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Initial evaluation of the Optimal Health Program for people with diabetes: 12-month outcomes of a randomised controlled trial

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Tables and Figures

Trial registration

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Abstract

OBJECTIVE

This study aimed to evaluate if a new Mental health IN DiabeteS Optimal Health Program (MINDS OHP) compared with usual care in adults with Type 1 and Type 2 diabetes would improve psychosocial outcomes including self-efficacy and quality of life.

DESIGN AND MAIN OUTCOME MEASURES

This initial randomised controlled trial evaluated MINDS OHP compared with usual care. Participants were recruited through outpatient clinics and community organisations. The intervention group received nine sessions with assessments over twelve months. Primary outcomes were self-efficacy and quality of life. Secondary outcomes included diabetes distress and anxiety.

RESULTS

There were 51 participants in the control group (mean age=52) and 55 in the intervention group (mean age=55). There were significant main effects of time in general self-efficacy, diabetes distress, diabetes self-efficacy, and illness perceptions, however no significant between-group differences in primary or secondary outcomes. Post-hoc analyses revealed MINDS OHP improved diabetes self-efficacy for participants with mild to severe depression and anxiety, with a small effect.

CONCLUSION

Initial evaluation found MINDS OHP was associated with improved diabetes self-efficacy for adults with diabetes, for people with mild to severe levels of distress, with small effect. Further research is required to explore whether this disease-specific, collaborative care-focused intervention benefits the mental health of people with diabetes.

Keywords

Diabetes; self-efficacy; psychosocial; educational; mental health; randomised controlled trial

1. INTRODUCTION

There are an estimated 451 million adults globally with diabetes, and of these 1.2 million Australian adults had diabetes (excluding gestational diabetes) in 2017-2018 (Australian Bureau of Statistics, 2018; Cho et al., 2018). Far more have blood glucose levels (BGLs) in the prediabetes range or undiagnosed diabetes (Cho et al., 2018), with increased risk for Type 2 diabetes placing a significant proportion of the world's population at risk of developing devastating diabetes complications. Diabetes contributed to 10.5% of Australian deaths in 2018 as an underlying or associated cause (Australian Institute of Health and Welfare, 2020).

Psychological difficulties, including depression, anxiety, maladjustment and eating disorders are highly prevalent in people with diabetes and are associated with adverse outcomes (Baumeister et al., 2012; Grigsby et al., 2002; Perrin et al., 2017; Subasinghe et al., 2015; Van der Feltz-Cornelis et al., 2010). At the centre of diabetes care is maintaining optimal BGLs, a task highly reliant on a person's successful negotiation of healthcare systems and coordination with clinicians (Marrero et al., 2013). Relationships between diabetes and mental health are bi-directional, for example, people with depressed mood may experience difficulty energising themselves to monitor BGLs, and similarly, worry over diabetes complications may develop into a pervasive mood or anxiety disturbance (Alzoubi et al., 2018). Recognition of these close relationships with diabetes and mental health, and the need for people with diabetes to adapt to treatment advances, has prompted the incorporation of psychological care of diabetes in national standards of care (Baumeister et al., 2012; Craig et al., 2011).

Psychosocial interventions have demonstrated potential benefits to improving mental health and wellbeing in people living with diabetes (Baumeister et al., 2012; Pascoe et al., 2017; Van der Feltz-Cornelis et al., 2010), thus also potential to impact on optimising BGLs. We have previously defined psychosocial interventions as those incorporating psychological

and social components including individual behaviour, cognition, emotions and social support (Thompson & Ski, 2013). Our recent systematic review and meta-analysis (Pascoe et al., 2017) found seven randomised controlled trials comparing the effects of psychosocial care to usual care in adults with diabetes. Whilst this is a small number of trials, it was promising to see a moderate to large improvement in depressive symptoms across five studies, and a small improvement in three studies that assessed quality of life. This review also found no benefit in the two studies that assessed levels of self-efficacy.

Reviews of intervention studies in diabetes have also explored the role of complementary pharmacological and psychological therapies. A systematic review and meta-analysis of psychotherapy, antidepressant medication and collaborative care for comorbid diabetes and depression (14 RCTs; n=1724) showed that pharmacotherapy and collaborative care reduced depressive symptoms; however, with the exception of sertraline, there was no effect on glycaemic control (Van der Feltz-Cornelis et al., 2010). The authors concluded that collaborative care containing psychological and pharmacological components that emphasise diabetes management is of clinical relevance, and encouraged further research into Type 1 diabetes (Van der Feltz-Cornelis et al., 2010). A Cochrane review of psychological and pharmacological interventions for depression in diabetes (8 RCTs; n=1122) found a moderate clinically significant effect on depression (Baumeister et al., 2012). It was also noted that evidence on the influence of psychological interventions on BGLs was sparse and inconclusive, largely due to substantial risk of bias and heterogeneity of populations and interventions (Baumeister et al., 2012).

More recently, a systematic review and meta-analysis (Mathiesen et al., 2019) of psychosocial interventions for vulnerable people with Type 2 diabetes, including people having difficulty maintaining BGL targets and possessing certain risk factors such as risky lifestyle behaviours, found low to moderate quality evidence for a small effect of

psychosocial interventions on diabetes distress and low-quality evidence for a small reduction in depression. The authors reported moderate quality evidence for no effect of the interventions on health-related quality of life. When sub-group analyses were conducted (individual v group and intensive v brief interventions), results showed that the significant improvements in diabetes distress were more pronounced in individual and intensive interventions (>4 sessions).

Other reviews have focused on strength-based or 'wellbeing' interventions. Massey et al. (2019) conducted a systematic review of wellbeing interventions, such as positive psychology, mindfulness, and resilience-based interventions that focus on improving self-efficacy and motivation. The review, which included studies of people with Type 1 and Type 2 diabetes, found that many interventions showed significant improvement in outcomes, with depression significantly improved in 14/19 studies. There was also a significant post-intervention effect in 6/16 studies for improved HbA1c.

A systematic review and meta-analysis of psychological interventions for people with diabetes where diabetes-distress was the primary outcome measure (Schmidt et al., 2018) found a significant medium effect size on diabetes distress. Analyses further suggested that HbA1c only declined in response to diabetes-tailored psychological interventions (those addressing disease and treatment-specific issues) compared to generic interventions. This highlights potential added benefit for diabetes-tailored interventions however the authors note the small sample sizes and emphasise the need for more rigorous studies to explore this further. In sum, there is growing evidence for the use of psychosocial interventions in adults with diabetes, yet questions regarding their efficacy and the small number of studies comparing interventions to usual care warrant further investigation (Fonte et al., 2015). A number of challenges noted in the literature included intervention cost-effectiveness, participation and attrition rates, and delivery that complements and coexists with usual

diabetes healthcare (Grigsby et al., 2002, Pascoe et al., 2017). Despite significant investment in this area of study, experts agree that it remains unclear which interventions are most effective and strongly recommend more rigorous and controlled intervention studies (Massey et al., 2019; Mathiesen et al., 2019; Schmidt et al 2018).

A focus of modern psychosocial interventions is collaboration between client and clinician/facilitator where clients can direct the focus and facilitators employ therapeutic techniques to help clients create personalised solutions and plans. Multidisciplinary care is also a hallmark of diabetes care, which tailors interventions to an individual's situation (Baumeister et al., 2012). As such, shared decision-making, pragmatic problem solving and promotion of behaviour change strategies are integral to achieving sustainable self-management of diabetes (Baumeister et al., 2012; van der Feltz-Cornelis et al., 2010). Effective disease management of diabetes requires strengthening of psychosocial skills, ideally within a collaborative care framework integrated with usual medical care (Baumeister et al., 2012; van der Feltz-Cornelis et al., 2010). Further, as highlighted by Mathiesen et al. (2019) and Schmidt et al. (2018), individually focused, intensive interventions that are tailored to diabetes care warrant exploration for their potential added value in improving the health and wellbeing of people with diabetes.

This very first randomised controlled trial (RCT) of the new Mental health IN DiabeteS Optimal Health Program (MINDS OHP) adopted an individual person-centred approach combining collaborative therapy (Anderson, 2012) and care coordination to support and improve the psychosocial health of people living with diabetes. Based on a collaborative therapy framework (Castle & Gilbert, 2012) the OHP was originally developed to support people with mental health disorders (Gilbert et al., 2012). An earlier trial of OHP in a Canberra, Australia adult mental health service demonstrated significant improvements in health and social functioning, a reduction in hospital admissions and net cost savings of

AU$6,000 per patient annually (Gilbert et al., 2012). With the intention of enhancing self-efficacy, self-management, care coordination and quality of life, the OHP has been adapted for the first time within the broader context of chronic disease. The new MINDS OHP includes supplementary material specific to living with diabetes with structured, individually tailored support, and pathways to multidisciplinary care to enhance the psychosocial wellbeing of people with Type 1 and Type 2 diabetes.

The MINDS OHP is holistic in that participants are not limited to focus discussion on diabetes, but other areas of health that might impact diabetes care e.g., occupational or spiritual health. The self-management foundations of the OHP are particularly relevant for adults with diabetes who face the daily challenge of simultaneously managing diet, exercise, insulin delivery, carbohydrate counting, blood glucose monitoring, and coping with the emotional impact of their condition and care regimen. The program recognises that though there are shared psychosocial impacts, Type 1 and Type 2 diabetes have separate aetiologies and disease processes, which the MINDS OHP allows for through individualised care. This initial evaluation and RCT is part of a larger research program which will evaluate three tailored OHPs across three chronic conditions – diabetes (MINDS OHP), stroke and stroke carer (SCOHP) (Minshall et al., 2020) and chronic kidney disease (KOHP). The aim of the current study is to evaluate the effectiveness of the new MINDS OHP on improving self-efficacy and quality of life for adults living with diabetes compared to usual care across 3-month, 6-month, and 12-month follow-up time points. Secondary outcome measures include diabetes-quality of life, diabetes self-efficacy, diabetes-distress, depressive and anxiety symptoms, coping styles, illness perceptions, and social and workplace functioning.

2. MATERIALS AND METHODS

This was a prospective parallel randomised controlled trial (allocation ratio 1:1) evaluating the effectiveness of the MINDS OHP compared to usual care. The Human Research Ethics Committee of St Vincent's Hospital Melbourne (036/14) approved the study protocol and the trial was reported according to CONSORT guidelines (Schulz et al., 2010). An executive steering committee (all authors) was responsible for study planning, conduct and monitoring. The study protocol was published previously (O'Brien et al., 2016).

2.1 Participants

Participants were recruited from St Vincent's Hospital, the Royal Victorian Eye and Ear Hospital (RVEEH) and community advertisements. Inclusion criteria were: a diabetes diagnosis, confirmed by medical records; be aged 18 years or above and be able to converse in English without an interpreter. Exclusion criteria were: presence of developmental disability or amnestic syndrome impairing ability to learn from the intervention; and comorbid serious acute medical illness defined by the treating physician.

Potential participants with diabetes at St Vincent's Hospital were identified by the diabetes clinical staff (e.g., diabetes educator) and provided with a study flyer so they could contact the research team. People with diabetes also provided permission for a researcher to approach them in clinic or by telephone to discuss the program. All participants who agreed to take part provided written informed consent via the research assistant or research coordinator, who then enrolled the participant in the study database. Study flyers were also posted online through community organisations and support groups such as Diabetes Australia, inviting people to self-refer to the study. A research assistant attended clinics at the RVEEH and discussed the study with people with diabetes identified by the clinic staff.

Recruitment was from 17th November 2014 to 30th June 2017 with data collection finalised at 17th September 2018. The trial timelines and completion date were agreed upon by the study governance committee based on funding timelines. To assess for potential selection bias, de-identified records were collected on how many people with diabetes were approached or self-referred to the study and reasons for decline/withdrawal where available. A variety of retention strategies were employed including follow-up telephone calls and reminder letters.

2.2 Setting

The study was conducted at St Vincent's Hospital, a large metropolitan teaching hospital in Melbourne, Australia. As of March 2015, the Endocrinology and Diabetes Unit had over 1,000 people with diabetes enrolled in the patient database: 370 people with Type I diabetes and 1313 with Type 2 diabetes. Researchers also advertised online for participants through diabetes community organisations and support groups. Following lower than expected retention and recruitment rates, the study team added a new recruitment site at the Royal Victorian Eye and Ear Hospital (RVEEH) to enhance chances of achieving statistical power. Study questionnaires were completed by participants at a time and place of convenience.

2.3 Randomisation, Allocation and Blinding

Participants were informed that they were taking part in a study exploring the effectiveness of the MINDS OHP in improving wellbeing, anxiety, and depression for people with diabetes through teaching coping and planning skills. Following receipt of written informed consent, participants were randomised to the MINDS OHP or usual care group. Participants were informed they would be allocated to the MINDS OHP treatment group or the control group where they would receive standard supportive care. A person external to the study and

without participant contact used a password-protected computer-generated block randomisation sequence to assign participants to a study condition. This person then informed the research coordinator who contacted participants about their allocation and the next steps. Due to the participatory nature of the intervention, it was not possible to mask either participant, facilitator, or investigator to the treatment allocation.

2.4 Intervention: MINDS OHP

As outlined in the Introduction, the MINDS OHP intervention adopts an individual person-centred approach combining collaborative therapy and care coordination to support and improve the psychosocial health of people living with diabetes. Based on a collaborative therapy framework (Anderson, 2012; Castle & Gilbert, 2012) the OHP was originally developed to support people with mental health disorders (Gilbert et al., 2012).

The structure of MINDS encompasses 9 sessions; 8 x 1-hour weekly individual sessions with a booster session 3 months after completion of session 8. Participants in the intervention group received the MINDS OHP plus usual care. The intervention is based on a structured treatment manual, participant workbook, and supplementary diabetes support material. Participants unable to meet with OHP facilitators face to face at St. Vincent's Hospital were offered telephone or videoconferencing sessions.

The MINDS OHP values this flexible mode of delivery that can adapt to different settings and facilitator-client preferences for using face to face, telephone, and videoconferencing technology. The face-to-face mode of delivery was preferable because the structured workbooks were simpler to navigate for facilitators and participants in person. The MINDS OHP facilitators were also able to offer flexibility of time so sessions could be held at a time and place convenient to the participant without interfering with their standard care.

Some participants also preferred face-to-face contact due to low confidence using a telephone or videoconference session (e.g., anxiety about technology that posed a barrier to engagement in the intervention).

Table 1 outlines the structure and content of the MINDS OHP. Learning is cumulative with each session designed to build on the previous session including tasks to complete between sessions, such as journaling and sleep logs.

In summary, session 1 introduces MINDS OHP within the 6 domains of 'optimal health'; considering perceived satisfaction with emotional, social, occupational, intellectual, physical, and values/spiritual health. Thus session 1 provides participants with the opportunity to explore and understand their current self-management behaviour and satisfaction levels of day-to-day functioning. Specific focus is on concerns, problems, and beliefs about diabetes including a person-centred space to tell the 'story' about the participant's lived experience with diabetes. Sessions 2 and 3 initiate development of the 'I Can Do' model which encompasses health plans exploring the participant's strengths and vulnerabilities, as well as understanding and monitoring diabetes impact through identifying stressors and developing strategies to overcome these. Here participants explore treatment regimens and learn about the relationship of diabetes and the stress response.

The focus of session 4 is on physical health monitoring and medication management. This session helps participants explore experiences with taking medication, adjustment to new treatments, making the most of their diabetes and health appointments, and explores lifestyle goals. Session 5 expands the health plans to include key partnerships and supports in the participant's network and community (e.g., GP, family, online forums). Participants can identify any gaps in their support and care and make plans to overcome any barriers to engaging support. Session 6 focuses on change enhancement by tracking health fluctuations across time and establishing new proactive avenues for change. The aim of session 7 is goal

setting via creative problem solving and planning around the complexities of changes related to diabetes, other areas of concern, and is guided by the priorities of the participant. Session 8 reviews well-being maintenance and sustainability by acknowledging any progress made towards goals. The objective of the 'booster session' (session 9) is to consolidate progress via reviewing health plans and achievements.

Table 1. The Mental Health in Diabetes Optimal Health Program (MINDS OHP)

2.5 Facilitator Training and Fidelity

All MINDS OHP facilitators had a psychology or allied health degree and completed a 2-day OHP facilitator workshop with the same trainer (GM) followed by training in the diabetes support supplement (CO). Adherence to the core MINDS OHP material was strict with some minor variation to allow for participant needs, for example if a participant felt unwell, a session may be split across two meetings. Additional training and resources were provided to facilitators to enhance their understanding of the lived experience of a person with diabetes and build confidence and skills to facilitate diabetes-focused discussion. For example, facilitators attended a tutorial delivered by an experienced diabetes educator to learn about diabetes causes, treatments, blood sugar monitoring devices, and insulin pump technology. Facilitators were also provided with diabetes and mental health education and supervision from a psychologist (CO) who had experience treating people with diabetes. All facilitators were required to participate in fortnightly supervision (individual and/or group supervision) to gain support with facilitation and ensure standardised delivery of the program across facilitators. Adherence to protocols was also monitored through all facilitators completing a summary of each MINDS OHP session using a standard template including

OHP topics covered and participant concerns raised. Supervisors (CO and GM) provided regular feedback on case note summaries.

2.6 Usual Care

The comparison group received usual care and no MINDS OHP intervention. Participants in the usual care group were invited to participate in MINDS OHP after their final questionnaire had been returned.

2.7 Outcome Measures

Primary and secondary outcomes were measured by self-report questionnaires. Self-efficacy is a core value of the OHP philosophy and it was considered warranted to include as a primary outcome. General self-efficacy and overall quality of life were chosen as primary outcomes because MINDS OHP, a holistic intervention, aims to improve overall wellbeing across multiple health domains. As the MINDS OHP is an adapted version of the original OHP, diabetes-specific outcome measures were included as secondary measures to assess the intervention's effectiveness at improving diabetes psychosocial wellbeing. All self-report measures were repeated across 3-month, 6-month, and 12-month follow-up time points. Analysis of biological outcomes such as routine HbA1c was planned, however unfortunately there was insufficient data for analysis. This was partially due to challenges with accessing medical records for participants not treated at St. Vincent's Hospital, as well as limited biological measurements aligning with the study follow-up timepoints.

2.7.1 Primary Outcome Measures

Quality of life was assessed by the Australian Assessment of Quality of Life 6-Dimensions (AQoL-6D) (Richardson et al., 2012). The AQoL-6D has good internal consistency (Allen et al., 2013). The AQoL-6D consists of 20 items including 6 separately scored dimensions of good health (independent living, relationships, mental health, coping, pain, and senses). For example, 'how often do you feel sad?' where participants rate their response from 1 = Never to 5 = Nearly all the time. A total score was obtained by adding the unweighted response orders of each question, with higher scores suggestive of lower quality of life. For the study data, across all time points, the minimum Cronbach α score for AQoL was 0.88, indicating strong internal consistency.

Self-efficacy, the belief that one can achieve goals and cope with stressful life events, was assessed using the Generalised Self-Efficacy Scale (GSES) (Schwarzer & Jerusalem, 1995). The scale comprises 10-items and participants rate the degree to which each statement is true during the last week (e.g., 'I can usually handle whatever comes my way'). Responses are recorded on a 4-point scale where 1 = Not at all true to 4 = Exactly true. Scores are added to create a total score where higher scores reflect higher levels of self-efficacy. The GSES demonstrated excellent internal consistency in an Australian diabetes cohort (Tregea et al., 2016) For the study data, across all time points, the minimum Cronbach α score for GSES was 0.88, indicating strong internal consistency.

2.7.2 Secondary Outcome Measures

Diabetes-specific quality of life was measured using the Diabetes Quality of Life Brief Clinical Inventory (DQoL-Brief), designed for Type 1 and Type 2 diabetes (Burroughs et al.,

2004). The DQoL-Brief measures diabetes-specific quality of life across 15 items with items assessed on a 5-point scale. For example, 'How satisfied are you with your current diabetes treatment?' (1 = Very satisfied to 5 = Very dissatisfied). Items are summed and averaged to attain an overall negatively valenced score, with higher scores reflecting higher frequencies of negative diabetes impacts and higher treatment dissatisfaction - lower QoL. For the study data, across all time points, the minimum Cronbach α score for DQoL-Brief was 0.83, indicating strong internal consistency.

Diabetes self-efficacy was measured by the Diabetes Empowerment Scale –Short Form (DES-SF) (Anderson et al., 2000). Diabetes self-efficacy is defined as the degree to which people believe they can make the right choices about their care, achieve diabetes goals, and cope with diabetes-related stress (Anderson et al., 2000). Participants are asked to rate in general how strongly they agree/disagree with eight statements (e.g. 'In general, I can find ways to feel better about having diabetes…') on a 5-point Likert scale where 0 = Strongly disagree and 4 = Strongly agree. High scores indicate higher levels of diabetes self-efficacy. The DES-SF has demonstrated reliability and validity including in an Australian diabetes cohort (Tregea at al., 2016). For the study data, across all time points, the minimum Cronbach α score for DES-SF was 0.83, indicating strong internal consistency.

Diabetes distress was measured by the Problem Areas in Diabetes scale (PAID) (Polonsky et al., 1995) a widely used measure of the severity of emotional problems in living with diabetes, with demonstrated reliability and validity across cultures (Schmitt et al., 2016). Participants indicate the degree to which 20 listed problems (e.g. 'Worrying about low blood sugar reactions') are relevant for them on a 5-point Likert scale (0 = Not a problem to 4 = Serious problem). Higher scores (range 0-100) indicate higher levels of diabetes distress and

a cut-off of 40 or above has been classified as severe diabetes distress (Snoek et al., 2015). For the study data, across all time points, the minimum Cronbach α score for PAID was 0.94, indicating strong internal consistency.

Anxiety and depression symptoms were measured by the Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983). The HADS is a 14-item scale chosen because it excludes somatic symptoms of depression that may overlap with diabetes symptoms (Bjelland et al., 2002). Each item is scored on a 4-point scale. Seven items assess anxiety (e.g., 'Worrying thoughts go through my mind' [0 = only occasionally – 3 = a great deal of the time]), and seven items assess depression (e.g., 'I still enjoy the things I used to enjoy' [0 = definitely as much – 3 = hardly at all]). Summed subscale values are interpreted as 0-7 (normal), 8-10 (mild), 11-14 (moderate), and 15-21 (severe) (Snaith, 2003). For the study data, across all time points, the minimum Cronbach α score for depression and anxiety were 0.76 and 0.85, respectively, indicating strong internal consistency.

Coping styles were measured using the Carver Brief coping questionnaire (Brief-COPE) (Carver, 1997). The Brief-COPE assesses an individual's coping reactions in response to a stressor. The questionnaire consists of 28 items measured on a 4-point rating scale where 0 = 'I haven't been doing this at all' and 3 = 'I've been doing this a lot'. Consistent with the approach of Carver et al. who recommends using cohort specific data to explore higher-order factors, and previous research (Knowles et al., 2020), an exploratory factor analysis using principle factor axis with an Oblimin rotation was performed using all scale items. Two factors were identified using the baseline data and the first component was identified as 'maladaptive coping' and had good fit and internal consistency (.78) using 8 items and the second component was identified as 'adaptive coping' and had good fit and internal

consistency (.81) using 8 items. Reliability analyses were also conducted for 3-months, 6-months and 12-month data, revealing good internal consistency with the minimum Cronbach α scores for maladaptive and adaptive coping 0.69 and 0.75, respectively.

Illness perceptions were measured using the Brief Illness Perceptions Questionnaire (BIPQ) (Broadbent et al., 2006). The BIPQ measures cognitive and emotional representations of illness on an 11-point rating scale. Using nine items, the following eight dimensions were assessed: consequences, timeline, personal control, treatment control, identity, concern, understanding, and emotional representation. For example, 'How concerned are you about your illness?' 0 = Not at all concerned to 10 = Extremely concerned. Items were summed and averaged to attain a total illness perception score (range 0-10), with higher scores reflecting a more threatening perception of the illness. Illness perception was found to have a strong internal consistency (.82) using 5 items for the base line data. Reliability analyses was again conducted for the illness perception factor across 3 months, 6 months and 12-month data, revealing good internal consistency with the minimum Cronbach α score of 0.74.

Work and social adjustment was measured using the Work and Social Adjustment Scale (WSAS) (Mundt et al., 2002). This scale assesses the individual's perspective of how health difficulties impact function. Participants rate five statements (e.g., 'Because of my health condition, my ability to work is impaired') on a 9-point Likert scale where 0 = Not at all impaired to 8 = Very severely impaired. Higher scores indicate greater impairment of function. The WSAS has demonstrated reliability and validity (Zahra et al., 2014). For the study data, across all time points, the minimum Cronbach α score for WSAS was 0.90, indicating strong internal consistency.

2.8 Sample Size Calculation

Power was calculated to detect a medium effect size of Cohen's d = 0.50. This was chosen as a clinically meaningful effect size that may be compared with previous RCT research in the area of chronic disease management programs (Krause, 2005). The calculations assumed two primary outcomes (AQoL-6D and GSES scores), four assessment points (baseline, 3-month, 6-month, and 12-month follow-ups), a study-wide Type I error rate (α) of .05, and hence a Type II error rate (β) of .20 (power of .80), a correlation of post-treatment scores with baseline measurements (ρ) of 0.81, and a two-tailed statistical test (Diggle et al., 2002). To detect the effect size of d = 0.50, 66 participants in each of the control and intervention groups were required. Allowing for up to 20% attrition, the recruitment target was 166 participants, or 83 in each group.

2.9 Statistical Analyses

Intention-to-treat (ITT) analyses were planned to prevent over-estimation of efficacy, due to missing data ITT may have underestimated the intervention effect (Shrier et al., 2017) and hence a mixed-effects model, repeated measures (MMRM) approach was employed to examine the longitudinal profile of all continuous variables at 3, 6- and 12-months post-baseline. Categorical variables were analysed using chi-squared tests (or Fisher's exact test for small samples). All dependant variables were found to have acceptable internal consistency (>.7).

3. RESULTS

Figure 1 presents the flow of participants through the trial. There were 27.9% of participants who dropped out before baseline measures (22 control; 19 intervention participants).

Sufficient baseline data was available for 106 participants; comprising 55 intervention participants and 51 in the control group. Prior to the primary analyses, initial screening indicated that there were no group differences (control versus intervention) across demographic details (age, gender, country of birth, education, marital status) or diabetes type (Type1 and Type 2).

Participants were aged between 21 to 77 (mean 52) and 21 to 90 (mean 55) years in the control and MINDS OHP groups, respectively. See Table 2 for participant demographics. Table 2 shows that a high proportion of participants were born in Australia, with a smaller proportion respectively born in the UK/Europe, Asia, or New Zealand. Approximately half the participants in each study group had achieved a minimum undergraduate degree in education. There were slightly higher numbers of married participants in the control group (and slightly higher single participants in the intervention group) however these differences were not significant. Approximately half those in the control and MINDS OHP groups respectively reported owning their own homes, approximately one-third of participants in each group were renting, with smaller numbers living with family or in public housing.

Figure 1. Flow of participants through the trial

Table 2. Baseline participant characteristics in the MINDS OHP and usual care groups

3.1 Impact of MINDS OHP on primary outcomes – AQoL-6D and GSES

Table 3 presents the effect of MINDS OHP between groups over the 12-month follow up period. There were no overall significant differences between control and MINDS OHP groups on AQoL and GSES measures. However, there was a significant time effect change in

GSES for both groups whereby there was an overall improvement in self-efficacy from baseline to 12-month follow-up. There was no significant interaction (Group x Time) in AQoL or GSES however results showed a near significant ($p = 0.07$) interaction trend for general self-efficacy, which demonstrated slightly increased improvement in self-efficacy in the MINDS OHP group between baseline and 3-months, and between 6 months and 12-months timepoints compared to the control group.

Table 3. The effect of the MINDS OHP between groups and over 12-month follow-up

3.2 Impact of MINDS OHP on secondary outcomes

As shown in Table 3, there was a significant improvement over time for both groups in diabetes distress, diabetes self-efficacy, and illness perceptions. There was a significant group effect where participants in the MINDS OHP group overall showed more threatening levels of illness perception and diabetes distress (PAID) compared to the control group. There were no significant interactions (Group x Time) in the secondary outcome measures.

3.2.1 Post-hoc Analyses

Given the lack of significant interaction effects, particularly for quality of life, depression, and anxiety measures, post-hoc analyses were conducted to further explore the data. As seen in Table 3, using the HADS (Snaith, 2003) categories, mean depression and anxiety baseline scores were in the 'normal' category. It could be argued that low pre-intervention levels of depression and anxiety may limit the amount of improvement participants could experience compared to participants with more severe symptoms. To explore this further post-hoc MMRM analyses were conducted on 48 participants (23 control; 25 MINDS OHP) who scored a minimum of 8 (meeting a cut-off score for mild to severe

depression and anxiety) on the Depression and the Anxiety scales on the HADS (Snaith, 2003). When participants with mild to severe levels of depressive and anxiety symptoms were included, there was an additional significant interaction (Group x Time) of small effect in diabetes self-efficacy as measured by the DES -SF (Anderson et al., 2000) *(*$F(3,60.13) = 3.31$, $p = 0.030$, $\eta^2 = 0.043$). Overall, the MINDS OHP group showed significantly greater improvement in diabetes self-efficacy across time compared to the control group, with the greatest improvement observed between baseline and 3-month follow-up. Figure 2 displays the interaction effect for diabetes self-efficacy (DES-SF) over time.

Figure 2. Post-hoc interaction effect of group and follow-up timepoint on diabetes self-efficacy (DES-SF) for participants with mild to severe depression and anxiety symptoms

3.3 Adherence

Analysis of MINDS OHP sessions revealed just under three-quarters (40/55 or 72.7%) of MINDS OHP participants completed all sessions. There were 1/55 (1.8%) of participants who completed 7 sessions, 0/55 (0%) completed 6 sessions, 0/55 (0%) completed 5 sessions, 0/55 (0%) completed 4 sessions, 1/55 (1.8%) completed 3 sessions, 4/55 (7.3%) completed 2 sessions, and 7/55 (12.7%) completed just the first session. Two intervention participants (3.6%) who submitted baseline data did not start the MINDS OHP. Of the MINDS OHP participants completing at least one session, 75.5% completed sessions face-to-face with a facilitator, 20.8% via telephone, and 3.8% via videoconference.

4. DISCUSSION

Our aim was to provide the first evaluation of the new MINDS OHP in improving psychosocial wellbeing for adults living with diabetes. We used MMMR to analyse changes

in primary and secondary outcomes from baseline to 12 months. Unfortunately, there were no significant interaction effects in primary or secondary outcome measures, suggesting this study lacks broader evidence that the new MINDS OHP was more effective than usual care. There are a variety of reasons as to why this initial evaluation lacked evidence for the overall effectiveness of MINDS OHP. Firstly, we were unable to reach the required sample size for statistical power, so our sample was not sufficiently powered to detect an effect where there might be one. As this was the first trial of MINDS OHP, with a new diabetes-specific supplement, it is important to consider that aspects of the program may need refinement before improvements in wellbeing are observed. For example, in our qualitative sub-study of Type I diabetes MINDS OHP participants (Ferrier et al., 2020), some participants expressed that MINDS OHP could be enhanced by including the diabetes educator in the program, or even as the MINDS OHP facilitator. Also, the participants' engagement with the workbook, written material, and worksheets varied, which may also have impacted study findings.

Our post-hoc analyses found that the new MINDS OHP was more effective than usual care in improving diabetes self-efficacy for participants with mild to severe depression and anxiety as measured by the HADS (Zigmond & Snaith, 2003). The improvement was greatest in the baseline to 3-month period, the timepoint immediately after the intervention. Therefore, MINDS OHP may have assisted more distressed participants to believe they could find ways to feel better about diabetes and ask for support when they need it. However, caution should be taken with this result as the post-hoc analyses were underpowered. Further, other diabetes-specific measures such as diabetes distress did not show similar improvement so further investigation is warranted.

It is interesting that in these initial post-hoc analyses, MINDS OHP was effective at improving diabetes self-efficacy, but not for the primary outcome of general self-efficacy. Whilst limited statistical power may have impacted results, it is also possible that MINDS

OHP may hold more potential to improve diabetes self-efficacy compared to overall self-efficacy, with benefits centring on its diabetes-focus compared to the original OHP. Our study advertisements also emphasised the potential benefits of the new MINDS OHP for diabetes, which may have attracted participants who were specifically motivated to focus on diabetes concerns rather than other areas of wellbeing.

These first adherence analyses revealed a positive trend in that the majority of participants completed the 8 primary MINDS OHP sessions, suggesting that despite lack of statistical results, participants remained engaged in the MINDS OHP and with their facilitator. Attrition was more likely to occur after session 1 or 2, with almost no attrition observed in the middle part of the MINDS OHP. This highlights the importance of introducing the MINDS OHP to participants (session one), developing rapport, and ensuring participant expectations mirror the MINDS OHP's offerings. Finally, significant main effects of time suggested that all participants improved in diabetes distress, diabetes self-efficacy, and had less threatening illness perceptions over time. One hypothesis is that participating in a diabetes wellbeing study and completing self-assessments was therapeutic for many participants across both groups and so future research would benefit from including a sham control treatment to differentiate the effects of the MINDS OHP from a placebo effect.

4.1 Clinical implications

This first study of the MIND OHP lacked overall evidence for clinical benefit and requires further investigation before clear recommendations are made. The significant (small effect) improvement in self-efficacy for participants with mild to severe depression and anxiety symptoms warrants further exploration, for example to clarify if MINDS OHP is most valuable for more vulnerable people who lack belief in their ability to achieve diabetes goals.

As there was no similar interaction for general self-efficacy, future research could further explore if the MINDS OHP may be more useful as a diabetes-specific intervention rather than for overall wellbeing. A highly powered sample would also allow exploration of whether a full 'dose' of MINDS OHP is required to observe improvements in diabetes wellbeing, or whether benefits can occur with fewer sessions.

Session adherence analysis revealed that attrition was more common in the early stages of the program. Further, this initial evaluation showed significant attrition after consent and enrolment (participants who did not start the study), so reviewing the research processes around MINDS OHP may be warranted in terms of interactions with the research team, and understanding why some participants changed their mind soon after enrolment.

4.2 Limitations

This initial evaluation study focused on a sample of largely educated and metropolitan living adults with diabetes in the Australian setting, and so results may not be applicable to other settings. Our study unfortunately did not reach the full target for statistical power and so this may have impacted the ability to detect significant effects where they existed. Further research of the new MINDS OHP including multi-centre trials with more diverse groups of participants is recommended. Efforts towards this include a culturally adapted version of the OHP (POHON SIHAT) being trialled in Malaysia for people with diabetes (Suhaimi et al., 2020).

Unfortunately, we had insufficient data on physical health indicators like HbA1c, so were unable to reliably explore in this initial evaluation whether the MINDS OHP was associated with improved BGLs, a key indicator in overall diabetes wellbeing. Finally, future

research could analyse the level of participant engagement with the MINDS OHP workbooks and utilisation of the tools and worksheets.

4.3 Conclusion

In conclusion, our initial evaluation found that MINDS OHP was associated with improved diabetes self-efficacy for adults with diabetes, particularly for people with mild to severe levels of distress, with small effect. The new MINDS OHP warrants further exploration as to its potential benefits as a diabetes-focused intervention to support the mental health of adults with diabetes, a group at higher risk of depression, anxiety, and lower quality of life (Baumeister et al., 2012; Grigsby et al., 2002; Perrin et al., 2017; Subasinghe et al., 2015; Van der Feltz-Cornelis et al., 2010). Further research with more highly powered samples would assist with clarifying the evidence for MINDS OHP and alongside the existing literature build an evidence-base sufficient to develop intervention specific recommendations. Whilst this study lacked evidence of the impact of MINDS OHP on other aspects of wellbeing, such as depression and anxiety, it was the first study of the intervention and we believe, too early to conclude that it is not effective in improving these outcomes.

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Author Contributions

DJC, CFS and DRT conceived the study. DJC developed the original OHP. DJC, CFS, DRT, GM, SK, and CLO designed the study. CFS and DJC wrote the protocol. GW and ML provided clinical consultation on trial implementation. DJC, DRT, GM, CLO, ML, GW, and SK reviewed the protocol. ZMJ conducted recruitment and data collection. CLO and GM supervised the clinical aspects of the study. PA and SK conducted statistical analyses. All authors have read and approved the final version of the manuscript.

The data that support the findings of this study are available from the corresponding author (CO), upon reasonable request.

Competing interests

David Castle: potential conflicts of interest (past 36 months: January 2022): DC has received grant monies for research from Servier, Boehringer Ingelheim; Travel Support and Honoraria for Talks and Consultancy from Servier, Seqirus, Lundbeck. He is a founder of the Optimal Health Program (OHP), and holds 50% of the IP for OHP; and is part owner of Clarity Healthcare. He does not knowingly have stocks or shares in any pharmaceutical company.

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Table 1. The Mental Health in Diabetes Optimal Health Program (MINDS OHP)

Session title	Objectives	Content
1. Introduction to OHP model	1. Define optimal health 2. Consider how our behaviour influences health 3. Self-assessment 4. Introduce Health Plans 1-3	Considers six domains; mental, emotional, social, occupational, physical and spiritual health. Provides opportunity to explore and understand current self-management behaviour and satisfaction with day-to-day functioning, and personal and family beliefs about diabetes.
2 & 3. "I-Can-Do" Model	1. Complete own "I-Can-Do" Model, 2. Identify own strengths, vulnerabilities 3. Understand Health Plan 1 1. Identify stressors, including those linked to diabetes 2. Explore early warning signs 3. Stress management strategies: Health Plan 2	Sessions 2 and 3 introduce 'I Can Do ' model, which encompasses health plans exploring the participant's strengths and vulnerabilities, and anticipates effects of crises and developing strategies to overcome these Balancing hope with reality – coping with diabetes complications. Exploring how anxiety affects diabetes and vice versa.
4. Medication and lifestyle	1. Identify +/− aspects of medication, medication monitoring *2.* Understand value of metabolic monitoring and healthy lifestyle	Lifestyle and physical health management, impact of healthy diet and exercise. Effective use/self-management of medication, any side-effects. Adjusting to diabetes treatments including medication, insulin delivery methods, diet and lifestyle changes.
5. Collaborative partners (CP) and strategies	1. Understand importance of CPs 2. Identify/plan roles of people/supports as CPs 3. Make Health Plan 3 and Eco Map	Develop an 'Eco Map ' detailing key partnerships and supports in the participant's network and community (e.g. GP, other healthcare supports, family). Identify gaps in support/care and make plans to overcome any barriers to engaging peer and community support for living with diabetes.
6. Change enhancement	1. Understand the Wellbeing Timeline 2. Explore 'Sub-optimal Health ' and episodes of illness 3. Revisit Health Wheel, meaning of change	Change enhancement by tracking health fluctuations across time and establishing new proactive avenues for change. Revisit Health Wheel: Visioning and Goal setting. Exploring how problem-solving can support diabetes self-management.

7. Visioning and goal setting	1. Identify change and its meaning 2. Explore key steps in problem solving and principles of goal setting	Discusses goal setting via creative problem solving and planning in diabetes, guided by own priorities. Allows reflection of what is useful in any future crises.
8. Maintaining wellbeing	1. Understand Health Plans 1-3, Health Journal 2. Introduce/plan booster session	Reviews well-being maintenance and sustainability by acknowledging any progress made towards goal, exploring concept of using rewards to improve progress.

Table 2. Baseline participant characteristics in the MINDS OHP and usual care groups

	Control	Intervention	*p*-value
Age (mean, SD, range) years	52 (15.4, 21-77)	55 (16.2, 21-90)	*p*=0.344
Gender (n, %)			*p*=0.400
Female	25 (49)	32 (57)	
Male	26 (51)	24(43)	
Country of birth (n, %)			*p*=0.631
Australia	27 (53)	34 (61)	
New Zealand	2 (4)	-	
Asia	2 (4)	2 (4)	
UK/Europe	16 (31)	16 (29)	
Other	4 (8)	4 (7)	
Education (n, %)			p=0.857
Postgraduate	15 (29)	19 (34)	
Undergraduate	8 (16)	9 (16)	
Further	10 (20)	9 (16)	
Secondary	14 (27)	12 (21)	
Other	4 (8)	7 (13)	
Marital status (n, %)			*p*=0.068
Married	20 (49)	13 (32)	
Single	14 (34)	24 (58)	
Widowed	4 (10)	4 (10)	
Separated	3 (7)	-	
Accommodation (n, %)			*p*=0.759
Own house	23 (45)	28 (50)	
Rental	18 (35)	16 (28)	
Public housing	5 (10)	3 (5)	
Supported	-	1 (2)	
Living with family	4 (8)	6 (11)	
Other	1 (2)	2 (4)	
Diabetes type (n, %)			*p*=0.802
Type 1	24 (47)	25 (45)	
Type 2	27 (53)	31 (55)	

Table 3. The effect of the MINDS OHP between groups and over 12-month follow-up

Outcome measure	Control N	Control Mean (SD)	Intervention N	Intervention Mean (SD)	Group p value, effect size	Time p value, effect size	Group x Time p value, effect size
AQoL-6D					0.548, η^2=0.003	0.260, η^2=0.011	0.377, η^2=0.001
Baseline	51	0.72 (0.19)	52	0.67 (0.18)			
3 months	38	0.74 (0.20)	39	0.70 (0.19)			
6 months	40	0.74 (0.18)	35	0.73 (0.18)			
12 months	39	0.75 (0.19)	32	0.72 (0.17)			
GSES					0.612, η^2=0.001	**0.001,** η^2=0.027	0.070, η^2=0.008
Baseline	50	30.76 (5.09)	39	29.53 (5.35)			
3 months	37	31.95 (3.79)	38	32.33 (4.36)			
6 months	40	32.18 (4.76)	30	31.57 (5.78)			
12 months	39	31.56 (4.28)	23	32.94 (5.74)			
DQoL					0.502, η^2=0.002	0.923, η^2=0.002	0.542, η^2=0.007
Baseline	43	3.04 (0.65)	55	3.09 (0.58)			
3 months	36	3.07 (0.67)	40	3.01 (0.60)			
6 months	40	3.08 (0.69)	35	3.06 (0.51)			
12 months	37	3.11 (0.59)	32	3.04 (0.54)			
Maladaptive cope Brief COPE					0.399, η^2=0.017	0.108, η^2=0.002	0.382, η^2=0.008
Baseline	50	1.62 (0.55)	48	1.82 (0.56)			
3 months	37	1.65 (0.57)	36	1.79 (0.58)			
6 months	40	1.62 (0.47)	31	1.62 (0.47)			
12 months	39	1.56 (0.43)	30	1.58 (0.40)			
Adaptive cope Brief COPE					0.105, η^2=0.007	0.253, η^2=0.006	0.136, η^2=0.006
Baseline	49	2.06 (0.55)	48	2.11 (0.59)			
3 months	37	2.03 (0.53)	37	2.35 (0.55)			
6 months	40	2.13 (0.54)	32	2.30 (0.59)			
12 months	38	2.14 (0.58)	30	2.27 (0.72)			
Depressive symptoms (HADS)					0.755, η^2=0.001	0.060, η^2=0.013	0.269, η^2=0.006
Baseline	50	4.92 (3.08)	51	5.98 (3.96)			
3 months	37	4.24 (3.51)	39	5.21 (3.41)			
6 months	40	4.55 (4.55)	36	4.42 (3.43)			
12 months	39	4.69 (4.28)	32	4.38 (3.30)			
Anxiety symptoms (HADS)					0.975, η^2=0.001	0.306, η^2=0.003	0.308, η^2=0.002
Baseline	50	6.26 (4.58)	51	6.45 (3.98)			
3 months	37	6.27 (4.68)	39	6.54 (4.42)			
6 months	40	5.50 (4.58)	36	6.14 (4.22)			
12 months	39	6.28 (4.70)	32	5.78 (4.27)			
PAID					**0.050,** $\eta^2$0.028	**0.001,** η^2=0.039	0.081, η^2=0.014
Baseline	50	25.10 (19.57)	51	37.65 (21.85)			
3 months	38	24.57 (19.91)	39	32.63 (20.01)			
6 months	40	21.06 (16.78)	34	23.82 (15.59)			
12 months	39	22.53 (17.23)	31	23.43 (16.73)			
WSAS					0.171, $\eta^2$0.011	0.241, $\eta^2$0.009	0.818, η^2=0.007
Baseline	50	9.74 (9.89)	52	12.96 (11.48)			
3 months	38	7.79 (8.62)	40	13.08 (11.08)			
6 months	39	7.31 (9.01)	36	10.33 (10.33)			
12 months	39	8.18(10.63)	30	8.03 (7.71))			
Illness perception BIPQ					**0.037,** $\eta^2$0.032	**0.010,** η^2=0.044	0.799, η^2=0.008
Baseline	49	5.73 (20.2)	49	6.69 (1.98)			
3 months	36	5.27 (2.28)	39	6.57 (1.97)			
6 months	39	5.32 (2.18)	33	5.61 (1.86)			
12 months	39	5.30 (1.67)	28	5.79 (1.73)			
DES-SF					0.437, $\eta^2$0.003	**0.001,** η^2=0.039	0.069, η^2=0.016
Baseline	50	2.69 (0.72)	49	2.47 (0.77)			
3 months	38	2.72 (0.89)	39	2.95 (0.68)			
6 months	40	2.75 (0.94)	34	2.99 (0.75)			
12 months	38	2.91 (0.77)	30	3.12 (0.72)			

Key: AQoL-6D Assessment of Quality of Life-6 Dimensions; GSES General Self-Efficacy Scale; DQoL Diabetes Quality of Life Brief Clinical Inventory; Brief COPE Brief version of the COPE Inventory; HADS Hospital Anxiety and Depression Scale; PAID Problem Areas in Diabetes Scale; WSAS Work and Social Adjustment Scale; BIPQ Brief Illness Perception Questionnaire; DES-SF Diabetes Empowerment Scale – Short Form.

Figure 1. Flow of participants through the trial

See separately attached document.

Figure 2. Post-hoc interaction effect of group and follow-up timepoint on diabetes self-efficacy (DES-SF) for participants with mild to severe depression and anxiety symptoms

see separately attached document.