Improving depressive symptoms in adults with vision impairment: a trial of evidence-based ‘Problem-Solving Treatment' integrated within low vision rehabilitation services

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Abstract

Depression is exceedingly prevalent in people with vision impairment (VI), which further exacerbates vision-related functioning, disability and quality of life when left untreated.\textsuperscript{1-5} Up to 43% of people with VI experience depressive symptoms,\textsuperscript{6-11} although only one fifth of those receive psychological intervention.\textsuperscript{11,12} The main objective of this thesis was to evaluate the feasibility, effectiveness and implementation of evidence-based Problem-Solving Treatment for Primary Care (PST-PC) integrated into low vision rehabilitation (LVR) services. In this model, LVR staff were trained to deliver PST-PC via telephone to adult clients identified as showing depressive symptoms.

To achieve the overall study objective, a multi-phase, mixed-methods approach was undertaken. In Phase 1, the evidence-base to support the integration of staff-delivered PST-PC in LVR services was delineated by conducting a review of the literature on depression and VI and a systematic review of the effectiveness of problem-solving interventions in this population. The findings underscored the need for pragmatic trials with longer-term follow-up to better understand the suitability of evidence-based problem-solving interventions delivered in routine LVR practice.

In Phase 2, the feasibility, acceptability and preliminary data for the effectiveness of PST-PC was investigated. Fourteen LVR staff were trained to deliver PST-PC following a 2-day training workshop and training cases under psychologist supervision. Training cases were 18 LVR clients who received 6 to 8 sessions of PST-PC and participated in a single-group pre-post intervention study. Post intervention, 67% of client participants demonstrated a clinically significant change (CSC; \textgeq5-point reduction on the Patient Health Questionnaire-9 (PHQ-9)) in depressive symptoms. PST-PC was found to be highly acceptable to clients with 83% reporting that they were very satisfied with PST-PC. Concerns were raised by both staff and clients regarding telephone delivery and the client retention rate for PST-PC was low (60% completed <6 sessions).

The main objective of Phase 3 was to investigate the clinical and cost-effectiveness of this model using a pragmatic, two-arm randomised controlled trial. Adult LVR clients with depressive symptoms (PHQ-9 score \textgeq5) were recruited from 28 LVR centres in
Australia and randomised to receive PST-PC plus usual care (N=81) or usual care alone (N=82; referral to a general practitioner). In the intention-to-treat (ITT) analysis of the primary outcome (reduced depressive symptoms at 6 months on the PHQ-9), a large treatment effect was found (Cohen’s d (d) = -0.81, 95% CI -1.15 to -0.46) and 40% of the intervention group achieved a CSC compared to 14% of controls (odds ratio (OR) 5.72, 95% CI 1.61 to 20.36). Treatment effects were not maintained at 12 months in ITT analysis, but a significant group difference was found using the per-protocol sample (completed ≥4 sessions; d=0.59, 95% CI -1.09 to -0.08). ITT analysis of the secondary outcomes found greater improvements in HRQoL (Assessment of Quality of Life; d=0.39, 95% CI 0.05 to 0.72) and vision-specific distress (Impact of Vision Impairment Questionnaire; d=0.40, 95% CI 0.07 to 0.73) in the intervention group at 6 but not at 12 months. The PST-PC model was cost-effective according to commonly used willingness-to-pay thresholds in Australia (incremental cost effectiveness ratio: AU$40,386 (bootstrapped 95% CI: 20,580 to 355,190) per quality-adjusted life years gained).

The aim of Phase 4 was to investigate and explore contextual factors associated with implementation of PST-PC in this setting. Given the low rate of participant retention with PST-PC in the RCT (79% completed <6 sessions), pre-treatment demographic, clinical and psychological predictors associated with early termination were investigated. 81 participants randomised to the intervention arm completed baseline and 6-month follow-up telephone assessments. Early termination was associated with being single (OR=8.77, 95% CI 2.15 to 35.66, p=0.002), having low perceived adequacy of social support (OR=0.48, 95% CI 0.30 to 0.75, p=0.001) and low acceptance of vision loss (OR=0.72, 95% CI 0.54 to 0.96, p=0.027).

Staff perspectives on the barriers and facilitators to PST-PC delivery were also explored in Phase 4. Guided by theoretical frameworks that seek to evaluate implementation research,13 14 22 key project staff participated in semi-structured qualitative interviews. Prominent barriers to delivery were a lack of role recognition for PST-PC practitioners (n=32), perceived unmet client expectation with PST-PC (n=28) and dissatisfaction with telephone-delivery (n=27). Facilitating factors included a recognised need for evidence-based psychological services (n=28), clients experiencing benefits in early sessions (n=38) and comprehensive PST-PC training (n=36).
In summary, this thesis supports the feasibility, clinical and cost-effectiveness of this integrated model for reducing depressive symptoms experienced by people attending Australian LVR centres. Strategies to improve retention with PST-PC are needed to ensure sufficient numbers achieve longer-term clinical benefit. Future research should also give attention as to whether staff-delivered PST-PC is scalable (or sustainable) and to developing services which are accessible to those who do not utilise LVR services (e.g. collaborative care models).
Declaration

This is to certify that:

i. the thesis comprises only my original work towards the PhD except where indicated in the Preface,

ii. due acknowledgement has been made in the text to all other material used,

iii. the thesis is fewer than 100 000 words in length, exclusive of tables, bibliographies and appendices.

Edith Holloway BA (Psych/Psychphys), BA Hons (Psych)
Preface

This thesis comprises original research that I have, for the most part, undertaken myself. This study was originally conceived by Dr Gwyneth Rees. Dr Gwyneth Rees and Professor Ecosse Lamoureux provided guidance and support with developing the study phases. Dr Jing Xie provided guidance with statistical analysis and interpretation of the data presented in Chapters 3, 5 and 6 and Professor Eric Finkelstein provided guidance with the cost-effectiveness analysis presented in Chapter 5.

Chapter 3 and Chapter 7 are multi-authored papers prepared specifically for inclusion in this thesis. As first author, I contributed more than 50% to the final manuscript including the design of the study, literature review, data collection, analysis and interpretation of results, writing the paper and integrating revisions by co-authors, submission of the articles to peer-reviewed journals, attending to reviewers’ comments, and proofing the final version of the manuscript prior to publication. The contributions of all co-authors are outlined below.

Chapter 3 – Identifying the evidence-base (systematic review of problem-solving interventions in VI)


The contribution of co-authors is as follows:

E Lamoureux and G Rees-Contributed to conception and design, manuscript editing and revisions, and final approval of the manuscript.

B Sturrock-Contributed to the literature searching, manuscript editing and revisions

J Xie-Contributed to the data analysis and interpretation, manuscript editing and revisions
Chapter 7 – Evaluating implementation (barriers and facilitators to delivering Problem-Solving Treatment)

**Holloway EE, Sturrock BA, Lamoureux EL, Keefe JE, Hegel MT, Casten R, Mellor D, Rees G.** Can we address depression in vision rehabilitation settings? Professionals’ perspectives on the barriers to integrating Problem-Solving Treatment. Disability and Rehabilitation. Accepted 16 Oct 2016.

**The contribution of co-authors is as follows:**

**E Lamoureux, D Mellor and G Rees**-Contributed to conception and design; manuscript editing and revisions, and final approval of the manuscript.

**B Sturrock**-Contributed to the data analysis and interpretation, manuscript editing and revisions.

**J Keefe, M Hegel and R Casten**-Contributed to manuscript editing and revisions.

**Chapters prepared as papers (under review)**

The following chapters were prepared as papers and are under review (or submitted for review). All co-authors listed contributed to manuscript editing and revisions.

**Chapter 4: Phase 2, Feasibility and piloting**


**Chapter 5: Phase 3, Effectiveness**

Chapter 6: Phase 4, Evaluating implementation (Factors associated with early termination)


Other publications arising from this study


Conference presentations

**Holloway E.** Xie J, Sturrock B, Lamoureux E, Hegel M, Casten R, Mellor D, Rees G. Improving engagement with Problem Solving Treatment for integrated depression management in low vision rehabilitation. 14th International Congress of Behavioral Medicine, Melbourne, Australia, Dec 2016 (selected from abstract).


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I gratefully acknowledge the National Health and Medical Research Council for awarding me a Postgraduate Scholarship and Australian Rotary Health for bestowing upon me an Ian Scott Mental Health postgraduate top-up – your generous support has allowed me to conduct this important research. I am grateful for the resources provided by the Centre for Eye Research Australia and the Royal Victorian Eye and Ear Hospital.

I would like to particularly acknowledge my parents who have always made sacrifices so that I could have endless opportunities. You have showed me what it means to work hard, never give up and to keep fighting – dad you have endured so much and shown this to be especially true in the last 24 months. During my candidature my husband and I welcomed our beautiful daughter Evolet. You made this experience near impossible through months of sleepless nights, particularly during the final writing phase - but also making it possible, motivating me, giving me a reason to laugh, and to remember the bigger picture every day. I would like to express my heartfelt thanks and appreciation to my husband, Paul. Your encouraging words, patience, love, and understanding have
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Abbreviations

ADLs  Activities of daily living
AMD  Age-related macular degeneration
CBT  Cognitive Behavioural Therapy
CERA  Centre for Eye Research Australia
CI  Confidence interval
CSC  Clinically significant change
DR  Diabetic retinopathy
HRQoL  Health-related quality of life
LVR  Low vision rehabilitation
M  Mean
OR  Odds ratio
PHQ  Patient Health Questionnaire
PST  Problem Solving Treatment
PST-PC  Problem-Solving Treatment for Primary Care
QALYs  Quality-adjusted life years
QoL  Quality of life
RCT  Randomised controlled trial
RVEEH  Royal Victorian Eye and Ear Hospital
SD  Standard deviation
SM  Self-management
VA  Visual acuity
VI  Vision impairment
Chapter 1: Introduction and overview of research

1.1 Statement of the problem

Worldwide, approximately 223 million people are blind or have vision impairment (VI). Vision loss has a myriad of negative consequences for the individual including reduced daily functioning, mobility and quality of life (QoL), which are further exacerbated by the co-occurrence of depression. Cross-sectional research suggests that around 7% of adults with VI will meet the criteria for major depressive disorder (MDD) and additionally around a third will experience subthreshold depressive symptoms (significant symptoms of depression that do not meet the criteria for MDD). To highlight the magnitude of this problem, 4% of the adult Australian population will meet the criteria for MDD and approximately 12% will additionally experience subthreshold depressive symptoms.

Challenges associated with detecting depression and barriers to accessing mental health services have been well documented in adults with VI. Empirical research indicates that as few as 20% of adults with VI and depressive symptoms receive evidence-based intervention and the outcomes for these individuals are not well understood. Developing accessible, effective and cost effective services to enhance early identification and treatment of depressive symptoms in people with VI is therefore crucial. Much of the research in this field has focused on the effectiveness of problem-solving interventions for preventing or reducing depression, given that problem-solving skills are associated with improved psychological health in this population. However, much work is needed. Notably, clinical trials have addressed questions of effectiveness, but tell us little about how interventions translate into real-world settings, for example the contextual factors (barriers, facilitators) that may arise when interventions are delivered in practice. These “implementation” issues are important to capture and largely determine the successful sustainability of a new health service.

A strong consensus has emerged calling for more integrated approaches in the health care system both in Australia and internationally, given the increasing presence of co-morbid mental health problems alongside long-term physical health conditions. In October 2009, the National Institute of Clinical Excellence (NICE) updated its depression treatment guidelines by including an emphasis on understanding and
treating the vulnerability to depression of people with functional impairment resulting from chronic physical illness. The guidelines recommended that health professionals identify those patients with subthreshold depression (or mild to moderate levels) and provide low-intensity intervention programs based on cognitive-behavioural therapy (CBT), centred specifically on problem-solving techniques. To date, research to support the adoption of the NICE clinical guidelines in LVR service provision is scarce.

**Problem-Solving Treatment for Primary Care (PST-PC)**

Problem Solving Treatment for Primary Care (PST-PC) is an evidence and skills-based treatment for depression which focuses on the acquisition and development of problem-solving strategies. A large body of empirical research supports the effectiveness of PST-PC for treating MDD and preventing the progression of subthreshold depressive symptoms in older adults and those with chronic health conditions.\(^{39-41}\) PST-PC was specifically developed to be used in busy clinical settings, delivered over a brief number of sessions (typically 6 to 8), and by a range of health care professionals including those without specialist mental health training.\(^42\) PST-PC can be delivered over the telephone\(^43\) or internet video\(^44\) with success, which may help to overcome practical barriers to accessing treatment for adults with VI. Given the strong evidence-base for the efficacy of PST-PC in reducing depressive symptoms in older adults, it is timely to determine the impact of PST-PC when implemented into *real-world* LVR setting.

**1.2 Aim and outline of thesis**

In this study, a new evidence-based integrated model of care was trialed within LVR services. The main study objective was to investigate the feasibility and effectiveness of PST-PC on clients’ level of depressive symptoms and person-centred outcomes as well as contextual implementation factors associated with delivery. LVR staff were trained to deliver PST-PC via telephone as part of rehabilitation service provision to those clients identified as showing depressive symptoms. This new model was designed to ensure that an effective psychological intervention is available and accessible at an early stage to those clients in need. To achieve this aim, this project evaluated PST-PC over four phases guided by the Medical Research Council (identifying the evidence base, feasibility/piloting, evaluation)\(^45\) and RE-AIM (Reach, Efficacy, Adoption)\(^46\) frameworks.
Chapter 2 and Chapter 3 provide a detailed review of the literature pertaining to VI and depression, identifying the research gaps and establishing the theoretical and empirical rational for an integrated model of care that promotes the use of problem-solving strategies. In Chapter 3 the first systematic review and meta-analysis to investigate the effectiveness of problem-solving interventions on depression and person-centred outcomes for adults with VI is presented. Chapter 4 describes the LVR staff training model and evaluates the feasibility, client acceptability and preliminary outcomes associated with telephone-delivered PST-PC using a pre-/post single group intervention study. In Chapter 5 the effectiveness and cost-effectiveness of PST-PC delivered by trained LVR practitioners on depressive symptoms and person-centred outcomes is rigorously investigated using a 2-arm, pragmatic randomised controlled trial. A novel component to this study was the evaluation of contextual implementation factors associated with PST-PC delivery in this setting (Phase 3). In Chapter 6, RCT data was evaluated in combination with qualitative semi-structured interviews to determine factors associated with early termination from PST-PC given the low rate of participant retention. Staff perspectives on the barriers and facilitators to delivering PST-PC are explored in Chapter 7 using a qualitative study design. Chapter 8 summarises the key findings presented in this thesis and discusses the strengths, limitations, and implications of the study. Areas for future research, specifically to enhance client engagement, facilitate wider-implementation, and the potential for collaborative care models are also discussed.

1.3 Study significance

This PhD study was developed to address a pressing need for evidence-based early interventions that are accessible, effective and cost-effective for people with VI and depressive symptoms. This study rigorously evaluates a new model of service provision within LVR services across Australia and examines the feasibility of delivering PST-PC, client outcomes, cost-effectiveness as well as implementation factors arising from delivery in this context. For the first time worldwide, LVR staff are trained to deliver an evidence-based psychological treatment for depression in a “real-world” national community-based LVR setting. The training of LVR professionals in the delivery of PST-PC via telephone as a first step in managing subthreshold, mild or moderate depressive symptoms has the potential to increase access to an evidence-based
psychological treatment in a manner that is likely to be more affordable for health care providers. This is particularly pertinent given the increasing global pressure for cost effective service delivery models. This study provides unique data on the implementation of the NICE clinical guidelines in a LVR setting. Importantly, the evidence gained in this study could be used to support wider implementation of this novel early intervention approach across a range of health care or community-based services in which depression has been identified as a pressing issue (e.g. diabetes, oncology and heart disease) and will provide the groundwork for enhancing integrated mental and physical health care models for people with VI and depression.
Phase 1: Building the evidence-base
Chapter 2: Vision impairment and depression. A review of the literature

2.1 The global burden of vision impairment: definitions, prevalence and impact

Vision impairment (VI), although largely avoidable, is a leading cause of disability worldwide affecting 223 million individuals and costing society $3 trillion globally in direct and indirect health care. VI refers to low vision and blindness, and includes any diagnosed condition of the eye or visual system that cannot be corrected to within normal limits, with refractive correction, medication, or surgery. The term ‘low vision’ is moderate or severe vision impairment and is defined by the World Health Organization (WHO) as visual acuity <6/18 but equal to or >3/60, or a corresponding visual field loss to less than 20°, in the better eye with best possible correction. In this doctoral project, ‘low vision’ is defined using established criteria (visual acuity (VA) <6/12 in the better eye, with correction), given that mild VI (<6/12 to 6/18) can have a significant impact on functional status (e.g. under Australian law a person with VA <6/12 would be unable to hold a drivers license), quality of life (QoL) and mental health. ‘Blindness’ is defined as VA <3/60, or a corresponding visual field loss to less than 10 degrees in the better eye with best possible correction. Globally, around 191 million people have moderate or severe VI and 32 million people are blind. VI will continue to be a major contributor to the global burden of disease as a result of socio-economic factors (i.e. uncorrected refractive errors in low-income countries) and the increasing aging population, which have the highest incidence of ocular conditions, such as age-related macular degeneration (AMD) and glaucoma.

In Australia, it is estimated that around 453,000 people are living with VI or blindness, the majority of whom are aged 50 years or older. The main causes of VI among Australians are uncorrected refractive error (63%) and cataract (17%). Other notable causes of VI are age-related macular degeneration (AMD), diabetic retinopathy (DR) and glaucoma. The annual economic cost of vision loss on the health system in Australia is estimated to be over $16 billion, ranked seventh among diseases, ahead of coronary heart disease, diabetes, depression and stroke. This is despite 90% of VI among Australians being preventable or treatable.
The prognosis and treatment options for ocular conditions that contribute to VI vary considerably; however, each condition presents unique challenges for the individual, health care system, and society. Refractive error is the leading cause of VI globally, despite the availability of cost effective treatment strategies (e.g. corrective glasses). VI due to uncorrected refractive error may have extensive social and economic impact, limiting educational and employment opportunities of otherwise healthy individuals. In AMD, which is the most common cause of blindness in developed countries affecting older people, disease progression can only be halted in about 10 to 15% of cases. Thus, the majority of older adults who are faced with AMD must adapt to ongoing and progressive visual loss which requires significant personal resources. Similarly, glaucoma (a leading cause of VI in adults over 40) often results in extensive and irreversible visual field loss or blindness due to the asymptomatic nature of the disease in the early stages. Because of its chronic nature, its potential for causing irreversible blindness, and the inherent side effects of the treatment, glaucoma often can impose a significant psychological burden to patients. DR is one of the most common causes of VI in working-age population in many countries and consequently, is associated with a significant socioeconomic burden. People with severe non-proliferative DR or proliferative DR have substantial difficulty undertaking vision-specific daily activities, contributing to a significant decline in QoL.

Regardless of the cause, VI is associated with functional disability and may restrict participation in both basic (e.g., functional mobility, getting dressed) and instrumental daily activities (e.g., driving, shopping, cooking), leading to reduced quality of life and placing individuals at an increased risk of mental health problems, most notably depression. Indeed VI affects individuals’ mental health and quality of life (QoL) more severely in comparison with other major chronic conditions including obesity and heart disease. One of the largest cross-sectional studies utilising national surveillance data in the USA examined quality of life in 60,807 respondents aged ≥65 years. Participants who self-reported moderate/severe VI had significantly more frequent physically unhealthy days, mentally unhealthy days, and activity limitation days and reported greater life dissatisfaction in the last 30 days compared to those reporting no VI.
2.2 The relationship between Depression and Vision impairment

2.2.1 Prevalence and consequences of depression in adults with VI

Depression is by far the most prevalent comorbid mental health condition in adults with VI and is much more widespread than general community adults without VI. Depression refers to a range of mental health problems characterised by the absence of positive affect (a loss of interest and enjoyment in ordinary things and experiences), low mood and a range of associated emotional, cognitive, physical and behavioural symptoms (see Appendix 1 for full Diagnostic and Statistical Manual of Mental Disorders 5th edition (DSM-5) definition). If left untreated, depressive symptoms may worsen over time, can exacerbate vision-related disability, decrease functioning and health-related QoL (HRQoL), contributing to a higher risk of premature mortality and greater health care costs (including hospitalisation and increased use of medical services).

It is estimated from cross-sectional studies that up to 43% of adults with VI will experience depressive symptoms and approximately 7% of these individuals will meet the criteria for Major Depressive Disorder (MDD) based on the DSM-5 criteria. Depressive symptoms that do not meet the criteria for MDD (termed subthreshold depression) are distressing and disabling if persistent, adversely affect levels of functioning, and are associated with an increased risk of developing MDD. Findings from longitudinal studies support cross-sectional associations found between VI and depression. Not only is VI associated with new onset of depression but the incidence of depression increases over time. For example, in a prospective cohort study, Rovner and Casten found the incidence of depression in older adults with bilateral AMD rose from 24% at baseline to 28% at 6-month follow-up without intervention. Studies that have looked at longer trajectories have reported similar results. In a population-based cohort study of 1,568 Australians aged ≥49 years, 27% and 32% of cases with VI at 5 and 10 years reported depressive symptoms.

2.2.2 Risk factors for depression in people with VI

Generic predictors of depression among older adults in the general community have also been reported in adults with VI. These include the presence of a physical health
condition, functional disability, poor self-perceived health, prior episodes of depression, lower levels of social support and female gender. Research studies with older adults with VI have generally failed to document a relationship between depression and the objective severity (e.g., measured by VA) and duration of vision loss. Rather, the literature underscores the importance of vision-related functioning and disability that result in restricted activities of daily living. Studies have shown that functional disability can increase the risk of developing depression and exacerbate depressive symptoms, while vision-related restriction of participation in daily living activities frequently leads to compromised vision-specific QoL. In addition, vision-specific distress, which refers to the emotional burden of managing the practical and social challenges of VI, has been identified as an important risk factor for depressive symptoms.

The association between VI and depression may also be determined by intrapersonal psychological factors, such as cognitive processes (e.g. illness cognitions) and coping responses. In a cross-sectional study of 873 LVR outpatient attendees across the Netherlands and Belgium, acceptance of vision loss was identified as a strong predictor of subthreshold depressive symptoms. Findings were validated with an Australian sample, using baseline data collected from this doctoral research study. Acceptance illness cognitions entail acknowledgement of low vision and confidence in living with and adapting to the limitations. Previous research has shown that illness cognitions also play an important role in protecting against depressive symptoms in the context of other chronic conditions.

The importance of adaptive coping responses to vision loss has also been highlighted as important in protecting mental health. A systematic review of 52 observational and cross-sectional studies investigating psychological adjustment to VI found that the use of instrumental coping (e.g. problem-solving) was associated with lower levels of depression. Research in other chronic health conditions also indicate that a person's confidence in their ability to cope (i.e., coping efficacy) is likely to be a key factor in determining psychological well-being. Baseline findings from this doctoral project published by our research group support this premise and found that lower self-efficacy in problem-focused coping amongst 163 LVR attendees was associated with greater depressive symptom severity. These findings suggest that interventions that enhance
the use of, and promote confidence in one’s ability to use adaptive coping strategies should be considered for this population to prevent or minimise depressive symptoms.

2.2.3 Adaptive coping using problem-solving improves psychosocial adjustment in VI

A substantial amount of research supports the importance of effective problem-solving for successful adjustment and coping in chronic illness. According to the theory proposed by Nezu, “problem-solving is an intervening variable that accounts to a significant degree for the causal relations between everyday problems and depression”. Problem-solving is considered a “coping strategy” involving the cognitive-behavioural processes through which an individual attempts to identify effective or adaptive solutions to cope with everyday problems. Effective problem-solving is hypothesised to reduce the negative impact of stressful life events (major negative events as well as daily problems) on well-being and to enhance positive functioning, whereas ineffective problem-solving is expected to increase the negative impact of stress on well-being (Figure 2.1). During the past three decades, numerous empirical studies have provided substantial support for these assumptions.

**Figure 2.1** Hypothesised model between problem-solving, stress and well-being (Nezu & D’Zurilla, 1989)
In adults with VI, the use of problem-solving strategies has been highlighted as beneficial for psychosocial adaptation to vision-loss.\textsuperscript{99} In a cross-sectional study, Dreer and colleagues\textsuperscript{30} investigated the association between problem-solving skills and psychosocial outcomes in adults participating in a low vision rehabilitation (LVR) program. Negative attitudes towards one’s ability to solve problems were associated with depression and emotional distress, whereas effective problem-solving abilities were linked to life satisfaction and optimal adjustment to vision loss. Effective problem-solving may also be protective over time. A seminal longitudinal study investigating predictors of adjustment among older adults with age-related macular degeneration (AMD) found that the use of problem-focused strategies predicted better psychosocial outcomes, such as reduced depressive symptoms, at 2-year follow-up.\textsuperscript{100}

### 2.3 Depression management in VI

#### 2.3.1 Challenges and barriers to the detection and management of depression in VI

The detection and management of depression in people with VI assumes great importance given the high prevalence and magnitude of associated consequences. However, currently there are limited and often fragmented services available to address the mental health needs of adults with VI. Nollett and colleagues found that 75\% of adults attending low vision rehabilitation clinics in the UK, with clinically significant depressive symptoms, were not receiving treatment.\textsuperscript{11} This is consistent with Australian research where only 20-25\% of patients attending tertiary eye clinics and LVR services with clinically significant levels of depressive symptoms were receiving any form of treatment for emotional problems.\textsuperscript{3,12,20}

Much emphasis has been placed on detecting depression in primary care settings. However, difficulties identifying depression in patients with chronic illness have been well-documented and patients with VI have been identified as a group in which depression is least likely to be recognised by general practitioners (GPs).\textsuperscript{101} In part, this is due to the symptomatic heterogeneity of depression and physical health problems, and the ongoing stigma that hinders many individuals from openly discussing their emotional well-being.\textsuperscript{102-104} Doctor-patient communication concerning emotional health has been highlighted as particularly problematic for older adults and those with sensory
Primary care professionals may also lack experience, perceive insufficient time to address depression during brief consultations, or focus on the physical rather than mental health problem, a phenomena known as “diagnostic overshadowing”. In the current Australian health system, only individuals meeting the diagnostic criteria for a clinical depressive disorder will be eligible for (Medicare) rebated treatment. As mentioned previously (Section 2.2.1) a large proportion of patients with VI show levels of depressive symptoms that do not meet full diagnostic criteria (known as sub-threshold depression). It is of great concern that currently there are no psychological service options available for this group. Furthermore, patient-identified barriers may impede access to psychological services, such as a lack of knowledge regarding available support, self-reliance (or stoicism), stigma and costs associated with mental health service utilisation. Physical impediments including mobility issues and a lack of transport have also been highlighted as problematic for adults with VI, older adults and those with long-term health problems.

2.3.2 Integrated depression management

The number of people living with a physical and mental health condition is rising rapidly, meaning that multi-morbidity and the challenges it brings for co-ordination of care are increasingly becoming the norm. If left untreated, mental health problems can significantly exacerbate physical illness and drive up the costs of care. In Australia, our health care system has been described as “robust” in responding to physical or mental health, but that neither system is easy to navigate; that they often work poorly together; and frequently provide inconsistent quality of health care that is neither cost-effective nor delivers optimal health outcomes across the population. Currently physical and mental health needs are addressed in a disconnected way and there is substantial evidence that the absence of integrated prevention and management strategies contributes to a greater burden of illness and disability.

To overcome this issue, it has been proposed that models of ‘integrated care’ be implemented. For example, the National Institute of Clinical Excellence (NICE) updated its depression treatment guidelines in 2009 (reviewed 2015) by including an emphasis on understanding and treating the vulnerability to depression of people with
functional impairment resulting from chronic physical illness. Greater attention, they argued, should be given to management of depressive symptoms that do not meet full diagnostic criteria (sub-threshold depression). The NICE guidelines recommend that health professionals identify those patients with sub-threshold depressive symptoms (or mild to moderate depression) and provide low-intensity psychosocial intervention programs based on the principles of cognitive-behavioural therapy (CBT), centred specifically on problem-solving techniques. The guidelines also recommend that these services be ‘co-ordinated or integrated within the current rehabilitation program’ for the specific physical health problem being treated.\textsuperscript{110}

The evidence-base for the effectiveness of integrated and collaborative models of care is increasing. Large international trials such as IMPACT\textsuperscript{111} and PROSPECT\textsuperscript{112} have shown that general health professionals (e.g. nurses) can be trained to screen and manage common mental disorders like depression effectively in older adults and those with diabetes. It has also been argued that the provision of integrated models for mental and physical health should not be limited to those people meeting formal diagnostic criteria for depression.\textsuperscript{113} As we know from previous studies conducted with patients who have AMD,\textsuperscript{114} physical health problems involve learning to live with a long-term condition, which may require a process of internal adaptation and can be accompanied by significant functional impairment and social isolation. From a person-centred approach, the provision of integrated psychological support may help people adapt and manage their health more effectively. Failure to do so can result in poorer outcomes and faster disease progression.\textsuperscript{113} Indeed, the case for addressing the mental health needs of people with VI in a more integrated way is compelling.

\textbf{2.3.3 What would an integrated approach look like?}

LVR services aim to address the restrictions posed by low vision and to enhance patient independence. Different models of low vision services exist and vary widely in content and intensity although the majority involves provision of aids, devices, and training to enhance use of residual vision. Psychological services, however, are infrequently offered as part of the rehabilitation program, predominantly due to limited resources.\textsuperscript{106,115,116} In the largest cross-sectional study to assess the frequency of psychological support to date, less than 5\% of service providers (\textit{N}=608) in the USA had a
psychologists working on site. In Australia, less than 20% of blindness or low vision service providers reported that their workforce included a psychologist.

New approaches to training and development are needed to create a workforce able to support the integration of mental and physical health. Specifically, the utilisation of existing workforce to provide cost-effective, early intervention for mental health problems has been advocated by health organisations and policy-makers alike. LVR staff are key health care providers for people with VI and previous work suggests that eye care and LVR professionals in Australia may be receptive to identifying and supporting clients with depression. Following a depression screening training program with 36 eye health and rehabilitation practitioners, staff were significantly more confident in working with patients who had depression and were significantly more likely to respond to depression in their patients for example, by providing written resources or discussing a referral to a GP. In a previous study conducted by our research group, a new depression screening system was implemented and evaluated in a national LVR setting. In this system, staff screen for depression and then refer clients with possible depression to their GP for a more detailed assessment. This is the first time a depression screening program has been introduced in a national LVR setting worldwide. However, screening and referral alone is not sufficient to change depression management or improve clinical outcomes. Feedback of depression screening results to GPs have shown limited impact on GPs subsequent management behaviour. In addition, clients referred from health services to external services for psychosocial support may not benefit from the referral due to a range of psychological, cost and logistical barriers to utilising this referral. However, if depression screening is combined with an integrated early intervention then improvements in client outcomes are seen and found to be as cost-effectiveness as other commonly performed preventative services such as mammography screening.

**2.3.4 Problem-Solving Treatment for Primary Care**

Problem Solving Treatment for Primary Care (PST-PC) is an evidence and skills-based treatment for depression derived from principles of cognitive behavioral therapy (CBT), the “gold standard” approach to the treatment of depressive disorders. PST-PC was specifically adapted and developed from traditional Problem-Solving Therapy to be used in busy clinical settings, delivered over a brief number of sessions (typically 6
to 8), and by a range of health-care professionals including those without specialist mental health training. PST-PC can be delivered over the telephone (or internet video) which may help to overcome practical barriers to accessing mental health services for adults with VI. In short, PST-PC promotes the rapid acquisition of seven problem-solving skills (Figure 2.2) that are introduced in the first session and reinforced in subsequent sessions. The therapist guides the client through problem-solving steps in order to improve their ability to cope with day-to-day practical challenges, thereby enhancing independence and functioning.

**Figure 2.2** The seven steps of Problem-Solving Treatment for Primary Care (PST-PC)

Research evidence supports the effectiveness of PST-PC for treating MDD and preventing the progression of subthreshold depressive symptoms in adults. PST-PC has also been shown to be efficacious in treating depression in older adults and patients with chronic medical problems such as diabetes, cancer and chronic pain. These studies have supported the effectiveness of PST-PC compared to pharmacological interventions, usual care and placebo. Given the important role of problem-solving for adjustment and psychological well-being in VI, the strong evidence-base for the efficacy of PST-PC in reducing depressive symptoms and the recommendations by
NICE, determining the effectiveness of PST-PC in routine LVR practice seems well-supported.

2.4 Study rationale, aims and hypotheses

2.4.1 Gaps in the literature

Best practice is to develop and implement interventions into routine care using the most robust evidence (and theory). To date, only one systematic review and meta-analysis has reported on the effectiveness of psychosocial interventions for improving the mental health of adults with VI. This review highlights the growing recognition of the need to address various psychological consequences of VI, particularly depression which generated the most published studies (n=19/22). However, the authors were unable to conclude that the interventions had a significant effect on depression. This may be attributable to the inclusion of non-randomised and single group studies which were assessed as having poor quality. Furthermore, the interventions were broad in focus (e.g. problem-solving treatment, expressive writing and peer-support), several of which have no theoretical or empirical basis for improving depression in this population.

Given the importance of problem-solving and psychological adjustment in VI, Chapter 3 describes the first systematic review and meta-analysis of published RCTs investigating the effectiveness of problem-solving interventions in people with VI. Taken together with Chapter 2, knowledge gaps were identified and used to shape the current study. Most notably, in the current body of literature problem-solving intervention effects have been studied only up to 6 months; however the longitudinal nature of depression in this population suggests the importance of determining maintenance effects. A rigorous RCT conducted in patients with VI resulting from AMD found a significant intervention effect of Problem-Solving Treatment compared to usual care in the short term (2 months), although effects were not sustained at 6 months. The authors argued that to produce sustainable effects at 6 months and beyond, this approach should be combined with “booster” or maintenance sessions and integrated into LVR care. Such integration will mean that PST-PC is incorporated into clients’ rehabilitation programs reducing practical and psychological barriers to uptake, and that maintenance sessions can easily be arranged and delivered as
an ongoing component of rehabilitation. A recent trial reporting on a stepped-care model with older LVR outpatients in the Netherlands and Belgium demonstrated a reduced incidence of depression in the intervention group at 2-year follow-up.\textsuperscript{138} However, the relative contribution of each step (including the offer of Problem-Solving Treatment at step 3) and the effectiveness of this model for reducing depression in those who are symptomatic cannot be extrapolated from their findings. Furthermore this trial exclusively investigated person-centred outcomes and did not evaluate factors associated with implementation (such as reach, uptake, barriers to implementation, cost-effectiveness).\textsuperscript{46}

Results from clinical trials that are better-designed\textsuperscript{26, 135-137, 138} focus exclusively on intervention efficacy. Efficacy trials are not designed to evaluate how interventions translate into practice, such as challenges and contextual factors which will impact upon implementation and delivery (e.g. reach, uptake, fidelity, barriers, and facilitators). Researchers have argued that pragmatic trials that demonstrate how to translate evidence into health service practice in a feasible and cost-effective way are required to bridge the evidence-practice gap.\textsuperscript{139} Pragmatic trials reflect more of the complexity and context of the real world, for example what type of clients will use the service.

The findings from existing studies are also limited in their generalisability. Most trials have been conducted with older adults (aged >60) with AMD, who predominantly have no co-morbid ocular conditions.\textsuperscript{27, 28, 140} The effectiveness of problem-solving interventions in individuals with other ocular conditions (e.g. diabetic retinopathy) and younger/working-age adults remains under researched and little is known about the suitability and effectiveness of problem-solving interventions in these groups. This will become increasingly pertinent, given that conditions such as diabetes (one of the most important risk factors for DR) is the fastest growing chronic condition in Australia.\textsuperscript{141}

2.4.2 Conclusion and study overview

Despite the widespread prevalence of depression and other psychosocial problems among adults with VI, few receive support or treatment for depression.\textsuperscript{101, 103-104, 116-118, 142}\textsuperscript{143} Challenges to identifying and managing depression and barriers to the receipt of care have been well-documented in this population yet few advancements have been made towards developing and integrating models of care into practice that can address these
issues. This doctoral research recognises a need to improve access to cost-effective early, evidence-based intervention in this population to prevent or minimise the progression of depression and improve or protect mental health. Therefore, the main objective of this PhD study was to investigate if telephone-delivered PST-PC administered by LVR practitioners and offered as an integrated component of LVR is feasible and effective for improving depressive symptoms and person-centred outcomes and to evaluate contextual factors associated with implementation. It is anticipated that this model of care could reduce practical and psychological barriers to the uptake of treatment for depressive symptoms in this population.

In line with the overall aim, this study was delivered over four phases using mixed-research methods (outlined in Figure 2.3). The use of mixed methods is critical to understanding trial results and the success or failure of implementation efforts. Specifically, qualitative methods were used to explore and obtain depth of understanding as to the barriers and facilitators of PST-PC delivery and to identify strategies for facilitating wider-implementation. In line with the Medical Research Council (MRC)\(^45\) (development, feasibility/piloting, evaluation) and RE-AIM\(^46\) (reach, efficacy, adoption, implementation, maintenance) framework, this project investigated person-centred outcomes (depression, health-related quality of life (HRQoL), emotional-distress) and implementation factors (intervention fidelity, qualitative methods to understand client engagement, barriers and facilitators to delivery). In brief, the MRC and RE-AIM frameworks were developed to evaluate and improve the sustainable adoption and implementation of evidence-based intervention and to improve their chances of working in “real-world” settings.
Figure 2.3 PhD research phases

| Phase 1 | Identifying the evidence-base (Chapter 2 and 3)  
*Design: Literature review, systematic review and meta-analysis*  
Identify the evidence-base for the effectiveness of problem-solving interventions and VI |
| --- | --- |
| Phase 2 | Piloting & Feasibility (Chapter 4)  
*Design: Single group pre/post intervention*  
Train staff in the delivery of PST-PC  
Investigate feasibility (recruitment/reach, retention/uptake)  
Explore client acceptability with staff-delivered PST-PC  
Gather preliminary evidence for the effectiveness  
Test procedures/intervention |
| Phase 3 | Effectiveness (Chapter 5)  
*Design: 2-arm, pragmatic RCT (pre-post and 6 and 12-month follow-up)*  
Depressive symptoms (primary outcome)  
HRQoL (secondary outcome)  
Vision-specific distress (secondary outcome)  
Cost-effectiveness |
| Phase 4 | Evaluating implementation (Chapter 6 and Chapter 7)  
*Design: RCT data, qualitative individual semi-structured interviews*  
Intervention fidelity (reported in Chapter 5)  
Qualitative methods to understand client engagement with PST-PC  
Barriers and facilitators to the delivery of PST-PC  
Factors important for wider-implementation (scale-up) |
2.4.3 Study objective, specific aims, and hypotheses

Main objective

The main objective of this doctoral research study was to investigate if telephone-delivered PST-PC administered by LVR practitioners and offered as an integrated component of LVR is feasible and effective for improving depressive symptoms and person-centred outcomes and to evaluate contextual factors associated with implementation.

Phase 1 (Identifying the evidence-base)

Aim
To systematically appraise published literature on the effectiveness of problem-solving interventions on depression and person-centred outcomes in adults with VI.

Phase 2 (Piloting and feasibility)

Aim 1
To successfully train 20 LVR staff to competently deliver PST-PC following the established training manual adapted for this setting. Competency is defined as achieving a score of ≥3 on the Problem-Solving Treatment for Primary Care Adherence and Competence Scale (PST-PC PAC) for three consecutively rated PST-PC sessions and completing at least one full training case (i.e. 6-8 PST-PC sessions).

Hypothesis:
Following training, 10 to 15 LVR staff will achieve competency in PST-PC delivery and commence Phase 3 as PST-PC practitioners.

Aim 2
Using a single-group pre/post study, gather preliminary evidence of the effectiveness of PST-PC on participants’ depressive symptoms and HRQoL.
**Hypotheses**

Participants will demonstrate significant reduction in depressive symptoms post-intervention from baseline (using 0.05 two-sided significance level). A clinically significant change (CSC) in depressive symptoms will be determined by a difference of ≥5-points on the 0-27 point scale of the Patient Health Questionnaire-9; PHQ-9).\(^{146,147}\)

Participants will demonstrate an improvement in HRQoL (assessed using the Assessment of Quality of Life instrument (AQoL-7D))\(^{148}\), specifically the global utility, vision-specific and mental-health domains. A clinically important difference (minimum increase of 0.06 from baseline to follow-up)\(^{149}\) and a statistically significant (\(p>0.05\)) mean change post-intervention compared to baseline will be considered as an improvement.

**Aim 3**

To evaluate patients’ views on the usefulness of PST-PC and their satisfaction with the new service using a semi-structured interview following the completion of the PST-PC sessions.

**Hypothesis**

On all quantitative measures, ≥80% of participants would rate each of the acceptability items favourably (i.e., rating of 4 or 5, where possible scores are 0-5 and higher scores indicate greater endorsement of the intervention).

**Phase 3 (Effectiveness)**

**Aim 1**

To determine using an RCT if telephone-delivered PST-PC is effective for reducing depressive symptoms (primary outcomes) compared to usual care alone at 6-month follow-up and to determine if these effects can be maintained in the longer term (12 months).
**Hypothesis**

Compared to participants who receive usual care, participants in the PST-PC group will report significantly fewer depressive symptoms assessed with the PHQ-9\(^{150}\) at 6-month follow-up. A ≥5-point reduction (and PHQ-9 score <10 at 6 months) was considered a CSC\(^{147}\).\(^{151}\)

**Aim 2**

To determine using an RCT if telephone-delivered PST-PC is effective for improving HRQoL and vision-specific distress at 6-months and to determine if these effects can be maintained in the longer term (12 months).

**Hypothesis**

Compared to participants who receive usual care, the intervention group will demonstrate a significantly greater improvement in HRQoL (AQoL-7D)\(^{148}\) and vision-specific distress (Impact of Vision Impairment Vision-Specific Distress subscale)\(^{152}\) with a moderate effect size (0.5) or greater determined using Cohen’s \(d\).

**Aim 3**

To determine if telephone-delivered PST-PC is cost-effective compared to usual care alone using incremental cost-effectiveness analysis.

**Hypothesis**

Compared to usual care, PST-PC will be cost-effective at the recommended willingness to pay threshold in Australia of AU$64000 per quality-adjusted-life-years (QALYs).\(^{153}\)
Phase 4 (Evaluating implementation)

Aim 1
To evaluate PST-PC practitioner competence and fidelity to the PST-PC protocol during the RCT using the PST-PAC.\textsuperscript{145}

**Hypothesis**
PST-PC practitioners will have a mean score of $\geq 3$ (satisfactory) on the PST-PAC overall fidelity scale.

Aim 2
Using mixed-methods, to investigate and identify predictors associated with early termination from PST-PC.

**Hypothesis**
Older age\textsuperscript{154}, a higher severity of depressive symptoms\textsuperscript{155} and low acceptance of one’s vision loss\textsuperscript{156} at baseline will be significantly associated with early termination.

Aim 3
To explore and identify staff-reported barriers and facilitators to the delivery of PST-PC using individual semi-structured qualitative interview developed using the Theoretical Domains Framework (TDF)\textsuperscript{13} and Consolidated Framework for Implementation Research (CFIR).\textsuperscript{14}
Chapter 3: Systematic review and meta-analysis of problem-solving interventions and vision impairment
Review

Do problem-solving interventions improve psychosocial outcomes in vision impaired adults: A systematic review and meta-analysis

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A B S T R A C T

Objective: To evaluate the effectiveness of problem-solving interventions on psychosocial outcomes in vision impaired adults.

Methods: A systematic search of randomised controlled trials (RCTs), published between 1990 and 2013, that investigated the impact of problem-solving interventions on depressive symptoms, emotional distress, quality of life (QoL) and functioning was conducted. Two reviewers independently selected and appraised study quality. Data permitting, intervention effects were statistically pooled and meta-analyses were performed, otherwise summarised descriptively.

Results: Eleven studies (reporting on eight trials) met inclusion criteria. Pooled analysis showed problem-solving interventions improved vision-related functioning (standardised mean change [SMC]: 0.15; 95% CI: 0.04–0.27) and emotional distress (SMC: −0.36; 95% CI: −0.54 to −0.19). There was no evidence to support improvements in depressive symptoms (SMC: −0.27, 95% CI: −0.66 to 0.12) and insufficient evidence to determine the effectiveness of problem-solving interventions on QoL.

Conclusion: The small number of well-designed studies and narrow inclusion criteria limit the conclusions drawn from this review. However, problem-solving skills may be important for nurturing daily functioning and reducing emotional distress for adults with vision impairment.

Practice implications: Given the empirical support for the importance of effective problem-solving skills in managing chronic illness, more well-designed RCTs are needed with diverse vision impaired samples.

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* Trial registration: This systematic review has been registered in the PROSPERO international prospective register of systematic reviews. The registration number is: CRD42014008978.

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0738-3991/ © 2015 Elsevier Ireland Ltd. All rights reserved.
1. Introduction

The psychosocial impact of vision impairment can be profound, placing individuals at increased risk of depression, reduced mental health and quality of life (QoL) compared to sighted peers [1–3]. The influence of vision impairment on functioning and restricted activities of daily living (ADLs), such as reading and driving, is one possible mechanism that increases the risk for depression and reduced QoL. Vision-related restriction of participation in daily living activities frequently leads to a compromised vision-related QoL, while functional disability can exacerbate depression [6–8]. Developing effective interventions that improve psychosocial outcomes may alleviate some of the patient burden associated with vision loss.

Internationally, guidelines have placed increasing emphasis on integrating evidence-based interventions into practice to improve patient-centred outcomes for chronic diseases [9,10]. Self-management (SM) programmes have become increasingly popular, adopting a group-based approach, with the aim of helping participants to take control of managing the consequences of their health condition. A critical component of SM training is to provide participants with the skills to problem-solve difficulties that they encounter [11]. Problem-solving involves the cognitive–behavioural processes through which an individual identifies and copes with everyday problems [12]. Effective problem-solving has been associated with optimal levels of adjustment and psychological well-being for patients and caregivers following chronic disease and disability [13,14].

Reviews of studies that have adopted SM programmes for chronic illnesses such as type 2 diabetes, arthritis and asthma have demonstrated significant improvements in disease management (e.g., reduced HbA1c in diabetic patients), decreased emotional distress and increased QoL following the intervention [15,16], although these findings are not consistent across studies nor chronic conditions [16]. Empirically supported treatments for depression, such as problem-solving therapy (PST), have also been effective in lowering distress, improving psychological outcomes, QoL and self-regulation among persons diagnosed with severe and chronic health problems (e.g., cancer, diabetes) [17,18], and have demonstrated better patient outcomes compared to no treatment, usual care and attention placebo [19].

Cross-sectional and longitudinal studies of adults participating in low vision rehabilitation programmes have shown that effective problem-solving strategies are linked to life satisfaction, optimal adjustment to vision loss and improved psychosocial outcomes, such as reduced depressive symptoms [20,21]. However, to date, no systematic reviews have assessed the role of problem-solving interventions to improve psychosocial outcomes in vision impaired adults. Therefore, the aim of this review was to systematically appraise published literature on the effectiveness of problem-solving interventions on depression, QoL, and functioning in vision impaired adults. A secondary aim was to explore intervention characteristics associated with optimal outcomes.

2. Methods

Methods reported on in this systematic review have been described according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (www.prisma-statement.org) [22,23]. A review protocol was specified in advance and registered on PROSPERO: an international prospective register of systematic reviews (CRD42014008978 http://www.crd.york.ac.uk/prospero).

2.1. Study selection

The inclusion criteria were defined according to the Patients, Interventions, Controls, Outcome (PICO) model [25]. Studies were included if they reported on participants aged 18 years and older with vision impairment (visual acuity 6/12 or worse in the better eye). Studies reporting data on problem-solving interventions, including problem-solving therapy and interventions based on problem-solving principles (e.g., self-management programmes that specifically highlighted the inclusion of problem-solving techniques) compared to alternative interventions (not based on problem-solving principles), usual care and no treatment were included. Only those studies that reported on outcomes assessing depression or mood, QoL or measures of vision-related functioning (i.e., ADLs) were included. Studies were limited to randomised controlled trials (RCTs) irrespective of follow-up duration. Two reviewers (E.H. and B.S.) independently read selected studies and made a decision whether the paper met the criteria for inclusion. Any disagreements were resolved by discussion and consensus.

2.2. Search strategy

PubMed (National Library of Medicine and National Institutes of Health), PsychINFO (a database of psychological literature), EMBASE (medical database), the Cochrane Library, National Institute for Health and Clinical Evidence (NICE) and Health Evidence Canada were searched using appropriate medical subject headings (MeSH) related to “low vision” and “problem-solving” (see Box 1 for detailed search strategy). A web search using google scholar was also performed. Searches were limited to the years from 1 January 1990 to 2 September 2013, English language articles and human subjects. Reference lists of relevant papers identified in the search were scanned for additional studies. Citations identified in the searches were imported to Endnote citation manager and duplicates were removed. Titles and
Box 1. Full search strategy for Embase including limits.

(“Problem-solving therapy” OR “Problem solving” OR “Problem-focused” OR “Problem-solving skills” OR “Problem-solving training” OR “Problem-solving treatment” OR PST OR “Problem-solving therapy for primary-care”) AND (glaucoma OR Retinopathy OR “Age-related macular degeneration” OR ARM OR Cataract OR “Impaired vision” OR “visually disabled” OR “vision impaired” OR “vision impairment” OR “vision disorder” OR blindness OR blind* OR “visual impairment” OR “low vision”) AND (“Activities of daily living” OR functioning OR “Quality of life” OR Depression OR “Depressive symptoms” OR Depress* OR Emotion* OR Adaptation OR Well-being OR QoL OR “Mental health” OR Adjustment OR Mood OR Affect OR Distress OR Dysthymia) NOT child* NOT adolesc* NOT youth.

2.3. Quality assessment

The quality of included studies was rated independently by two authors (E.H. and B.S.) using the Effective Public Health Practice Project Quality Assessment tool (EPHPP) [26]. The EPHPP tool was developed for use in public health to evaluate the study design of RCTs. This tool has been found to be acceptable for use in systematic reviews of effectiveness [27], has demonstrated excellent inter-rater reliability when compared to the Cochrane Collaboration Risk of Bias Tool (CCRBT) [28] and includes additional assessment of intervention fidelity, the presence of confounders and assessment of both the internal and external validity of data collection methods. These items are not directly assessed by the CCRBT. The tool assesses eight domains: (1) selection bias, (2) study design, (3) confounders, (4) blinding, (5) data collection method, (6) withdrawals/dropouts, (7) intervention integrity and (8) analysis. Guidelines (see Appendix A) for the EPHPP tool indicate that each domain be rated as strong (3 points i.e., low risk of bias), moderate (2 points; i.e., possible risk of bias) or weak (1 point; i.e., high risk of bias) and based on their total score, studies are assigned a quality rating of strong (low risk of bias with no weak ratings across domains), moderate (plausible bias that raises some doubt about the results or unclear risk of bias and at least one domain suggesting high risk) or weak (high risk of bias for two or more domains). Additional assessment of the method used to generate the allocation sequence, allocation concealment, reasons for attrition and selective outcome reporting were also conducted in accordance with the approach described in the Cochrane Handbook for Systematic Reviews of Interventions [29].

2.4. Data extraction

Data extraction (Table 1) was conducted independently by two reviewers (E.H. and B.S.) and included: (1) study design, (2)
Table 1
Characteristics of reviewed studies.

<table>
<thead>
<tr>
<th>Study Author, year</th>
<th>Study design (follow-up)</th>
<th>Sample</th>
<th>Problem-solving intervention</th>
<th>Control group(s)</th>
<th>Outcome measure: tool</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rovner et al. (2013) [43]</td>
<td>2-Arm RCT 3 and 6 months</td>
<td>Sample size: N=247 Setting, country: Retina Clinics, Philadelphia, USA Inclusion: patients with AMD; aged ≥65 years; bilateral AMD (neovascular and/or geographic atrophy); best-corrected visual acuity 20/70 to 20/400 in the better eye; moderate difficulty in valued vision-function goal. Exclusion: presence of uncontrolled glaucoma, diabetic retinopathy, or planned cataract surgery within 6 months; cognitive impairment; presence of a medical condition that would preclude participation; residence in a skilled nursing facility</td>
<td>Description: PST, manual driven [44] Goal: reduce vision-related task difficulty Format: individual in-home sessions Duration: no. of sessions not described (M=5.8, SD=0.8); frequency and length of sessions not described Provider: BA or MA qualified in social sciences and were trained by a clinical psychologist Fidelity: yes Homework assigned: yes</td>
<td>Description: supportive therapy (ST), manual driven Format: individual sessions Duration: no. of sessions not described (M=5.5, SD=0.5); frequency and length of sessions not described Provider: BA or MA trained in social sciences and were trained by a clinical psychologist</td>
<td>Primary outcomes Targeted Vision Function (TVF): The Activities Inventory Vision-related functioning: 25-item National Eye Institute Vision Function Questionnaire plus Supplement (NEI-VFQ). Secondary QoL: NEI-VFQ social functioning, mental health, role difficulty and dependency subscales Depressive symptoms: Patient Health Questionnaire-9 (PHQ-9)</td>
</tr>
<tr>
<td>Girdler et al. (2010) [42]</td>
<td>2-Arm RCT Post-intervention (T2) and 12 weeks (T3)</td>
<td>N=77 Setting, country: Association for the Blind, Western Australia, Australia Inclusion: aged ≥65; diagnosed with age-related vision loss; best corrected vision equivalent of ≤6/12 in both eyes; living in independently; had sufficient physical stamina, mental functioning, hearing and communication ability to attend the group intervention; were newly referred to the agency or had recontacted the agency after a significant deterioration in their vision (defined as ‘need for new low vision aids’)</td>
<td>Description: problem-solving model Goal: maximise remaining vision Format: group sessions (6-8 per group) Duration: 8-week (24h contact) Provider: occupational therapist and social worker Fidelity: no Homework assigned: yes</td>
<td>Usual care, assessment of service needs, visual assessment, referral to internal services (e.g., occupational therapy) and external service providers</td>
<td></td>
</tr>
<tr>
<td>Rovner et al. (2007) [36] Rovner and Casten (2008) [37]</td>
<td>2-Arm RCT 2 and 6 months</td>
<td>N=206 Setting, country: Retinovitreous Clinics of Wills Eye Hospital, Philadelphia, USA Inclusion: aged ≥64 years; neovascular AMD in one eye diagnosed within the preceding 6 months; pre-existing AMD in the fellow eye Exclusion: diagnosis of DSMIV defined depressive disorders or current receiving treatment for depression</td>
<td>Description: PST, manual driven [54] Goal: prevent depression Format: individual in-home sessions Duration: 6 sessions of 45–60 min (over 8 weeks) Therapist: 2 nurses, one master's level counselor Fidelity: no Homework assigned: unclear</td>
<td>Usual care (not described)</td>
<td>Primary outcomes Depression: DSM-IV diagnosis Depressive symptoms: Hamilton Depression Rating Scale (HDRS) (binary outcome = incidence/no incidence) Secondary outcome Vision disability: NEI-VFQ-17</td>
</tr>
<tr>
<td>Eklund et al. (2004, 2008) [38,39]</td>
<td>2-Arm RCT 28 Months</td>
<td>N=229 Setting, country: new referrals to low vision clinics, Sweden Inclusion: primary diagnosis of AMD; distance visual acuity of the better eye with best correction 0.1; aged ≥65 years; living independently; capable of group discussions Exclusion: none</td>
<td>Description: Problem-solving model Goal: to sustain and restore ADLs Format: group (4-6 per group) Duration: 8 weekly 2-h sessions Provider: OTs skilled in leading groups and trained in the theoretical foundations of programme Fidelity: no Homework assigned: yes</td>
<td>Individual programme, provision of visual aids, information about AMD, 1–2 1-h sessions at the clinic followed up by telephone contact within 2–4 weeks</td>
<td></td>
</tr>
</tbody>
</table>

Confounders
Age, sex, race, marital status, living arrangements, education, physical health status

Primary outcomes
Participation in life activities: Activity Card Sort (ACS) Depressive symptoms: Geriatric Depression Scale (GDS) QoL: SF-36 (physical and mental components)

Secondary outcomes
Vision disability: NEI-VFQ-17

Confounders
Age, gender, marital status, living arrangements, education, health conditions, previous use of low vision rehabilitation services, subjective vision impairment
Table 1 (Continued)

<table>
<thead>
<tr>
<th>Study Author, year</th>
<th>Study design (follow-up)</th>
<th>Sample</th>
<th>Problem-solving intervention</th>
<th>Control group(s)</th>
<th>Outcome measure: tool</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brody et al. [2006] [47]</td>
<td>3-Arm RCT 6 Months</td>
<td>N = 32 Setting, country: Ophthalmologists and AMD Registry, USA Inclusion: aged ≥60; AMD; visual acuity of &lt;20/60 in the better eye and &lt;20/100 other eye with habitual correction; adequate hearing; diagnosis of DSM-IV defined major or minor depressive disorder; score ≥5 on GDS-15 Exclusion: vision loss due to other eye disease; cognitive impairment; current alcohol abuse</td>
<td>Description: problem-solving techniques Goal: reduce depressive symptoms Format: group (8–10 per group) Duration: 6-weekly 2-h group sessions Provider: experienced professional in public health and behavioural medicine Fidelity: not described Homework assigned: not described</td>
<td>(1) Tape recorded education, 12-h of audio of health lectures on AMD and health ageing to be listen to during a 6-week period (2) Wait-list controls</td>
<td>Primary outcome Depression: Structured Clinical Interview for DSM-IV Depressive symptoms: GDS-15</td>
</tr>
<tr>
<td>Brody et al. [2005] [41]</td>
<td>3-Arm RCT Post-intervention and 6 months</td>
<td>N = 231 Setting, country: Ophthalmologists and AMD Registry, USA Inclusion: aged ≥60; AMD; visual acuity of &lt;20/60 in the better eye and &lt;20/100 other eye with habitual correction; adequate hearing Exclusion: vision loss due to other eye disease; cognitive impairment; current alcohol abuse</td>
<td>Description: problem-solving strategies Goal: improve mood and functioning Format: group (8–10 per group) Duration: 6-weekly 2-h group sessions (12h in total) Provider: an experienced professional in public health and behavioural medicine Fidelity: no Homework assigned: not described</td>
<td>(1) Tape recorded education, 12-h of audio of health lectures on AMD and health ageing to be listen to during a 6-week period (2) Wait-list controls</td>
<td>Primary outcome Emotionless distress: POMS</td>
</tr>
<tr>
<td>Ivanoff et al. [2002] [46]</td>
<td>2-Arm RCT 4-Month post-intervention</td>
<td>N = 253 Setting, country: low vision optical clinic, Sweden Inclusion: aged ≥65 years; AMD; distance visual Acuity of the better eye with best correction &gt;0.1; living independently Exclusion: none</td>
<td>Description: problem-solving model Goal: foster problem-solving to sustain and restore ADLs Format: group (4–6 per group) Duration: 8-weekly 2-h group sessions Provider: OTs skilled in leading groups and trained in the theoretical foundations of programme Fidelity: no Homework assigned: not described</td>
<td>Standard intervention programme: provision of optical aids; information about AMD provided on request Format: individual Duration: 1–2 1-h sessions + follow-up calls over 4 weeks Facilitator: OT with special training in low vision</td>
<td>Primary outcome ADLs: perceived security in performing daily occupations</td>
</tr>
<tr>
<td>Brody et al. [1999] [45]</td>
<td>2-Arm RCT Intervention group: 6-week post-intervention Controls: prior to commencing intervention and post-intervention</td>
<td>N = 54 Setting, country: University Ophthalmology Clinic, USA Inclusion: aged ≥60 years; AMD; best corrected vision of 20/200 Exclusion: vision loss due to other eye disease; psychiatric conditions; cognitive impairment</td>
<td>Description: problem-solving techniques Goal: empower participants to improve their quality of life within the context of their visual impairment Format: group (7–10 per group) Duration: 6-weekly 2-h group sessions Provider: not described Fidelity: no Homework assigned: not described</td>
<td>Wait-list control</td>
<td>Primary outcome Emotional distress: POMS</td>
</tr>
</tbody>
</table>

PST, problem-solving therapy; NEI-VFQ, National Eye Institute Vision Function Questionnaire; Qol, quality of life; ADLs, activities of daily living; GDS, Geriatric Depression Scale; PNAS, positive and negative affect scale; HDRS, Hamilton Depression Rating Scale; POMS, profile of mood states; DSM-IV, Diagnostic and Statistical Manual of Mental Disorders Fourth Edition; SCID, Structured Clinical Interview for DSM-IV Axis I Disorders; RP, relative position.

characteristics of participants, (3) details of the problem-solving interventions, (4) control group(s), (5) measured outcomes and (6) results.

2.5 Quantitative data synthesis

Study identification (author, year) and outcome measures were extracted using a customised data extraction form. For each outcome measure, the number of participants in the intervention and the control groups and the mean change from baseline and standard deviation (SD) of mean changes were extracted. When the SD was not available in an explicit format, it was estimated from the standard error (SE), confidence interval, the p-value, the inter-quartile range, or other methods as recommended by the Cochrane Collaboration [29]. As described by Morris [31], the standardised mean change was computed (with raw score
standardisation) for the intervention and control group. Substantial diversity in the outcome measures was found in the eligible trials. For each study, we calculated the between-group difference in change scores (changes from baseline) and divided this difference by the standard deviation of change. This calculation creates a unitless measure of the effect (quantifying its magnitude in number of standard deviations), also called effect size (ES), that allows for comparison and pooling across trials. For each outcome measure, we reported the estimate of ES and the associated 95% confidence interval (CI). We used Cohen’s categories for classifying effect sizes: 0.20 = small, 0.50 = medium, 0.80 = large [32].

Meta-analyses were performed using R Package ‘metafor’ [version 1.9-4] [33]. Egger’s test was used to assess publication bias among the included trials. A probability of \( p < 0.05 \) was regarded as statistically significant. The assessment for statistical heterogeneity was calculated using the \( \chi^2 \) and \( I^2 \) tests. Heterogeneity was assessed by the \( I^2 \) statistic describing the percentage of variation across studies due to heterogeneity rather than chance [34,35]. A value of 0.25% corresponds to low, 0.50% to moderate and 0.75% to high heterogeneity. A fixed-effects model was applied only in the absence of heterogeneity. If the \( p \)-value for the \( \chi^2 \) test was \( <0.1 \) or the \( I^2 \) value was \( >50\% \), there was substantial evidence of heterogeneity. A random-effects model should be applied in a corresponding meta-analysis when the source of heterogeneity cannot be found.

Where insufficient data prevented the pooling of data across trials, descriptive analysis instead of meta-analysis is reported.

3. Results

3.1. Search results

The number of identified and excluded studies at each stage is presented in Fig. 1. Overall, 1351 studies were identified through the initial search, of which 1171 titles and abstracts were reviewed. From these, 45 full-text articles were retrieved for full review of the inclusion criteria. A total of 11 articles reporting on 8 RCTs met the inclusion criteria and were included in this review. Articles that reported on findings from the same trial (and sample) were merged (i.e., [36–41]).

3.2. Study characteristics

The number of participants in the RCTs ranged from 32 to 241 (total \( n = 1159 \)), of which 3 studies (38%) had a sample size \( <100 \) (Table 1). The mean age of the participants ranged from 79 years [42] to 83 years [43]. All studies included participants with a diagnosis of age-related macular degeneration (AMD) as an inclusion criterion; however, one study [42] enrolled participants with other age-related causes of vision loss which comprised 21% of the total study sample (\( n = 9/77 \)). For studies that reported baseline visual acuity, the mean Logarithm of the Minimum Angle of Resolution (LogMAR) distance acuity in the better eye was 0.83 (approximately 6/40) with a range of 0.56–1.43 (approximately 6/20–6/160; where presenting distance visual acuity of 6/18–6/60 is categorised as moderate vision impairment and worse than 6/60 is categorised as severe). There was an overall participant attrition rate of 28% from baseline to the final follow-up time point which ranged from 6 weeks to 28 months. Reasons for loss-to-follow up were reported in 50% of the trials [36,38,40,42] and were primarily due to illness/poor health or mortality.

3.3. Problem-solving interventions

The problem-solving interventions (Appendix B) delivered in the studies were categorised as: (1) manual-driven problem-solving therapy (PST) or (2) problem-solving skills training incorporated into self-management or health-promotion programmes. In the two trials that reported on PST [36,43], trained therapists including nurses- and masters-level counsellors delivered the intervention according to the manual developed by Hegel and Arean [44]. PST was delivered individually and face-to-face in the participant’s home. Participants completed an average 5.9 sessions of 45–60 min duration (over 8 weeks). PST was compared to supportive therapy [43] or usual care [36], which was not described.

Six trials incorporated problem-solving skills training into self-management or health-promotion programmes and were all delivered in group settings, with the number of participants in each group ranging from 3 to 8. The number of sessions also varied from 3 to 8 with the duration of session being 2–3 h. Providers of the intervention included occupational therapists, nurses, individuals with a background in clinical psychology and experienced professional in public health and behavioural medicine. One study did not describe who delivered the intervention [45]. Comparison groups ranged from usual care [38,42,46], to 3-armed trials, which compared the problem-solving intervention to audio information sessions and a wait-list control group [40,47]. Overall, in three [38,42,43] of the eight trials homework tasks were assigned to the problem-solving intervention group.

3.4. Methodological quality

The methodological quality of the eight RCTs is summarised in Table 2. Four trials were judged to be at low risk of bias [40,42,43,47], one as moderate (or unclear) [36], and three to be at high risk of bias [38,45,46]. Most studies appeared to use good methodological rigour in their data collection methods; however, baseline group comparisons were reported in less than half of the studies. Only three RCTs [36,40,43] described the method used to generate and conceal the allocation sequence and only one [40] trial appeared to carry out adequate blinding. Attrition bias was present in two trials [38,46], in which one [46] may have significantly impacted on the results (i.e., assigned a weak rating). In addition, selection and analytical bias were also present across most studies; however, the risk of selective outcome reporting was low across most studies. Only three RCTs [36,42,43] used intention-to-treat analyses and two described procedures for intervention fidelity [36,43].

3.5. Outcome analysis

We first calculated the standardised mean change (SMC) (with raw score standardisation) for the intervention and control group [31] (Table 3). Data for three outcomes (depressive symptoms, emotional distress and functioning) extracted from six trials [36,40,42,43,45,47] were sufficiently reported and pooled in meta-analyses. Four studies included in meta-analyses were judged to be of good methodological quality (i.e., low risk of bias).

Pretest–posttest correlations (\( r \)) were not reported in most studies, so we assumed that the pretest–posttest correlations were the same for the intervention and control groups. Approximate values of 0.6 were substituted, based on known properties of the dependent variable being measured, and a sensitivity analysis (\( \rho = 0.8 \); as described by Morris [31]) was conducted to ensure that the conclusions from the meta-analysis are unchanged when those correlations varied (Table 4).

3.5.1. Depressive symptoms

Three trials assessed depressive symptoms [42,43,47] and one trial [36] made a formal diagnosis of depression according to the Diagnostic and Statistical Manual of Mental Disorders, Axis, I, Fourth Edition [48]. A lower SMC across trials indicated a greater improvement in depressive symptoms for the treatment group.
<table>
<thead>
<tr>
<th>Study Author, year</th>
<th>Selection bias (1) Representative sample (2) Participation rate</th>
<th>Study design (1) Design (2) Method used to generate allocation sequence described (3) Method used to conceal allocation concealment described</th>
<th>Confounders (1) Between group differences reported at baseline (2) Confounders controlled for</th>
<th>Blinding (1) Outcome assessors masked (2) Participants blinded (3) Key personnel blinded</th>
<th>Data collection methods (1) Data collection tools valid (2) Data collection tools reliable (3) Consistency in outcome assessments</th>
<th>Incomplete outcome data (withdrawals and dropouts) (1) Attrition rate (2) Reasons reported</th>
<th>Intervention integrity (1) % that received intervention (2) Consistency of intervention measured (3) Likely contamination of control group</th>
<th>Analysis (1) Appropriate analysis undertaken (2) Intention-to-treat analysis used (3) Sample size calculation reported</th>
<th>Selective outcome reporting (1) Results for all key outcomes appropriately reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rovner et al. (2013) [43]</td>
<td>Moderate (somewhat; 64%)</td>
<td>Strong (RCT; yes; yes)</td>
<td>Moderate (baseline data reported but no p-values for between-group differences; stratified by severity of AMD only)</td>
<td>Moderate (yes; insufficient information; no – statistician aware of treatment assignment, possible risk of bias)</td>
<td>Moderate (yes; TVF poor test-retest reliability; likely)</td>
<td>Moderate (13%; no)</td>
<td>Strong (100%; yes; no)</td>
<td>Strong (yes; yes)</td>
<td>Strong (yes)</td>
</tr>
<tr>
<td>Girdler et al. (2010) [42]</td>
<td>Moderate (somewhat; insufficient information)</td>
<td>Moderate (RCT; yes; no)</td>
<td>Strong (yes – no differences)</td>
<td>Strong (yes; yes; likely)</td>
<td>Strong (3%; yes)</td>
<td>Moderate (81%; insufficient information; insufficient information)</td>
<td>Strong (yes; yes; strong)</td>
<td>Strong (yes; yes)</td>
<td>Strong (yes)</td>
</tr>
<tr>
<td>Rovner et al. (2007) [36]</td>
<td>Weak (somewhat; 34%)</td>
<td>Strong (RCT; yes; yes)</td>
<td>Moderate (yes – however potential variables associated with primary outcome (e.g., previous history of depression was not controlled for))</td>
<td>Strong (yes; yes)</td>
<td>Strong (18%; yes)</td>
<td>Moderate (89%; insufficient information; insufficient information)</td>
<td>Strong (yes; yes; insufficient information)</td>
<td>Strong (yes; yes)</td>
<td>Strong (yes)</td>
</tr>
<tr>
<td>Eklund et al. (2004, 2008) [38,39]</td>
<td>Moderate (somewhat; 73%)</td>
<td>Moderate (RCT; yes; no)</td>
<td>Moderate (yes; no – group differences reported at baseline which were not controlled for in subsequent analyses)</td>
<td>Weak (no; insufficient information; insufficient information)</td>
<td>Strong (yes; yes)</td>
<td>Moderate (43%; yes)</td>
<td>Moderate (89%; insufficient information; insufficient information)</td>
<td>Moderate (yes; no; no)</td>
<td>Strong (yes)</td>
</tr>
<tr>
<td>Brody et al. (2006) [47]</td>
<td>Strong (yes; insufficient information)</td>
<td>Moderate (RCT; yes; no)</td>
<td>Strong (yes – however small sample size limited exploration of potential confounders such as antidepressant use)</td>
<td>Moderate (yes; no – insufficient information if aware of research question; insufficient information)</td>
<td>Strong (yes; yes)</td>
<td>Strong (15%; no)</td>
<td>Moderate (93%; insufficient information; insufficient information)</td>
<td>Strong (yes; yes; strong)</td>
<td>Strong (yes)</td>
</tr>
<tr>
<td>Brody et al. (2002, 2005) [40,41]</td>
<td>Strong (yes; 93%)</td>
<td>Moderate (RCT; yes; yes)</td>
<td>Strong (yes – no differences)</td>
<td>Strong (yes; yes; likely)</td>
<td>Strong (3%; yes)</td>
<td>Strong (8%; yes)</td>
<td>Moderate (93%; insufficient information; insufficient information)</td>
<td>Strong (yes; yes; insufficient information; no)</td>
<td>Strong (yes);</td>
</tr>
<tr>
<td>Ivanoff et al. (2002) [46]</td>
<td>Moderate (somewhat; 73%)</td>
<td>Moderate (RCT; yes; no)</td>
<td>Strong (yes – no differences)</td>
<td>Weak (no; insufficient information; insufficient information)</td>
<td>Strong (yes; yes; likely)</td>
<td>Weak (25%; no)</td>
<td>Unclear (insufficient information – numbers allocated to each group at randomisation not reported; insufficient information; insufficient information)</td>
<td>Moderate (yes; no; no)</td>
<td>Strong (yes)</td>
</tr>
<tr>
<td>Study</td>
<td>Author, year</td>
<td>Overall rating</td>
<td>Weak (yes/no)</td>
<td>Moderate (0%-25%)</td>
<td>Moderate (25%-50%)</td>
<td>Moderate (50%-75%)</td>
<td>Moderate (75%-100%)</td>
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<tr>
<td>E.E. Holloway et al. (1999)</td>
<td>[45]</td>
<td>Overall rating: weak</td>
<td>Moderate (0%-25%)</td>
<td>Moderate (25%-50%)</td>
<td>Moderate (50%-75%)</td>
<td>Moderate (75%-100%)</td>
<td>Weak (yes/no)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3.5.2. Vision-related functioning

Seven trials assessed vision-related functioning with the National Eye Institute Visual Function Questionnaire being the most frequently utilised measure. A higher SMC score across all trials indicated greater improvements in functioning for the treatment group compared with controls. Sufficient information was available in five trials [36,40,42,43,47] for a pooled analysis and showed that compared with controls, the problem-solving intervention had a small but significant effect in improving functioning (SMC: 0.15; 95% CI: 0.04–0.27, p = 0.01) (Fig. 3). Of the remaining trials [38,46], a statistically significant improvement in functioning compared to controls were reported in one trial [38], while there was insufficient data to allow group comparisons in the second [46]. When stratified by depression status, the intervention compared to controls was found to have a moderate (d = 0.42) effect on improving functioning in those with depression post-intervention. There was no significant effect for non-depressed participants.

3.5.3. Emotional distress

Two trials [40,45] reported on emotional distress using the Profile of Mood States scale. A lower SMC score indicates greater improvements in emotional distress. There was a significant effect of the intervention for improving emotional distress (SMC: −0.36; 95% CI: −0.54 to −0.19; p < 0.001) (Fig. 4). When stratified by depression status, Brody et al. [40] reported that the problem-solving intervention had a short-term (post-intervention) significant effect (d = 0.75) on improving emotional distress in depressed participants. This was maintained at 6-month follow up (d = 0.86) [41].

3.5.4. Quality of life

Three trials investigated QoL as an outcome [42,43,45]. Although statistically significant (physical p = 0.005; mental p = 0.019), the problem-solving intervention had no clinically relevant effect on improving QoL post-intervention (both d < 0.2) and only a small effect for the “physical” QoL subscale at 12-week follow-up (d = 0.23) [42]. The remaining two trials provided insufficient data [43,45].

3.5.5. Association between functioning and depression

Of the four RCTs [36,42,43,47] that investigated both depression and functioning as independent outcomes, one trial [36] explored the mediating association of functioning on depression. After controlling for vision-related functioning, the problem-solving intervention was no longer associated with depression (p > 0.05) suggesting that the intervention reduced the odds of depression to the extent that it prevented loss of a valued activities.

3.5.6. Intervention characteristics associated with improved outcomes

Of the studies that were deemed to have a strong quality rating [36,40,42,43,47], three trials delivered the intervention in a group setting over 6-8 sessions, while in the remaining two, the intervention was delivered individually and face-to-face. Girdler et al. [42], who reported significant improvements in both depressive symptoms and functioning in the intervention group, included a practical component that allowed participants to practice ways in which the problem-solving model could be applied in the home environment.
Table 3
Effect of problem-solving interventions on depressive symptoms, functioning and emotional distress.

<table>
<thead>
<tr>
<th>Study</th>
<th>Problem-solving group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>Follow-up</td>
</tr>
<tr>
<td></td>
<td>N</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Depression symptoms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rovner and Casten (2013)</td>
<td>121</td>
<td>1.40 (2.30)</td>
</tr>
<tr>
<td>Rovner et al. (2007)</td>
<td>36</td>
<td>10.58 (4.12)</td>
</tr>
<tr>
<td>Brody et al. (2006)</td>
<td>12</td>
<td>7.50 (2.35)</td>
</tr>
<tr>
<td>Vision-related functioning</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rovner and Casten (2013)</td>
<td>121</td>
<td>2.71 (0.52)</td>
</tr>
<tr>
<td>Rovner and Casten (2008)</td>
<td>121</td>
<td>66.2 (14.3)</td>
</tr>
<tr>
<td>Brody et al. (2007)</td>
<td>105</td>
<td>34.28 (14.12)</td>
</tr>
<tr>
<td>Emotional distress</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brody et al. (2002, 2005)</td>
<td>86</td>
<td>60.61 (29.96)</td>
</tr>
<tr>
<td>Brody et al. (1999)</td>
<td>86</td>
<td>60.84 (29.96)</td>
</tr>
</tbody>
</table>

Table 4
Sensitivity analysis for the meta-analyses using different pretest–posttest correlations (r).

<table>
<thead>
<tr>
<th>r</th>
<th>Depressive symptoms</th>
<th>Vision-function</th>
<th>Emotional distress</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SMC (95% CI)</td>
<td>p</td>
<td>SMC (95% CI)</td>
</tr>
<tr>
<td>0</td>
<td>–0.21 (–0.60, 0.18)</td>
<td>0.291</td>
<td>0.15 (–0.03, 0.332)</td>
</tr>
<tr>
<td>0.4</td>
<td>–0.25 (–0.64, 0.14)</td>
<td>0.214</td>
<td>0.15 (0.01, 0.29)</td>
</tr>
<tr>
<td>0.6</td>
<td>–0.27 (–0.66, 0.12)</td>
<td>0.173</td>
<td>0.15 (0.04, 0.27)</td>
</tr>
<tr>
<td>0.8</td>
<td>–0.29 (–0.67, 0.08)</td>
<td>0.127</td>
<td>0.15 (0.07, 0.24)</td>
</tr>
</tbody>
</table>

SMC, standardised mean change.

4. Discussion and conclusions

4.1 Discussion

This review is the first systematic synthesis of studies that have investigated the effect of problem-solving interventions on psychosocial outcomes in vision impaired adults. Due to a small number of methodologically rigorous studies and their sample inclusion, we were unable to draw strong conclusions regarding the benefits of problem-solving interventions in this population. A lack of homogenous outcome measures and a variety of intervention types also makes interpretation of these findings complex, however problem-solving interventions do appear beneficial in improving functioning and reducing emotional distress in vision-impaired adults.

We found no overall effect of problem-solving interventions for improving depressive symptoms. Reviews on the effectiveness of SM programmes for improving depression in other chronic illnesses are mixed [16,17], and this may be due to a limited number of good quality trials, variable content across problem-solving interventions and an emphasis on different objectives of

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![Fig. 2](image2.png)

**Fig. 2.** Forest plot of effect of problem-solving interventions on depressive symptoms.

![Fig. 3](image3.png)

**Fig. 3.** Forest plot of effect of problem-solving interventions on vision-related functioning.
the interventions across chronic conditions. Clear evidence for improvements in depression following problem-solving therapies have previously been reported [48], and more recently, established in depressed older adults [50]. Our null findings may in part be explained by the sample inclusion of selected trials. With the exception of Brody et al. [47], who found a large effect of the intervention on depression, mean depression scores at baseline for included trials fell within the normal range (i.e., no or minimal depressive symptoms). Therefore, any reduction in depressive symptoms post-intervention may not hold much clinical relevance. Furthermore while the rate of depression is higher in adults with vision impairment compared to the general population [51], individuals recruited into SM programmes and psychosocial interventions might have lower levels of depression [52]. In contrast, we found a significant effect of the problem-solving interventions for improving emotional distress. In light of the available evidence, further research on the effectiveness of problem-solving interventions in individuals with varying degrees of depressive symptomology is warranted.

In line with the results of a previous review [16], which looked at the effects of self-management interventions on asthma, arthritis and diabetes, we found the problem-solving interventions has a small but significant effect on functioning, and this association was magnified in depressed sub-groups. The relationship between diminished functioning and depressive symptoms is often reported on in the literature [4,53] and, although we were unable to draw conclusion about the mechanisms of this association, one well-designed study found that functioning mediated the association between problem-solving and depression. Problem-solving skills may help individuals regain a sense of control over their situation by developing realistic appraisals of their disability, which may in turn improve their level of depression.

Despite its widespread assessment in ophthalmic and chronic disease literature, only one study with a strong quality rating included QoL as an outcome and found little improvement following the intervention. The relationship between problem-solving interventions and quality of life is not well understood and this has been highlighted previously [16]. Because QoL is comprised different domains (i.e., social, physical, and psychological), it is possible that variability in QoL measures and variation in the types of interventions used limited their impact on QoL. Further research is needed to understand the complex relationship between problem-solving interventions and quality of life and studies should seek to refine a uniform clinical measurement of QoL.

Characteristics of the problem-solving interventions associated with improved outcomes could not be analysed in this review owing to insufficient information provided, and the small number of included trials. However, the optimal number of sessions and format of delivery should be investigated in future RCTs. Findings from previous literature point to a possible dose-effect [54] which may diminish over time [55,56]. These factors would have important implications on client outcomes.

The methodological quality of included trials is an important limitation of this review. Only half of the included trials were judged to be at low risk of bias and few were adequately powered. Several studies conducted completers-only analyses, which have been found to overestimate the intervention effects [57]. Intervention fidelity (or adherence) was only described in two RCTs. Guidelines for the reporting of interventions (TIDIER – template for intervention description and replication) [58] recommend that trials also assess and describe intervention fidelity and adherence procedures as this is an important source of variation affecting the credibility and utility of research [59]. A lack of intervention fidelity can weaken outcomes, leading to improper conclusions about the effectiveness of the intervention [60].

Other methodological weaknesses of the included studies pertain to the method of assessment of outcomes. Rovner et al. [43] reported poor test–retest reliability for one measure of vision-functioning (TVF scores). Furthermore, recent studies have shown that the National Eye Institute Visual Functioning Questionnaire-25 is not psychometrically optimal for assessing overall functioning due to multidimensionality (i.e., an emotional well-being domain) [61]. Transformed scores that have undergone item-response theory, such a Rasch analysis, could be used for future application as this would ensure that items grouped under ‘vision-functioning’ for the NEI-VFQ was a psychometrically valid construct.

There was also considerable diversity in the ascertainment of outcome measures making comparisons in findings across trials complex. For example, some studies used a formal diagnostic interview schedule to determine depression, whereas others used scales to determine level of depressive symptoms which are not comparable. The inclusion of studies based on depressive symptoms alone, without a formal diagnosis of depression (i.e., “gold standard” diagnostic interview) may also be a potential weakness, due to the possibility of false positives.

The heterogeneity of the problem-solving interventions could also be considered a weakness of this review. The content and format varied considerably, particularly with the self-management and health education programmes. It is difficult to distinguish what effect the use of problem-solving strategies alone had on the outcomes of interest. However given the small number of published trials in this population and the statistical methods used to calculate pooled SMC scores in the current review, our findings may provide the most comprehensive indication as to the effectiveness of problem-solving interventions in vision impaired adults.

The generalisability of these findings is limited to older adults with AMD, who predominantly have no co-morbid eye conditions. The effectiveness of problem-solving interventions in individuals with other causes of vision loss (e.g., diabetic retinopathy) and younger/working-age adults remains under researched and little is known about the suitability and effectiveness of problem-solving interventions in these groups. Low vision rehabilitation services are not organised by eye condition, therefore we need to know more about the effectiveness of problem-solving interventions in those with vision loss across differing ophthalmic conditions. Furthermore, this review is limited in its generalisability because it excludes studies published in languages other than English, grey literature and unpublished studies.
4.2. Conclusion

We found encouraging support for the effectiveness of problem-solving interventions for improving functioning and reducing emotional distress in vision impaired adults. The conclusions of this review pertaining to other outcomes (including depressive symptoms and QoL) are limited by a small number of good quality trials, their narrow inclusion criteria and focus on participants without depression. Importantly, the synthesis of available evidence underscores the need for well-designed and adequately powered pragmatic trials that include valid and reliable measures for assessing intervention fidelity. Further research with diverse vision impaired samples is also needed to ensure interventions are appropriately targeted.

4.3. Practice implications

Evidently, a larger number of methodologically rigorous trials, with broader participant inclusion criteria, are needed before further conclusions can be reached on the effectiveness of problem-solving interventions in vision impaired adults. Our findings demonstrate that at the very least, problem-solving interventions can improve functioning, which in turn has been shown to impact psychological well-being and QoL [4]. Future pragmatic trials should seek to evaluate the feasibility and cost-effectiveness of implementing problem-solving interventions into low vision services.

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Conflict of interest

None of the authors have any proprietary interests or conflicts of interest related to this submission.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.pec.2015.01.013.

References


Phase 2: Feasibility and piloting
Chapter 4: Phase 2 (Feasibility and piloting)

4.1 Introduction

Vision loss is a leading cause of disability worldwide and is associated with an increased risk of depression and reduced quality of life (QoL). Cross sectional studies estimate the prevalence of depression in adults with vision impairment (VI) to range from 14% to 63%, which is much greater than that of the general population of people without VI. Recent data from a randomised controlled trial (RCT) found that almost fifty-percent of adults attending low vision rehabilitation (LVR) services presented with clinically significant depressive symptoms.

Cognitive-behavioural therapy (CBT), the “gold standard” approach to the treatment of depressive disorders has been shown to be effective in people with chronic health conditions. CBT is delivered by a qualified mental health practitioner, typically over 6 to 18 sessions of 1 hour duration. While adults with VI have a desire for psychological support, few report receiving psychological intervention. Related barriers include a lack of knowledge about mental health services, self-reliance, stigma towards seeking psychological support, and impediments to accessing services including a lack of transport or mobility issues. Within eye care and LVR settings, the availability of trained mental health professionals who can provide psychological interventions remains low, highlighting the need to enhance access to evidence-based psychological therapies in this population.

Problem-solving is an important component of CBT and deficits in problem-solving have been associated with depression in adults with VI. According to the problem-solving framework, individuals who have inadequate problem-solving skills are more vulnerable to depression because they feel unable to change their situation. By enhancing existing problem-solving skills, individuals might cope more effectively with everyday challenges and reduce their vulnerability to depressive symptoms. A body of literature supports this premise and demonstrates the utility of interventions based on problem-solving principles for improving depressive symptoms.

Problem Solving Treatment for Primary Care (PST-PC) has gained popularity due to its brevity and broad application; and is an evidence-based psychological therapy for the treatment of depression. PST-PC can be successfully delivered by mental health as
well as non-mental health professionals and typically disseminated over fewer and briefer sessions compared to other forms of CBT. Empirical research also supports the effectiveness of PST-PC when delivered via telephone or internet video, which may help overcome practical barriers to accessing mental health services for adults with VI.

This study explored the feasibility of rehabilitation practitioners delivering PST-PC by telephone to LVR adult clients with depressive symptoms. Changes in depressive symptoms and health-related quality of life (HRQoL) post-intervention and client acceptability with PST-PC delivery was also investigated. Results from this study were used to inform the design of Phase 3 (effectiveness).

4.2 Method

4.2.1 Design

A single-group, pre-test post-test design study was conducted. Participants provided written consent regarding their participation in the study. The study was approved by the Royal Victorian Eye and Ear Hospital Human Research Ethics Committee (project number 12/1061H) and Deakin University Human Research Ethics Committee (project number 2012-139), and was conducted in accordance with the Declaration of Helsinki.

4.2.2 Participants and procedure

Participants were recruited from LVR centres across Australia (Vision Australia) by intake staff between July, 2012 and June, 2013. Potential participants were aged ≥18, with best corrected visual acuity <6/12 in the better eye and with minimal depressive symptoms (score of ≥3 the Patient Health Questionnaire-2 (PHQ-2)) accessing rehabilitation services for the first time. Potential participants were contacted by a researcher (E. Holloway) who assessed the following eligibility criteria: adequate hearing with a hearing aid if necessary, no cognitive impairment (score of ≤7 on the six-item Cognitive Impairment Test (CIT6), and not currently receiving treatment for a mental health condition. Participants were rescreened for the presence of at least mild depressive symptoms (Patient Health Questionnaire-9 (PHQ-9) score ≥5). All eligible
participants completed a baseline telephone assessment with a trained research assistant/PhD level student (E.Holloway).

Participants were allocated to a LVR PST-PC practitioner and completed 6 to 8 weekly telephone sessions of PST-PC. At the completion of their treatment, participants completed a semi-structured follow-up telephone interview to assess outcomes and to identify challenges, determine acceptability, and provide feedback on the sessions. Participants who completed <6 sessions were contacted to explore reasons for their withdrawal.

LVR PST-PC practitioners were recruited nationally across 28 Vision Australia centres and volunteered to be expertly trained to deliver PST-PC. At the completion of their supervised training cases, practitioners took part in a semi-structured telephone interview to determine acceptability and difficulties encountered in delivering PST-PC. Practitioners who withdrew from PST-PC delivery were contacted to ascertain the reasons for withdrawing. As for the low vision participants, semi-structured interviews with participating practitioners were conducted by a research assistant/PhD level student (E.Holloway) and were recorded and transcribed.

4.2.3 Intervention

PST-PC is a manualised psychological therapy delivered over 6 to 8 sessions. Seven problem-solving steps are introduced in the first session and reinforced in subsequent sessions. The steps include: (1) clarifying and defining the problem; (2) setting a realistic goal; (3) brainstorming multiple solution alternatives; (4) evaluating each solution for its advantages and disadvantages; (5) choosing a preferred solution; (6) making a specific action plan to implement the solution; and (7) evaluating the action plan from the previous session. All consenting clients participated in an introductory session outlining PST-PC aims, followed by 6 to 8 weekly sessions of 45-60 minutes duration each. All sessions were conducted over the telephone and delivered by LVR practitioners as part of their supervised training. Participants received weekly homework tasks which included taking steps towards implementing the preferred solution.
4.2.4 PST-PC staff training

PST-PC training consisted of: (1) participation in two full-day workshops and (2) ongoing supervised training practice. PST-PC training was provided by the clinical psychologist who developed the original PST-PC training manual (Professor M. Hegel) and a second clinical psychologist based at the Centre for Eye Research Australia (Dr B. Sturrock). The 2-day workshop was derived from an established training program which has demonstrated high-level performance results among trainees (i.e. nurses, social workers, and psychologists). The first day (i.e. 8-h duration) was a group instructional workshop in which the theory and effectiveness of PST-PC were presented, observational videos of PST-PC were screened, and treatment resources were provided (i.e. session narratives, worksheets, checklists, client resources, and the treatment manual adapted for LVR staff in Australia). Staff were then provided with the opportunity to participate in role plays of an introductory and first PST-PC session. The second day, duration of 6–8 h, was run in small groups of 4–5 participants; this included participation in one-on-one videoed role plays, observation of each of the participant’s role plays, and detailed feedback from a clinical psychologist (B. Sturrock).

Following completion of the workshops, staff were allocated training cases (≥2) for delivery of PST-PC. Training cases were Vision Australia clients who had a score above the clinical cut-off (score ≥3) on the PHQ-2 and had consented to be a training case.

The introductory session and PST-PC sessions 1, 3, and 5 were audio-recorded using a cloud-based call-recording software. The recorded sessions were then reviewed by a clinical psychologist (B. Sturrock) using the PST-Adherence and Competence Scale. The PST-PAC assesses practitioner fidelity to technical skills and completion of the specific problem-solving steps. Fidelity is rated from 0 (very poor) to 5 (very good), and detailed feedback and supervision for the staff was provided on their ratings over the telephone (45 to 60 minutes duration). To be deemed competent in PST-PC, the staff member was required to complete 6 to 8 sessions with ≥1 training cases and achieve an overall score of at least 3 (satisfactory) on the PST-PAC for three consecutively rated sessions. Staff retention rates and reasons for withdrawal were recorded. After reaching competency in PST-PC, staff were certified to use PST-PC and given a new role within Vision Australia as a PST-PC Practitioner. Staff were then able to accept client referrals and were provided with on-going monthly supervision (≤1 h duration) from a clinical
psychologist (B. Sturrock). Staff were offered monthly peer conferences (≤1h duration) facilitated by B. Sturrock to discuss enablers and challenges to PST-PC in practice; topics included the role of PST-PC in Vision Australia, working with older persons, building and maintaining PST-PC skills, specialist burnout and self-care, and use of facilitating language.

4.2.5 Outcomes and measures

Feasibility

Participant acceptance and retention rates were recorded (Figure 4.1) in addition to practitioner retention following the supervised PST-PC training. Participating clients and practitioners who chose to cease their involvement in PST-PC prior to completion of 6 to 8 sessions or supervised training cases were asked to describe their reasons for doing so (single open-ended item). Difficulties experienced by the PST-PC practitioners and clients were explored using open-ended questions such as “what aspects of the PST-PC sessions did you find difficult or challenging.”

Acceptability of PST-PC

Client acceptability with the PST-PC sessions was explored by items adapted from existing measures of patient acceptability of psychological interventions. Suggestions for improving the sessions were also elicited using an open-ended item.

Practitioners were asked to report on the perceived usefulness of PST-PC for their clients on a 5-point rating scale (‘1’ extremely useful to ‘5’ not at all useful) and the perceived fit/appropriateness of PST-PC within their LVR service (open-ended item).

Person-centred outcomes

The PHQ-9\textsuperscript{150} was used to assess symptoms of depression at baseline and 3-months. Participating clients reported to what degree they had experienced nine symptoms in the past 2 weeks. Responses were rated on a four-point Likert scale from “not at all” to “nearly every day” with a summed score range of 0-27. A score of ≥10 on the 0-27 point scale has been identified as an important threshold for clinical levels of depression, with sensitivity and specificity of 88% for detecting major depressive disorder.\textsuperscript{150} A clinically significant change (CSC) in depressive symptoms is a ≥5-point
The PHQ-9 has been validated as a tool for assessing depressive symptoms in individuals with VI\textsuperscript{170} and for telephone administration.\textsuperscript{171}

The Vision-Related Assessment of Quality of Life (AQoL-7D) instrument\textsuperscript{172,173} is a 26-item health-related multi-attribute utility instrument to assess health-related quality of life (HRQoL). The AQoL-7D is comprised of seven domains including independent living (3-items), mental health (4-items), coping (3-items), relationships (4-items), pain (3-items), senses (3-items) and an additional dimension of vision-related QoL (6-items; VISQoL). Each domain (or health state) is given a “utility” value calculated by the application of an algorithm. Utilities are calculated for overall HRQoL and each of the seven HRQoL domains. Values range between 0-1.00, where a score of 0 represents a state of death and 1.00 would represent best possible HRQoL. A change score of 0.06 is considered a clinically important difference.\textsuperscript{149} The seven dimensions of the AQoL-7D have been validated in adults with VI.\textsuperscript{173}

### 4.2.6 Data analysis

Descriptive statistics were used to summarise client and practitioners’ demographic characteristics. The Kolmogorov-Smirnov test of normality was statistically significant (p<0.05) for all continuous variables indicating that the data were not normally distributed and nonparametric tests were warranted. Demographic differences between groups (i.e. participants who completed 6 to 8 PST-PC sessions/practitioners who completed their training) were determined using chi-square and Mann-Whitney U tests. Differences in the outcome variables pre-post intervention were analysed using Wilcoxon signed rank test. Ordinal data was analysed via SPSS\textsuperscript{174} and qualitative data was analysed using NVIVO version 10.

### 4.3 Results

#### 4.3.1 Feasibility

**Client acceptance and retention**

Of the 92 clients who were invited to take part, two did not meet the eligibility criteria, three were not contactable, and 25 (29\%) declined to participate (Figure 4.1). The
reasons provided for decline were a lack of interest \((n=9)\), insufficient time to commit to the study \((n=6)\), poor health \((n=5)\), lack of perceived need for help \((n=4)\), and participation in other programs \((n=1)\). Of the 62 enrolled participants, 25 \((40\%)\) completed 6-8 sessions of PST-PC, 18 \((29\%)\) of whom completed PST-PC with a practitioner who achieved competency as assessed using the PST-PAC.\(^{145}\) The reasons participating clients withdrew from PST-PC \((n=37)\) are presented in Figure 4.1. The average number of sessions completed by clients who withdrew prematurely from PST-PC was 2.25 \((SD=1.89)\). Participants who completed fewer than 6 sessions \((n=37)\) were significantly older in age \((M=66.68 \text{ vs. } M=52.94; \ p=0.007)\) and less likely to have a tertiary degree \((8\% \text{ vs. } 33\%; \ p=0.046)\) than those who completed 6 to 8 sessions \((n=18; \ \text{Table 4.1})\).

**Staff retention**

Fourteen of the twenty practitioners met competency criteria for the delivery of PST-PC. Six \((30\%)\) withdrew from the supervised training cases and research study due to: limited time because of the demands of their current work role \((n=3)\), redundancy \((n=1)\), chronic ill health \((n=1)\), and loss of enthusiasm in PST-PC \((n=1)\). Practitioners who withdrew did not differ from those who completed their supervised training on any demographic characteristics (all \(p>0.05; \ \text{Table 4.2})\). Participating LVR staff \((n=14)\) were mostly female \((93\%)\), had some previous mental health training \((64\%)\), and had worked in LVR settings for approximately 10 years \((M=9.99, \ SD=9.99)\).
Figure 4.1 Participant flow through the study

Recruitment

- Referred into study by Vision Australia (n=92)
- Assessed for eligibility by research staff (n=92)
- Completed baseline assessment (n=62)
- Completed 6-8 PST-PC sessions (n=25)

PST-PC intervention

- Completed post-intervention assessment (n=18)
- Completed acceptability semi-structured interview (n=18)

Follow-up

- Analysed (n=18)
  - Excluded from analysis (n=7)
    - Reason: Participant completed sessions with a staff member who had not completed training.

Analysis

- Withdrew from PST-PC (n=37)
  - Reasons: PST-PC perceived as not relevant or valuable (n=12), factors unrelated to the PST-PC (e.g. illness) (n=11), goals achieved from < 6 sessions (n=4), unknown (n=4), no problems to work on (n=4), someone to talk to without the structure of PST-PC (n=2)
    - Completed 0 sessions (n=9)
    - Completed 1 sessions (n=7)
    - Completed 2 sessions (n=2)
    - Completed 3 sessions (n=9)
    - Completed 4 sessions (n=7)
    - Completed 5 sessions (n=3)

Excluded (n=2)
- Language difficulties (n=1)
- Hearing difficulties (n=1)
- Failed CIT (n=0)
- Declined to participate (n=25)
- Unable to contact (n=3)
Table 4.1 Sociodemographic characteristics of LVR clients

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Completed PST-PC (n=18)</th>
<th>Withdrew (n=37)</th>
<th>Total (n=55+)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean[SD];</td>
<td>Mean[SD];</td>
<td>Mean [SD];</td>
</tr>
<tr>
<td></td>
<td>or N (%)</td>
<td>or N (%)</td>
<td>or N (%)</td>
</tr>
<tr>
<td>Age M ± SD</td>
<td>52.94 ± 16.16</td>
<td>66.68 ± 16.59</td>
<td>62.18 ± 17.55</td>
</tr>
<tr>
<td>Sex, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>11 (61.1)</td>
<td>29 (78.4)</td>
<td>40 (72.7)</td>
</tr>
<tr>
<td>Country of birth, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Australia</td>
<td>15 (83.3%)</td>
<td>26 (70.3)</td>
<td>41 (74.5)</td>
</tr>
<tr>
<td>Marital status, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married/partner</td>
<td>6 (33.3)</td>
<td>18 (48.6)</td>
<td>24 (43.6)</td>
</tr>
<tr>
<td>Divorced/separated</td>
<td>6 (33.3)</td>
<td>7 (18.9)</td>
<td>13 (23.6)</td>
</tr>
<tr>
<td>Widowed/never married</td>
<td>6 (33.3)</td>
<td>12 (32.4)</td>
<td>18 (32.7)</td>
</tr>
<tr>
<td>Level of education, n (%)</td>
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</tr>
<tr>
<td>Degree qualified</td>
<td>6 (33.3)</td>
<td>3 (8.1)</td>
<td>9 (16.4)</td>
</tr>
<tr>
<td>Comorbid physical illness, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>14 (77.8)</td>
<td>27 (73.0%)</td>
<td>41 (74.5%)</td>
</tr>
<tr>
<td>Visual acuity, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;6/12</td>
<td>4 (22.2)</td>
<td>2 (5.4)</td>
<td>6 (11.3)</td>
</tr>
<tr>
<td>&lt;6/12-6/18</td>
<td>4 (22.2)</td>
<td>11 (29.7)</td>
<td>16 (30.2)</td>
</tr>
<tr>
<td>&lt;6/18-6/60</td>
<td>6 (33.3)</td>
<td>15 (40.5)</td>
<td>20 (37.7)</td>
</tr>
<tr>
<td>&lt;6/60</td>
<td>4 (22.2)</td>
<td>9 (24.3)</td>
<td>11 (20.8)</td>
</tr>
<tr>
<td>Eye condition (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Macular degeneration</td>
<td>5 (31.3)</td>
<td>9 (24.3)</td>
<td>14 (26.4)</td>
</tr>
<tr>
<td>Other</td>
<td>5 (31.3)</td>
<td>11 (29.7)</td>
<td>16 (30.2)</td>
</tr>
<tr>
<td>Glaucoma</td>
<td>3 (18.9)</td>
<td>6 (16.2)</td>
<td>9 (17.0)</td>
</tr>
<tr>
<td>Diabetic retinopathy</td>
<td>3 (18.9)</td>
<td>7 (18.9)</td>
<td>10 (18.9)</td>
</tr>
<tr>
<td>Cataracts</td>
<td>0 (0.0)</td>
<td>4 (10.8)</td>
<td>4 (7.5)</td>
</tr>
<tr>
<td>PHQ-9 clinical threshold for depression (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Score &lt; 10</td>
<td>6 (33.3)</td>
<td>20 (54.1)</td>
<td>26 (47.3)</td>
</tr>
<tr>
<td>Score ≥ 10</td>
<td>12 (66.7)</td>
<td>17 (45.9)</td>
<td>29 (52.7)</td>
</tr>
<tr>
<td>History of depression, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No, never</td>
<td>3 (16.7)</td>
<td>16 (43.2)</td>
<td>19 (34.5)</td>
</tr>
<tr>
<td>Yes, only in the past</td>
<td>7 (33.9)</td>
<td>8 (21.6)</td>
<td>15 (27.3)</td>
</tr>
<tr>
<td>Yes, currently</td>
<td>7 (44.4)</td>
<td>13 (35.1)</td>
<td>21 (38.2)</td>
</tr>
</tbody>
</table>

± seven clients completed PST-PC sessions with a staff member who was still working towards achieving competency and were excluded from analysis.
Table 4.2 Sociodemographic characteristics of LVR staff delivering PST-PC

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Achieved competency (n=14)</th>
<th>Withdrew (n=6)</th>
<th>Total (n=20)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean [SD]; or N (%)</td>
<td>Mean [SD];</td>
<td>Mean [SD];</td>
<td></td>
</tr>
<tr>
<td>Age M ± SD</td>
<td>47.64 ± 12.68</td>
<td>50.00 ± 9.57</td>
<td>48.35 ± 11.64</td>
<td>0.74</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female n (%)</td>
<td>13 (92.86)</td>
<td>6 (100.0)</td>
<td>40 (72.7)</td>
<td>0.50</td>
</tr>
<tr>
<td>Professional background n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>8 (57.1)</td>
<td>1 (16.7)</td>
<td>9 (45.0)</td>
<td></td>
</tr>
<tr>
<td>Orientation &amp; mobility</td>
<td>3 (21.4)</td>
<td>1 (16.7)</td>
<td>4 (20.0)</td>
<td></td>
</tr>
<tr>
<td>Social work</td>
<td>2 (14.3)</td>
<td>2 (33.3)</td>
<td>4 (20.0)</td>
<td></td>
</tr>
<tr>
<td>Occupational Therapy</td>
<td>1 (7.1)</td>
<td>2 (33.3)</td>
<td>3 (15.0)</td>
<td>0.24</td>
</tr>
<tr>
<td>No. years in low vision, M ± SD</td>
<td>9.86 ± 10.11</td>
<td>10.67 ± 10.17</td>
<td>10.10 ± 9.87</td>
<td>0.62</td>
</tr>
<tr>
<td>Previous mental health training, Yes n (%)</td>
<td>9 (64.3)</td>
<td>5 (83.3)</td>
<td>14 (70.0)</td>
<td>0.39</td>
</tr>
</tbody>
</table>

4.3.2 Difficulties experienced with PST-PC

Participating clients identified individual steps in the PST-PC process as difficult (n=4). For example, one client stated “the action plan was difficult…quantifying things…putting them into words.” Three clients found the PST-PC sessions too structured and repetitive “the processes were frustrating as it’s not what I was expecting to do. I found the sessions repetitive.” Two clients found the homework tasks difficult to complete and one client reported that identifying problems to work on was the most challenging aspect.

Challenges raised by practitioners in the delivery of PST-PC during their supervised training were limited time to commit to delivering PST-PC (n=8); clients’ lack of commitment to the PST-PC sessions (n=7); feeling inexperienced or unskilled in PST-PC (n=6); and delivering PST-PC to complex (n=6) and older (n=5) clients.

4.3.3 Acceptability of PST-PC

Participating client acceptability with various aspects of PST-PC are presented in Table 4.3. Most participating clients felt that the number (83%) and duration of sessions
(72%) was just right and almost two thirds were happy to receive the sessions over the telephone (61%). The majority of participants felt they had benefited from the PST-PC sessions (83%), and had continued using the PST-PC steps after completing their sessions. Client feedback on how the sessions could be improved demonstrated that there needed to be greater flexibility around the delivery of PST-PC sessions (n=8), specifically the number and length of sessions: “shortening it, do people need the 8 weeks? Maybe 4 weeks and if they want further help they can extend it further.” Four clients suggested face-to-face contact with the practitioner delivering the sessions, another suggested between session contact and support, one client requested a follow-up after completing PST-PC, and another wanted the opportunity to role play possible solutions.

Practitioners perceived PST-PC to be ‘extremely/very useful’ (79%) with 21% reporting that it was ‘somewhat useful.’ Most practitioners (n=13; 93%) felt that there was a place for PST-PC within LVR services. However, staff felt that PST-PC needed to be established as an independent service that had dedicated personnel to deliver PST-PC (n=11). Six practitioners felt that PST-PC may not be appropriate for all clients (e.g. older clients with comorbidities) “A lot of them have huge health issues which makes it quite difficult...I just found for the older clients that they just accepted that was it.. like one woman said to me, I’m 90, you know;” four reported that PST-PC could provide clients with important skills to enhance their rehabilitation and adjustment to vision loss “I see that it can have a place in helping people who are you know perhaps a bit stuck with their vision loss, or they’re experiencing low mood and depression, in giving them a practical sort of framework;” three expressed concerns around telephone delivery and its impact on establishing rapport “I don’t know whether it would work better face-to-face, you know whether if clients actually...you made an appointment that they had to actually physically get to.” One practitioner considered PST-PC to be a useful intervention to offer family members and carers, and felt that PST-PC provided a stepping-stone to accessing psychological intervention from a qualified mental health practitioner.
Table 4.3 Participating client (n=18) acceptability with the PST-PC sessions

<table>
<thead>
<tr>
<th>Item: Client</th>
<th>Response</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Preferred mode of delivery</td>
<td>Telephone</td>
<td>11 (61.1)</td>
</tr>
<tr>
<td></td>
<td>Both phone/face-to-face</td>
<td>5 (27.8)</td>
</tr>
<tr>
<td></td>
<td>Face-to-face only</td>
<td>2 (11.1)</td>
</tr>
<tr>
<td>2. Number of PST-PC sessions</td>
<td>Just right</td>
<td>15 (83.3)</td>
</tr>
<tr>
<td></td>
<td>Too little</td>
<td>2 (11.1)</td>
</tr>
<tr>
<td></td>
<td>Too many</td>
<td>1 (5.6)</td>
</tr>
<tr>
<td>3. Duration of PST-PC sessions</td>
<td>Just right</td>
<td>13 (72.2)</td>
</tr>
<tr>
<td></td>
<td>Too short</td>
<td>3 (16.7)</td>
</tr>
<tr>
<td></td>
<td>Too long</td>
<td>2 (11.1)</td>
</tr>
<tr>
<td>4. PST clearly explained to me</td>
<td>Strongly agree</td>
<td>16 (88.9)</td>
</tr>
<tr>
<td>(by staff delivering PST-PC)</td>
<td>Agree slightly</td>
<td>1 (5.6)</td>
</tr>
<tr>
<td></td>
<td>Neither agree nor disagree</td>
<td>1 (5.6)</td>
</tr>
<tr>
<td></td>
<td>Disagree slightly</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Strongly disagree</td>
<td>-</td>
</tr>
<tr>
<td>5. Benefited from the PST-PC sessions</td>
<td>Strongly agree</td>
<td>15 (83.3)</td>
</tr>
<tr>
<td></td>
<td>Agree slightly</td>
<td>3 (16.7)</td>
</tr>
<tr>
<td></td>
<td>Neither agree nor disagree</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Disagree slightly</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Strongly disagree</td>
<td>-</td>
</tr>
<tr>
<td>6. Level of satisfaction with PST</td>
<td>Completely/very satisfied</td>
<td>15 (83.3)</td>
</tr>
<tr>
<td></td>
<td>Somewhat satisfied</td>
<td>3 (16.7)</td>
</tr>
<tr>
<td></td>
<td>Neither satisfied/dissatisfied</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Somewhat dissatisfied</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Completely/very dissatisfied</td>
<td>-</td>
</tr>
<tr>
<td>7. Recommend PST-PC to others with vision impairment</td>
<td>Strongly agree</td>
<td>17 (94.4)</td>
</tr>
<tr>
<td></td>
<td>Agree slightly</td>
<td>1 (5.6)</td>
</tr>
<tr>
<td></td>
<td>Neither agree nor disagree</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Disagree slightly</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Strongly disagree</td>
<td>-</td>
</tr>
<tr>
<td>8. Participate in PST-PC again</td>
<td>Yes</td>
<td>18 (100)</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>-</td>
</tr>
</tbody>
</table>
4.3.4 Person-centred outcomes

A 53% improvement in depressive symptoms was observed at follow-up (Pre mean =10.67 vs. Post mean =5.67, \( p<0.001 \); Table 4.4); 67% \((n=12)\) of participants demonstrated a CSC in depressive symptoms (≥5-point reduction on PHQ-9); and 50% \((n=9)\) presented with minimal or no depressive symptoms at follow-up (PHQ-9 score <5). Improvements for the VISQoL \((p<0.001)\), independent living \((p=0.022)\), mental health \((p=0.001)\) and coping \((p=0.025)\) AQoL-7D domains exceeded the suggested minimal clinically important difference (change score of 0.06).

Table 4.4 Mean change in depressive symptoms (PHQ-9) and HRQoL domains (AQoL-7D-Vision) pre-post PST-PC sessions

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Baseline ((N=18))</th>
<th>3-months ((N=18))</th>
<th>( p)-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depressive symptoms (PHQ-9)</td>
<td>10.67 4.12</td>
<td>5.67 4.60</td>
<td>(&lt;0.001)</td>
</tr>
<tr>
<td>AQoL_independent living</td>
<td>0.46 0.30</td>
<td>0.58 0.26</td>
<td>(=0.022)</td>
</tr>
<tr>
<td>AQoL_relationships</td>
<td>0.60 0.29</td>
<td>0.64 0.26</td>
<td>(=0.794)</td>
</tr>
<tr>
<td>AQoL_mental health</td>
<td>0.31 0.24</td>
<td>0.61 0.26</td>
<td>(=0.001)</td>
</tr>
<tr>
<td>AQoL_coping</td>
<td>0.42 0.27</td>
<td>0.60 0.27</td>
<td>(=0.025)</td>
</tr>
<tr>
<td>AQoL_pain</td>
<td>0.76 0.30</td>
<td>0.85 0.18</td>
<td>(=0.214)</td>
</tr>
<tr>
<td>AQoL_senses</td>
<td>0.70 0.19</td>
<td>0.73 0.14</td>
<td>(=0.090)</td>
</tr>
<tr>
<td>AQoL_vision</td>
<td>0.50 0.21</td>
<td>0.72 0.15</td>
<td>(&lt;0.001)</td>
</tr>
<tr>
<td>AQoL_overall</td>
<td>0.47 0.10</td>
<td>0.58 0.13</td>
<td>(=0.001)</td>
</tr>
</tbody>
</table>

4.4 Discussion

4.4.1 Summary of findings

This is the first study to explore the feasibility of rehabilitation practitioners delivering PST-PC to adults with VI and depressive symptoms in LVR services. Findings from this study indicate that demand exists for this type of intervention within LVR services and with sufficient organisational support and flexibility in the delivery, PST-PC is acceptable to the majority of both clients and practitioners. Data also provide
encouraging preliminary support for improvements in depressive symptoms and HRQoL following PST-PC sessions when delivered in this manner.

The modest attrition rate (60%) observed in the current study is of some concern, but is not uncommon in trials delivering psychological interventions.\textsuperscript{175} Recent meta-analyses of attrition in studies of depression and CBT identified a wide range from 0-63%.\textsuperscript{176} It has been noted that attrition rates are generally higher among individuals with depression compared with other mental disorders as the symptoms often lead to diminished hope and social withdrawal, hindering therapeutic alliance, which is pivotal to retention in therapy.\textsuperscript{177} Participants who withdrew from PST-PC prematurely in this study were more likely to have mild symptoms of depression. This warrants further investigation to determine if a greater level of depression severity may be more appropriate to target for PST-PC. Results showed that older adults were more likely to discontinue PST-PC sessions which is inconsistent with previous studies of problem-solving therapy in older adults.\textsuperscript{168, 178} In these studies, PST was delivered face-to-face either in the client’s home or in a clinical setting. Older clients may have a preference for face-to-face contact with their therapist which may help to establish rapport, and thereby improve retention. This reflects participating clients’ suggestions for modifications and practitioner concerns that face-to-face contact may be important for establishing rapport.

Qualitative reports from clients and practitioners highlighted the need for flexibility in the delivery of PST-PC (e.g. number of sessions, mode of delivery). This study employed the recommended number of 6 to 8 PST-PC sessions, however trials have shown \( \geq 4 \) sessions to be effective in reducing depression.\textsuperscript{168, 179} As highlighted in clients’ reasons for withdrawing, for some, it may be that with fewer than 6 sessions, the goals of the treatment have been accomplished and the ongoing need for therapy has diminished.\textsuperscript{180} Flexibility may also improve retention rates, particularly in adults with comorbid health conditions.\textsuperscript{181} Staff indicated that a lack of time to commit to the intervention was also problematic. Resources, such as sufficient time, ongoing support, adequate staffing and funding are important criteria when establishing a new health service\textsuperscript{182} and would need to be carefully considered if PST-PC were to be integrated into LVR services.
4.4.2 Strengths and limitations of this study

Since the development of this feasibility study, trials have been conducted in the United Kingdom\textsuperscript{183 184} and the Netherlands.\textsuperscript{185} These studies seek to investigate the effectiveness of Problem Solving Treatment (delivered by a qualified therapist) in preventing or improving depressive symptoms in adults with VI. A major strength of my study is that for the first time, the feasibility of training rehabilitation practitioners to deliver PST-PC within LVR service provision was explored. Furthermore, data represents both the client and practitioner perspective, which is important because the perspectives of the client and therapist do not always align.\textsuperscript{186}

Whilst the results of this study are promising, the small sample size, simple univariate analysis on raw scores, and the absence of a control group and randomisation preclude the ability to make inferences about the causal relationship between PST-PC and client outcomes. These limitations will be most effectively addressed in Chapter 5, which allows for rigorous investigation of the clinical, person-centred and cost effectiveness of PST-PC. These findings also underscore the need to understand factors associated with client retention with PST-PC in more depth.

4.4.3 Conclusion

This study points to the feasibility, acceptability and potential benefits of integrating an evidence-based problem-solving intervention into LVR settings. Furthermore, the delivery of PST-PC by rehabilitation practitioners who are already working with adults with VI has the potential to be a cost-efficient, early intervention that could be offered alongside a referral to psychological services. An RCT is warranted to rigorously test the effectiveness of PST-PC delivered as an integrated component of LVR services and to ascertain for whom this intervention is most suited.
Phase 3: Effectiveness
Chapter 5: Phase 3, Effectiveness

5.1 Introduction

Depression is prevalent in individuals with vision impairment (VI) causing reduced quality of life, productivity, independence, excess mortality and imposing a significant economic burden (in excess of US$15 billion/year in high income countries). Up to 43% of adults with VI will experience depressive symptoms, which can adversely affect levels of functioning, notwithstanding an increased risk of developing Major Depressive Disorder. Despite the high prevalence of depression and the magnitude of associated consequences, up to 75% of adults with VI in high income countries do not receive treatment for depression. In low-to-middle income countries, where 90% of the population with VI reside, this proportion is even higher. Consequently, effective, accessible and cost-effective methods for managing depression in adults with VI are needed.

Integrated models of care delivered within rehabilitation programs have been recommended by clinical guidelines for the management of subthreshold symptoms (or mild to moderate depression) for people with chronic physical health conditions. Specifically, patients should be offered low intensity cognitive and behavioural interventions that include problem-solving techniques. Problem-solving skills are particularly important to individuals with VI given the protective effect they can have on psychological well-being and adjustment to chronic conditions.

Problem Solving Treatment for Primary Care (PST-PC) is an evidence and skills-based treatment derived from principles of cognitive behavioural therapy (CBT). PST-PC was specifically developed to be used in busy clinical settings, delivered over a brief number of sessions (typically 4 to 8), and by a range of health-care professionals including those without specialist mental health training. Research evidence supports the effectiveness of PST-PC for treating MDD and preventing the progression of subthreshold depressive symptoms in older adults. However, little is known about the long-term clinical and cost-effectiveness of PST-PC for reducing depressive symptom severity in those with VI when integrated into routine practice.

In this pragmatic trial, the effectiveness and cost effectiveness of an integrated model of care for reducing depressive symptoms and improving person-centred outcomes in
adults with VI was investigated. It was hypothesised that telephone-delivered PST-PC administered by a trained low vision rehabilitation (LVR) practitioner would be clinically and cost effective for reducing depressive symptoms (primary outcome) compared to usual care alone.

5.2 Methods

5.2.1 Study design and participants

This study was a pragmatic, multicentred, randomised controlled trial (RCT) as described in the protocol (Appendix 3). Participants were randomised to one of two parallel groups: (i) telephone-based PST-PC delivered by an expertly trained LVR practitioner plus usual care (intervention group), or (ii) usual care alone (control group).

Participants were new or returning clients recruited by intake staff from 28 LVR centres in five states of Australia. During the intake assessment all prospective participants were screened for depressive symptoms using the Patient Health Questionnaire-2 (PHQ-2) as standard procedure. Individuals with a PHQ-2 score of >3 were the study and if they agreed, were contacted via telephone by a trained researcher/PhD level student who assessed individuals for eligibility. Inclusion criteria were adults (>18 years) living independently in the community, with best corrected visual acuity <6/12 in the better eye, adequate hearing (use of a hearing aid if necessary), no cognitive impairment (score ≤7 on the six-item Cognitive Impairment Test [CIT6], and not currently receiving treatment (i.e. talking therapy or antidepressant medication) for a mental health condition. Participants were rescreened for the presence of at least mild depressive symptoms (score ≥5 on the PHQ-9). This two-step procedure has been recommended previously. Those with mild symptoms were eligible given the increased risk of developing more severe depressive symptoms.

All eligible participants were mailed a written consent form in an accessible format (e.g. large print), provided written consent regarding their participation in the study and completed a baseline telephone assessment with a trained research assistant/PhD level student. They were then randomised to the intervention or control group. Those ineligible to take part were offered a letter to their general practitioner (GP) stating their PHQ-9 score and recommending a follow-up appointment with their GP.
The study was approved by the Royal Victorian Eye and Ear Hospital Human Research Ethics Committee (project number 12/1061H) and Deakin University Human Research Ethics Committee (project number 2012-139), and was conducted in accordance with the Declaration of Helsinki. This trial has been registered with the Australian New Zealand Clinical Trials Registry (ACTRN12612000318886).

5.2.2 Randomisation

Participants were randomly allocated (1:1) to the intervention or control group. Block randomisation (block sizes of 15 and 30) using a computer-generated list of random numbers was performed by a clinical trials expert independent of the study. Following the baseline assessment, sequentially numbered opaque sealed envelopes were opened by the supervising clinical psychologist (B. Sturrock) who notified participants of their group allocation by telephone. The allocation sequence was concealed from the researcher (E. Holloway) enrolling and assessing participants and breaches of masking were recorded. Participants, PST-PC practitioners and participants’ GPs were not masked to treatment assignment. Follow-up assessments were conducted post-intervention at 6 and 12 months following baseline assessments over the telephone by a masked interviewer.

5.2.3 Intervention

Participants randomised to the intervention received a one hour introduction session to ensure understanding of the PST-PC rationale and to build rapport, followed by up to eight PST-PC treatment sessions. Four sessions was considered the minimum number for the trial based on evidence from previous published literature.\textsuperscript{131} 168 193 194 Homework tasks were assigned at each session which included taking steps towards implementing the preferred solution and engaging in pleasant daily activities. Participants who completed at least four PST-PC treatment sessions were offered up to four maintenance sessions on a monthly basis with their PST-PC practitioner. This was revised from 10 sessions in the study protocol due to the challenges of retaining clients in the PST-PC sessions. The goals of the maintenance sessions were to reinforce skills and prevent worsening of depressive symptoms.\textsuperscript{42} The PST-PC sessions were delivered by a LVR practitioner who had undertaken extensive training in PST-PC (details regarding staff training are provided in Chapter 4, Section 2).\textsuperscript{190} 195 In brief, this
included a two-day training workshop based on an established training program\textsuperscript{42} plus training cases under the supervision of a clinical psychologist who provided regular feedback. All staff training and client treatment sessions were delivered over the telephone and recorded using a cloud-based call recording and monitoring system.

**Usual care**

Participants in both groups received usual care. This involved the provision of information regarding depression and available supports in the community. With the participant’s consent, a letter outlining their level of depressive symptoms, involvement in the study and a recommendation for a follow-up appointment was sent to participant’s GP.

**5.2.4 Outcomes and measures**

The primary outcome was a reduction in depressive symptom severity assessed with the nine-item PHQ\textsuperscript{150} at 6-month follow-up. A \( \geq 5 \)-point reduction and PHQ-9 score <10 at 6 months was considered clinically significant\textsuperscript{147 151}. A score of \( \geq 10 \) is the threshold for clinical levels of depression, with a sensitivity and specificity of 88\% in detecting major depressive disorder\textsuperscript{150}. The PHQ-9 has been validated as a tool for assessing depressive symptoms in individuals with VI\textsuperscript{170} and for telephone administration\textsuperscript{171}.

Secondary outcomes were maintenance effects on the PHQ-9 at 12-months, changes in HRQoL based on the Assessment of Quality of Life questionnaire [AQoL-7D]\textsuperscript{148} and vision-specific distress based on the Impact of Vision Impairment Questionnaire [IVI]\textsuperscript{196} at 6 and 12-months. The AQoL-7D\textsuperscript{148} is described in Chapter 4. In brief, it is a 26-item health-related multi-attribute utility instrument comprised of seven domains (including a 6-item vision-related HRQoL domain).\textsuperscript{172 173} Utility values are calculated for overall HRQoL and each of the seven HRQoL domains by the application of an algorithm.\textsuperscript{173} Utility values range between 0 and 1, where a score of 0 represents a state of death and 1 represents best possible HRQoL. The AQoL-7D have been validated in adults with vision impairment\textsuperscript{173} and allows utility values and QALYs to be calculated for the purpose of economic evaluation in vision-related\textsuperscript{197}.

The vision-specific distress domain of the IVI comprises 8-items that assesses the extent to which a person’s level of vision has caused them to feel: embarrassed, frustrated,
lonely/isolated, sad/low, worried about eyesight getting worse, concerned about coping with everyday life, being a nuisance/burden and the extent to which their eyesight has interfered with life in general. Items are rated on a 4-point Likert scale (“not at all” (0) to “a lot of the time” (3)) and are summed to provide a total score (0 to 24). The IVI has undergone extensive psychometric validation.16 196

At baseline, socio-demographic characteristics, prior episodes of depression, previous treatment for depression/mental health conditions and psychological co-morbidities were collected by self-report (Table 5.1). At each follow-up time-point, the uptake of treatment (antidepressant medication and talking therapy) and new incidence of a chronic health conditions were determined. The primary cause of vision loss and visual acuity were obtained from Vision Australia records for the participant’s most recent clinic appointment prior to the trial enrolment. Visual acuity was assessed using Snellen charts (using best corrected vision) and VI levels were defined using either presenting or best-corrected visual acuity in the better eye and categorised as mild (<6/12-6/18), moderate (<6/18-6/60) or severe (<6/60). Visual acuity at 6 and 12 months were obtained from the participants’ ophthalmologist, optometrist or following their Vision Australia clinic appointment. Self-reported change in vision was determined at each follow-up.

Follow-up of non-respondents by telephone and email was attempted. During the course of the trial five participants died due to comorbid health conditions, three in the intervention group and two in the control group and were excluded from follow-up analyses. No adverse events associated with the intervention were reported by participants or PST-PC practitioners.

5.2.5 Assessment of fidelity of treatment delivery

Practitioner competence and fidelity to the PST-PC protocol were assessed using seven items of PST-PC Adherence and Competence Scale (PST-PAC).145 Twenty percent of audio-recorded telephone sessions, randomly selected using a computer generated number sequence, were independently rated by two professionals trained in PST-PC. Six items of the PST-PAC assessed the problem-solving steps (including fidelity to technical skills, adherence to the problem-solving steps, process tasks, communication and interpersonal effectiveness) using a 5-point scale (“very poor” (0) to “very good”
Item seven is a global rating of the overall performance of the practitioner taking into account the complexity of the client presentation (rated “easy” (0) to “difficult” (5)). The PST-PAC has demonstrated internal reliability of 0.83 to 0.89.

5.2.6 Costs

Costs were assessed from the health system perspective, specifically how much more it would cost the health system to deliver PST-PC relative to usual care. Labour costs for staff time associated with PST-PC training and delivery were tracked in Excel using an Activity-Based costing approach. Assigned costs were cross-referenced with times logged in the cloud-based monitoring and recording system and valued at national average wages for individuals performing these functions. Non-labour costs included call-recording software for staff training and intervention materials (e.g. photocopies for training purposes and client worksheets). Sunk costs to develop the program are not included as these are not relevant for incremental cost effectiveness analysis. Costs were assigned to each participant and averaged across the total number who received PST-PC.

5.2.7 Statistical analysis

Analysis was conducted according to CONSORT guidelines, following an analysis plan reported in the trial protocol (Appendix 3). The sample size calculation was conservatively based on detecting mean change of 4-points on the PHQ-9 at 6-month follow-up, this is one point below the minimal clinically significant change. A final sample size of 64 in each group was estimated to have 80% power to detect a difference in means of 4-points at 6-months assuming that the common standard deviation is 8.0 with a 0.05 two-sided significance level. A loss to follow-up rate of 30% was anticipated, therefore the recruitment target for each group was 91 participants.

All analyses were performed with STATA version 14.1. A two-sided alpha level of 0.05 was used to indicate statistical significance. The primary analysis was conducted on an intention-to-treat (ITT) basis according to participants’ randomisation group. Per-protocol (PP) analysis was also carried out with participants who completed at least four PST-PC sessions (representing the minimum frequency) to enable the influence of any missing data to be investigated. Primary outcome analysis was carried out using PHQ-9 raw scores and repeated using Rasch person measures (Appendix 4). Secondary
outcome analysis was conducted using AQoL-7D utility scores and IVI-distress Rasch scores.

For the primary outcome, unadjusted mean differences in PHQ-9 scores at 6 months were analysed using paired sample t-tests for within group differences and two-sample t-test for between groups. To indicate effect sizes between groups, Cohen's $d$ were calculated by dividing the differences between means by the pooled baseline standard deviations. Mixed-effects logistic regression models were used to determine if the proportion of participants achieving a clinically significant change in symptoms at 6-month follow-up differed between groups. The binary outcome was defined as a minimum 5-point reduction on the PHQ-9 (and score <10), adjusting for age, gender, history of depression, treatment for depression and self-reported change in visual acuity. Odds ratios and corresponding 95% confidence intervals were obtained.

Finally the average rate of change over time between-groups for the PHQ-9 was investigated using a linear mixed model (LMM) by fitting an interaction between the trial group and follow-up time point. The mixed-effects model included covariate adjustment (age, gender, history and treatment for depression and self-reported changes in vision at each time-point). To assess the likely effect of missing data, we ran sensitivity analyses using multiple imputation models. Imputation by treatment group using chained equations (MICE) was performed to create 10 complete datasets under the assumption that data were missing at random. Imputation models included covariates as defined for the LMM model and auxiliary variables that were predictive of outcomes. After analysis, the effect estimates from the imputed datasets using Rubin’s rules were combined.

Analyses were repeated for each of the secondary outcomes (AQoL-7D and IVI-distress) and to determine longer-term (12-month follow-up) treatment effects for each outcome.

5.2.8 Cost-effectiveness analysis

An incremental cost-effectiveness analysis from the payer perspective was performed. The incremental cost-effectiveness ratio (ICER) was calculated using the AQoL-7D (HRQoL) to estimate effect, and the point-estimate from non-parametric bootstrapping
with 1,000 repetitive computations. The base-case analysis was performed using the ITT sample.

Two separate regression models were performed to estimate the mean difference in cost and the adjusted effect (covariates included age, gender, depression history, and baseline AQoL-7D utility weights) between groups at 6 months. We assumed no differences beyond six months given that the 12-month HRQoL results were not statistically significant between groups. Regression coefficients for each model were stored and used to calculate the ICER. The ICER indicates the average incremental cost to gain one additional quality‐adjusted life year (QALY), where the difference in effect (HRQoL) was multiplied by 0.5 to account for the fact that these QOL gains were only accrued for one half of a year. Cost data were skewed due to the high proportion of participants with zero (or small) cost values. Therefore, using non-parametric bootstrapping, 1,000 replicates were generated to estimate the 95% confidence intervals around the ICER. These were generated using the stored mean cost and effect differences and repeated random samples with replacement drawn from the ITT sample. A cost-effectiveness acceptability curve (CEAC) was produced that shows the probability that the intervention was cost-effective, compared to usual care, over a range of values a decision maker may be willing to pay (WTP) per increase in QALYs. Values of AU$64000 per QALY gained or lower were considered to be cost effective based on established figures for Australia. Given the time horizon of 6-months, costs were not discounted.

**Sensitivity analysis of effectiveness**

Using the bootstrapping methods detailed earlier, deterministic sensitivity analysis was conducted to generate ICERs illustrating variation in effectiveness by altering the effectiveness results. The base-case analysis assumed no intervention effect on HRQoL beyond 6 months. Analysis was repeated using 12 month HRQoL values to show the influence of attenuating HRQoL effects on cost effectiveness. Second, the base-case scenario was repeated using the NICE recommended EQ-5D health utility measure.
5.3 Results

5.3.1 Baseline characteristics and participant flow

Participants were recruited between 15 January, 2013 and 8 August, 2014. Five hundred and twenty-eight prospective participants were referred into the study, 200 (38%) declined participation and were significantly older in age (declined: mean=78.3, Standard deviation (SD) =17.4 versus accepted: mean=62.4, SD=16.9, \( p<0.001 \)). Reasons for not meeting the eligibility criteria are reported in Figure 5.1. The 163 participants were randomised to the intervention (\( n=81 \)) or control group (\( n=82 \); Figure 5.1). Primary outcome data were obtained for 68 (84%) participants in the intervention group and 75 (91%) in the usual care group at 6 months. One participant randomised to the intervention revealed their group to the research assistant at the 12 month assessment and their 12 month data was excluded from analysis. Seventy-nine percent (\( n=128 \)) of participants were retained until the final 12-month follow-up assessment and retention rates did not differ significantly between the two groups.

Participants’ demographic characteristics at baseline are presented in Table 5.1. The groups were mostly balanced, although intervention participants were more likely to have been born in Australia and receiving a disability support pension. The average age of participants was 62.4 years (SD=16.9) and most were female (61%). Almost half of participants had moderate VI (44%) and 26% had age-related macular degeneration. Almost two thirds (61%) had moderate to moderately severe depressive symptoms (PHQ-9 score 10-19).

Twenty-seven percent (\( n=22 \)) of participants in the intervention group engaged in the minimum number of sessions (\( \geq 4 \)), of whom 50% (\( n=11 \)) completed at least one maintenance session. All maintenance sessions were completed by the 6-month follow-up. Forty-five percent (\( n=39 \)) of participants withdrew prior to commencing session 1. Participants (\( n=39 \)) declined treatment for the following reasons: poor health (\( n=14 \)), PST-PC not perceived as relevant/valuable (\( n=9 \)), unable to commit time (\( n=7 \)), could not be contacted (\( n=5 \)), grief/loss (\( n=2 \)) and unknown (\( n=2 \)).
**Figure 5.1** Flow of participants in trial of telephone-delivered PST-PC for depressive symptoms in low vision rehabilitation
<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Intervention group</th>
<th>Control group</th>
<th>Total sample</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n=81)</td>
<td>(n=82)</td>
<td>(n=163)</td>
</tr>
<tr>
<td>Age, Mean years (SD)</td>
<td>63.8 (15.4)</td>
<td>61.0 (18.2)</td>
<td>62.4 (16.9)</td>
</tr>
<tr>
<td>Female</td>
<td>53 (65.4)</td>
<td>45 (54.9)</td>
<td>98 (60.1)</td>
</tr>
<tr>
<td>Marital Status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single/widowed/never married</td>
<td>49 (60.5)</td>
<td>44 (53.7)</td>
<td>93 (57.1)</td>
</tr>
<tr>
<td>Married/defacto</td>
<td>32 (39.5)</td>
<td>38 (46.3)</td>
<td>70 (42.9)</td>
</tr>
<tr>
<td>Country of birth (Australia)</td>
<td>62 (76.5)</td>
<td>51 (62.2)</td>
<td>113 (69.3)</td>
</tr>
<tr>
<td>Highest education level achieved</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No qualifications</td>
<td>58 (71.6)</td>
<td>49 (59.8)</td>
<td>107 (65.6)</td>
</tr>
<tr>
<td>Secondary/ TAFE/Diploma</td>
<td>13 (16.0)</td>
<td>16 (19.5)</td>
<td>29 (17.8)</td>
</tr>
<tr>
<td>Degree or higher degree</td>
<td>10 (12.4)</td>
<td>17 (20.7)</td>
<td>27 (16.6)</td>
</tr>
<tr>
<td>Employment status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical disability pension</td>
<td>67 (82.7)</td>
<td>51 (62.2)</td>
<td>118 (72.4)</td>
</tr>
<tr>
<td>Retired/unemployed/home duties</td>
<td>8 (9.9)</td>
<td>21 (25.6)</td>
<td>29 (17.8)</td>
</tr>
<tr>
<td>Full /part-time employment</td>
<td>6 (7.4)</td>
<td>10 (12.2)</td>
<td>16 (9.8)</td>
</tr>
<tr>
<td>Living with someone (yes)</td>
<td>52 (64.2)</td>
<td>57 (69.5)</td>
<td>109 (66.7)</td>
</tr>
<tr>
<td>Primary cause of vision loss</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age-related macular degeneration</td>
<td>20 (24.7)</td>
<td>23 (28.0)</td>
<td>43 (26.4)</td>
</tr>
<tr>
<td>Other#</td>
<td>8 (9.9)</td>
<td>16 (19.5)</td>
<td>24 (14.7)</td>
</tr>
<tr>
<td>Diabetic retinopathy</td>
<td>14 (17.3)</td>
<td>9 (11.0)</td>
<td>23 (14.1)</td>
</tr>
<tr>
<td>Optic nerve pathology</td>
<td>9 (11.1)</td>
<td>11 (13.4)</td>
<td>20 (12.3)</td>
</tr>
<tr>
<td>Retinitis pigmentosa</td>
<td>12 (14.8)</td>
<td>4 (4.9)</td>
<td>16 (9.8)</td>
</tr>
<tr>
<td>Other genetic disorder</td>
<td>8 (9.9)</td>
<td>4 (4.9)</td>
<td>12 (7.4)</td>
</tr>
<tr>
<td>Glaucoma</td>
<td>4 (4.9)</td>
<td>6 (7.3)</td>
<td>10 (6.1)</td>
</tr>
<tr>
<td>Unspecified</td>
<td>3 (3.7)</td>
<td>6 (7.3)</td>
<td>9 (5.5)</td>
</tr>
<tr>
<td>Uveitis</td>
<td>3 (3.7)</td>
<td>3 (3.7)</td>
<td>6 (3.7)</td>
</tr>
<tr>
<td>Level of vision impairment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>28 (34.6)</td>
<td>20 (24.4)</td>
<td>48 (29.4)</td>
</tr>
<tr>
<td>Moderate</td>
<td>30 (37.0)</td>
<td>42 (51.2)</td>
<td>72 (44.2)</td>
</tr>
<tr>
<td>Severe / blindness</td>
<td>23 (28.4)</td>
<td>20 (24.4)</td>
<td>43 (26.4)</td>
</tr>
</tbody>
</table>

Table 5.1 continued on next page (page 71)
### Table 5.1 Baseline characteristics of the participants† (continued)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Interventio</th>
<th>Control</th>
<th>Total sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>History of depression (yes)</td>
<td>41 (50.6)</td>
<td>34 (41.5)</td>
<td>75 (46.0)</td>
</tr>
<tr>
<td>Previously treated for depression (yes)</td>
<td>36 (44.4)</td>
<td>30 (36.6)</td>
<td>66 (40.5)</td>
</tr>
<tr>
<td>PHQ-9 raw score, Mean (SD)</td>
<td>12.14</td>
<td>12.21</td>
<td>12.17</td>
</tr>
<tr>
<td>PHQ-9 median score (range)</td>
<td>(4.77)</td>
<td>(4.27)</td>
<td>(4.51)</td>
</tr>
<tr>
<td>PHQ-9 Rasch score, Mean (SD)</td>
<td>-0.24</td>
<td>-0.23</td>
<td>-0.23</td>
</tr>
<tr>
<td>PHQ-9 score by symptom severity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5-9 (mild)</td>
<td>26 (32.1)</td>
<td>25 (30.5)</td>
<td>51 (31.3)</td>
</tr>
<tr>
<td>10-14 (moderate)</td>
<td>31 (38.3)</td>
<td>30 (36.6)</td>
<td>61 (37.4)</td>
</tr>
<tr>
<td>15-19 (moderately severe)</td>
<td>16 (19.8)</td>
<td>23 (28.0)</td>
<td>39 (23.9)</td>
</tr>
<tr>
<td>20-27 (severe)</td>
<td>8 (9.9)</td>
<td>4 (4.9)</td>
<td>12 (7.4)</td>
</tr>
<tr>
<td>AQoL-7D</td>
<td>0.48 (0.09)</td>
<td>0.48 (0.09)</td>
<td>0.48 (0.09)</td>
</tr>
<tr>
<td>IVI-emotion Rasch score</td>
<td>-1.65</td>
<td>-1.74</td>
<td>-1.69</td>
</tr>
</tbody>
</table>

†Figures are numbers (percentages) of participants unless stated otherwise. PHQ-9 = Patient Health Questionnaire 9 (raw score 0-27, Rasch score -5 to 5); AQoL-7D = Assessment of Quality of Life seven dimensions (scored 0 to 1); IVI-emotion = Impact of Vision Impairment Questionnaire-distress subscale (scored -5 to 5)

#### 5.3.2 Practitioner fidelity

Fourteen (70%; 14/20) LVR practitioners participated in the trial (mean age=47.6, SD=12.68). They were mostly female (93%), had some previous mental health training (64%), and had worked in low vision rehabilitation settings for approximately 10 years (mean =9.99, SD=9.99). A high level of inter-rater reliability was found for the overall fidelity scale (computed using PST-PAC items 1-6) and global competence scale (97.8% and 94.1%, respectively). Consequently the average mean summary scores from the two raters were chosen as the final process measure. The practitioners achieved a satisfactory score or better (≥ 3) on the overall fidelity scale (mean =3.55, SD=1.17) and for the global competence scale (mean =1.35, SD=1.56), demonstrating that PST-PC was delivered with high fidelity.
5.3.3 Primary outcome

Intention-to-treat analysis (ITT; Table 5.2) showed a significant treatment effect at 6 months with a mean difference in PHQ-9 scores between groups of -3.99 (95% CI -5.77 to -2.22, \( p<0.001 \); raw score \( d=0.75 \), 95% CI -1.08 to -0.40; Rasch score \( d=-0.81 \), 95% CI -1.15 to -0.46). The average rate of change in depressive symptoms was significantly greater in the intervention group compared to controls (ITT: \( \beta=-0.84 \), 95% CI -1.29 to -0.39, \( p<0.001 \) and PP: \( \beta=-1.05 \), 95% CI -1.66 to -0.45, \( p=0.001 \)). A CSC (Table 5.4) in depressive symptoms at 6 months was achieved in 40% (\( n=19/47 \)) of participants in the intervention group and 14% (\( n=7/51 \)) in the control group (odds ratio (OR) =5.72, 95% CI 1.61-20.36, \( p=0.001 \)) for those with a baseline PHQ-9 score \( \geq 10 \). For participants with subthreshold depressive symptoms or greater (baseline PHQ-9 score \( \geq 5 \)), the odds of achieving a 5-point reduction on the PHQ-9 increased by 6 fold for the intervention group relative from controls (OR=6.18, 95% CI 2.19 to 17.44, \( p=0.001 \)). LMM results were robust to sensitivity analysis (Table 5.5).

At 12-month follow-up treatment benefits were not maintained in ITT analysis but a significant group difference was found in the PP sample (mean difference=-3.21, 95% CI -5.96 to -0.45; \( d=0.59 \), 95% CI 1.09 to -0.08; Table 5.3). The average rate of change in depressive symptoms was significantly greater in the intervention group compared to controls at 12 months using the PP sample only (\( \beta=-0.80 \), 95% CI -1.42 to -0.18, \( p=0.011 \)). At the 12-month follow-up, individuals who completed at least four PST-PC sessions maintained fewer depressive symptoms compared to controls (\( \beta=-0.79 \), 95% CI -1.47 to -0.11), however intervention participants who completed fewer than 4 sessions did not differ to controls (\( \beta=-0.09 \), 95% CI -0.61 to 0.42; Figure 5.2).
### Table 5.2 ITT analyses of primary outcome (PHQ-9) post-treatment, 6 and 12-months

<table>
<thead>
<tr>
<th></th>
<th>Intervention group</th>
<th>Control group</th>
<th>Between-group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Unadjusted Mean (SD)</td>
<td>n</td>
</tr>
<tr>
<td><strong>PHQ-9 raw score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>81</td>
<td>12.14 (4.77)</td>
<td>82</td>
</tr>
<tr>
<td>Post-treatment</td>
<td>79</td>
<td>9.05 (5.88)‡</td>
<td>81</td>
</tr>
<tr>
<td>6-months</td>
<td>68</td>
<td>8.99 (5.27)‡</td>
<td>75</td>
</tr>
<tr>
<td>12-months</td>
<td>62</td>
<td>9.16 (6.48)†</td>
<td>67</td>
</tr>
<tr>
<td><strong>PHQ-9 Rasch score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>81</td>
<td>-0.24 (0.94)</td>
<td>82</td>
</tr>
<tr>
<td>Post-treatment</td>
<td>79</td>
<td>-1.02 (1.63)‡</td>
<td>81</td>
</tr>
<tr>
<td>6-months</td>
<td>68</td>
<td>-0.99 (1.28)†</td>
<td>75</td>
</tr>
<tr>
<td>12-months</td>
<td>62</td>
<td>-1.13 (1.76)†</td>
<td>66</td>
</tr>
</tbody>
</table>

† Difference in means = mean change (intervention) – mean change (control)
Δ Cohen's d. Effect size based on pooled SD of baseline measures
‡ Significant within group difference at time-point compared to baseline
PHQ-9=Patient Health Questionnaire-9; PHQ-9 Rasch (scores closer to 5 indicate lower depressive symptomology)
‡ Results from linear mixed-model, adjusted for age, gender, history of depression, treatment for depression, self-reported change in vision, time and an interaction between time-point and treatment as fixed effects. Demographic characteristics for which imbalances were detected at baseline were analysed in univariate analysis however as these were non-significant, they were not included in the final model
<table>
<thead>
<tr>
<th></th>
<th>Intervention group</th>
<th>Control group</th>
<th>Between-group</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PHQ-9 raw score</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>22</td>
<td>83</td>
<td>N/C</td>
<td>N/C</td>
<td>N/C</td>
<td>N/C</td>
<td>N/C</td>
</tr>
<tr>
<td>Post-treatment</td>
<td>21</td>
<td>82</td>
<td>-4.64 (-6.90 to -2.38)</td>
<td>&lt;0.001</td>
<td>-0.99 (-1.49 to -0.49)</td>
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<tr>
<td>6-months</td>
<td>21</td>
<td>75</td>
<td>-5.08 (-7.51 to -2.65)</td>
<td>&lt;0.001</td>
<td>-1.03 (-1.53 to -0.52)</td>
<td>N/C</td>
<td></td>
</tr>
<tr>
<td>12-months</td>
<td>20</td>
<td>67</td>
<td>-3.21 (-5.96 to -0.45)</td>
<td>0.023</td>
<td>-0.59 (-1.09 to -0.08)</td>
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<tr>
<td><strong>PHQ-9 Rasch score</strong></td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>22</td>
<td>83</td>
<td>N/C</td>
<td>N/C</td>
<td>N/C</td>
<td>N/C</td>
<td>N/C</td>
</tr>
<tr>
<td>Post-treatment</td>
<td>22</td>
<td>82</td>
<td>-1.22 (-1.77 to -0.66)</td>
<td>&lt;0.001</td>
<td>-1.04 (-1.53 to -0.55)</td>
<td>-1.04 (-1.64 to -0.44), 0.001</td>
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<tr>
<td>6-months</td>
<td>21</td>
<td>75</td>
<td>-1.09 (-1.60 to -0.59)</td>
<td>&lt;0.001</td>
<td>-1.06 (-1.57 to -0.55)</td>
<td>-1.05 (-1.66 to -0.45), 0.001</td>
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<tr>
<td>12-months</td>
<td>20</td>
<td>66</td>
<td>-0.80 (-1.52 to -0.09)</td>
<td>0.028</td>
<td>-0.57 (-1.08 to -0.06)</td>
<td>-0.80 (-1.42 to -0.18), 0.011</td>
<td></td>
</tr>
</tbody>
</table>

† Difference in means = mean change (intervention) – mean change (control)

Δ Cohen's d. Effect size based on pooled SD of baseline measures

¥ Significant within group difference at time-point compared to baseline

PHQ-9=Patient Health Questionnaire-9; PHQ-9 Rasch (scores closer to -5 indicate lower depressive symptomology)

‡ Results from linear mixed-model, adjusted for age, gender, history of depression, treatment for depression, self-reported change in vision, time and an interaction between time-point and treatment as fixed effects. Demographic characteristics for which imbalances were detected at baseline were analysed in univariate analysis however as these were non-significant, they were not included in the final model.
### Table 5.4 Logistic regression models for clinically significant change in depressive symptoms (PHQ-9) at 6-month follow-up

<table>
<thead>
<tr>
<th></th>
<th>Intention-to treat</th>
<th></th>
<th>Adjusted* odds ratio (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control group</td>
<td>Intervention group</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Reference)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Baseline</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PHQ-9 score &lt; 10</td>
<td>25/82 (30.5)</td>
<td>26/81 (32.1)</td>
<td>NC</td>
<td>NC</td>
</tr>
<tr>
<td>PHQ-9 score ≥ 10</td>
<td>57/82 (69.5)</td>
<td>55/81 (67.9)</td>
<td>NC</td>
<td>NC</td>
</tr>
<tr>
<td><strong>6-months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Model 1</td>
<td>7/51 (13.7)</td>
<td>19/47 (40.4)</td>
<td>5.72 (1.61 to 20.36)</td>
<td>0.007</td>
</tr>
<tr>
<td>Model 2</td>
<td>10/75 (13.3)</td>
<td>28/68 (41.2)</td>
<td>6.18 (2.19 to 17.44)</td>
<td>0.001</td>
</tr>
</tbody>
</table>

Data are n/N (%) unless otherwise stated. NC= not calculated.
Lost-to-follow-up at 6-months n=13 (intervention group), n=7 (control group).
*Adjusted for age, gender, history of depression, treatment for depression and self-reported change in visual acuity.

Model 1. Participants baseline PHQ-9 score ≥ 10. Odds ratios is for a clinically significant change in depressive symptoms (≥5 point reduction on the PHQ-9 and a PHQ-9 score less than 10) at 6 months in the intervention group.

Model 2. Participants with subthreshold depressive symptoms at baseline (PHQ score ≥ 5). Odds ratios is for a ≥5 point reduction on the PHQ-9 at 6-months in the intervention group.

### Table 5.5 Imputation of data for primary outcome (PHQ-9) post-intervention and at 6 and 12-months for the intervention group relative to controls

<table>
<thead>
<tr>
<th></th>
<th>Predicted values</th>
<th>Predicted and imputed values*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Adjusted‡ β</td>
<td>p value</td>
</tr>
<tr>
<td></td>
<td>(95 % CI)</td>
<td></td>
</tr>
<tr>
<td><strong>PHQ-9 Rasch score</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post-treatment</td>
<td>-0.76 (-1.19 to -0.32)</td>
<td>0.001</td>
</tr>
<tr>
<td>6 months</td>
<td>-0.84 (-1.29 to -0.39)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>12 months</td>
<td>-0.30 (-0.77 to 0.17)</td>
<td>0.209</td>
</tr>
</tbody>
</table>

*Based on 10 imputed datasets using chained equations.
Figure 5.2 ITT predicted mean PHQ-9 Rasch scores at each time-point, by group

PHQ-9=Patient Health Questionnaire-9 (scores closer to -5 indicate lower depressive symptom severity)
Table 5.6 ITT analyses of secondary outcomes (AQoL, IVI-distress) post-treatment, 6 and 12-month follow-up

<table>
<thead>
<tr>
<th></th>
<th>Intervention group</th>
<th>Control group</th>
<th>Between-group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Unadjusted Mean (SD)</td>
<td>n</td>
</tr>
<tr>
<td>HRQoL (AQoL-7D)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>81</td>
<td>0.48 (0.09)</td>
<td>82</td>
</tr>
<tr>
<td>Post-treatment</td>
<td>79</td>
<td>0.52 (0.11)</td>
<td>81</td>
</tr>
<tr>
<td>6-months</td>
<td>66</td>
<td>0.53 (0.10)*</td>
<td>72</td>
</tr>
<tr>
<td>12-months</td>
<td>62</td>
<td>0.52 (0.11)*</td>
<td>66</td>
</tr>
<tr>
<td>Distress (IVI Rasch score)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>81</td>
<td>-1.62 (1.60)</td>
<td>82</td>
</tr>
<tr>
<td>Post-treatment</td>
<td>79</td>
<td>1.11 (1.25)*</td>
<td>81</td>
</tr>
<tr>
<td>6-months</td>
<td>68</td>
<td>1.34 (1.44)*</td>
<td>75</td>
</tr>
<tr>
<td>12-months</td>
<td>62</td>
<td>0.98 (1.41)*</td>
<td>67</td>
</tr>
</tbody>
</table>

\(\Delta\) Difference in means = mean change (intervention) – mean change (control)
\(\Delta\) Cohen's d. Effect size based on pooled SD of baseline measures
\* Significant within group difference at time-point compared to baseline
\(\Delta\) Rasch (scores closer to 5 indicate greater depressive symptomology); AQoL=Assessment of Quality of Life-seven dimensions (scores closer to 1 indicate better quality of life); IVI-emotion=Impact of Vision Impairment vision-specific distress (scores closer to -5 indicate greater distress)
\(\hat{\beta}\) Results from linear mixed-model, adjusted for age, gender, history of depression, treatment for depression, self-reported change in vision, time and an interaction between time-point and treatment as fixed effects. Demographic characteristics for which imbalances were detected at baseline were analysed in univariate analysis however as these were non-significant, they were not included in the final model
### Table 5.7 PP analysis of secondary outcomes (AQoL, IVI-distress) post-treatment, 6 and 12-month follow-up

<table>
<thead>
<tr>
<th></th>
<th>Intervention group</th>
<th>Control group</th>
<th>Between-group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Mean (SD)</td>
<td>n</td>
</tr>
<tr>
<td>HRQoL (AQoL-7D)</td>
<td>22</td>
<td>0.48 (0.10)</td>
<td>83</td>
</tr>
<tr>
<td>Baseline</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post-treatment</td>
<td>21</td>
<td>0.51 (0.10)</td>
<td>82</td>
</tr>
<tr>
<td>6-months</td>
<td>20</td>
<td>0.56 (0.10)(^\¥)</td>
<td>72</td>
</tr>
<tr>
<td>12-months</td>
<td>20</td>
<td>0.51 (0.08)</td>
<td>66</td>
</tr>
<tr>
<td>Distress (IVI Rasch score)</td>
<td>22</td>
<td>-1.94 (1.28)</td>
<td>83</td>
</tr>
<tr>
<td>Baseline</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post-treatment</td>
<td>21</td>
<td>0.85 (1.03)(^\¥)</td>
<td>82</td>
</tr>
<tr>
<td>6-months</td>
<td>21</td>
<td>1.37 (1.44)(^\¥)</td>
<td>75</td>
</tr>
<tr>
<td>12-months</td>
<td>20</td>
<td>0.89 (1.26)(^\¥)</td>
<td>66</td>
</tr>
</tbody>
</table>

\(^\dagger\) Difference in means = mean change (intervention) – mean change (control)
\(^\Delta\) Cohen's d. Effect size based on pooled SD of baseline measures
\(^\¥\) Significant within group difference at time-point compared to baseline
Rasch (scores closer to 5 indicate greater depressive symptomology); AQoL=Assessment of Quality of Life-seven dimensions (scores closer to 1 indicate better quality of life); IVI=Impact of Vision Impairment vision-specific distress (scores closer to -5 indicate greater distress)
\(^\ddagger\) Results from linear mixed-model, adjusted for age, gender, history of depression, treatment for depression, self-reported change in vision, time and an interaction between time-point and treatment as fixed effects. Demographic characteristics for which imbalances were detected at baseline were analysed in univariate analysis however as these were non-significant, they were not included in the final model.
5.3.4 Secondary outcomes

ITT (Table 5.6) and PP analysis (Table 5.7) shows a significant treatment effect at 6 months on HRQoL (ITT: $d=0.39$, 95% CI 0.05 to 0.72; PP: $d=0.51$, 95% CI 0.01 to 1.02) and vision-specific distress (ITT: $d=0.40$, 95% CI 0.07 to 0.73; PP: $d=0.58$, 95% CI 0.08 to 1.07) favouring PST-PC. For both the secondary outcomes, treatment effects were not maintained at 12 months in ITT (Table 5.6) or PP analysis (Table 5.7). The rate of improvement in HRQoL (ITT: $\beta =0.04$, 95% CI 0.01 to 0.07) and vision-specific distress (ITT: $\beta =0.57$, 95% CI 0.10 to 1.04) was significantly greater in the intervention group compared to controls up until 6-month follow-up.

5.3.5 Cost effectiveness analysis

In the base-case scenario, the net difference in cost per participant was AU$776 ($SD=115.9$). The net difference in QoL was 0.04 ($p=0.024$) over 6 months or 0.02 QALYs. Using these estimates, the incremental cost-effectiveness ratio (ICER) was AU$40,386 (bootstrapped 95% CI: 20,580 to 355,190) per QALY gained. At the commonly used WTP threshold of AU$64,000/QALY in Australia, the intervention would be cost-effective in 82% of simulations compared to usual care alone, even if HRQoL benefits do not extend beyond 6 months. Figure 5.3 presents the probability that the intervention is cost-effective at different WTP thresholds. Sensitivity analysis using 12 month HRQoL results (AU$47,852, bootstrapped 95% CI: 21,420 to 138,030) showed the ICER was slightly higher but still below the threshold for cost effectiveness in 69% of simulations. Using the EQ-5D as an alternative measure of effectiveness we found that the intervention would be cost-effective in 59% of simulation (AU$50,078, bootstrapped 95% CI: 15,640 to -47,320).
Figure 5.3 Cost-effectiveness acceptability curve showing the probability that PST-PC is cost-effective compared to usual care over a range of willingness to pay values for one additional QALY gained

4.4 Discussion

5.4.1 Summary of findings

The results show that integrated telephone-delivered PST-PC administered by trained LVR practitioners is a clinically effective model for reducing depressive symptoms among people with low vision, resulting in continued benefits at 1-year follow-up when a minimum of four sessions was completed. Almost 50% of participants receiving PST-PC showed a clinically significant reduction in depressive symptoms compared to 14% in the control group and furthermore, showed greater improvements in HRQoL and vision-specific emotional distress at 6 months. At the WTP threshold of $64000/QALYs gained, this model has a 82% probability of being cost-effective compared to usual care alone.
The findings support a large body of research demonstrating the effectiveness of PST-PC for managing depression in the general adult community and more specifically in older adults with VI in the short term. The benefits in relation to depressive symptoms were maintained at 12 months when at least four treatment sessions were completed. These are encouraging data to support this rehabilitation staff-delivered model, given that many efficacy trials of psychological therapies are delivered by mental-health professionals and are limited to 6-month follow-up of study participants. Those that investigate longer trajectories find maintaining the benefits challenging. The provision of maintenance sessions or the integration of PST-PC into low vision rehabilitation may have contributed to sustained benefits in this study.

It is noteworthy that the control group demonstrated a small decrease (2-points) on the PHQ-9 between 6 and 12 months, however mean scores still remained at a level that would be considered clinically significant and meeting the criteria for moderate depression. Participants in the control group who withdrew from the trial had a higher baseline PHQ-9 score (mean=13.9) compared to those who were retained until the 12-month assessment (mean=11.8) which could bias the results towards lower symptom severity in controls at 12 months. Treatment within usual care (i.e. antidepressants or psychological services) or the use of low vision rehabilitation services, which have demonstrated a positive effect on emotional well-being, may also have contributed to improvements in the control group.

The benefits of PST-PC observed in this study must be regarded in the context of the high withdrawal rate; 73% did not complete the minimum number of sessions largely due to poor health. Encouraging rates for PST-PC treatment adherence have been reported in RCTs conducted with adult community samples. However, our study was pragmatic in nature, drawing on an older-population with complex comorbid health issues, and would more closely reflect routine clinical practice. Nonetheless, early termination from treatment is a problem shared by all psychological modalities and is a major concern given the impact it has on treatment outcomes. This finding underscores the need to understand this issue in more depth and develop strategies to improve client engagement with PST-PC.
5.4.2 Strengths and limitations of this study

This pragmatic trial has several strengths, including the delivery of PST-PC, an evidence-based psychological intervention, by trained low vision rehabilitation staff in routine practice, and the follow-up of participants over a longer period than is typically reported in trials of PST-PC. Due to the geographic dispersal of low vision rehabilitation service users across Australia, training LVR practitioners in telephone delivery of PST-PC ensures that the treatment could potentially be implemented more widely. A 5-point reduction in depressive symptoms for participants with subthreshold symptoms indicates that this model of care also provides early intervention to those with subthreshold symptoms and may prevent the progression of symptoms to MDD.

This trial has several limitations. The generalisability of these findings is limited to adults who utilise LVR services and cannot be extended to adults with VI more broadly who do not take up these services. In this study and also a depression-prevention stepped-care trial of PST in outpatients attending LVR services, older adults were more likely to decline participation.138 Strategies to encourage uptake in this group are needed given that older adults comprise a significant proportion of the population with VI.214 Due to the pragmatic nature of this trial, a structured diagnostic interview schedule was not used for the primary outcome. However, the PHQ-9 is a well-validated self-report tool of depressive symptoms, which can be easily administered by non-specialist mental health workers in routine practice. History of depression, previous treatment and uptake of depression treatment during the course of the trial were collected via self-report and not verified with GP records. Furthermore, this study was underpowered to analyse the contribution of the maintenance sessions on the sustained benefits observed at 12-month follow-up and this requires further investigation.

5.4.3 Implications for practice and future research

Given the increasing global pressure for cost effective service delivery models, the findings have substantial implications. Ninety percent of the world’s vision impaired population reside in low-income countries where access to specialist mental health professionals is limited and often unaffordable. The training of low vision and eye care professionals in the
delivery of PST-PC as a first step in managing subthreshold, mild or moderate depressive symptoms has the potential to increase access to an evidence-based psychological treatment in a manner that is likely to be more affordable for health-care providers. The EQ-5D as a measurement of effect resulted in a higher ICER. The EQ-5D, which does not include a vision-specific dimension may not be sensitive enough to evaluate the HRQoL burden associated with vision loss and evidence to support this has been documented previously. However, using condition-specific utility measures has implications for the interpretation and comparison of findings across health disciplines and further research is needed to delineate the advantages and disadvantages of this approach.

The benefits from PST-PC in the present study are sufficiently promising to justify further development of the intervention. Strategies to encourage treatment uptake are needed, particularly for older adults who may hold beliefs that they can “make do” (i.e. stoicism) without the need for psychological intervention. Motivational interviewing (MI) techniques, which impact important behavioural indices such as ambivalence and uptake with mental health treatment, could be integrated into standard pre-treatment procedures to facilitate the client’s beliefs regarding the importance of engaging with PST-PC. Practitioners could also receive additional training in age-appropriate treatment techniques which take into account life experiences and emphasise strategies to decrease functional limitations imposed by age-related changes. The use of technology to provide face-to-face interaction may promote sustained engagement. Staff-supported computer-based treatments such as internet-delivered CBT or Skype sessions have an increasing evidence-base for their efficacy and have the advantage of being cost effective and highly accessible to a range of populations including older adults. Incorporating the principles of PST-PC within group-based or stepped-care models, which has shown promise in people with low vision, could also be considered.

5.4.5 Conclusions

This study demonstrates that an integrated telephone-delivered PST-PC model administered by a LVR practitioner for adults with VI is clinically and economically effective in reducing depressive symptoms. The treatment effects are maintained after one year when at
least four sessions are completed. Strategies to encourage client uptake, sustained engagement and modalities for improving client access are however needed to ensure sufficient numbers receive benefit from this model.
Phase 4: Evaluating implementation
Chapter 6: Phase 4, Evaluating Implementation (Part A - factors associated with early termination)

6.1 Introduction

Vision impairment (VI) is a leading cause of disability worldwide affecting 223 million individuals and costing society $3 trillion globally.\(^{15,48}\) Disability associated with vision loss significantly increases the risk of developing depression,\(^{1-3}\) contributing to a higher risk of premature mortality\(^4\) and greater health care costs\(^5\) if depression is left untreated. Cross-sectional studies demonstrate that up to 43% of adults with VI will experience depressive symptoms, and for the majority, these symptoms will fall below the criteria for major depressive disorder ((MDD) termed subthreshold depression).\(^6-11,21,22\) Subthreshold symptoms are distressing if persistent, further reduce functioning, and are associated with an increased risk of developing MDD.\(^74,75,74\)

Early identification and treatment of depressive symptoms in people with VI is therefore critical in reducing and preventing symptom progression and excess disability. To address these issues ‘models of integrated care’ implemented in rehabilitation programs for people with depression and functional impairment resulting from chronic physical illness have been recommended.\(^37,110\) This is particularly important in VI where up to 80% of affected people are not receiving treatment for depression\(^11,12\) due to salient barriers such as self-reliance (or stoicism), stigma towards receiving support from a mental health professional and physical barriers to accessing services (e.g. poor mobility or health, lack of transport).\(^24,25\)

In Chapter 5, the clinical and cost-effectiveness of PST-PC was investigated, however, rates of early termination from PST-PC were high and understanding the reasons for this are imperative, given the emphasis on Problem-Solving Treatment in clinical trials targeting depression in people with VI.\(^26,29,134,137,138,140\) Early termination from treatment may also impede the overall effectiveness of PST-PC, resulting in poorer clinical outcomes, greater health care needs in future and the inefficient use of resources for the rehabilitation provider.\(^213,222,223\)
This study aimed to investigate pre-treatment demographic, clinical and psychological predictors associated with early termination from PST-PC. Drawing on data obtained from Phase 2 (Chapter 4) and empirical research, it was hypothesised that older age, a higher severity of depressive symptoms, and low acceptance of one’s vision loss at baseline would be significantly associated with early termination. The minimum number of PST-PC sessions associated with a clinically significant change (CSC) in depressive symptoms and client reasons for early termination were also explored.

6.2 Methods

6.2.1 Study design and participants

This was a prospective longitudinal study with baseline and 6-month follow-up assessments. Participants were adult low vision rehabilitation (LVR) clients enrolled in a pragmatic, multi-centred randomised controlled trial to evaluate the clinical and cost-effectiveness of PST-PC plus usual care compared to usual care alone (referral to a general practitioner). Study participants were 81 individuals randomised to the intervention arm and offered 6 to 8 weekly telephone sessions of PST-PC delivered by a trained LVR practitioner. A detailed description of the trial design is presented in Appendix 3.

Prospective participants were recruited by intake staff from 28 LVR centres in five states of Australia. Individuals were screened for depressive symptoms using the Patient Health Questionnaire-2 (PHQ-2) as a standard intake procedure and were referred into the study if their score was >3 (optimal cut-off point for screening purposes). A trained researcher/PhD student (E. Holloway) then assessed prospective participants for eligibility via telephone. Inclusion criteria were being 18 years or older, with best corrected visual acuity <6/12 in the better eye, adequate hearing (use of a hearing aid if necessary), no cognitive impairment (score <7 on the six-item Cognitive Impairment Test [CIT6], and not currently receiving treatment (i.e. talking therapy or antidepressant medication) for a mental health condition. Participants were rescreened for the presence of depressive symptoms (Patient Health Questionnaire-9 (PHQ-9)) and were eligible to participate if
they had a score ≥5, given the high prevalence of subthreshold depression in this population.²¹²²

Participants completed a baseline assessment followed by 6 to 8 sessions of PST-PC delivered by an expertly trained LVR practitioner between January 2014 and January 2015. PST-PC is described in detail in Chapter 4. In brief, PST-PC a manualised psychological treatment that focuses on teaching individuals the skills and processes of problem-solving in order to enhance their ability to cope with daily challenges.⁴² Participants received an introductory session outlining PST-PC aims and rationale followed by weekly sessions of 45-60 minutes duration where seven problem-solving steps are introduced in the first session and reinforced in subsequent sessions. Participants who completed 6 to 8 sessions were offered a further four monthly maintenance sessions to reinforce the skills. All sessions were delivered over the telephone. Following the treatment sessions, participants completed a 6-month assessment. Baseline and 6-month assessments were completed via telephone with a trained research assistant/PhD level student (E. Holloway). Participants who completed at least one PST-PC session (and fewer than six) were invited to take part in a semi-structured telephone interview completed by a research assistant independent from the project team.

The study was approved by the Royal Victorian Eye and Ear Hospital Human Research Ethics Committee (project number 12/1061H) and Deakin University Human Research Ethics Committee (project number 2012-139), and was conducted in accordance with the Declaration of Helsinki. Participants provided written consent regarding their participation in the study which was part of an RCT (registered with the Australian New Zealand Clinical Trials Registry, trial number: ACTRN12612000318886).
6.2.2 Outcomes and measures

Pre-treatment predictors associated with early termination

Demographic factors
Age, gender, marital status, living arrangements, country of birth, level of education, health comorbidities, employment and perceived general health statuses were collected at baseline.

Clinical factors
Visual acuity was obtained from Vision Australia records for the participant’s most recent clinic appointment prior to the study enrolment. Visual acuity was assessed using Snellen charts (using best corrected vision) and VI levels were defined using either presenting or best-corrected visual acuity in the better eye and categorised as mild (<6/12-6/18), moderate (<6/18-6/60) or severe (<6/60).

Self-reported depressive symptom severity was assessed using the PHQ-9. The PHQ-9 asks participants the degree to which they had experienced nine symptoms in the past 2 weeks (“not at all” (0) to “nearly every day” (3)), with a summed score range of 0-27. A score of 5 to 9 is considered mild and ≥10 is the threshold for clinical levels of depression, with a sensitivity and specificity of 88% in detecting major depressive disorder. The PHQ-9 has demonstrated validity in vision impaired samples and for telephone administration. Prior episodes of depression, previous treatment for depression/mental health condition and psychological co-morbidity were collected by self-report.

Psychological factors
Acceptance of one’s VI was assessed using the 6-item Acceptance subscale of the Illness Cognition Questionnaire. The Acceptance subscale reflects acknowledgement of one's low vision and perceived ability to positively manage its negative consequences—for example, “I have learned to live with my vision impairment”. The four-point response format ranges from “not at all” (1) to “completely agree” (4). Scores are summed with higher scores indicating a greater level of acceptance of one’s vision impairment. The ICQ
has demonstrated strong internal reliability, as well as good construct and predictive validity across chronic conditions.\(^8\)

Confidence in one's ability to cope effectively with life challenges was assessed using the 26-item Coping Self-Efficacy (CSE) Questionnaire.\(^{225}\) The three subscales are: “Problem-Focused”—for example, “Make a plan of action and follow it when confronted with a problem” (12 items); “Stop Unpleasant Emotions/Thoughts”—for example, “Look for something good in a negative situation” (9 items); and “Support from Friends/Family”—for example, “Get emotional support from friends and family” (5 items). Participants indicate the extent to which they could perform each coping statement using an 11-point anchored scale for each item “cannot do at all” (0) to “certainly can do” (10), with a higher score indicating greater CSE. The CSE has demonstrated excellent internal reliability and concurrent and predictive validity.\(^{225}\)

Perceived availability and adequacy of social support were assessed using items previously developed to assess social support in individuals with low vision.\(^2\) Two summed items assessed the perceived availability of practical and emotional support from family and friends and two summed items assessed the perceived adequacy of support. Each item was rated on a 4-point response scale ranging from “most of the time” (1) “not at all” (4). In addition, perceived quality of social relationships was assessed using the four-item Relationships domain of the Assessment of Quality of Life (AQoL-7D) measure.\(^{148}\) Utility scores ranging from 0-1.00 are calculated, where a score of 0.00 would represent worst possible relationship quality and 1.00 would represent best possible quality. Pre-treatment levels of both quantity and quality of social support/relationships have previously been linked to treatment outcomes (e.g. attendance of sessions) for depression in chronic illness.\(^{226}\)

Rasch analysis was used to measure the psychometric properties of all ordinal measures (i.e. PHQ-9, ICQ and CSE) using the Andrich rating scale model \(^{227}\) with Winsteps software (version 3.75), Chicago, Illinois, USA.\(^{228}\) \(^{229}\) All measures demonstrated acceptable fit to Rasch model parameters (Appendix 4).
Number of sessions to achieve a clinically significant change in depressive symptoms

Six to eight PST-PC sessions are recommended,\textsuperscript{37,42} however previous studies of PST have shown clinically significant treatment effects with as few as four sessions.\textsuperscript{131,168,193,194} To aid efficiency of PST-PC delivery, the minimum number of sessions associated with a CSC in depressive symptoms ($\geq$5-point reduction on the Patient Health Questionnaire-9 [PHQ-9])\textsuperscript{230,231} at 6-month follow-up was investigated.

Client reasons for early termination

Clients who completed $<$6 PST-PC sessions were contacted by the research assistant and asked to describe the main reason they decided to terminate the PST-PC sessions early. Those who completed at least one PST-PC session were also invited to participate in a brief telephone interview regarding the therapeutic relationship with their practitioner, perceived need for emotional support and expectations regarding the PST-PC treatment. These items were adapted from previous studies assessing therapist-client rapport.\textsuperscript{169,232}

6.2.3 Analysis

All analyses were performed with STATA version 14.1. A two-sided alpha level of 0.05 was used to indicate statistical significance. Descriptive statistics were computed (chi-square tests or two-sample t-tests) to compare characteristics between those who completed $\geq$6 sessions and those who completed $<$6 sessions. Global Search Regression (GSREG) was performed to assess the relative importance of each baseline covariate associated with early termination from PST-PC. GSREG allows automatic model selection for time series and cross-sectional data regressions providing parameter robustness comparisons.\textsuperscript{233} GSREG is a complete-exhaustive algorithm, particularly useful for small size samples as it guarantees optimality with out-of-sample selection criteria and allows residual testing for each alternative, hence reducing cumulative type I errors. Using GSREG, a list containing all possible combinations of covariates was generated, followed by a regression for each alternative combination of covariates (providing estimated coefficients and statistics). Model selection and fit was determined using the Akaike’s Information Criterion (AIC) and Bayesian Information Criterion (BIC), where smaller values indicate a better fit.\textsuperscript{234} In
addition, normalized linear combination of model selection criteria (nindex) statistics were generated ranking each regression model from highest to lowest normalised accuracy. Based on these parameters (AIC, BIC, and nindex), variables identified in the best fitting model were entered into a multivariable logistic regression analysis to obtain odds ratios (OR) and corresponding 95% confidence intervals (CI). Bonferroni correction was performed to adjust for multiple comparisons of the same dependent variable.

To explore the minimum number of sessions associated with a CSC on the PHQ-9, predictive margins, with covariate adjustment, were calculated from a fitted linear regression model. A profile plot with marginal means and their 95% confidence intervals (CI) for each session (0 to 8) was generated. Reasons for early termination from PST-PC were coded using inductive thematic analysis\(^{235}\) and grouped under themes with corresponding frequencies calculated. Frequencies were obtained for all response-option items in the early termination interview.

### 6.3 Results

#### 6.3.1 Sample characteristics

Baseline data were collected from all participants randomised to the intervention group (\(n=81\)), of whom 84% (\(n=68/81\)) completed 6-month follow-up (Table 6.1). The mean age of participants was 63.81 (\(SD=1.71\)), 65.4% were female and 65.4% had moderate to severe levels of VI. The most common cause of VI was age-related macular degeneration (25%). Sixty-eight percent had at least moderate levels of depressive symptoms (Mean PHQ-9=12.14, \(SD=4.8\)). Sixty-four (79%) participants completed <6 PST-PC sessions of 39 (61%) withdrew prior to completing session 1 (i.e. introductory session).

#### 6.3.2 Pre-treatment predictors of early termination from PST-PC sessions

Using all pre-specified covariates, 12,444 models were generated using GSREG to identify pre-treatment predictors associated with early termination and the best 5 models based on the AIC, BIC and nindex are presented in Table 6.2. Multivariable logistic regression using
the variables from the best model showed that those who terminated early were more likely to be single (widowed) (Odds ratio ($OR$) = 8.77, 95% CI 2.15 to 35.66, $p=0.002$), have lower acceptance of their vision loss ($OR=0.72$, 95% CI 0.54 to 0.96, $p=0.027$) and lower perceived adequacy of social support ($OR=0.48$, 95% CI 0.30 to 0.75, $p=0.001$) compared to those who completed 6 to 8 sessions, accounting for 27% of the variance (Table 6.3).
<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Completed 6-8 sessions (n=17)</th>
<th>Completed &lt; 6 sessions (n=64)</th>
<th>Total (n=81)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, Mean years (SD)</strong></td>
<td>61.76 (11.0)</td>
<td>64.35 (16.4)</td>
<td>63.8 (15.4)</td>
<td>0.540</td>
</tr>
<tr>
<td><strong>Female</strong></td>
<td>11 (64.7)</td>
<td>42 (65.6)</td>
<td>53 (65.4)</td>
<td>0.944</td>
</tr>
<tr>
<td><strong>Marital Status</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single/widowed/never married</td>
<td>5 (29.4)</td>
<td>44 (68.8)</td>
<td>49 (60.5)</td>
<td>0.003</td>
</tr>
<tr>
<td>Married/defacto</td>
<td>11 (70.6)</td>
<td>20 (31.3)</td>
<td>32 (39.5)</td>
<td></td>
</tr>
<tr>
<td><strong>Country of birth (Australia)</strong></td>
<td>13 (76.5)</td>
<td>49 (76.5)</td>
<td>62 (76.5)</td>
<td>0.994</td>
</tr>
<tr>
<td><strong>Health comorbidities (yes)</strong></td>
<td>10 (58.8)</td>
<td>53 (82.8)</td>
<td>63 (77.7)</td>
<td>0.034</td>
</tr>
<tr>
<td><strong>Highest education level achieved</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No qualifications</td>
<td>9 (52.9)</td>
<td>49 (76.6)</td>
<td>58 (71.6)</td>
<td>0.140</td>
</tr>
<tr>
<td>Secondary/ TAFE/Diploma</td>
<td>5 (29.4)</td>
<td>8 (12.5)</td>
<td>13 (16.0)</td>
<td></td>
</tr>
<tr>
<td>Degree or higher degree</td>
<td>3 (17.7)</td>
<td>7 (10.9)</td>
<td>10 (12.4)</td>
<td></td>
</tr>
<tr>
<td><strong>Employment status</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical disability pension</td>
<td>55 (86.0)</td>
<td>12 (70.6)</td>
<td>67 (82.7)</td>
<td>0.325</td>
</tr>
<tr>
<td>Retired/unemployed/home duties</td>
<td>5 (7.8)</td>
<td>3 (17.7)</td>
<td>8 (9.9)</td>
<td></td>
</tr>
<tr>
<td>Full /part-time employment</td>
<td>4 (6.3)</td>
<td>2 (11.8)</td>
<td>6 (7.4)</td>
<td></td>
</tr>
<tr>
<td><strong>Living with someone (yes)</strong></td>
<td>13 (76.47)</td>
<td>39 (60.94)</td>
<td>52 (64.2)</td>
<td>0.235</td>
</tr>
<tr>
<td><strong>Primary cause of vision loss</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age-related macular degeneration</td>
<td>5 (29.4)</td>
<td>15 (23.44)</td>
<td>20 (24.7)</td>
<td>0.285</td>
</tr>
<tr>
<td>Diabetic retinopathy</td>
<td>1 (5.9)</td>
<td>13 (20.3)</td>
<td>8 (9.9)</td>
<td></td>
</tr>
<tr>
<td>Retinitis pigmentosa</td>
<td>2 (11.8)</td>
<td>10 (15.6)</td>
<td>14 (17.3)</td>
<td></td>
</tr>
<tr>
<td>Other#</td>
<td>4 (23.5)</td>
<td>7 (10.9)</td>
<td>9 (11.1)</td>
<td></td>
</tr>
<tr>
<td>Optic nerve pathology</td>
<td>4 (23.5)</td>
<td>5 (7.8)</td>
<td>12 (14.8)</td>
<td></td>
</tr>
<tr>
<td>Other genetic disorder</td>
<td>1 (5.88)</td>
<td>7 (10.94)</td>
<td>8 (9.9)</td>
<td></td>
</tr>
<tr>
<td>Glaucoma</td>
<td>-</td>
<td>4 (6.25)</td>
<td>4 (4.9)</td>
<td></td>
</tr>
<tr>
<td>Unspecified</td>
<td>-</td>
<td>3 (4.69)</td>
<td>3 (3.7)</td>
<td></td>
</tr>
<tr>
<td><strong>Level of vision impairment</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>7 (41.2)</td>
<td>20 (24.4)</td>
<td>28 (34.6)</td>
<td>0.429</td>
</tr>
<tr>
<td>Moderate</td>
<td>4 (23.5)</td>
<td>42 (51.2)</td>
<td>30 (37.0)</td>
<td></td>
</tr>
<tr>
<td>Severe / blindness</td>
<td>6 (35.3)</td>
<td>20 (24.4)</td>
<td>23 (28.4)</td>
<td></td>
</tr>
<tr>
<td><strong>History of depression (yes)</strong></td>
<td>8 (47.1)</td>
<td>33 (51.6)</td>
<td>41 (50.6)</td>
<td>0.741</td>
</tr>
<tr>
<td><strong>Previously treated for depression (yes)</strong></td>
<td>7 (41.2)</td>
<td>29 (45.3)</td>
<td>36 (44.4)</td>
<td>0.760</td>
</tr>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>------------------------------------</td>
<td>--------------------</td>
<td>--------------------</td>
<td>--------------------</td>
<td>--------------------</td>
</tr>
<tr>
<td>PHQ-9 raw score, Mean (SD)</td>
<td>12.82 (5.0)</td>
<td>11.95 (4.7)</td>
<td>12.14 (4.8)</td>
<td>0.507</td>
</tr>
<tr>
<td>Range</td>
<td>6-21</td>
<td>6-25</td>
<td>6-25</td>
<td></td>
</tr>
<tr>
<td>PHQ-9 rasch score, Mean (SD)</td>
<td>-0.11 (0.96)</td>
<td>-0.27 (0.94)</td>
<td>-0.24 (0.94)</td>
<td>0.551</td>
</tr>
<tr>
<td>PHQ-9 score above clinical cut-off</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes (score &gt; 9)</td>
<td>12 (70.6)</td>
<td>43 (67.2)</td>
<td>55 (67.90)</td>
<td>0.789</td>
</tr>
<tr>
<td>Acceptance of vision loss rasch,</td>
<td>0.33 (3.03)</td>
<td>-0.29 (2.89)</td>
<td></td>
<td>0.440</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CSE - Problem-focused coping rasch,</td>
<td>0.78 (0.79)</td>
<td>0.65 (0.93)</td>
<td>0.67 (0.90)</td>
<td>0.617</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CSE - Emotion-focused coping rasch,</td>
<td>0.03 (1.11)</td>
<td>-0.02 (1.15)</td>
<td>-0.01 (1.14)</td>
<td>0.881</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CSE - Seeking social support rasch,</td>
<td>0.06 (1.18)</td>
<td>0.10 (1.02)</td>
<td>0.10 (1.05)</td>
<td>0.881</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adequacy social support, Mean (SD)</td>
<td>4.47 (1.91)</td>
<td>3.30 (1.66)</td>
<td>3.54 (1.77)</td>
<td>0.014</td>
</tr>
<tr>
<td>Availability of social support, Mean (SD)</td>
<td>4.24 (2.31)</td>
<td>3.73 (1.84)</td>
<td>3.84 (1.94)</td>
<td>0.347</td>
</tr>
<tr>
<td>QoL relationships, Mean (SD)</td>
<td>0.70 (0.26)</td>
<td>0.53 (0.27)</td>
<td>0.57 (0.27)</td>
<td>0.023</td>
</tr>
</tbody>
</table>

† Figures are numbers (percentages) of participants unless stated otherwise

PHQ-9 = Patient Health Questionnaire 9; CSE = Coping Self-Efficacy; QoL = quality of life
Table 6.2 Best selected model according to Global Search Regression (n=81)

<table>
<thead>
<tr>
<th>order</th>
<th>Marital status</th>
<th>Illness acceptance</th>
<th>Adequacy social support</th>
<th>QoL relationships</th>
<th>Education level</th>
<th>Constant</th>
<th>Number of covariates</th>
<th>AIC</th>
<th>BIC</th>
<th>nindex</th>
</tr>
</thead>
<tbody>
<tr>
<td>320</td>
<td>-2.17</td>
<td>-0.32</td>
<td>-0.74</td>
<td></td>
<td></td>
<td>5.34</td>
<td>4</td>
<td>69.15</td>
<td>78.73</td>
<td>2.41</td>
</tr>
<tr>
<td>348</td>
<td>-1.23</td>
<td></td>
<td>-0.64</td>
<td>-3.55</td>
<td></td>
<td>6.62</td>
<td>4</td>
<td>69.31</td>
<td>78.89</td>
<td>2.39</td>
</tr>
<tr>
<td>2414</td>
<td>-1.48</td>
<td>-0.24</td>
<td>-0.81</td>
<td>-2.65</td>
<td></td>
<td>6.86</td>
<td>5</td>
<td>68.83</td>
<td>80.80</td>
<td>2.28</td>
</tr>
<tr>
<td>802</td>
<td></td>
<td>-0.65</td>
<td>-5.14</td>
<td>-1.14</td>
<td></td>
<td>7.30</td>
<td>4</td>
<td>70.19</td>
<td>79.76</td>
<td>2.27</td>
</tr>
<tr>
<td>719</td>
<td>-0.18</td>
<td>-0.81</td>
<td>-4.33</td>
<td></td>
<td></td>
<td>7.18</td>
<td>4</td>
<td>70.53</td>
<td>80.10</td>
<td>2.23</td>
</tr>
</tbody>
</table>

Based on n=12,444 Global Search Regression models; AIC= Akaike’s Information Criterion; BIC= Bayesian information criterion; nindex=normalized linear combination of model selection criteria; QoL = quality of life
Table 6.3 Odds ratios for the association between early termination from PST-PC (completing <6 sessions) by marital status, illness acceptance and perceived adequacy of social support

<table>
<thead>
<tr>
<th></th>
<th>Odds Ratio</th>
<th>95% Confidence Interval</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Married/defacto</td>
<td>8.77</td>
<td>2.15 to 35.66</td>
<td>0.002</td>
</tr>
<tr>
<td>Illness acceptance</td>
<td>0.72</td>
<td>0.54 to 0.96</td>
<td>0.027</td>
</tr>
<tr>
<td>Perceived adequacy of social support</td>
<td>0.48</td>
<td>0.30 to 0.75</td>
<td>0.001</td>
</tr>
</tbody>
</table>

Pseudo R2 = 0.265

6.3.3 Minimum number of sessions needed to achieve clinically significant change in depressive symptoms

Forty-one percent of participants achieved a CSC (>5-point reduction) on the PHQ-9 (38% <6 sessions versus 50% ≥6 session). Figure 6.1 shows a positive linear association between PHQ-9 change scores and the number of PST-PC sessions completed. With each additional session completed a greater reduction in depressive symptoms was achieved, however this association did not reach statistical significance for a 5-point change ($\beta = 0.19$, 95% CI -0.37 to 0.76, p=0.06). Predicted margins indicated that 6 to 8 PST-PC sessions were associated with a 4-point reduction (1 point below the criteria for a CSC; Table 6.4) in depressive symptoms.
Figure 6.1 Predictive margins of PHQ-9 change scores for number of PST-PC sessions and 95% confidence intervals*

PHQ-9 = Patient Health Questionnaire-9
* Adjusting for age, gender, history of depression and self-reported change in vision
Table 6.4 Predictive margins for PHQ-9 change scores from baseline to 6-month follow-up by number of sessions completed (n=81)

<table>
<thead>
<tr>
<th>Number of sessions</th>
<th>n</th>
<th>Observed mean</th>
<th>Standard error</th>
<th>95% confidence interval</th>
<th>Predictive margin (PHQ-9 change score)</th>
<th>standard error</th>
<th>95% confidence interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>introduction</td>
<td>39</td>
<td>3.34</td>
<td>1.18</td>
<td>0.99 to 5.70</td>
<td>3.01</td>
<td>0.99</td>
<td>1.04 to 4.99</td>
</tr>
<tr>
<td>1</td>
<td>8</td>
<td>5.25</td>
<td>2.37</td>
<td>0.51 to 9.99</td>
<td>3.21</td>
<td>0.81</td>
<td>1.59 to 4.82</td>
</tr>
<tr>
<td>2</td>
<td>3</td>
<td>0.33</td>
<td>0.33</td>
<td>-0.33 to 1.00</td>
<td>3.40</td>
<td>0.70</td>
<td>2.00 to 4.80</td>
</tr>
<tr>
<td>3</td>
<td>9</td>
<td>0.14</td>
<td>1.79</td>
<td>-3.43 to 3.72</td>
<td>3.59</td>
<td>0.70</td>
<td>2.19 to 4.98</td>
</tr>
<tr>
<td>4</td>
<td>2</td>
<td>4.00</td>
<td>4.00</td>
<td>-3.98 to 11.98</td>
<td>3.78</td>
<td>0.80</td>
<td>2.18 to 5.39</td>
</tr>
<tr>
<td>5</td>
<td>3</td>
<td>5.67</td>
<td>1.20</td>
<td>3.27 to 8.07</td>
<td>3.97</td>
<td>0.98</td>
<td>2.01 to 5.94</td>
</tr>
<tr>
<td>6</td>
<td>9</td>
<td>2.00</td>
<td>1.50</td>
<td>-0.99 to 4.99</td>
<td>4.17</td>
<td>1.20</td>
<td>1.76 to 6.57</td>
</tr>
<tr>
<td>7</td>
<td>2</td>
<td>4.00</td>
<td>-</td>
<td>-</td>
<td>4.36</td>
<td>1.44</td>
<td>1.47 to 7.25</td>
</tr>
<tr>
<td>8</td>
<td>6</td>
<td>8.17</td>
<td>3.24</td>
<td>1.70 to 14.63</td>
<td>4.55</td>
<td>1.70</td>
<td>1.15 to 7.95</td>
</tr>
</tbody>
</table>
6.3.4 Client reasons for early termination from PST-PC

Reasons for early termination from PST-PC were obtained from 63/64 participants who completed <6 sessions, and are summarised in Table 6.5. The most salient practical reasons, included poor health and time constraints (n=51) followed by a lack of interest or perceived relevance of PST-PC (n=26). Only 3 participants reported that they terminated the treatment early due to the rapport/relationship with the LVR practitioner.

Sixteen (64%) of the invited participants provided further feedback on the therapeutic alliance, perceived need for emotional support and expectations of the treatment. Most agreed that the practitioner was interested in them as a person (n=15; 94%) and felt comfortable discussing personal issues with the practitioner (n=12; 75%). Around a third (n=5; 31%) did not feel the need for emotional support while 63% (n=10) did not feel that further sessions would help. Seventy-five percent (n=12) had a clear understanding about what their role in the sessions would be, however, 44% (n=7) reported that the PST-PC practitioner’s role did not meet their expectations. Fifty percent (n=8) expressed a desire for face-to-face sessions.
Table 6.5 Reasons for early termination from PST-PC (n=63±)

<table>
<thead>
<tr>
<th>Theme</th>
<th>Description</th>
<th>n</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Practical issues</td>
<td>Health issues, time restraints, telephone delivery</td>
<td>51</td>
<td>17 (27)</td>
</tr>
<tr>
<td></td>
<td>“I had a fall in January and was in hospital all of January. I had so much going on with my health... it was too hard to continue.”</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Processes</td>
<td>What participants expect will occur during treatment</td>
<td>26</td>
<td>9 (14)</td>
</tr>
<tr>
<td></td>
<td>(e.g. own role and that of the practitioner)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>“The questions and support weren’t what I expected. I needed someone to talk to”</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lack of interest</td>
<td>PST-PC is perceived as not relevant</td>
<td>21</td>
<td>10 (16)</td>
</tr>
<tr>
<td></td>
<td>“It just simply wasn’t something I was interested in. It should be offered to someone who really needs it.”</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outcome expectations</td>
<td>Expectations participants have about benefits they will achieve with PST-PC</td>
<td>13</td>
<td>7 (11)</td>
</tr>
<tr>
<td></td>
<td>“I found the questions very frustrating... thought it was to help me to get through the depression, but it didn’t really help.”</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Planned ending</td>
<td>Goals of the treatment have been accomplished and the ongoing need for PST-PC has diminished; client feels they have got all they can from the sessions</td>
<td>12</td>
<td>5 (8)</td>
</tr>
<tr>
<td></td>
<td>“It seems that my girl [PST-PC practitioner] was so good at solving my problems that I did have in 4 sessions...we’ve done well and she helped me and there’s nothing else that really worries me. I did it”</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sociodemographic characteristics</td>
<td>Age, gender, socioeconomic status, ethnicity</td>
<td>9</td>
<td>5 (8)</td>
</tr>
<tr>
<td></td>
<td>“I’m too old for this. Better to let someone younger have a go”</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lack of motivation</td>
<td>Due to low mood or feelings of hopelessness towards one’s situation; unwillingness to change situation or learn/refine skills</td>
<td>8</td>
<td>4 (6)</td>
</tr>
<tr>
<td></td>
<td>“It was difficult to answer the questions [pleasant daily activities] when I had no enthusiasm to do anything”</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychological (emotional) factors</td>
<td>Fear of treatment, desire to avoid discussing distressing information, desire to avoid experiencing painful feelings, shame, stigma</td>
<td>6</td>
<td>3 (5)</td>
</tr>
<tr>
<td></td>
<td>“I wasn’t really in the right frame of mind, I have been going through very bad depression, my husband dying... my father died, and then I was sort of put into a unit all by myself just feeling lost.”</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Therapist (therapeutic alliance)</td>
<td>Disagreement of goals between client and practitioner, lack of connection/rapport between the client and practitioner</td>
<td>3</td>
<td>3 (5)</td>
</tr>
<tr>
<td></td>
<td>“When selecting a problem that I wanted to work on, the PST-PC practitioner said the problem was too big and to try smaller problems. She (Practitioner) didn’t understand where I was coming from.”</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* n=1 deceased  
* Frequency of participants who cited reason, n  
** Frequency of participants who cited as the main reason, n (%)
6.3 Discussion

6.4.1 Summary of findings

This study investigated factors associated with early termination from PST-PC in a sample of Australian LVR clients. Being single, having lower perceived adequacy of social support and less acceptance of one’s vision loss increased the risk of completing fewer than the recommended number of 6 to 8 sessions. While a 5-point change on the PHQ-9 was unable to be detected with this number of sessions, results indicate increased treatment benefit with continued session engagement.

This study found that lack of social support, specifically marital status and perceived adequacy of social support, was associated with early termination. These findings do not support one of the largest published meta-analysis (n=669 studies) which found no association between marital status and early termination in adults receiving psychological treatment for a mental health condition. Social support may be a more salient factor for people with VI because of the higher levels of social isolation and dependency in this population. Low social support may also contribute to early termination as these individual may be seeking greater emotional and social interaction with the PST-PC practitioner. PST-PC is a structured approach that focuses on skills-building rather than a non-directive orientation to treatment, such as supportive counselling. This fits with client reasons for early termination regarding expectations of the treatment processes. Participants reported that the practitioners’ role in facilitating skill development and the PST-PC process was contrary to their expectations (e.g. “needing someone to talk to”).

As hypothesised, individuals with lower levels of acceptance in relation to their vision impairment were more likely to terminate PST-PC sessions early. Previous research has shown that low levels of acceptance towards vision loss is associated with a lack of perceived capability to engage in problem-focused coping, which in turn promotes depressive symptoms. This would suggest that acceptance may be a necessary prerequisite for engaging in PST-PC and strategies that target acceptance may be an important component of managing depression. To date, acceptance-based interventions have not been investigated in VI samples, however given that greater acceptance of
vision impairment is associated with improved psychological adjustment,\textsuperscript{88, 237} it seems warranted to explore strategies that foster acceptance of vision loss further.

In the analysis a 5-point change on the PHQ-9 was unable to be detected when 6 to 8 PST-PC sessions were completed - this finding is largely attributable to the small sample size, an important limitation of this study. However, participants who completed \( \geq 6 \) sessions were more likely to achieve a CSC in depressive symptoms compared to participants who completed \(< 6 \) sessions (50\% vers. 38\%) underscoring the importance of sustained engagement with treatment. Previous studies that have demonstrated benefits with fewer than 6 sessions\textsuperscript{131, 168, 193, 194} have been conducted with otherwise healthy, community samples. Participants in our study were older in age, with a high prevalence of complex health comorbidities, and who may require the recommended number of 6 to 8 sessions to reinforce the skill set each week. It is worth noting, that some benefits were still achieved with \(< 6 \) sessions (38\% achieved a CSC). If treatment is to terminate early (i.e. \(< 6 \) sessions) this should be based on objective outcomes such as the acquisition of problem-solving skills and improvements in depressive symptoms. For example the brief Outcome and Sessions Rating Scales (ORS, SRS),\textsuperscript{238} recommended by the International Centre for Clinical Excellence, could be administered throughout PST-PC to track client outcomes and the quality of the therapeutic alliance. The ORS and SRS have demonstrated success in reducing rates of early termination when used in conjunction with psychological treatment.\textsuperscript{239, 240}

A dedicated introduction session was included in the current model and considered important for building rapport and ensuring client’s understood the rationale and process of PST-PC, as this has been linked to successful outcomes.\textsuperscript{155} However, a significant proportion of early termination from PST-PC occurred during the introductory session, with the most frequently cited reason being practical issues, including poor health (81\% of participants). Co-occurring physical health problems may compete for time and attention among older adults with VI, and when depression is seen as a low priority, the risk of early termination from treatment may increase.\textsuperscript{241, 242} In a sample of community-based older adults with depression and comorbid physical health problems, medical and functional problems were ranked as higher priority with just 6\% ranking depression as the most important of their problems and 45\% ranking depression as least important.\textsuperscript{243} LVR staff may need to elicit older adults’ perspectives on
depression and approach treatment rational within a biopsychosocial (interaction of biological, psychological and social factors on health outcomes) framework. Motivational interviewing (MI), health education, and assessment of treatment priorities may be necessary in helping older adults with VI value and accept depression care. For example, MI, which is a promising strategy for increasing treatment engagement, could be integrated at multiple points throughout treatment to address issues of motivation and ambivalence to depression treatment.

6.4.2 Strengths and limitations of this study

Despite previous studies in VI reporting suboptimal levels of patient engagement (<6 sessions) with Problem-Solving Treatment, this study is the first to investigate client-related factors when PST is delivered in practice. The use of GSREG to identify important covariates associated with early termination is a major strength of this study given the robustness of this method, particularly for small sample sizes, compared to other search algorithms such as stepwise techniques. Although the sample size was small, participants were recruited for further follow-up interviews on the reasons for early termination, which is often difficult when participants have withdrawn from a health service.

This study also has several limitations. The results are based on a small sample of Australian LVR clients who volunteered to participate in a trial, therefore limiting generalisability of the findings. This study was underpowered to detect a 5-point change on the PHQ-9 (n=64, 8% power) increasing the risk of type II error. Furthermore, while Bonferroni correction was used to counteract the problem of multiple comparisons in the primary analysis, this statistical technique is vulnerable to type II error. Findings from this study should be replicated using a larger sample and non-LVR populations with depressive symptoms to determine their robustness and generalisability to adults with VI more broadly. Early termination from PST-PC may be attributable to a number of client, practitioner and treatment factors including the client’s readiness and motivation to change, practitioners’ attitudes, confidence and skill level as well as factors that arise during treatment which were not investigated in this study but may play an important role.
6.4.3 Implications for practice and future research

The need for accessible and effective early interventions in adults with VI and depressive symptoms cannot be refuted given that few individuals currently utilise mental health services. The integration of telephone-based PST-PC into LVR programs has the potential to reduce practical and psychological barriers to the uptake of psychological support. Importantly, the findings reported in this study provide insight into strategies that may foster engagement with PST-PC. For example, in those clients with limited social support, practitioners could set aside some time each session for supportive counselling or offer PST-PC in a group-based format. Previous longitudinal studies in chronic disease have shown improved outcomes following group-based psychosocial interventions for those with low social support compared to those with high levels of support. The integration of acceptance-based strategies may also be a useful addition to the current PST-PC model. Acceptance and Commitment Therapy (ACT) is a third wave cognitive behavioural therapy (CBT) that encourages individuals to experience and manage negative emotions and thoughts. ACT may be particularly relevant in VI as it aims to encourage patients to tolerate problems and direct their behaviours towards living in the present moment rather than focussing on their fears for the future. This may be useful for those facing a poor prognosis (e.g. irreversible vision loss). To date, no studies have investigated the effectiveness of ACT on depressive symptoms in people with VI.

A final consideration is the delivery of PST-PC via telephone. This mode of delivery has the potential to reach a large number of LVR clients in a cost-effective manner. However 50% of participants who terminated PST-PC early (and participated in further follow-up interviews) had a preference for face-to-face sessions. It remains an empirical question whether those with low social support might indeed benefit more if PST-PC was delivered face-to-face, or whether delivery of the introduction session via face-to-face may bolster sustained engagement. A recent exploratory trial of PST-PC effectiveness in older LVR clients found that in-home sessions delivered by a psychologist were neither feasible nor cost effective. Alternative or proxy face-to-face service delivery models, such as Skype or video conferencing, should be explored and have been shown to be effective and acceptable to older homebound adults with depression receiving PST-PC.
6.4.4 Conclusions

Social support and acceptance of vision loss may play an important role in reducing early termination from PST-PC in LVR clients, which is imperative given that continued engagement is associated increased clinical benefit. Importantly, this novel study presents an opportunity to learn more about how best to deliver evidence-based psychological treatments to people with VI.
Chapter 7: Phase 4, Evaluating implementation (Part B – Exploring barriers and facilitators to delivery)
Can we address depression in vision rehabilitation settings? Professionals’ perspectives on the barriers to integrating problem-solving treatment

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ABSTRACT

Purpose: Low vision rehabilitation (LVR) is a pertinent context for integrating early, evidence-based psychological interventions given the high prevalence of untreated depression in adults with vision impairment. This study aims to identify the perceived barriers and facilitators to staff-delivered telephone-based problem-solving treatment for primary care (PST-PC) offered as an integrated component of LVR.

Methods: Qualitative semi-structured interviews, developed using the theoretical domains framework (TDF) and Consolidated Framework for Implementation Research (CFIR), were conducted with 21 LVR professionals and a clinical psychologist involved in the delivery of PST-PC. Barriers and facilitators at the practitioner, client, intervention, and organizational level were identified with thematic analysis using a “theoretical” approach.

Results: Prominent barriers were a lack of role recognition for PST-PC practitioners (n = 32), unmet client expectation with PST-PC (n = 28), dissatisfaction with telephone delivery (n = 27), and limited organizational awareness of PST-PC (n = 39). Facilitating factors included a recognized need for evidence-based psychological services (n = 28), clients experiencing benefits in early sessions (n = 38), PST-PC promoting practical skills (n = 26), and comprehensive PST-PC training (n = 36).

Conclusions: PST-PC may provide an accessible early intervention for LVR clients with depressive symptoms. Ongoing practitioner training, clinical support, and screening potential LVR clients for treatment suitability are likely to enhance delivery in this setting.

IMPLICATIONS FOR REHABILITATION

- Depression is highly prevalent in adults engaged in low vision rehabilitation (LVR) programs, yet few receive support.
- Clinical guidelines recommend integrated models of care be offered within rehabilitation settings as early intervention for mild to moderate levels of depressive symptoms.
- Integrated telephone-based problem-solving treatment for primary care (PST-PC) delivered by trained LVR practitioners is a practical, skills-based model that has potential to increase access to an early psychological intervention in LVR clients with depressive symptoms.
- LVR clients are often older in age, have multiple comorbid health conditions and a significant level of functional disability, requiring flexibility in the delivery of PST-PC and specialized staff training, and support in working with older and more complex clients.

Introduction

Vision impairment is a leading cause of disability worldwide affecting approximately 285 million individuals.[1] It is associated with functional disability and restricted activities of daily living, placing individuals at increased risk of mental health comorbidities, such as depression.[2–5] Recent cross-sectional data suggests that around 40% of adults accessing low vision rehabilitation (LVR) programs experience clinically significant depressive symptoms, yet few LVR settings routinely offer evidence-based psychological interventions as part of their service provision.[6]

Clinical guidelines recommend early intervention for subthreshold or mild to moderate levels of depression in adults with chronic illness. Specifically, that low-intensity interventions based on the principles of cognitive behavioral therapy (CBT) that include problem-solving techniques be integrated or co-ordinated within rehabilitation programs.[8] One such intervention that has robust empirical support is problem solving treatment (PST), a psychotherapy for depression that facilitates patients to regain a sense of control over their lives.[9] Delivered over 6–8 sessions of 45 min duration, problem-solving treatment for primary care (PST-PC) was adapted from PST and specifically developed for use in...
busy and time-constrained settings. PST-PC was also designed so that it could be delivered by health professionals other than qualified therapists and studies have shown that a range of health professionals can deliver PST-PC with success.\textsuperscript{10–12}

Randomized controlled trials (RCTs) have demonstrated the effectiveness of PST-PC for improving symptoms of minor and major depression and quality of life (QoL) in adults,\textsuperscript{13} including patients with chronic health conditions, such as arthritis and diabetes.\textsuperscript{14,15} For older adults with age-related macular degeneration, vision-related functioning and levels of emotional distress have improved following engagement with PSTs,\textsuperscript{16,17} while current ongoing trials will determine effectiveness more broadly in adults with vision impairment engaged in rehabilitation programs.\textsuperscript{18–21}

This study explores the potential for a novel application of PST-PC in the context of LVR services. PST-PC is particularly suited to low vision because of the high incidence of depression in this population\textsuperscript{2–5} and the associated benefits of problem-solving strategies in reducing depressive symptomology.\textsuperscript{22} In a large pragmatic multi-center RCT we trained rehabilitation practitioners in the principles and delivery of PST-PC.\textsuperscript{23} The delivery of the intervention was via telephone due to the geographic dispersal of LVR service users and lack of rehabilitation counseling services. Given our novel application of PST-PC and the challenges with implementing evidence-based interventions into routine practice,\textsuperscript{24} in this article, we report on the barriers and facilitators to this approach.

The use of theory is important for understanding the barriers and facilitators that exist when delivering a new health service as it aids in identifying influences that may ultimately lead to successful implementation.\textsuperscript{25} The theoretical domains framework (TDF)\textsuperscript{26} seeks to identify theoretical explanations for implementation difficulties and determinants of professional behavior that can be possible targets for interventions. Fourteen domains are evaluated in the TDF including “Knowledge”, “Skills”, and “Beliefs about Capabilities.” The Consolidated Framework for Implementation Research (CFIR)\textsuperscript{27} is another approach that takes into consideration characteristics of the individual’s involved (i.e., professional and client), intervention characteristics, and the process of implementation and delivery (e.g., training, resources).

The aim of this study was to explore the barriers and facilitators to telephone-delivered PST-PC by trained LVR practitioners in a multi-center national LVR setting. To ensure a comprehensive assessment of the difficulties experienced with delivery at a professional, client, intervention and organizational level, the TDF, and CFIR were used to guide analysis. Factors believed to be critical for wider implementation and sustainability of PST-PC in practice were also explored.

Methods

Design

This was a qualitative study with individual semi-structured telephone interviews. This study was part of a two-arm pragmatic multi-center RCT conducted from June 2012 to July 2015 to determine the effectiveness of PST-PC plus usual care (a referral to a general practitioner for further psychological assessment and treatment as needed) compared to usual care alone on depressive symptoms and QoL in adults seeking LVR services.\textsuperscript{21}

Participants and procedure

Professionals involved in the delivery of PST-PC were invited to take part in the study. All participants, with the exception of the supervising clinical psychologist, were employed at Vision Australia, one of the largest LVR service providers in the country operating 28 centers Australia-wide. The sample included expertly trained Vision Australia rehabilitation practitioners delivering PST-PC ($n = 14$), the manager for each PST-PC practitioner ($n = 7$), the Vision Australia project manager responsible for coordinating the delivery of PST-PC ($n = 1$), the Vision Australia manager of adult rehabilitation services ($n = 1$), and the clinical psychologist who provided PST-PC practitioner supervision ($n = 1$).

PST-PC practitioners who delivered PST-PC received a high level of training and support (details regarding staff training have been published previously).\textsuperscript{21,23} In brief, this included a two-day training workshop based on an established training program\textsuperscript{10} and training cases under the supervision of a clinical psychologist who provided regular feedback. Following the training, PST-PC practitioners engaged in monthly peer sessions facilitated by the supervising Clinical Psychologist that provided staff with the opportunity to discuss challenges, strategies for working with complex clients and techniques to optimize delivery. Allocation of clients to PST-PC practitioners was performed by the LVR PST-PC project manager and clinical psychologist. PST-PC practitioners were responsible for scheduling treatment sessions with their clients during working clinic hours. With the exception of the two-day training workshop, which was delivered face-to-face, all staff training and client treatment sessions were delivered over the telephone and recorded using a cloud-based call recording, and monitoring system. A standardized protocol for allocating clients, scheduling PST-PC sessions, terminating sessions early and reporting problems was developed and followed by PST-PC practitioners across all sites. Adherence to the protocol was monitored by the LVR PST-PC project manager.

A semi-structured interview schedule was developed using the TDF and CFIR to systematically explore the barriers and facilitators to the implementation of telephone delivered PST-PC (Table 1). Combined, these frameworks distinguish four overarching domains (individual-professional, individual-client, intervention, and environment/organization characteristics) with 18 sub-categories. Interviews took place between August and September 2014 and lasted approximately 60 min for PST-PC practitioners and 30 min for all other participants. Interviews were conducted over the telephone by the first author (E.H.) who is trained in qualitative research methods. Interviews were audio-recorded and later transcribed verbatim for analysis.

This study was approved by the Royal Victorian Eye & Ear Hospital Human Research & Ethics Committee (HREC) (project number 12/1061H) and Deakin University HREC (project number 2012–139). All participants provided written informed consent. This research adhered to the tenets of the Declaration of Helsinki.

Data analysis

Data were imported into NVivo 10\textsuperscript{28} and de-identified. Qualitative data were analyzed using thematic analysis. Thematic analysis is a method for identifying, analyzing, and reporting patterns (themes) within data.\textsuperscript{29} Specifically, the researcher who conducted the interviews read and familiarized herself with the data and generated initial codes. Themes were then identified and named. A theoretical or deductive process of thematic analysis\textsuperscript{29,30} was used to allocate each theme to the appropriate domain within the TDF/CFIR framework. Any themes that did not fit pre-defined domains were recorded. A random subset of 20% of interviews was independently coded and analyzed by a second researcher (B.S) with expertise in qualitative methods. Differences
Table 1. Semi-structured interview schedule informed by the TDF and CFIR.

<table>
<thead>
<tr>
<th>Domain</th>
<th>Framework</th>
<th>Interview questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Individual (professional)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knowledge (scientific rationale, awareness/client need)</td>
<td>TDF/CFIR</td>
<td>Rational for delivering PST-PC; how well do you feel you understand PST-PC</td>
</tr>
<tr>
<td>Skills/goals and feedback</td>
<td>TDF/CFIR</td>
<td>How competent do you feel delivering PST-PC; do you feel the PST-PC training was sufficient; personal strengths/weaknesses helped/hindered PST-PC in practice</td>
</tr>
<tr>
<td>Motivation/stage of change</td>
<td>CFIR</td>
<td>How motivated are you to continue delivering PST-PC?</td>
</tr>
<tr>
<td>Beliefs about capabilities/self-efficacy</td>
<td>TDF/CFIR</td>
<td>How confident do you feel in delivering PST-PC?</td>
</tr>
<tr>
<td>Professional role</td>
<td>TDF</td>
<td>How do you feel about taking on PST-PC as part of your role?</td>
</tr>
<tr>
<td>Beliefs about consequences/outcome expectancy/ reinforcement/incentives/effort</td>
<td>TDF/CFIR</td>
<td>What benefits do you feel you received from delivering PST-PC and taking on the PST-PC role; benefits outweigh the effort; how useful do you think PST-PC is for clients</td>
</tr>
<tr>
<td>Optimism</td>
<td>TDF</td>
<td>Do you think PST-PC will continue?</td>
</tr>
<tr>
<td>Emotions</td>
<td>TDF</td>
<td>How does delivering PST-PC make you feel; impact of feelings</td>
</tr>
<tr>
<td>2. Individual (client)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knowledge &amp; skills</td>
<td>CFIR</td>
<td>Extent to which client’s understood PST-PC; sessions how client’s expected them to be</td>
</tr>
<tr>
<td>Motivation to change/adopt new skill</td>
<td>CFIR</td>
<td>How motivated were clients to participate in the PST-PC sessions; main reasons clients continued with PST /decided not to complete the PST-PC sessions</td>
</tr>
<tr>
<td>Other personal attributes</td>
<td>CFIR</td>
<td>In what ways have individual characteristic about clients helped or hindered PST-PC in practice?</td>
</tr>
<tr>
<td>3. Intervention characteristics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Credibility (evidence strength &amp; quality, scientific basis)</td>
<td>CFIR</td>
<td>Are you aware of the research evidence to support PST-PC?</td>
</tr>
<tr>
<td>Complexity/feasibility/compatibility</td>
<td>CFIR</td>
<td>What has been your experience of using PST-PC with your clients; do you agree that PST-PC is practical to deliver within low vision rehabilitation services; do you agree that it is practical for low vision rehabilitation staff to deliver PST-PC in low vision rehabilitation settings</td>
</tr>
<tr>
<td>Motivation/stage of change</td>
<td>CFIR</td>
<td>How important do you feel the client-PST-PC practitioner relationship is to the PST sessions?</td>
</tr>
<tr>
<td>Optimism</td>
<td>TDF/CFIR</td>
<td>What changes (if any) have you made to the PST-PC model when working with clients?</td>
</tr>
<tr>
<td>Relative advantage</td>
<td>CFIR</td>
<td>Advantages/disadvantages to delivering PST-PC vs. other emotional support services?</td>
</tr>
<tr>
<td>4. Environmental/Organization</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social influences</td>
<td>TDF/CFIR</td>
<td>What do you think the perception is among other staff regarding PST-PC? Level of satisfaction with support received from colleagues/managers in your role as PST-PC specialist</td>
</tr>
<tr>
<td>Resources</td>
<td>TDF/CFIR</td>
<td>Do you feel adequate resources have been allocated; satisfied with input from research team</td>
</tr>
<tr>
<td>Implementation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perceived fit/usefulness with Vision Australia/relative priority/compatibility/agreement with recommended change</td>
<td>CFIR</td>
<td>To what extent do you agree that PST-PC has been successfully implemented?</td>
</tr>
<tr>
<td>Factors affecting sustainability (readiness for implementation, executing implementation, priorities)</td>
<td>CFIR</td>
<td>Factors most important for PST-PC to continue as a service within Vision Australia</td>
</tr>
</tbody>
</table>

TDF: theoretical domains framework; CFIR: consolidated framework for implementation research.

in interpretation were resolved by consensus. Inter-rater reliability was calculated with Cohen’s kappa and results revealed excellent agreement (κ = 0.84–0.99).

**Results**

The final sample comprised 21/23 (92%) invited staff and the supervising clinical psychologist (Table 2). One PST-PC practitioner left the organization and one manager withdrew due to poor health. The mean age of participants was 49.5 years (SD = 11.9) and most were female (82%). Participating staff were employed in a broad range of roles, including orientation and mobility (23%), and management (55%). The LVR practitioners who delivered PST-PC (n = 14) were mostly female (93%), had worked in LVR settings for approximately 10 years (M = 9.86, SD = 10.11), and had some previous metal health training (64%). Qualifications of the practitioners included mental health training (psychology, social work or welfare; n = 5), orientation and mobility (n = 4), occupational therapy (n = 1), disability studies (n = 1), nursing (n = 1), and case management (n = 1).

**Barriers and facilitators to delivering PST-PC**

All themes initially identified through the inductive process were mapped to domains within the TDF/CFIR framework. Barriers and facilitators are reported in Table 3.

**Individual characteristics (professional)**

PST-PC practitioners were required to complete their regular duties in addition to PST-PC delivery and this was reported as one of the most salient barriers with 86% of staff reporting a lack of role recognition (n = 19/22) and 82% reporting juggling roles (n = 17/22) as challenging: “So being tacked onto people’s roles in local teams...it’s not a specific role. It’s not part of their (PST-PC practitioners) job description (P20, female, aged 42, Manager).” Almost half of the participants (n = 9/22; 41%) expressed uncertainty regarding the sustainability of PST-PC and were not optimistic that it would be implemented into usual care: “I think I’m just a bit unsure as to how you would do it. We’ve certainly got a good basis for it, but there’s been other services that have gone by the way side...so I don’t know (P2, female, aged 40, PST-PC Practitioner).”
Participants recognized a current gap and need for the provision of emotional support services at Vision Australia “not really a lot in the way of adult counseling that sort of on-one kind of emotional support (P17, female, aged 41, Manager).” Over a third of PST-PC practitioners reported that how they felt about PST-PC impacted on their delivery; specifically PST-PC practitioners who found PST-PC delivery rewarding (P11, female, aged 47, PST-PC Practitioner) had a lot of case studies and role playing. It was quite good training for people who are used to connecting, having it over the phone created distance potentially (P5, female, aged 32, PST-PC Practitioner).” PST-PC was also perceived by some participants as being a limited model “It is only going through problem solving. So it is not looking at other ways that clients can cope with emotional difficulties (P19, female, aged 52, Manager).” PST-PC was also regarded by participants as not being appropriate for all rehabilitation clients (e.g., those with health comorbidities, profound and multiple disabilities, and older clients).

Facilitating factors related to the intervention included the teaching of practical, long-term problem-solving skills, the brevity and evidence-base for the intervention, and that it complemented other services offered by the organization. Dissemination of PST-PC by LVR practitioners was also perceived to be an enabling factor.

Environment/organization factors
Sixty-eight percent of staff (n = 15/22) felt that adequate resources had been allocated to the delivery of PST-PC. The main concerns were a lack of time to dedicate to delivering PST-PC “no one got cover for their other job to do this program” and limited organizational awareness of the new service delivery “to them (organizational staff) it is just another acronym. It really isn’t much more than that (P14, male, aged 55, Manager).”

The majority of PST-PC practitioners (n = 11/13; 85%) reported that the PST training they received was sufficient and this was also regarded as a valuable component of the dissemination process “It was quite a high level engagement around training…we had a lot of case studies and role playing. It was quite good training (P11, female, aged 47, PST-PC Practitioner).”

Participants views on wider implementation and sustainability of PST-PC
Most participants (n = 20/22; 92%) recommended that PST-PC should continue as a service after the research trial had ceased, 85% of PST-PC practitioners (n = 11/13) were very motivated to continue delivering PST-PC, and 82% of participants (n = 18/22) agreed that it was practical to deliver PST-PC within LVR services. Factors identified by participants that would assist in maintaining PST-PC as a routine service are presented in Table 1. Flexibility around the delivery of PST-PC was highlighted as an important factor (n = 21/22). This included flexibility around (1) the number of sessions “I think not necessarily that people need the six to eight sessions, some people get it in the first couple of sessions (P8, female, aged 42, PST-PC Practitioner); (2) mode of delivery “so a combination, and again that can be thrown open to the client, there’s a choice, so that it’s not necessarily just delivered in one way (P3, female, aged 59, PST-PC Practitioner); (3) type of clients who were offered PST-PC “by opening up the program to all Vision Australia client’s we’ll not only reach more people but it will help to raise the profile. The current limited criteria just cuts out so many of our client (P15, female, aged 56, Manager); and (4) the way in which sessions were delivered “I think it’s really important to know – to be able to modify the part of the model as well to suit client needs (P11, female, aged 47, PST-PC Practitioner).”

Improving communication of PST-PC to rehabilitation clients (i.e., what is PST-PC, what are the expectations of my involvement) was also highlighted as important. This was reflected in participants’ suggestions of the value of the “introduction session” “In the very first introductory session, I really try my hardest to explain - but really try to get them to get a hold on what it’s really about… - that introductory session I think is really terribly important (P4, female, aged 73, PST-PC Practitioner).”

Table 2. Demographic characteristics of participants.

<table>
<thead>
<tr>
<th></th>
<th>PST-PC practitioners</th>
<th>Other staff</th>
<th>Total n = 22</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Mean (SD)</td>
<td>50.8 (13.0)</td>
<td>47.6 (10.8)</td>
</tr>
<tr>
<td></td>
<td>Range (30–71)</td>
<td>(33–68)</td>
<td>(30–71)</td>
</tr>
<tr>
<td>Sex, n (%)</td>
<td>Male</td>
<td>8 (66.7)</td>
<td>6 (66.7)</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>4 (33.3)</td>
<td>3 (13.6)</td>
</tr>
<tr>
<td>Orientation and mobility</td>
<td>Program manager</td>
<td>7 (58.3)</td>
<td>3 (33.3)</td>
</tr>
<tr>
<td></td>
<td>Program coordinator</td>
<td>4 (33.3)</td>
<td>3 (13.6)</td>
</tr>
<tr>
<td></td>
<td>Occupational therapist</td>
<td>2 (16.7)</td>
<td>2 (9.1)</td>
</tr>
<tr>
<td></td>
<td>Low vision advisor</td>
<td>2 (16.7)</td>
<td>1 (4.5)</td>
</tr>
<tr>
<td></td>
<td>Project manager</td>
<td>1 (8.3)</td>
<td>1 (4.5)</td>
</tr>
<tr>
<td></td>
<td>Clinical psychologist</td>
<td>1 (8.3)</td>
<td>1 (4.5)</td>
</tr>
<tr>
<td>Employed at Vision Australia (years)*</td>
<td>Mean (SD)</td>
<td>10.23 (9.3)</td>
<td>7.5 (5.5)</td>
</tr>
<tr>
<td></td>
<td>Range (3–32)</td>
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<td>(1–32)</td>
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*aIncludes n = 1 clinical psychologist (not employed by Vision Australia).
Providing ongoing PST-PC practitioner training \( n = 22/22 \), support \( n = 21/22 \), and clinical supervision \( n = 13/13 \) were deemed to be critical factors for the successful ongoing delivery of PST-PC following the trial completion. Key areas for further practitioner development included dealing with complex clients, keeping clients on track and improving language, and communication. Committing resources to establishing PST-PC as a service was also identified by participants as important \( n = 22/22 \). This included ensuring that the “PST-PC practitioner” role is recognized within the organization, ensuring PST-PC practitioners had dedicated time to commit to their role and allocating resources to increase organizational awareness of PST-PC, such as marketing and the provision of information (e.g., feedback of client outcomes). Training more rehabilitation practitioners in the delivery of PST-PC and sourcing external funding were also considered to be important factors for wider implementation and sustainability.

**Discussion**

The integration of evidence-based interventions into practice can pose many challenges. Using qualitative methods, this study provides novel insight into the factors at a professional, client,
intervention, and organization level which may help or hinder successful delivery and implementation of PST-PC in a multi-site national vision rehabilitation setting. The importance of comprehensive PST-PC practitioner training and support with their role, the value of early response to treatment and ensuring rehabilitation client’s expectations are understood and met are important for success. These can be achieved through flexibility in the delivery of PST-PC, the appropriate allocation of organizational resources, ongoing practitioner training, and clinical supervision and screening PST-PC practitioners and clients for their readiness, motivation, and capacity for commitment to the treatment.

Contrary to the current focus on organizational barriers in implementation research,[31] participants reported numerous barriers at the individual (i.e., professional and client) level. Specifically, participants highlighted a lack of role recognition and juggling dual professional roles as well as perceived lack of motivation and unmet expectations of clients as salient barriers. Qualitative research in the delivery of psychotherapies demonstrates that managing client expectations enables them to more meaningfully engage in the therapeutic process and this is associated with improved retention.[32] Introducing PST-PC to the client effectively is crucial to establishing and managing shared expectations about the therapeutic process and the roles that each party should fulfill. The importance of the introductory session and improving communication of PST-PC to rehabilitation clients was also reflected in participants’ suggestions for wider implementation and sustainability. To help facilitate client understanding of their involvement in the treatment, the first session could be delivered in person with subsequent sessions in person or via telephone/secure video, depending on availability, and preference. These modes of delivery have been trialed in PST-PC and shown to increase treatment accessibility without differential treatment response.[33]

Client recognition of the benefits of PST-PC in the early sessions was regarded by staff as an important enabler. This finding is encouraging as RCTs have identified early response to psychotherapy as a predictor for positive treatment outcome among patients with depressive disorders[34,35] and specifically for PST-PC.[36] Seeing benefits in the early sessions may also be related to the rapport or therapeutic alliance established with the PST-PC practitioner. It has been well-documented that clients often attribute their positive therapy outcome to the personal attributes of their therapist, for example, having an empathetic disposition.[37]

Difficulties at an intervention level included the desire for face-to-face delivery of PST-PC and perceived limited applicability, particularly for older clients, and those with comorbid health conditions. These beliefs/concerns are contrary to the research literature which suggests that telephone-delivered therapy is equally effective for the treatment of depressive disorders as face-to-face or other modalities, and is associated with lower attrition rates compared to face-to-face delivery.[38] Furthermore cross-sectional data have highlighted a preference for telephone-delivered psychotherapy among older adults accessing LVR services.[7] Rehabilitation and implementation researchers may need to systematically assess and target PST-PC practitioners’ beliefs, attitudes, and readiness prior to the initiation of training. For example, if practitioners endorsed the belief that PST-PC does not work as effectively for clients with health comorbidities, the evidence-base could be highlighted and demonstrations (e.g., role-plays) with more complex cases could be integrated into training. A pre-intervention assessment with rehabilitation clients to determine their suitability may also enhance the sustainability of PST-PC. This may include an understanding of clients’ needs and competing priorities (e.g., level of disability, high-intensity treatment for a chronic condition), readiness to engage in the intervention, personal commitments (e.g., travel which may interfere with the continuity of sessions), and motivation to participate.

The structured approach of PST-PC was reported as both a barrier and a facilitator because while it helped guide PST-PC practitioners through the steps, it was also seen to be too rigid. Studies have shown that clinicians in community mental health settings often make modifications to EBIs in an effort to improve the fit of the intervention to the clients’ needs or to the practitioner’s therapeutic style. Intervention “drift” or deviation from the original protocol has implications for implementation and sustainability.
of EBIs. For example, flexibility in decision making, planning and dissemination have been shown to improve therapists attitudes, and motivation toward empirically-supported treatments,[39] while research findings imply that lower fidelity may have a negative impact on client-level outcomes.[40] Flexibility in the delivery of PST-PC would need to be carefully weighed against intervention fidelity and additional research is necessary to fully understand the implications of such changes.

At the organizational level a lack of available resources, specifically time, was consistently identified as a strong influence on the delivery of PST-PC. This finding replicates previous research.[41,42] The PST-PC training, study support and clinical supervision for PST-PC practitioners were all perceived to facilitate delivery. Ongoing support has been identified as an important strategy to improve adoption of evidence-based practices. A review of mental health treatments implemented in community settings[43] found that multi-component training that specifically involved workshop follow-ups, such as ongoing consultation and supervisor feedback enhanced clinician skill, adherence, knowledge, and rates of implementation, as well as client outcomes. The supervision of PST-PC Practitioners by a clinical psychologist was provided to ensure staff delivered the treatment as prescribed in the manual (treatment fidelity) and to support staff through a protocol and referral process (i.e., to a GP or psychologist) for dealing with clients who presented with complex mental health issues (e.g., thoughts of suicide). Data from this qualitative study suggests that clinical supervision is an important component to the successful delivery of PST-PC by LVR staff, particularly as LVR clients may have challenging circumstances, which benefit from a mental health professionals expertise.

A limitation of this study is that client perspectives were not reported and may shed further insight into the challenges associated with PST-PC delivery. Participants were volunteers and PST-PC practitioners had agreed to be trained in PST-PC, suggesting an interest and positive view of PST-PC implementation and delivery. The authors of this article acknowledge that reflexivity issues may have influenced the results. Only one researcher coded the entire dataset with a second researcher coding a subset of 20% of transcripts. To promote reflexivity, existing values, and beliefs of the authors conducting the analysis and how these may have influenced data analysis could have been recorded. Despite this limitation, we are confident that our study gives insight into the experiences of staff involved in the delivery of PST-PC and provides valuable information to aid rehabilitation staff in the wider implementation of PST-PC. Due to the exploratory qualitative design of this study our findings cannot be generalized to other contexts. However, previous implementation research suggests several of these factors are common and may arise in other settings. Although pragmatic in nature, this study was conducted within the context of a research trial and wider implementation of PST in rehabilitation settings may generate unique challenges. For example, funding within community rehabilitation settings is often limited and important implementation components, such as ongoing practitioner supervision under a clinical psychologist may not be feasible.

The findings from this study have important implications. A substantial proportion of people accessing LVR services will experience clinically significant depressive symptoms that do not meet the criteria for a depressive disorder, however, fewer than 20% receive psychological support.[6] This is due to barriers, such as GP's under-detecting depression, stigma associated with seeking mental health care, and practical issues, such as poor mobility and lack of available transport.[44,45] Staff-delivered telephone-based PST-PC offered alongside a GP referral may have the potential to improve access to an early, evidence-based intervention in a cost-effective manner. This will be investigated in a pragmatic RCT where PST-PC plus usual care (referral to a GP) will be compared to usual care alone. The GP referral for additional psychological assessment and treatment is an important component of the model which may not be standard practice in other LVR settings. If this model is shown to be effective and cost-effective, this exploratory study provides significant insight into the challenges and strengths that should be considered for wider-implementation of PST-PC into routine practice.

Furthermore, an important consideration for future implementation studies is the potential for flexibility in PST-PC delivery. LVR clients are frequently older in age and have complex comorbid health issues, which may augment their level of disability and functioning. When training rehabilitation practitioners, it may be beneficial to highlight components of the intervention that can be modified (e.g., number of sessions and mode of delivery) to suit the individual client's needs, while still upholding core elements of the treatment. Our findings indicate that training practitioners in relationship skills, such as empathy and rapport building, should also be included and evaluated in training programs.

Conclusions

Despite the widespread prevalence of depression and other mental health problems among adults with vision impairment, and more widely in chronic illness, few rehabilitation services offer early interventions designed to protect or improve mental health as a routine part of service provision. Clinical guidelines recommend the implementation of brief evidence-based problem-solving interventions in rehabilitation settings for adults with chronic health problems and subthreshold symptoms (or mild to moderate levels of depressive symptoms)[8] and more widely in chronic disease management (e.g., diabetes).[46,47] This novel study provides the first data on factors that can impact on the implementation of these recommendations in a unique area. Our data, guided by theoretical models, provides groundwork for enhancing implementation efforts in practice, and also a basis for comparison of the difficulties that may be encountered in other rehabilitation settings. Future implementation efforts should ensure comprehensive and ongoing practitioner training in addition to widespread promotion of the psychological service offered as an integrated component of the rehabilitation program.

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Chapter 8: General discussion

8.1 Introduction

Depression is exceedingly prevalent in people with vision impairment (VI) contributing to a heightened level of disability and functional decline, reduced QoL and a higher risk of premature mortality for the individual, notwithstanding increased health-care costs for society.\(^1\)\(^5\) Research indicates that up to 43% of people with VI will experience depressive symptoms \(^6\)\(^{-11}\) while as few as 20% of these receive psychological support,\(^11\)\(^12\) underscoring the need for accessible and cost-effective models of care suitable for this population. This doctoral research evaluated a world-first integrated approach to managing depressive symptoms in adults with VI. Low vision rehabilitation (LVR) staff were expertly trained to deliver an evidence-based psychological treatment via telephone, Problem-Solving Treatment for Primary-Care (PST-PC), to adult LVR clients across Australia who screened positive for depressive symptoms. This chapter summarises the key findings from the four study phases (1. identifying the evidence base, 2. feasibility/piloting, 3. effectiveness, and 4. evaluating implementation) and discusses the strengths, limitations, and implications of the study. Areas for future research, specifically to enhance client engagement and facilitate wider-implementation, are also discussed.

8.2 Summary of findings

In \textit{Chapter 2} and \textit{Chapter 3}, attention was drawn to the limited empirical evidence available to support the effectiveness of problem-solving intervention for reducing depression in this specific population- owing to the small number of trials conducted, brief follow-up periods investigated (<6 months), narrow demographic (adults aged 60+) and clinical representation (patients with age-related macular degeneration) and lack of pragmatic trials conducted in real-world settings. These findings are consistent with a recent systematic review and meta-analysis of psychosocial interventions for adults with VI\(^134\) and underscores the need for this doctoral research.

The findings from the feasibility and pilot study (Phase 2; \textit{Chapter 4}) support previous research demonstrating that successful training of non-mental health professionals in
PST-PC can be achieved. Participating clients showed statistically and clinically significant improvements in depressive symptoms and health-related QoL (HRQoL) providing preliminary support for a randomised controlled trial to rigorously test the effectiveness of this model. Furthermore, PST-PC was found to be highly acceptable to clients, although one third of clients had a preference for face-to-face session. An unanticipated finding from this pilot study was the high rate of early termination from PST-PC (60% completed <6 sessions); and those who withdrew were significantly older. While improved attrition rates have been reported in trials of PST in older adults, studies including samples with more complex needs (health comorbidities, disability or cognitive decline) have reported difficulties with retaining participants. The main reasons for early termination in Phase 2 were due to health comorbidities or not perceiving PST-PC to be relevant. For these clients, their focus might be on receiving LVR services to help them utilise existing vision and to function better, and perhaps are not readily open to receiving a service to target their depressive symptoms. Future studies could investigate the optimal timing of offering PST-PC whilst receiving LVR services.

Findings reported in Chapter 5 (Phase 3: Effectiveness) provide evidence for the clinical and cost-effectiveness of this integrated model and support the growing evidence base for the effectiveness of integrated models of care for depression in patients with long-term chronic health conditions, such as cancer, diabetes and heart disease. It is noteworthy that treatment effects were maintained at 12-month follow-up in per-protocol but not intention-to-treat analysis highlighting the importance of sustained engagement with PST-PC. Due to the small numbers who completed maintenance sessions, this study was not sufficiently powered to investigate their effect, although the provision of maintenance sessions may have contributed to sustained benefits at 12-month follow-up. This would support previous work that has shown “booster” PST sessions following the intervention period were associated with the prevention of depression in stroke patients at 1-year follow-up. Further research is needed to explore the uptake, perceived usefulness and impact of maintenance sessions. This is important to determine the necessity to deliver booster sessions in practice.

The intervention group showed greater improvements in HRQoL and vision-specific distress at 6 but not at 12 months suggesting that beneficial effects of PST-PC for these
outcomes may attenuate over time. These results are consistent with findings from an RCT conducted with older Chinese patients where PST-PC was associated with greater improvement in HRQoL at 3 but not 12-months. Vision-specific distress is associated with a person's ability to manage the practical and social challenges of vision impairment while HRQoL is multi-dimensional construct including domains related to physical and social functioning. So, while depressive symptoms and vision-specific distress/HRQoL are associated, there are distinct risk factors for each, for example, vision-specific distress has been associated with reduced confidence in managing social interactions. One hypothesis is that PST-PC did not specifically target vision-specific distress or HRQoL, but initial effects may have been achieved by working on problems in these areas in the short term but were not maintained/sustained following the intervention. A further hypothesis is that participants in the intervention group may have been more responsive to the support offered by phone. Previous studies have shown that telephone support is associated with improvements in distress and functioning in women diagnosed with breast cancer and improved HRQoL in people with chronic heart failure in the short-term. Further research is needed to explore what factors are associated with distress/HRQoL outcomes and how PST-PC could be adapted to better target these in the longer-term.

To support the delivery and implementation of PST-PC on a larger scale, the cost-effectiveness of this integrated model in comparison to usual care was evaluated using an incremental cost-effectiveness analysis from a third party-payer perspective (Chapter 5). Findings showed that in addition to clinical effectiveness, telephone-delivered PST-PC administered by a trained LVR practitioner provided a cost-effective model resulting in a gain of 0.02 quality-adjusted-life-years (QALYs) in comparison to usual care alone. This gain in QALYs compares favorably to trials targeting subthreshold and clinical depression in community-based adults using Problem-Solving Treatment or Cognitive Behavioural Therapy (CBT) that report gains ranging from 0.002 to 0.01 up to 12-months. Findings are comparable with large-scale collaborative care models for depression management in adults attending primary care practices (reporting a 0.02 QALYs gain). In this doctoral study, the intervention was cost-effective according to commonly used willingness-to-pay thresholds in Australia and this finding was robust to sensitivity analyses. Driving these findings is the delivery of PST-PC via telephone by existing staff who work within the LVR setting. Employing
A specialist mental health professional to provide early intervention for subthreshold symptoms on a national level may result in higher costs and extended wait-times for services. A recent exploratory trial of PST delivered in the patient’s home or research centre by trained psychological therapists, to LVR attendees across Britain, found that this model was neither cost-effective nor feasible.

In Phase 3, implementation factors arising from PST-PC delivery in this context were evaluated in more depth. As observed in the pilot study, a high proportion of participants terminated PST-PC sessions early (79% completed <6 sessions). Using mixed research methods, results showed that being single, having low perceived adequacy of social support and poor acceptance of vision loss were the most important predictors of early termination. Social support may be particularly relevant for people with VI because of the higher levels of social isolation and dependency in this population. Those with low social support may be more likely to utilise ineffective coping strategies (e.g. disengagement coping), have reduced self-esteem and self-efficacy, characteristics which may place them at a greater risk of declining or terminating treatment early. Strategies to facilitate engagement by those with low levels of social support require exploration and investigation. The finding in relation to acceptance of one’s vision loss supports previous work from our team. Analysis of baseline data from this PhD study showed that lower levels of acceptance were associated with poor self-efficacy to use problem-focused coping. This would suggest that greater levels of acceptance in relation to one’s vision impairment may be necessary prerequisite for ability to engage in PST-PC.

Chapter 7 describes the barriers and facilitators to PST-PC delivery in a national LVR setting and explores influential factors in wider-implementation and sustainability. The most salient reported by staff were a lack of role recognition for PST-PC practitioners, clients’ not being ready to engage in PST-PC, unmet client expectations regarding PST-PC and the absence of face-to-face sessions. Facilitating factors included a recognised need for an emotional support services by staff, PST-PC being a practical, skills-based model and the ongoing high level of training, supervision and support provided to the PST-PC practitioners. Three key areas were highlighted as important for wider implementation and sustainability of this model in practice including flexibility in the
delivery, raising organisational awareness (marketing PST-PC) and ongoing staff training and support.

In summary, findings from this study demonstrated that telephone-delivered PST-PC administered by trained LVR staff can reduce the severity of depressive symptoms to a clinically significant degree among individuals with VI in a cost-effective manner. Sustained engagement with PST-PC is needed to achieve benefits at one-year follow-up, however given the high rate of early termination from PST-PC, development of the model is needed.

8.3 Study strengths and limitations

This study took an innovative approach by training LVR staff who are highly skilled in working with older adults with LV to deliver, for the first time, an evidence-based psychological treatment. The findings demonstrate that LVR staff can deliver PST-PC with high fidelity, producing similar effect sizes as those reported in depression trials of CBT in patients with diabetes or cancer. Furthermore, the approach of embedding PST-PC into existing workflows and training a large pool of LVR staff ensures continued service provision beyond the life of this doctoral research project. Other strengths of this study include the involvement of an expert clinical psychologist in the staff training of PST-PC, the use of a fidelity measure to examine staff adherence to PST-PC steps, and the provision of on-going supervision to staff to maintain PST-PC skills which is unique to other implementation research in this area.

A novel component to this doctoral research was the extension beyond an “efficacy” trial to explore PST-PC delivery and implementation issues in a real-world LVR setting. Through the explicit use of theoretical frameworks, Phase 4 conceptualised, using a systematic and replicable approach, the potential determinants of successful PST-PC delivery and implementation in a national LVR setting. The combination of deductive coding (informed by conceptual frameworks to guide barrier and facilitator identification) and inductive analysis (to allow unanticipated findings and participant insights to emerge) are strengths of this thesis. Furthermore, the results provide the first data on factors that can impact on the implementation of the NICE clinical guidelines in
LVR, provide the groundwork for enhancing implementation efforts in practice, and a basis for comparison of the difficulties that may be encountered in other health settings.

A further strength of this thesis is the comprehensive evaluation of PST-PC delivery guided by existing implementation frameworks (e.g. RE-AIM, MRC) including feasibility, demand, effectiveness, cost-effectiveness, intervention fidelity and delivery issues using mixed research methods. Previous studies have identified salient barriers to the uptake of psychological services in adults with VI. These findings make an important contribution to the literature by investigating for the first time factors associated with poor engagement with an evidence-based treatment for depression. The use of Rasch analysis to validate outcome measures and provide estimated linear interval measures, sophisticated statistical techniques, such as Global Search Regression, and the pragmatic RCT design are further strengths of this study.

In this study, participants were followed up over 12-months which is typically longer than other effectiveness trials of PST-PC. It is also one of the first published studies to evaluate the cost-effectiveness of a health-service targeting psychological well-being in LVR settings. Subthreshold depressive symptoms affect around a third of adults with VI and can adversely affect levels of functioning in this group. Findings from Phase 3 (Chapter 5) demonstrated that that this model of care also provides early intervention to those with subthreshold symptoms (41% achieved a 5-point reduction) and therefore may prevent or reduce the risk of developing major depressive disorder (MDD). This could be an important avenue for further research to determine if this integrated model can prevent the onset of a depressive disorder in people with subthreshold symptoms or who are asymptomatic.

The main limitation of this study pertains to the generalisability of these findings. PST-PC practitioners were volunteers suggesting an interest and positive view of PST-PC delivery. Therefore, their skills and views may not be representative of other LVR staff. Participants who took up LVR services and agreed to take part in this research project (45% accepted) may be more likely to utilise services in general. Therefore, it cannot be inferred that these findings would be replicated in all adults attending LVR or those with VI who do not take up LVR services. In Australia, it is estimated that approximately 80% of individuals’ do not access low vision or blindness services raising some broader questions regarding the management of depression in this
In a recent report published in JAMA Ophthalmology,\textsuperscript{265} it was recommended that clinicians treating individuals with chronic disabling eye disease should take specific steps to detect depression and then refer those who have symptoms for further assessment and treatment. If this integrated PST-PC model (including a GP referral) was imbedded into routine LVR service provision, this could present an opportunity to work with clinicians, to increase referrals to LVR services. Furthermore, PST-PC can be delivered by allied health professionals, therefore in eye care settings that have sufficient resources, professionals could be trained to deliver this brief intervention. Nonetheless, models of care to address depression in those with VI who do not access LVR services (and those in LVR settings with more complex mental health problems) need to be developed and will be discussed in more detail in Section 8.4.

Due to the small number of participants completing the recommended number of PST-PC sessions (6 to 8), this project was not adequately powered to conduct sub-group analyses. For example, this study was underpowered to investigate if the severity of depressive symptoms at baseline was associated with outcomes at 6 and 12-months or to determine the effect of the maintenance sessions in sustaining treatment effects 1-year on. With the exception of visual acuity, all data were collected via self-report and potential confounders such as uptake of treatment for depression and history of depression were not verified. Finally, the early-termination rate from PST-PC was high, and whilst an analysis of predictors was able to be conducted, this study was not initially designed with this in mind. Given the small sample size and population from which they were drawn, findings should be interpreted with caution. The mean pre-treatment PHQ-9 score in the intervention group was 12.4 (range 6 to 21). Thus, it would be inappropriate to generalise these results to a clinically depressed sample. Furthermore, owing to the small sample size, I was not able to identify, with a high degree of confidence, the minimum number of sessions needed to achieve a CSC. Although the data do indicate that 6 sessions might produce a 4.17-point reduction in depression scores, the confidence intervals are wide (expected true value lies somewhere between 1.8 to 6.6). Furthermore, the small sample size and numerous analyses to determine the most important covariates associated with early termination make it likely that this study is underpowered and prone to Type I error. Future research should seek to replicate these findings in a larger sample and consider utilising previously validated outcome measures useful for predicting patient’s most suited to
psychological treatment. Such measures are based on theoretical constructs that contribute to the understanding of the mechanisms for improved outcomes from treatment. Understanding the relative importance of a broad range of suitability characteristics to determine for whom PST-PC is more beneficial could improve client outcomes and efficiency of this service in practice.

8.4 Implications for practice and future research

This thesis highlights several implications warranting further investigation. First, whilst this model has demonstrated clinical and cost effectiveness in reducing depressive symptoms in this sample of Australian LVR clients, much is to be gained by developing the current PST-PC to improve uptake and retention – specifically targeting those individuals who are least likely to engage. Second, the question remains “where to from here”? Consideration should be given to how this model could be scaled-up, implemented more widely and sustained across LVR services in Australia. Third, this thesis points to a need for models of care to be developed outside of LVR. The formation of collaborative, multidisciplinary care models could be one approach.

Developing the current integrated model for LVR

Adults with VI are generally older in age and frequently present with multimorbidities which may augment their level of disability and functioning. When training LVR practitioners, it may be beneficial to highlight components of PST-PC that can be modified (e.g. number of sessions, mode of delivery) to suit the individual client’s needs, while still upholding core elements of the treatment. Incorporating age-appropriate techniques, such as those described by Laidlaw and colleagues is one approach. For example, adjusting the pace when working with older adults to account for difficulties in information processing, allowing flexibility in delivery to overcome any medical and physical barriers, reinforcing clients’ unique strengths to capitalise on their past experience and wisdom, and ensuring clients are provided with a clear rationale for any new skills. Further research could focus on the added value of incorporating these techniques into PST-PC and the impact on retention and outcomes for older people with VI.

Flexibility in delivery and the integration of age-appropriate techniques requires staff training and supervision. Indeed, data from Chapter 7 suggested that ongoing clinical
supervision and training are the most important factors necessary for wider implementation of PST-PC. Training and supervision may also enhance PST-PC practitioner skills in facilitating client uptake and retention using evidence-based approaches such as Motivational Interviewing (MI). MI is a strategy to strengthen a person’s motivation to change by helping them explore and resolve ambivalence. MI has been used extensively in diabetes care to promote behaviour change with success. Recently, MI has been proposed as an integrative framework to enhance the effectiveness of evidence-based treatments for depression through improving engagement and retention. Simon and colleagues used structured MI exercises delivered over the telephone to enhance CBT engagement in depressed primary care patients and found significantly improved client satisfaction and clinical outcomes in this group compared to those receiving telephone care management or usual primary care. Furthermore, evidence shows that non-mental health professionals can be trained successfully in MI techniques. In a cluster RCT comparing MI plus standard depression care or depression care alone, MI training for primary care professionals resulted in improved MI ability for practitioners and significant and clinically meaningful improvements for their patients in depressive symptoms over 1-year follow-up. To date, studies that combine MI with Problem Solving Treatment are limited to substance abuse and disease prevention, however these have shown some promise.

Developing strategies for those with low levels of social support may also increase retention. Individuals identified as having low levels of social support (for example using a brief, pre-intake assessment) could be offered additional supportive counselling sessions before or alongside PST-PC. Trials of CBT offered with adjunct telephone support versus CBT alone have demonstrated improved patient outcomes and patient satisfaction in older adults. A further consideration is to offer a group-based PST-PC model, in order to provide opportunities for engagement and social support. Previous research with oncology patients supports this delivery format and has shown those who lacked social support had improved outcomes from a peer support group program compared to those with high levels of social support. In VI research, group-based self-management programs have resulted in improved outcomes (e.g. distress, QoL), however to date no studies have conducted subgroup-analysis to determine if levels of pre-existing social support or support achieved within the group moderate outcomes.
To target those most at risk of early termination from PST-PC, the current model could also include strategies to promote positive acceptance of one’s vision loss. Acceptance-based interventions such as mindfulness-based programs and acceptance and commitment therapy (ACT) are “third-wave” CBT interventions for treating mental health problems. ACT, for example, focuses on building acceptance (thoughts, bodily sensation, feelings) and enhancing individuals engagement in personally valued behaviours. LVR clients could receive education and training where they learn to apply acceptance and mindfulness skills to negative thoughts and feelings related to vision loss and re-engage with their valued activities. This could be targeted to those with low acceptance prior to PST-PC or integrated into the intervention. Evidence to support this approach comes from an RCT in diabetes, in which 81 patients with type 2 diabetes were randomly assigned either to either a 1-day education workshop alone or to a combination of education and ACT. Those in the ACT condition learned to apply acceptance and mindfulness skills to diabetes-related thoughts and feelings. At 3-month follow-up participants in the ACT group rated higher on acceptance and reported better diabetes self-care (e.g. glycaemic control). Recent trials in diabetes have also shown increases in the use of effective coping strategies (e.g. problem-solving) following ACT. Results from this study and findings in the area of diabetes suggest that the integration of ACT principles into PST-PC may impact on retention, skill development and outcomes and requires further investigation.

Wider-implementation (scaling) of this model

Consideration should be given to wider-implementation (or scaling) of this integrated model in LVR services across Australia. Scaling is defined as the “deliberate efforts to increase the impact of successfully tested health interventions so as to benefit more people and to foster policy and program development on a lasting basis.” Ongoing evaluation and monitoring should continue to occur if PST-PC is implemented more widely. This should include (i) planning: evaluation of the scope for sustainability, cost considerations, infrastructure and system-level factors needed to support wider-implementation; (ii) data collection and reporting systems (e.g. for monitoring client outcomes, client satisfaction); (iii) rates of reach/uptake and adoption/early termination; (iv) areas for ongoing staff training and development (including monitoring of fidelity); and (v) dissemination of outcomes at all levels (decision makers, key stakeholders,
Economic evaluation should be built into the process and strategies to enhance cost-effectiveness should be investigated. For example, monitoring of depressive symptoms (up to two weeks as recommended by NICE)\textsuperscript{37} and offering those clients with persistent depressive symptoms PST-PC could improve efficiency given depressive symptoms may remit in up to a third of individuals with VI experiencing subthreshold depressive symptoms.\textsuperscript{71} Cost-savings and sustainability could also be underpinned by delivery of a “train the trainer” (TTT) program, in which PST-PC practitioners take on responsibility for future training of staff. This initiative would further bridge the gap from evidence to practice through enabling service providers to embed this service into workflow with minimal research input. Research on TTT programs is emerging and preliminary data suggest this model is an effective scaling-up strategy for evidence-based mental health services where ongoing involvement of experts is not feasible.\textsuperscript{285 286}

Beyond integrated care in LVR: collaborative, multidisciplinary models of care

This thesis describes a model of care that provides early intervention for mild to moderate levels of depressive symptoms in the LVR setting. To ensure those within LVR services with more complex mental health needs (including severe and persistent depressive symptoms) and adults with VI who do not access LVR receive appropriate care, integration of collaborative, multidisciplinary care models in the wider health care system are needed. Collaborative care provides an evidence-based approach for supporting people with co-morbid physical and mental health problems in primary or secondary care using a multidisciplinary team (typically a primary care provider, specialist secondary physical health-service provider and highly skilled mental health professional). In terms of the clinical approach to depression, collaborative care programs follow the principles of stepped care,\textsuperscript{37} where each patient’s progress is closely tracked using validated clinical rating scales (e.g., PHQ-9)\textsuperscript{150}, treatment is systematically adjusted – stepped up – if patients are not improving as expected.

Collaborative care is recommended by the National Institute for Health and Care Excellence (NICE)\textsuperscript{37} and the World Health Organisation (WHO) for the management of mental health problems in those with chronic physical health conditions.\textsuperscript{287} In Australia, influential papers such as those issued by the Australian Health Policy Collaboration (AHPC), have described collaborative care for physical and mental health as “seeds of
the future health system”. More than 70 RCTs have established a robust evidence base for the effectiveness and cost-effectiveness of collaborative care models compared to usual care across diverse patient populations. Specifically in chronic disease management, strong evidence is emerging internationally in diabetes, cancer and chronic obstructive pulmonary disease where integrated multidisciplinary teams in the community have provided co-ordinated physical and mental health-care. The 3 Dimensions of care for Diabetes (3DfD) service in the UK is a prime example of collaborative, multidisciplinary care for the physical, mental and social aspects of diabetes (biopsychosocial model). A team including diabetologist, psychiatrist, clinical psychologist, and community support workers simultaneously provide care, eliminating the need for multiple referrals to separate services. In addition to caring for patients, mental health staff provide formal and informal training to diabetes physicians and nurses – for example, in MI techniques, basic principles of CBT, and general training in mental health. Outcome evaluation demonstrates significant improvements in glycaemic control among those using the service, as well as statistically significant improvements in psychological scores relating to depression (PHQ-9 scale), anxiety (GAD7 scale) and diabetes-specific distress (Diabetes Distress Scale). Specifically for adults with VI, collaborative care models could include the provision of tailored and co-ordinated services provided by ophthalmologists, optometrists, LVR staff, psychologists, social workers, and general practitioners, in a range of organisations, including outpatient hospital and community eye-care services.

8.9 Conclusion

This study rigorously tested a new model of service provision within LVR services across Australia and examined client outcomes as well as cost-effectiveness and delivery issues. The overall conclusion from this body of work is that integrated telephone-delivered PST-PC administered by LVR staff is an effective and cost-effective model for reducing depressive symptoms in adults attending LVR services in Australia, and, that treatment effects can be maintained at one-year follow-up. Strategies to encourage client uptake and sustained engagement with PST-PC are however needed to ensure sufficient numbers receive benefit from this model. Furthermore, issues of wider implementation and sustainability beyond this project need to be addressed. Nonetheless, this study places Australia at the forefront of LVR care, with results
supporting the provision of telephone-delivered PST-PC-an affordable, integrated psychological treatment within a program of rehabilitation for physical disability. This pioneering study serves as a model for health service delivery within Australia and internationally, suitable for application not only to other LVR services but also other healthcare settings in which depression is also a pressing issue such as oncology, diabetes and heart disease.
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## Appendices

### Appendix 1: DSM-V definition of depression

<table>
<thead>
<tr>
<th>Major depressive disorder</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Five (or more) of the following symptoms have been present during the same 2-week period and represent a change from previous functioning;</td>
</tr>
<tr>
<td></td>
<td>at least one of the symptoms is either (1) depressed mood or (2) loss of interest or pleasure.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Depressed mood most of the day, nearly every day, as indicated by either subjective report (e.g., feels sad, empty, hopeless) or observation made by others (e.g., appears tearful).</td>
</tr>
<tr>
<td>2.</td>
<td>Markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day (as indicated by either subjective account or observation).</td>
</tr>
<tr>
<td>3.</td>
<td>Significant weight loss when not dieting or weight gain (e.g., a change of more than 5% of body weight in a month), or decrease or increase in appetite nearly every day. (Note: In children, consider failure to make expected weight gain.)</td>
</tr>
<tr>
<td>4.</td>
<td>Insomnia or hypersomnia nearly every day.</td>
</tr>
<tr>
<td>5.</td>
<td>Psychomotor agitation or retardation nearly every day (observable by others, not merely subjective feelings of restlessness or being slowed down).</td>
</tr>
<tr>
<td>6.</td>
<td>Fatigue or loss of energy nearly every day.</td>
</tr>
<tr>
<td>7.</td>
<td>Feelings of worthlessness or excessive or inappropriate guilt (which may be delusional) nearly every day (not merely self-reproach or guilt about being sick).</td>
</tr>
<tr>
<td>8.</td>
<td>Diminished ability to think or concentrate, or indecisiveness, nearly every day (either by subjective account or as observed by others).</td>
</tr>
<tr>
<td>Persistent Depressive Disorder (Dysthymia)</td>
<td>Depressed mood for most of the day, for more days than not, as indicated by either subjective account or observation by others, for at least 2 years.</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>Presence, while depressed, of two (or more) of the following:</td>
</tr>
<tr>
<td></td>
<td>Symptoms characteristic of a depressive disorder that cause clinically significant distress or impairment in social, occupational, or other important areas of functioning predominate but do not meet the full criteria for major depressive disorder.</td>
</tr>
<tr>
<td>Other specified depressive disorder (Subsyndromal symptomatic depression)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Depressed affect and at least one of the other eight symptoms of a major depressive episode associated with clinically significant distress or impairment that persist for at least 2 weeks</td>
</tr>
<tr>
<td></td>
<td><strong>OR</strong></td>
</tr>
<tr>
<td></td>
<td>Short-duration depressive episode (4–13 days): Depressed affect and at least four of the other eight symptoms of a major depressive episode associated with clinically significant distress or impairment that persists for more than 4 days, but less than 14 days</td>
</tr>
<tr>
<td></td>
<td><strong>OR</strong></td>
</tr>
<tr>
<td></td>
<td>Recurrent brief depression: Concurrent presence of depressed mood and at least four other symptoms of depression for 2–13 days at least once per month (not associated with the menstrual cycle) for at least 12 consecutive months</td>
</tr>
</tbody>
</table>
# Appendix 2: Patient Health Questionnaire-9 (PHQ-9)

## Patient Health Questionnaire-9 (PHQ-9)

Over the last 2 weeks, how often have you been bothered by any of the following problems? (Use ✓ to indicate your answer)

<table>
<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>Several days</th>
<th>More than half the days</th>
<th>Nearly every day</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Little interest or pleasure in doing things</td>
<td>0 1 2 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Feeling down, depressed, or hopeless</td>
<td>0 1 2 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Trouble falling or staying asleep, or sleeping too much</td>
<td>0 1 2 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Feeling tired or having little energy</td>
<td>0 1 2 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Poor appetite or overeating</td>
<td>0 1 2 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>Feeling bad about yourself — or that you are a failure or have let yourself or your family down</td>
<td>0 1 2 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>Trouble concentrating on things, such as reading the newspaper or watching television</td>
<td>0 1 2 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual</td>
<td>0 1 2 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>Thoughts that you would be better off dead or of hurting yourself in some way</td>
<td>0 1 2 3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

For office coding

\[ \text{Total Score: } \]

---

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

<table>
<thead>
<tr>
<th></th>
<th>Not difficult at all</th>
<th>Somewhat difficult</th>
<th>Very difficult</th>
<th>Extremely difficult</th>
</tr>
</thead>
</table>

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Integrated Depression Management: A Proposed Trial of a New Model of Care in a Low Vision Rehabilitation Setting

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ABSTRACT

Purpose: Depression is a common problem among people with visual impairment and contributes to functional decline. This article presents a study protocol to evaluate a new model of care for those patients with depressive symptoms in which psychological treatment is integrated into low vision rehabilitation services. Low vision staff will be trained to deliver “problem solving therapy for primary care” (PST-PC), an effective psychological treatment developed specifically for delivery by non-mental health care staff. PST-PC is delivered in 8 weekly telephone sessions of 30–45 minutes duration and 4 monthly maintenance sessions. We predict this new integrated model of care will significantly reduce depressive symptoms and improve the quality of life for people with visual impairment.

Methods and Design: A randomized controlled trial of PST-PC will be implemented nationally across low vision rehabilitation services provided by Vision Australia. Clients who screen positive for depressive symptoms and meet study criteria will be randomized to receive PST-PC or usual care, consisting of a referral to their general practitioner for more detailed assessment and treatment. Outcome measures include depressive symptoms and behaviors, quality of life, coping and psychological adjustment to visual impairment. Masked assessments will take place pre- and post-intervention as well as at 6- and 12-month follow-up.

Conclusion: We anticipate that this innovative service delivery model will lead to sustained improvements in clients’ quality of life in a cost effective manner and provide an innovative service delivery model suitable for other health care areas in which depression is co-morbid.

Keywords: Depression, low vision rehabilitation, problem solving therapy, visual impairment

INTRODUCTION

Visual Impairment and Depression

Visual impairment resulting mainly from age-related eye conditions such as age-related macular degeneration, glaucoma, as well as diabetic retinopathy, is a growing problem due to our aging population. Visual impairment is a known risk factor for depression and can lead to heightened levels of disability and functional decline.¹,² Even minimal depressive symptoms that do not meet the diagnostic criteria for clinical depressive disorder (known as sub-threshold depression) are associated with functional decline and...
reduced quality of life not accounted for by the eye disease or general medical problem.3 Furthermore, sub-threshold depression is associated with an increased risk of developing clinical depression.4,5 Early identification and treatment of depressive symptoms among people with visual impairment is therefore critical in reducing and preventing disability and costs for the medical system. However, despite the availability of evidence-based interventions for depression, it is rarely managed in this population.6 Recent reviews have highlighted that emotional support options are often sought after by people experiencing vision loss, but rarely offered in current services.7,8

Low vision rehabilitation services aim to address the restrictions posed by low vision and to enhance patient independence. Different models of low vision services exist and vary widely in content and intensity although the majority involve provision of aids, devices, and training to enhance use of residual vision. Vision Australia is the main low vision rehabilitation service provider in Australia. Clients are assessed by a member of the multi-disciplinary team and offered appointment/s with an optometrist and prescribed relevant optical aids. This may be followed by further training provided by the multi-disciplinary team to meet client-specified goals.9 Low vision rehabilitation staff are key care providers and have the potential to play a crucial role in managing depression in this group. Recent surveys of low vision rehabilitation staff indicate that whilst staff recognized that depression is an issue for their clients they felt they did not possess the skills or resources to manage depression systematically.10,11

Integrating Problem Solving Therapy into Low Vision Rehabilitation Services

In recently updated depression treatment guidelines, the National Institute of Clinical Excellence argued that early intervention should be integrated into rehabilitation programs for people at risk of depression due to functional impairment.12 The guidelines recommend that health professionals identify those patients with symptoms of depression and provide low-intensity intervention programs based on cognitive-behavioral therapy, specifically problem solving techniques and behavioral activation.

Problem solving therapy (PST) teaches patients problem solving skills in order to enhance their ability to cope with the challenges they face and thereby preserve independence and function. In turn, this can enhance feelings of control, acceptance and reduce or prevent the development of depressive symptoms. PST is particularly applicable for individuals with low vision since poor coping skills and activity loss have been related to depressive symptoms in this population, and it has been hypothesized that enhancing patient skills at goal setting and problem solving will lead to improved psychological health.13-15

PST has been shown to be efficacious in treating depression in older adults and patients with chronic medical problems such as diabetes, cancer and chronic pain.16 Meta-analyses have found PST to be more effective than no treatment, usual care and attention/supportive control treatments.17,18 While PST was originally designed to be delivered by specialists in mental health care settings, a version suitable for delivery by other health care providers in different settings has been developed. It is known as “problem solving therapy for primary care” (PST-PC).17 The efficacy and feasibility of PST-PC as a treatment for clinical depression, as well as sub-threshold symptoms of depression, have been demonstrated in randomized controlled trials18,19 For example, PST-PC resulted in more depression-free days, fewer depressive symptoms and better functioning in older adults (≥60 years) treated in primary care than those receiving community-based psychotherapy.19 PST-PC has also been shown to be more effective than placebo and equivalent to antidepressants in the treatment of major depression.20

Efficacy trials of PST-PC have been conducted in patients with age-related macular degeneration attending outpatient ophthalmology offices.21 In that study a reduced incidence of clinical depression was shown in the short term although the effects were not sustained at 6 months.21 The authors argued that to produce sustainable effects at 6 months and beyond, PST-PC should be integrated into low vision rehabilitation care. Such integration will mean that PST-PC is incorporated into patients’ rehabilitation programs, thereby reducing practical and psychological barriers to uptake. Given the strong evidence base for the efficacy of PST in reducing depressive symptoms it is timely to determine the impact of PST when implemented into real world settings.

Aims and Hypotheses

We will conduct a pragmatic trial of a new model of care in which the evidence-based psychological therapy PST-PC is integrated into low vision rehabilitation services. We will train staff to deliver PST-PC as part of the rehabilitation program to clients identified as showing depressive symptoms. This new system is designed to ensure that an effective psychological intervention is available and accessible at an early stage to those clients in need. We aim to determine, using a randomized controlled trial, the impact of this new integrated system on short- and long-term client outcomes compared to usual care. We also aim to examine the cost-effectiveness of this new model.
It is hypothesized that compared to clients who receive usual care, those who receive PST-PC will show significantly reduced depressive symptoms. We predict that PST-PC will significantly improve coping skills and psychological adjustment to visual impairment as well as activate goal-directed or pleasant behaviors and reduce depressive behaviors. We predict that these effects will be maintained at 6-month follow-up, and we will explore the long-term outcomes at 12 months.

METHODS

PST-PC Training Program for Vision Australia staff

Low vision rehabilitation staff members across Vision Australia centers were asked to volunteer for the training program. Staff members from a range of backgrounds (occupational therapy, orientation and mobility, social work, and social welfare) have expressed an interest in the program. Training includes a 2-day workshop based on an established training program, which has been demonstrated to result in high level performance among trainees (Table 1). The first day is a group didactic workshop in which the background and theory behind PST-PC is outlined and videos of PST-PC are observed. Trainees are given the opportunity to role play the delivery of an introduction and the first session of PST-PC. Day 2 is conducted in small groups (4–5 trainees) and includes conducting and observing role plays with detailed feedback and direction from PST-PC trainers. Trainees are provided with a PST-PC treatment manual which has been adapted for low vision rehabilitation staff at Vision Australia. This includes a range of additional tools: session narratives, checklists, worksheets, a list of treatment strategies and client handouts.

Following attendance at the 2-day workshops, trainees will be allocated 2–5 training cases. Training cases are Vision Australia clients who screened positive for depressive symptoms and have agreed to take part in the pilot phase of the new intervention. Each session will be recorded and 4 sessions per case will be reviewed by a clinical psychologist using the problem solving treatment for primary care adherence and competence scale (PST-PAC). This scale assesses fidelity to technical skills, completion of the specific problem solving stages (Table 2), and the efficient use of time, communication and interpersonal effectiveness. Aspects of the session are rated from 0 (deficient) to 5 (well above standard). A telephone supervision session will also be held for each of the four review sessions where detailed feedback will be provided by the clinical psychologist. To be judged as competent the trainee must achieve an overall score of

| Table 1. Overview of staff training in Problem Solving Therapy for Primary Care (PST-PC). |
|----------------------------------|----------------------------------|
| **Workshop 1** | **Workshop 2** |
| Workshop 1 | Workshop 2 |
| 1-day large group didactic workshop | 1-day small group work (4–5 participants) |
| Background to PST-PC | Detailed role play of PST-PC sessions |
| Theory behind PST-PC | Observation of recorded role play |
| Provision of PST-PC treatment manual, including session narratives, worksheets, checklists and client resources | Detailed feedback from a clinical psychologist |

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at least 3 (competent) on the PST-PAC for three consecutively rated sessions.

Following demonstrated proficiency on the PST-PAC rehabilitation staff will be certified to use PST-PC, and will be given an additional role as a ‘PST-PC specialist’ within Vision Australia. This will mean that they are able to accept referrals from other staff. It is anticipated that 10–20 staff members will become certified PST specialists. PST-PC specialists will continue to receive monthly supervision from the clinical psychologist.

### Design

A prospective, longitudinal, randomized controlled trial of the new integrated model compared to usual care will be conducted. Rehabilitation service clients will be randomized to receive either PST-PC as an integrated component of their rehabilitation or usual care. Assessments will take place at baseline and 3 months to determine initial effects. Assessments at 6 and 12 months will be conducted to determine if changes are sustained in the longer term.

### Participants and Recruitment

Low vision clients will be recruited from Vision Australia centers across Victoria, New South Wales, Queensland, Australia Capital Territory and Northern Territory. Potential participants will be identified by Vision Australia staff during the intake assessment in which a brief two question validated depression screening tool (Patient Health Questionnaire – Two Items, PHQ-2)²³ is administered. This screening tool is designed for use in busy clinical settings as part of a wider assessment. We have recently implemented the PHQ-2 as a standard component of intake assessment in Vision Australia and have shown this tool to be...
Randomization and Masking

All interviews will be conducted over the phone by trained research assistants using a computer-assisted interview. Baseline interviews will be conducted prior to randomization. Following the baseline assessment, participants will be allocated to the intervention or control groups based on the code contained within the next sequential sealed envelope. Generation of the random allocation sequence will be conducted by a clinical trials expert who is not part of the project team using a computer-generated process.

Follow-up interviews will be conducted by research assistants masked to participant allocation and participants will be instructed not to reveal their group allocation to the interviewers. Breaches of masking will be recorded and reasons obtained. In addition, success of masking at the end of the trial will be evaluated by asking interviewers to guess group assignment for each participant and compare results to actual assignment. Participants and PST specialists are not masked to group assignment. PST specialists are asked to keep client assignment to PST-PC confidential.

Intervention Group: Problem Solving Treatment

PST-PC is a manual-driven psychological treatment that teaches problem solving skills. It aims to help people with vision loss to find practical solutions to vision-related problems, reduce avoidance behaviors, and adopt a positive problem solving orientation. The focus of PST-PC is on teaching participants the skills and process of problem solving, rather than solving specific problems per se in a didactic manner. Therefore, with the guidance of the specialist, participants are able to choose and work on problems from any area of life. Following an introductory session, PST-PC will be delivered by PST-PC specialists in 8 weekly telephone sessions (30–45 minutes duration). The introductory session outlining PST-PC aims to ensure that the client has a full understanding of the approach. This is important since understanding of that rationale and process of PST-PC have been linked to subsequent successful outcomes. A dedicated introduction was considered important in this elderly population who may not be able to make easy use of written resources. The following eight PST-PC sessions consist of taking the participant through the problem solving steps: (1) clarifying and defining the problem; (2) setting a realistic goal; (3) brainstorming multiple solution alternatives; (4) evaluating each solution for its advantages and obstacles to implementation; (5) choosing a preferred solution; (6) making a specific action plan to implement the solution; and (7) evaluating the outcomes from the previous session (Table 2). Activity scheduling is also conducted at each session to increase pleasant activities. Where additional Vision Australia services (e.g., occupational therapy, orientation and mobility training) are considered to be a possible solution to a particular problem, the PST specialist can provide knowledge of these options and support the client to develop an action plan to gain access to these services.

Following the acute treatment sessions, 4 monthly maintenance sessions with clients will be administered by telephone. The goals of the maintenance sessions are to reinforce skills, to maintain treatment benefits, and prevent the reoccurrence of depressive symptoms. To determine fidelity to treatment, all sessions will be recorded and made available for review at random by the clinical psychologist using the PST-PAC.

Usual Care

Participants in the control group will be referred to their general practitioner (GP) for psychological assessment and intervention.

Participants in each group will receive information about depression and have access to all usual Vision Australia services and community-based services. A letter outlining the client’s level of depressive symptoms and involvement in the study will be sent to the client’s GP.

Measures

Primary Outcomes

(1) Depressive symptoms: The PHQ-9 is based on the Diagnostic and Statistical Manual of Mental Disorders criteria for depressive disorders. The PHQ-9 asks participants to report if they have been bothered with 9 symptoms in the last
2 weeks. Responses are rated using a 4-category Likert scale from “Not at all” to “Nearly every day.” The questionnaire provides a continuous severity score of depressive symptoms. Scores of 5, 10, 15, and 20 represent valid thresholds demarcating the lower limits of mild, moderate, moderately severe and severe depressive symptoms. The cut-off score of 10 is the conventional score for clinically significant symptoms for which treatment should be considered. In addition, a scoring algorithm can be used to determine provisional diagnosis for major depressive disorder. The PHQ-9 shows high sensitivity and specificity in older adults and has been validated for telephone administration. The PHQ-9 is recommended as the depression screening tool of choice in primary care, general medical settings and for older adults. We have recently validated the use of the PHQ-9 as a tool to assess depressive symptoms in visually impaired individuals. This is a version of the Assessment of Quality of Life (AQoL) instrument which assesses a range of dimensions including independent living, coping, mental health and an additional dimension of the impact of visual impairment. It is a standardized and validated tool and has been calibrated using Australian preference scores. Quality-adjusted life years (QALYs) can be derived for economic evaluation.

Secondary Outcomes

(1) Coping: Coping Self-Efficacy Scale. This scale assesses one’s perceived ability to cope effectively with life challenges. It was developed specifically as a measure to detect change in coping with chronic health conditions following cognitive behavioral interventions. It consists of three subscales “use of problem-focused coping”, “stop unpleasant emotions and thoughts”, “get support from friends and family.” The three subscales have shown good internal consistency, test-retest reliability and predictive validity.

(2) Depressive behaviors: Behavioral Activation Scale-Short Form. This measure was developed to assess when and how patients respond to treatment for depression. Nine items assess two subscales of “activation” designed to capture activation towards goal directed or pleasant behaviors and “avoidance.” Good internal consistency, reliability, construct validity and predictive validity have been reported.

(3) Psychological adjustment to visual impairment: The Illness Cognition Questionnaire for Chronic Diseases. This questionnaire assesses both adaptive and maladaptive illness cognitions along three subscales of “helplessness,” “acceptance,” and “perceived benefit.” The measure has been reworded to focus on “vision” rather than “illness.” Adequate internal consistency, test-retest reliability and predictive validity have been reported.

Service Use
At each assessment point, all participants will be asked about any treatments for a mental health condition including medication received in community-based services over the previous 3 months. Verification of participant report will be sought from GP records. Participants will also be asked about their satisfaction with any community-based services they have received, with a focus on perceived accessibility, acceptability and barriers to uptake. The nature and extent of any Vision Australia services received will be documented by review of electronic service files.

Sociodemographic and Clinical Characteristics
Age, sex, cause of vision loss, visual acuity, duration of vision loss, marital status, co-morbidities, medications, prior episodes of a depressive disorder, number of previous episodes, previous treatment and psychological co-morbidity will be assessed. Perceived social support will be assessed using items previously developed to assess social support in individuals with low vision. Changes in visual acuity, co-morbidities and living conditions will be assessed at each time point. Participants who drop out from the study will be contacted and the reasons for this established.

Statistical Analysis
Descriptive statistics and bivariate comparisons of participants by treatment group will be conducted to characterize the sample and assess the success of randomization. An intent-to-treat approach will be used for all analyses. The main outcome measure will be severity of depressive symptoms as assessed by the PHQ-9. A minimal clinically important difference for individual change on the PHQ-9 is 5 points on the 0–27 point scale. In a recent paper comparing methods to define successful treatment outcomes using the PHQ-9 this was the recommended method for quantifying improvement when clinical and non-clinical distributions overlap as is the case in this study. A repeated measure mixed model will be used to determine the effect of the new model of care on depressive symptom severity, coping, adjustment and depressive behaviors adjusted for baseline scores and change in visual acuity at 3 and 6 months. Sustained effects at 12 months will also be examined.

To test if the new model is cost-effective compared to usual care we will conduct an incremental cost-effectiveness analysis from the societal perspective using the within-trial cost and effectiveness data.
collected prospectively throughout the trial duration. We will use standard cost collection techniques to quantify intervention and other related costs and potential cost offsets.42,43 This includes all costs for intervention resources, inpatient, non-inpatient, and prescription drug use throughout the study period. The primary health benefit will be depression scores from the PHQ-9. We will also convert AQoL-7D to QALYs using the methods previously described.44 Our approach for quantifying cost/effectiveness will follow that described in the literature.45 We will quantify the incremental costs (or savings) for the intervention group relative to the control group from baseline to 12 months. Next, we will quantify the incremental effectiveness relative to any changes in depression seen among control participants. As part of this analysis, we will present cost-effectiveness acceptability curves that will show the probability that the integrated model is cost-effective for a range of monetary values that a decision-maker might be willing to pay for a unit change in QALY or other measures of effectiveness.

**Sample Size Calculation**

Our sample size calculation is cautiously based on detecting a mean change of 4 points on the PHQ-9, this is 1 point below the minimal clinically important difference.40,41 A sample size of 64 in each group will have 80% power to detect a difference in means of 4 points assuming that the common standard deviation is 8.0 with a 0.05 two-sided significance level. Taking into account a loss to follow-up rate of 30%, the final sample size would be 91 in each group. We will oversample the usual care group by 25% in order to allow for later exclusion due to exposure to PST specialists during the rehabilitation program.

**Consent and Ethics**

All participants will be provided with a plain language statement and will provide written consent to participate in the project. Ethics approval has been obtained from the Royal Victorian Eye & Ear Hospital’s Human Research Ethics Committee (HREC; project number 12/1061H) and Deakin University HREC (project number 2012-139).

**DISCUSSION**

This trial takes an innovative approach by training vision rehabilitation staff who are highly skilled in working with older adults with low vision to deliver evidence-based psychological techniques to improve the mental health of the clients for whom they care. This integrated model means that more low vision clients will have access to early intervention for depressive symptoms in an accessible and acceptable manner. Furthermore, our approach of embedding this service into existing workflows ensures continued service provision beyond the life of this research project. This novel approach to service delivery can overcome barriers to psychological service provision identified in Australia including a lack of psychologists skilled in working with older adults, a lack of mental health professionals in rural areas, emphasis on crisis response, rather than early intervention, and artificial segregation of physical and psychological health care services.

It has been recognized that current health care services are lagging behind research evidence which clearly points to the need to implement integrated care systems addressing both physical and psychological needs.49 Researchers have also argued that pragmatic trials that demonstrate how to translate evidence into health service practice in a feasible and cost-effective way are required to bridge the evidence-practice gap.50 This project rigorously tests a new model of service provision within low vision services across Australia and examines client outcomes as well as cost-effectiveness. This project will serve as a model for health service delivery within Australia and internationally, suitable for application not only to other low vision services but also other healthcare settings in which depression is also a pressing issue such as diabetes, heart disease and oncology.

**AUTHORS’ CONTRIBUTIONS**

GR conceived of the study and drafted the initial manuscript. EH, BS, JK, DM, MH, EF, RC EL and XJ contributed to the methods and design of the study. BS, GR, MH and RC adapted PST-PC for use in an Australian low vision population. All authors have had critical input into the production of the final manuscript and have read and approve of the final manuscript.

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**DECLARATION OF INTEREST**

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of this paper.
This research is supported under Australian Research Council’s Linkage Projects funding scheme (project number LP110200035). Vision Australia and beyondblue: the national depression and anxiety initiative are partner organizations contributing to the funding of this project. The Centre for Eye Research Australia receives operational infrastructure support from the Victorian Government.

REFERENCES


Appendix 4: Psychometric assessment of the outcome measures

Rasch analysis was used to assess the psychometric properties of the PHQ-9, Impact of Vision Impairment distress scale (VI-distress), Illness Cognitions Questionnaire (ICQ) – acceptance subscale and the Coping Self-Efficacy (CSE) subscales using the Andrich rating scale model\textsuperscript{227} with Winsteps software (version 3.75), Chicago, Illinois, USA.\textsuperscript{228} Rasch analysis is a form of Item Response Theory where the ordinal raw questionnaire scores are transformed to estimates of interval measures (expressed in log of the odds units or logits) for use in subsequent parametric analyses.\textsuperscript{293} Rasch analysis provides significant insight into the psychometric properties of the scale, including (a) appropriate use of response categories; (b) measurement precision; (c) how well items ‘fit’ the underlying trait; (d) unidimensionality; (e) targeting of item difficulty to patients’ ability; and (f) differential item functioning.\textsuperscript{294} It was important to establish that differences between the outcome scores at baseline and follow-up are valid indicators of changes over time.\textsuperscript{295} Consequently, the baseline and follow-up data were stacked, and the absence of DIF was used to establish invariance over time. This technique has been described previously.\textsuperscript{295} The fit parameters of the PHQ-9, IVI-distress subscale, coping self-efficacy scale and illness cognitions questionnaire subscales are presented below. Once fit to the Rasch model was achieved, the person measures were exported to excel. Scores ranged across a negative to positive logit scale (-5 to 5), where scores closer to 5 indicate that a person possesses a high level of the assessed latent trait (e.g. depressive symptoms).\textsuperscript{296}

The PHQ-9 demonstrated acceptable fit to Rasch model parameters with no evidence of multidimensionality or misfitting items. The person separation index ((PSI) 1.94, target >2.0) and person reliability ((PR) 0.79, target >0.8) approached an acceptable level. The IVI-vision-specific distress demonstrated excellent fit to the Rasch model, with good precision (PSI=2.81, PR=0.89) and no evidence of multidimensionality or misfitting items.
Table A4.1 Fit parameters of the PHQ-9 and IVI-distress outcomes compared to the Rasch model requirements

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Rasch model requirement</th>
<th>PHQ-9</th>
<th>IVI-distress</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disordered thresholds</td>
<td>No</td>
<td></td>
<td>No</td>
</tr>
<tr>
<td>Person separation index &gt; 2.0</td>
<td>&gt; 2.0</td>
<td>1.96</td>
<td>2.81</td>
</tr>
<tr>
<td>Person reliability &gt; 0.8</td>
<td>&gt; 0.8</td>
<td>0.79</td>
<td>0.89</td>
</tr>
<tr>
<td>PCA, variance by 1st factor (%) &gt; 50%</td>
<td></td>
<td>50.3</td>
<td>61.6</td>
</tr>
<tr>
<td>PCA, Eigenvalue for 1st contrast &amp; % unexplained variance in 1st contrast &lt; 3.0, &lt;5.0%</td>
<td></td>
<td>1.9, 10.4</td>
<td>1.9, 9.1</td>
</tr>
<tr>
<td>Item fit &lt; 1.5</td>
<td>&lt; 0.15</td>
<td>Item 5 &gt; 1.5 (1.58)</td>
<td>All &lt; 1.5</td>
</tr>
<tr>
<td>DIF contrast</td>
<td>&lt; 1.0 logits and p &lt; 0.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>&lt; 1.0 logits</td>
<td>&lt; 1.0 logits</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td>&lt; 1.0 logits</td>
<td>&lt; 1.0 logits</td>
<td></td>
</tr>
<tr>
<td>Marital status</td>
<td>&lt; 1.0 logits</td>
<td>Item 3 more difficult for single group</td>
<td></td>
</tr>
<tr>
<td>Visual acuity</td>
<td>&lt; 1.0 logits</td>
<td>Item 5 more difficult for mild vision loss group</td>
<td></td>
</tr>
<tr>
<td>Allocation group</td>
<td>&lt; 1.0 logits</td>
<td>&lt; 1.0 logits</td>
<td></td>
</tr>
</tbody>
</table>

PCA=Principal Components Analysis

The ICQ Acceptance subscale demonstrated excellent fit to the Rasch model, with good precision (PSI=2.52, PR=0.86) and no evidence of multidimensionality, misfitting items or DIF. The three subscales of the CSE, where possible response options ranged from 0 to 10, each had disordered thresholds resulting in response categories being collapsed. The problem-focused coping subscale demonstrated excellent fit to the Rasch model, with good precision (PSI=2.70, PR=0.88) and no evidence of multidimensionality or DIF. There was some evidence of minor item misfit (Item 5 “think about one part of the problem at a time”), however this item was retained as removal resulted in decreased scale precision and reduced targeting. The social-support subscale demonstrated an acceptable fit to the Rasch model, with precision falling just below the rasch fit parameter requirements (PSI=1.83, PR=0.77). There was no evidence of multidimensionality, misfitting items or DIF. The emotion-focused subscale demonstrated good precision (PSI=2.42, PR=0.85) and no evidence of multidimensionality. Item 9 “pray or mediate” demonstrated some evidence of minor item misfit and differential item functioning, with males and those who were single/never married/widowed experiencing greater difficulty with this item.
### Table A4.2 Fit parameters of the ICQ compared to the Rasch model requirements

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Illness Cognitions subscales</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rasch model requirement</td>
</tr>
<tr>
<td>Disordered thresholds</td>
<td>Helplessness</td>
</tr>
<tr>
<td>Person separation index &gt;2.0</td>
<td>No</td>
</tr>
<tr>
<td>Person reliability &gt;0.8</td>
<td>&gt; 2.0</td>
</tr>
<tr>
<td>PCA, variance by 1st factor (%) &gt;50%</td>
<td>&gt;0.80</td>
</tr>
<tr>
<td>PCA, Eigenvalue for 1st contrast &amp; % unexplained variance in 1st contrast</td>
<td>&gt;50%</td>
</tr>
<tr>
<td>Item fit &lt;1.5</td>
<td>&lt;0.15</td>
</tr>
<tr>
<td>DIF contrast</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>All &lt;1.0 logits</td>
</tr>
<tr>
<td>Gender</td>
<td>All &lt;1.0 logits</td>
</tr>
<tr>
<td>Marital status</td>
<td>&lt;1.0 logits and p&lt;0.05</td>
</tr>
<tr>
<td>Visual acuity</td>
<td>Item 5 more difficult for mild vision loss group</td>
</tr>
<tr>
<td>Allocation group</td>
<td>All &lt;1.0 logits</td>
</tr>
</tbody>
</table>

* *removing item results in lower precision and targeting therefore item was not removed*
Table A4.3 Fit parameters of the CSE compared to the Rasch model requirements

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Rasch model requirement</th>
<th>Coping Self-Efficacy subscales</th>
<th>Social-support</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disordered thresholds</td>
<td>Yes*</td>
<td>Problem focused</td>
<td>Emotion-focused (item 9 removed)</td>
</tr>
<tr>
<td>Person separation index &gt;2.0</td>
<td>&gt; 2.0</td>
<td>2.7</td>
<td>2.42</td>
</tr>
<tr>
<td>Person reliability &gt;0.8</td>
<td>&gt;0.80</td>
<td>0.88</td>
<td>0.85</td>
</tr>
<tr>
<td>PCA, variance by 1st factor (%) &gt;50%</td>
<td>&gt;50%</td>
<td>56.4</td>
<td>52.4</td>
</tr>
<tr>
<td>PCA, Eigenvalue for 1st contrast &amp; % unexplained variance in 1st contrast</td>
<td>&lt;3.0, &lt;5.0%</td>
<td>&lt;3.0, &lt;5.0%</td>
<td>2.0, 7.4</td>
</tr>
<tr>
<td>Item fit &lt;1.5</td>
<td>&lt;0.15</td>
<td>Item 2 &gt; 1.5 (1.82), item 11 &gt;1.5 (1.56)</td>
<td>Item 9 &gt; 1.5 (3.43)</td>
</tr>
<tr>
<td>DIF contrast</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>&lt;1.0 logits</td>
<td>&lt;1.0 logits</td>
<td>&lt;1.0 logits</td>
</tr>
<tr>
<td>Gender</td>
<td>&lt;1.0 logits</td>
<td>Item 9 &gt; difficulty for males</td>
<td>&lt;1.0 logits</td>
</tr>
<tr>
<td>Marital status</td>
<td>&lt;1.0 logits</td>
<td>Item 9 &gt; difficulty for single</td>
<td>&lt;1.0 logits</td>
</tr>
<tr>
<td>Visual acuity</td>
<td>&lt;1.0 logits</td>
<td>&lt;1.0 logits</td>
<td>&lt;1.0 logits</td>
</tr>
<tr>
<td>Allocation group</td>
<td>&lt;1.0 logits</td>
<td>&lt;1.0 logits</td>
<td>&lt;1.0 logits</td>
</tr>
</tbody>
</table>

* Categories were disordered so collapsed the following response options= 0 1 2 2 3 4 5 6 7 8
‡ Categories were disordered so collapsed the following response options= 0 1 1 2 2 3 4 5 6 7 8
¥ Categories were disordered so collapsed the following response options= 0 1 1 2 2 3 4 5 6 7 8
Author/s:
Holloway, Edith Eva

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