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Problem-solving therapy for adults with diabetic retinopathy and diabetes-specific distress: a pilot randomized controlled trial

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ABSTRACT

Objective: To provide preliminary evidence for the impact of problem-solving therapy for diabetes (PST-D) in adults with diabetic retinopathy (DR) and diabetes distress.

Research design and methods: In a pilot randomized controlled trial, 40 participants with DR and diabetes distress were allocated to the PST-D or control groups. Diabetes distress (DDS), depressive symptoms (PHQ-9), self-care activities (SDSCA), and HbA$_{1c}$ were assessed at baseline, and 3 and 6-month follow-ups.

Results: At the 6-month follow-up, the PST-D group showed significant improvements relative to the control group, in 'regimen-related distress' (PST-D: −1.3±1.4; control: −0.4±1.1), depressive symptoms (PST-D: −4.3±6.1; control: −0.3±4.6), and HbA$_{1c}$ (PST-D: −1.2%±1.01; control: 0.2%±1.2%) (all p<0.05). In multiple regression analysis, adjusting for baseline values and sociodemographic factors, PST-D was associated with significant improvement in 'regimen-related distress', depressive symptoms, and HbA$_{1c}$ at the 6-month follow-up (p<0.05).

Conclusions: PST-D is a promising intervention for improving psychological outcomes and glycemic control. A fully powered study is required to confirm these findings and examine mechanisms of change in HbA1c.

Trial registration number: ACTRN12616001010482; results.

Significance of this study

What is already known about this subject?
- We know that diabetes distress and depressive symptoms are common in people with diabetes and have a huge impact on many aspects of life.
- Evidence-based low-intensity psychological treatments exist but are not targeted or easily available within diabetes services.

What are the new findings
- This study provides preliminary evidence that problem-solving therapy tailored to diabetes can improve diabetes distress, depressive symptoms, and HbA$_{1c}$ in people with diabetic retinopathy who are distressed by diabetes.

How might these results change the focus of research or clinical practice?
- These findings highlight an approach that could be delivered by staff in the diabetes or primary care team allowing full integration into existing services.
- Further research is needed to examine the causal mechanisms underlying change in HbA$_{1c}$ and determine the longer term impact on psychological and clinical outcomes.
- Practical issues regarding implementation of problem-solving therapy tailored to diabetes as an integrated component of diabetes services require investigation.

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INTRODUCTION

There is overwhelming evidence that diabetes distress and depressive symptoms are common in people with diabetes and have detrimental implications for quality of life, family functioning, diabetes outcomes, and healthcare costs.[1] Rates of depression are higher in those with complications of diabetes[2] and prospective studies have identified that depression is a risk factor for the progression of diabetic microvascular complications.[3] For example, depressive symptoms were related to a threefold increased risk of progression from non-proliferative diabetic retinopathy (NPDR) to proliferative DR (PDR) in a 6-year period.[3]

Recent reviews and meta-analyses of depression interventions in diabetes have found few studies that have shown simultaneous improvement in psychological outcomes and HbA$_{1c}$.[4] This may be because depression treatments are often delivered in isolation from diabetes care. An integrated approach that focuses on depressive symptoms and diabetes distress in the context of diabetes management is likely to be more effective. Indeed,

diabetes distress is more common than depression in people with diabetes, and more closely associated with diabetes self-management and glycemic control.[5][6] This has led to the hypothesis that psychological interventions, which specifically address diabetes and are integrated in diabetes care, could improve psychological *and* biomedical outcomes in those with high levels of diabetes distress.[5][6] Evidence from a large trial of stepped care for depression in people with diabetes suggests that the greatest gains were obtained by those people presenting with micro and macrovascular complications.[7] To date though, few studies have specifically focused on diabetes distress,[8] and no study has targeted psychological interventions tailored for people with DR. The implications are clear: interventions that target the distress associated with diabetes as well as general depressive symptoms are likely to be most effective in improving mental health and clinical outcomes. However, this is yet to be tested empirically in those with the highest rates of depressive symptoms, that is, people with microvascular complications. To address this need, we recently adapted an evidence-based treatment for depression, namely 'problem-solving therapy for primary care' (PST-PC),[9] to target diabetes-related problems that cause distress in people with DR. We chose to adapt PST-PC because it can be delivered by clinicians without specific mental health qualifications, enabling us to deliver the intervention via health professionals such as diabetes educators, eye care health professionals, or other allied health professionals responsible for the care of individuals with diabetes and DR. We tailored PST-PC to focus on problem-solving skill development to address specific barriers to diabetes management and aspects of diabetes and its complications that cause distress. Therefore, our approach enabled participants to identify and address challenges they experience in living with, and managing diabetes, as well as achieve the generic problem-solving skills and behavioral activation that reduces depression.

We hypothesized that this intervention would reduce diabetes distress and depressive symptoms; and improve diabetes self-care and HbA$_{1c}$. We chose to focus on diabetes distress as our primary outcome (and inclusion criterion) rather than heightened depressive symptoms, since diabetes distress is more common and maybe more amenable to change through interventions that can be delivered in non-mental health setting.[8] However, given that our intervention was an adaptation of an evidence-based intervention for depression, depressive symptoms were investigated as a secondary outcome measure. The aim of this pilot study was to establish preliminary evidence for the efficacy of diabetes-specific PST (PST-D).

RESEARCH DESIGN AND METHODS
Recruitment and eligibility
Forty participants were recruited from retinal clinics at the Royal Victoria Eye and Ear Hospital (RVEEH), Melbourne, Australia. A sample size of 40 was chosen for pragmatic reasons to be a feasible recruitment target for a pilot study. Inclusion criteria were (1) diagnosis of type 2 diabetes; (2) confirmed diagnosis of DR; (3) at least moderate diabetes-specific distress on the Diabetes Distress Scale (DDS) (overall score ≥2.0),[10] (4) at least 18 years old. Exclusion criteria were (1) insufficient English language skills to engage in PST-D sessions and the research interviews as determined by the research assistant; (2) insufficient cognitive ability to engage in PST-D as indicated by the 6-item Cognitive Impairment Test.[11]

Medical files were screened and individuals who could be identified as having type 2 diabetes and DR were approached at the clinic or called by telephone to discuss the study. All potential participants were provided with a plain language statement and provided written consent to participate in the project. Ethics approval was obtained from the Royal Victorian Eye and Ear Hospital's Human Research Ethics Committee (HREC; project number 08/815H). Potential participants were invited to attend an appointment in which eligibility criteria were assessed and a retinal image of each eye obtained for grading to confirm DR diagnosis. Those individuals who met the study eligibility criteria completed a baseline assessment.

Data collection
Retinal photographs were obtained from two-field fundus photographs (Canon CR6—45NM, Canon, Japan) and clinical signs of DR graded following the modified Airlie House classification system.[12]

All assessments were conducted by a research assistant blinded to allocation. At baseline, clinical assessments included HbA$_{1c}$ collected by venepuncture and analyzed via a pathology service and presenting visual acuity using a 3 m logarithm of the minimum angle of resolution chart (LogMAR). Diabetes duration, medications, and sociodemographic details were assessed by self-report. Structured interviews were conducted at baseline, and then again 3 and 6 months later (1) 17-item diabetes-specific distress (DDS[13]) which provides a total score and four subscales: 'physician-related distress', 'regimen-related distress', 'diabetes-related interpersonal distress', and 'emotional burden'; (2) depressive symptoms (9-item Patient Health Questionnaire (PHQ-9)[14]); and (3) diabetes self-care behaviors (revised version of the Summary of Diabetes Self-Care Activities (SDSCA)[15]) which provides an overview of specific diabetes self-management activities in the last 7 days (eg, general diet, specific diet, exercise, smoking, and blood glucose testing). HbA$_{1c}$ was also assessed at all visits.

Randomization and intervention groups
After the baseline interview, all participants in both groups were provided with publically available information brochures on diabetes-specific topics produced by Diabetes Victoria (ie, Living well with type 2 diabetes, Managing stress and diabetes, Diabetes and the eyes,

and Monitoring blood glucose levels). Following baseline assessment, participants were randomized to the PST-D intervention (n=21) or control (n=19) group using a computer-generated random number sequence, generated and concealed using sealed envelopes by a clinical trials expert (external to the study team). The control group received care as usual.

We adapted the PST manual so that participants focused on problems specifically related to their diabetes and DR. The PST-D intervention consisted of up to eight sessions, each lasting 45–60 min, and delivered via telephone or in person (depending on participant's availability and preference) by a research assistant trained in PST-D delivery, under the supervision of a clinical psychologist (BS). During the first session, the participant was introduced to PST-D, and the rationale explained in the context of diabetes, complications, and distress. The interventionist then worked with the participant to identify problems related specifically to diabetes and its complications. This was facilitated initially by discussing participants' responses on the DDS and subsequently the development of a problem list related to diabetes across all domains of life. In all sessions, the participant chose a specific diabetes-related problem to work on and was guided through the problem-solving steps: (a) clarifying and defining the problem; (b) setting a realistic goal; (c) brainstorming multiple solution alternatives; (d) evaluating each solution for its advantages and obstacles to implementation; (e) choosing a preferred solution; (f) devising a specific action plan to implement the solution; and (g) evaluating outcomes from the previous session (sessions 2–8). Also, each session included activity scheduling, whereby participants make specific plans to engage in enjoyable activities, which are concordant with optimizing diabetes management during the following week. Sessions all followed the same structure with the interventionist working toward ensuring that the participant was taking a more active role in leading the problem-solving process as sessions progressed.

Statistical analyses

Univariate analysis assessed for group differences between participant characteristics at baseline and changes in outcome measures at 3 and 6 months. Controlling for confounders (baseline values, age, gender, duration of diabetes, diabetes medication, visual acuity), multiple regression analyses were used to assess the impact of PST-D on outcome variables at 3 and 6-month follow-up. Post hoc power estimations were conducted to determine the power to detect an intervention effect, and based on our 6-month follow-up with PST intervention and six covariates noted above in the multiple linear regression analysis. We estimated the power based on the changes in the adjusted R^2 when the intervention is included in the model. For PHQ-9, the R^2 is 48.01% for the full model (including the intervention group) and 39.00% for the reduced model (excluding

the intervention group). The R^2 change is 0.09, with a sample size of 34 and a significance level of 0.05, we had 45.30 power to detect the difference between the PST intervention and usual care group. The power to detect an intervention effect on HbA1c and DDS was 92% and 12%, respectively.

Univariate analysis assessed for group differences at baseline between participants in the intervention group who completed follow-up assessments and those who were lost to follow-up.

RESULTS

The mean age of participants was 59.9±7.8 years and 67.5% (n=27) were men. The average duration of type 2 diabetes was 21.0±16.0 years, and HbA$_{1c}$ was 8.2±1.6% (65.6 mmol/mol). At baseline, the PST-D and control groups were comparable in terms of sociodemographic and clinical characteristics, as well depressive symptoms and diabetes distress scores, except for the DDS 'diabetes-related interpersonal distress' subscale which was significantly higher in the PST-D group than the control group (PST-D: 3.0±1.2; control: 2.5±1.2, p=0.009) (table 1).

Two participants declined further PST-D after one session. One participant received only four PST-D sessions due to illness. The remaining 18 participants received between 5 and 8 sessions. Six participants in the PST-D group did not attend the final follow-up, with an additional two declining the final HbA$_{1c}$ assessment. All control group participants attended the follow-up assessments; although at each follow-up, HbA$_{1c}$ was not obtained from one participant. Compared with participants in the intervention group who completed the study, those who were lost to follow-up assessments had lower scores on the DDS 'regimen-related distress' subscale at baseline (PST-D completers: 3.4±1.4; PST-D lost to follow-up: 2.1±0.9; p=0.04). There was also a trend to suggest that those lost to follow-up were more likely to be living alone (60%) than those who completed all follow-up assessments (13.3%; p=0.07). No other differences were observed.

At 3 months, there was a non-significant trend, suggesting a slightly greater reduction in 'regimen-related distress' in the PST-D group (−1.2±1.2) relative to the control group (−0.4±1.4; p=.08). At the 6-month follow-up, the between-group difference in change scores reached statistical significance (PST-D: −1.3±1.4; control: −0.4±1.1; p=0.03). Compared with the control group, the PST-D group also showed a significantly greater reduction at 3 months in 'diabetes-related interpersonal distress' relative to the control group which demonstrated an increase (PST-D: −0.9±1.4; control: 0.2 ±1.1; p=0.01). Depressive symptoms reduced significantly more so in the intervention compared with control group at 3-month follow-up (PST-D: −3.8±3.0; control: −1.1±3.9; p=0.03). This latter difference was higher at 6 months with the PST-D group showing a −4.3±6.1

Table 1 Participants' characteristics at baseline and 3 and 6-month primary and secondary outcomes

Characteristics	Total sample (n=40)	PST-D (n=21)	Control group (n=19)	p Value
Categorical variables	*n (%)*			
Gender (male)	27 (67.5)	14 (66.7)	13 (68.4)	0.906
Education (>high school)	21 (50.0)	11 (52.4)	9 (47.4)	0.752
Living alone (yes)	8 (20.5)	5 (25.0)	3 (15.8)	0.476
Continuous variables	*Mean (SD)*			
Age (years)	59.9 (7.8)	60.1 (7.0)	59.6 (8.8)	0.839
Duration of diabetes (years)*	21.0 (16.0)	17.5 (10.0)	23.0 (15.0)	0.190
Worse eye best presenting distance visual acuity (logMAR)*	0.2 (0.3)	0.2 (0.2)	0.2 (0.4)	0.923

	Baseline				3-month follow-up			6-month follow-up		
Outcome Measures	Total Sample (n=40)	PST-D (n=21)	Control (n=19)	p Value	PST-D (n=16)	Control (n=19)	p Value	PST-D (n=16)	Control (n=19)	p Value
DDS: total score	2.8 (0.7)	2.9 (0.8)	2.7 (0.6)	0.734	2.2 (1.1)	2.5 (0.9)	0.457	2.2 (1.1)	2.5 (0.8)	0.427
DDS: emotional burden	3.6 (0.9)	3.6 (0.9)	3.7 (1.0)	0.734	2.8 (1.2)	3.3 (1.4)	0.248	2.8 (1.3)	3.2 (1.6)	0.372
DDS: physician-related distress	1.0 (1.0)	1.9 (1.1)	1.8 (1.0)	0.679	1.9 (1.3)	1.7 (1.1)	0.542	1.6 (1.3)	176 (0.6)	0.768
DDS: regimen-related distress	3.0 (1.2)	3.0 (1.4)	3.0 (1.0)	0.834	2.1 (1.2)	2.5 (1.0)	0.236	2.1 (1.1)	2.6 (0.9)	0.175
DDS: diabetes-related interpersonal distress	2.5 (1.2)	3.0 (1.2)	2.0 (0.9)	**0.009**	2.0 (1.4)	2.2 (0.9)	0.658	2.3 (1.3)	2.1 (1.0)	0.674
HbA$_{1c}$ %, mmol/mol	8.2% (1.57) 66.1 mmol/mol	8.1 (1.2) 65.0 mmol/mol	8.2 (2.0) 66.1 mmol/mol	0.964	7.6 (0.9) 59.6 mmol/mol	8.3 (2.1) 67.2 mmol/mol	0.295	7.1 (1.1) 54.1 mmol/mol	8.4 (2.5) 68.3 mmol/mol	0.093
PHQ-9: depressive symptoms	10.4 (5.4)	10.5 (5.2)	10.2 (5.7)	0.832	7.1 (5.9)	9.1 (7.0)	0.364	6.7 (5.9)	9.9 (6.5)	0.144
SDSCA: general diet	5.2 (0.3)	5.5 (1.7)	4.9 (1.8)	0.321	5.2 (1.8)	4.8 (2.0)	0.546	6.1 (1.1)	5.0 (1.5)	**0.026**
SDSCA: specific diet	4.9 (1.5)	4.9 (1.2)	4.8 (1.5)	0.790	4.6 (1.7)	4.8 (1.5)	0.728	4.7 (1.3)	5.4 (1.4)	0.161
SDSCA: exercise	3.2 (0.3)	3.3 (2.3)	3.2 (2.1)	0.941	3.84 (2.31)	2.79 (2.13)	0.170	3.60 (2.69)	3.37 (2.11)	0.780
SDSCA: blood sugar testing	5.4 (0.4)	5.3 (2.4)	5.5 (2.5)	0.855	5.94 (1.89)	5.53 (2.29)	0.571	5.97 (1.87)	5.13 (2.71)	0.317

Bold indicates significance.
*Median (IQR).
DDS, Diabetes Distress Scale; HbA$_{1c}$, hemoglobin A$_{1c}$ (average blood glucose over 12 weeks); logMAR, logarithm of the minimum angle of resolution; PHQ-9, Patient Health Questionnaire 9; SDSCA, Summary of Diabetes Self-Care Activities.

Table 2 Multiple linear regression outlining the impact of problem-solving therapy for diabetes on diabetes distress, depressive symptoms, and glycemic control at 6-month follow-up

Characteristics	DDS: diabetes-related interpersonal distress at 6 months β (95% CI)	p Value	DDS: regimen-related distress at 6 months β (95% CI)	p Value	HbA$_{1c}$ % at 6 months β (95% CI)	p Value	PHQ-9 at 6 months β (95% CI)	p Value
Multiple linear regression analysis*								
Intervention	−0.24 (−0.94 to 0.46)	0.485	−0.63 (−1.26 to 0.01)	0.054	−1.40 (−2.25 to −0.56)	0.002	−3.74 (−7.39 to −0.10)	0.044
Multiple linear regression analysis†								
Intervention	−0.21 (−0.96 to 0.54)	0.573	−0.62 (−1.24 to −0.03)	0.049	−1.52 (−2.23 to −0.81)	<0.001	−3.79 (−7.34 to −0.24)	0.037

*Adjusted for baseline values.
†Adjusted for baseline values, age, gender, diabetes duration, diabetes medication, visual acuity at baseline.
DDS, Diabetes Distress Scale; HbA1c, hemoglobin A1c (average blood glucose over 12 weeks); PHQ-9, Patient Health Questionnaire-9.

reduction on the PHQ-9 from baseline relative to −0.3 ±4.6 in the control group (p=0.04). For diabetes self-care, no significant between-group differences in change scores were found at 3 or 6 months, although a trend for increased frequency in self-monitoring of blood glucose in the PST-D group relative to the control group at 6 months was identified (PST_D: 1.2±2.7; control: −0.3±2.5; p=0.09). At 6 months, there was a significant between-group difference in change in HbA$_{1c}$ from baseline representing a reduction in the intervention group (−1.2%±1.01) with no change in the control group (0.2%±1.2%) (p=0.002).

Multivariate analysis, adjusting for baseline values, sociodemographic, and clinical factors (age, gender, duration of diabetes, diabetes medication, visual acuity at baseline), identified a significant impact of PST-D on 'regimen-related distress', HbA$_{1c}$, and depressive symptoms at the 6-month visit (p<0.05; table 2).

CONCLUSIONS

This is the first pilot randomized controlled trial to examine the effectiveness of a diabetes-specific problem-solving intervention in adults with DR, experiencing at least moderate diabetes distress. Our findings provide preliminary evidence that this intervention may improve diabetes distress, particularly associated with the diabetes regimen. Furthermore, our results suggest that PST-D has the potential to improve depressive symptoms and produce a clinically significant reduction in HbA1$_c$ of −1.2%. These are important data as few interventions for people with diabetes have been able to improve psychological and clinical outcomes.[16] Targeting this intervention to individuals with early-stage DR and distress may also offer longer term outcomes, given that improved glycemic control in this group may delay the progression of NPDR to the vision-threatening stage.[17] A benefit of the diabetes-specific PST is that it is designed to be delivered by diabetes or primary care clinicians, rather than by mental health specialists. Therefore, with brief training, existing members of the diabetes or primary care team could deliver this intervention. In addition, PST-D could be delivered in accessible formats, including telephone or online.

Consistent with emerging evidence, our study suggests that addressing the distress associated with diabetes management may impact on wider outcomes, such as depressive symptoms and glycemic control. For example, the REDEEM trial showed that reductions in 'regimen-related distress' were associated with improved diabetes self-management and glycemic control.[18] However, we found no significant effect on self-management behaviors, that is, diet and exercise as assessed by the SDSCA. One explanation is that the SDSCA may not have been sufficiently responsive to the PST-D intervention. Notably, we did not assess diabetes medication taking behaviors, which may have impacted on glycemic control. Hence, the mechanisms underlying change in

HbA_{1c}, which may be due to a range of neuroendocrine, inflammatory, or behavioral pathways, require further exploration in a fully powered study. In addition, only the 'regimen-related distress' subscale of the DDS showed a significant change. This may be due to the study's lack of power. Post hoc power estimations revealed this study has sufficient power to detect differences as a result of the intervention on HbA1c, but lower power for the PHQ-9 and DDS. Our findings may also reflect poor precision of the DDS total score and other subscales, as indicated by our recent Rasch analysis of the DDS.[19] A fully powered study with a psychometrically sound assessment of diabetes distress is required to confirm these findings.

Our pilot study was limited by a small sample size and was potentially underpowered. All participants were retained in the control group, and engagement in PST-D was high; however, attrition in the intervention group attendance at follow-up assessments was lower (76% and 71% attending for assessments at 3 and 6 months). While this is concerning, attrition in the range of 20–30% is considered acceptable in behavioral studies of this nature.[20] Loss to follow-up may have been due to the burden of participation, or it may represent a self-selection bias skewing results. Indeed, we found that those who dropped out had lower levels of regimen-related distress at baseline. This may suggest that those with lower regimen-related distress may need less intensive intervention. That those who dropped out showed a trend to be living alone may indicate the importance of social support in the uptake of such interventions and may point to the need for alternative delivery options (eg, group-based programs). This requires further examination in future studies. A qualitative study would worthwhile to explore reasons for attrition as well as the applicability and utility of the PST-D in participants' daily lives. Our sample also included a higher proportion of men than women, which is unusual and may indicate recruitment bias, given that previous research has indicated higher levels of diabetes distress in women.[21] Research has also indicated that gender differences in the association between diabetes distress and health behaviors (eg, physical activity, smoking)[21] which requires investigation in a full-scaled study. Finally, our study included a 'usual care' control group rather than an active (support/attention) condition controlling for non-specific intervention effects.

In conclusion, these preliminary findings suggest the potential of PST-D, but a fully powered study is needed to: (1) confirm these findings, (2) test the causal mechanisms underlying change in HbA_{1c} taking into account gender differences; (3) determine longer term impact on psychological, diabetes, and DR outcomes; (4) examine the cost-effectiveness of this approach; and (5) explore the practical issues regarding implementation as an integrated component of diabetes services.

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