and are collected by the trial coordinator who is masked to the randomisation and is not involved in the therapy sessions. Although the control group will not receive an intervention, every effort will be made to collect details regarding services received (such as rehabilitation services) across all participants. Further, by measuring self-reported problem-solving ability in addition to our main outcomes, we can explore changes to this ability as an impact of the intervention. The type and frequency of services offered to the individuals in each group will be coded, and these will be controlled for in our analyses.

Service users have been heavily involved in the study, being consulted for the development of the Patient Information Sheets and other materials used in the study as well as being present on the Trial Steering Committee. Other advantages of the study include the use of qualitative research methods to evaluate the intervention, which again emphasises the views of the service users, and will guide us in the best delivery of PST in practice, and in any future trials. Another advantage of the trial is the use of Rasch analysis.<sup>38</sup> Rasch analysis is important because it provides greater insight into the psychometric properties of the instrument compared to traditional methods. Several techniques are available to determine how well items fit the latent trait being measured; how well the items discriminate between the respondents; and how well item difficulty targets person ability.<sup>43</sup> Rasch analysis will be performed to ensure the validity and reliability of the obtained measures in our sample population.

Nevertheless, there are challenges to this trial. First, encouraging those who have recently been diagnosed as blind or visually impaired to engage in an intervention may be challenging. Individuals may feel overwhelmed at this time point, which may limit their uptake of services such as PST. Additionally, their vision impairment may make it difficult for them to engage in standard methods of information dissemination, such as a participant information sheet. For this reason this study has also provided an audio CD version of the information sheet. It is hoped this audio CD will encourage a wider number of participants to engage with the study.

In conclusion, the POSITIVE pilot trial aims to investigate the impact of PST on the psychological well-being of people newly diagnosed with visual impairment, which we believe will include a large proportion of older adults. These individuals are not necessarily clinically depressed, but nevertheless, face challenges to their daily lives in light of their new diagnosis.

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**Figure 1. POSITIVE CONSORT Flow Diagram**

