Effectiveness of psychoeducational interventions for the treatment of diabetes-specific emotional distress and glycaemic control in people with type 2 diabetes: a systematic review and meta-analysis

Abstract

Aims Psychological comorbidity, such as depression and/or diabetes-specific emotional distress (DSD), is highly prevalent in people with type 2 diabetes (T2DM) and associated with poorer treatment outcomes. While treatments for depression are well established, interventions specifically designed for DSD are sparse. The aim of this study was to determine interventions that successfully address DSD and HbA1c in people with T2DM.

Methods Seven databases were searched to identify potentially relevant studies. Eligible studies were selected and appraised independently by two reviewers. Multiple meta-analyses and meta-regression analyses were performed to synthesise the data; the primary analyses determined the effect of interventions on DSD, with secondary analyses assessing the effect on HbA1c.

Results Thirty-two studies (n=5206) provided sufficient DSD data, of which 23 (n= 3818) reported data for HbA1c. Meta-analyses demonstrated that interventions significantly reduced DSD (p=0.034) and HbA1c (p=0.006) compared to controls, although subgroup meta-analyses and meta-regression to explore specific intervention characteristics that might mediate this effect yielded non-significant findings.

Conclusions The findings demonstrate that existing interventions successfully reduce DSD and HbA1c in people with T2DM. While promising, deductions should be interpreted tentatively, highlighting a stark need for further focused exploration of how best to treat psychological comorbidity in people with T2DM.

Introduction

Psychological comorbidity is high in people with T2DM, with extensive research demonstrating that approximately 30% of patients experience depressive affect [1-3]. More recently linked to T2DM is diabetes-specific emotional distress (DSD), demonstrating similar prevalence (36%) to depression [4], but encapsulates a much wider affective experience than depression, constituting distinctive emotional concerns within the 'spectrum of patient experience' for those living with a progressive and chronic condition [5,6].

DSD refers to psychological distress specific to living with diabetes encompassing a wide range of emotions, such as feeling overwhelmed by the demands of self-management, worrying and ruminating about existing or future complications, holding concerns about existing comorbidities, being fearful of hypoglycaemia, and/or harbouring feelings of guilt or shame, notably in relation to obesity or lifestyle [7,8].

Both depression and DSD have been shown to impact negatively on diabetes through reduced self-care [9-12]. Both conditions are shown to overlap with moderate to strong associations identified in a recent appraisal of existing literature [6]. The authors estimated a co-occurrence of depression and DSD to be around 5% based on epidemiological studies, concluding that, although highly correlated, the constructs are not interchangeable and both require routine assessment and appraisal within diabetes care.

The literature suggests that DSD has a greater impact upon, and is more closely associated with diabetes self-management and diabetes-related behavioural and biomedical outcomes than depression. Most notably, there appears to be an effect of DSD on HbA1c whereas the impact of depression appears to be equivocal [8,13-17].

Specific examination of the relationships between depression, DSD and HbA1c demonstrated that only DSD, and not major depressive disorder or depressive symptoms, held cross-sectional and time-varying longitudinal relationships to HbA1c, highlighting the importance of DSD and its impact on glycaemic control [17-19]. With an increasing body of work revealing this importance, assessment of the effectiveness of interventions has been advocated to mitigate distress. As such, the current review set out to identify randomised controlled trials (RCTs) testing psychoeducational interventions to determine their effect on DSD, as well as HbA1c, in adults with T2DM.

Methods

Search strategy and selection

Bibliographic databases were searched using a combination of free-text and medical subject heading (MeSh)/Thesaurus terms, including EMBASE (1974 to 2016 week 44), MEDLINE (1946 to week 44 2016), PsycINFO (1954-2016), CINAHL (1993-2016), The Cochrane Library, the ASSIA (All dates) and SCOPUS (All years to present). The search strategy was circulated to members of the project team (KK, FS, NR, MD) to advise on any further potential terms and these were added to the search. The finalised search for this review was conducted on the 5th November 2016 [Supplementary Fig 1].

The inclusion and exclusion criteria for this review were developed alongside the review question using the PICOS approach [20]. Inclusion criteria consisted of RCTs testing psychoeducational interventions within adult populations ($\geq$18 years) with T2DM. Psychoeducational interventions were defined as any intervention that provided information and guidance for diabetes and/or psychological self-management and support. Solely pharmacotherapeutic interventions were excluded.

If a population was mixed T1DM and T2DM, the study was eligible if it included ≥70% of T2DM participants. Studies needed to report DSD, as either a primary or secondary outcome, measured with a psychometrically validated tool; either the Problem Areas in Diabetes scale (PAID) [21] or the Diabetes Distress Scale (DDS) [22]. Only studies reported in the English language were included. Two reviewers (NP, NA) independently assessed abstracts and titles for eligibility and retrieved potentially relevant articles. Following this, the reviewers met to discuss any differences in opinion, which were resolved through discussion: there was no requirement for a third reviewer.

Data extraction

The primary data extracted was the mean (SD) DSD scores. Where available, the secondary data extracted was the mean (SD) for HbA1c scores. Further data extracted included study design, sample size and distribution, study location, population demographics, intervention and control group details, length of follow-up and DSD measure used. Data reported in the study text were checked against data in tables and where discrepancies were found the data was taken from the tables. Where data were incomplete or unsuitable for analyses, authors were contacted for additional data and/or clarification.

Study quality

Overall study quality was evaluated using The Grades of Recommendation, Assessment, Development and Evaluation (GRADE) approach [23,24], using the Cochrane Collaboration's tool for assessing risk of bias within studies was used to facilitate the appraisal of evidence [25]. Using this approach, all RCTS began with an a priori quality rating of 'high'. The quality of evidence was then assessed across five factors and studies were 'downgraded' if limitations are identified. Studies are

considered high quality if they remain as they are, they are considered moderate quality if they are once downgraded, they are considered low quality if they double-downgraded, and very low if they are triple-downgraded. The overall quality of this review was rated per outcome, as GRADE is 'outcome centric' resulting in quality appraisal for DSD and HbA1c separately.

Meta-analyses

The primary analyses synthesised the mean (SD) change-from-baseline DSD score at the end of follow-up in intervention groups compared to control groups. End of follow-up was defined as the latest point of follow up. The results from different studies were combined using a standardised random effects meta-analysis to produce a standardised mean difference (SMD). Heterogeneity was assessed using an I^2 statistic. Publication bias was assessed using Egger's test [26] and funnel plots. Potential sources of heterogeneity were investigated using meta-regression analyses with the following potential study-level confounders: year of study, length of follow-up, study location, gender majority, mean age, ethnicity, mean BMI, mean HbA1c, and mean years diagnosed with T2DM. Further standardised random effects meta-analyses and meta-regression analyses were performed to assess how specific intervention characteristics affected DSD by comparing studies that used a particular method against those that did not. The secondary outcome of interest was the mean (SD) HbA1c score at end of follow up, repeating the same analyses as with DSD but using non-standardised random effects meta-analyses to produce a weighted mean difference (WMD). Analyses were performed in STATA v14.1.

Results

Fig 1 demonstrates the study selection process.

Studies included in the meta-analyses are summarised in Table 1.

All studies were conducted within the last eight years, length of follow-up varied from one week to two years, with an average of eight and a half months.

The average age of participants was 59 years (range: 40.4 to 70.2), with an even split between male and female genders (53% male). Forty percent of participants were of Caucasian ethnicity and had been diagnosed with T2DM for an average of nine years (range: 3.7 to 18.6 years) with an average HbA1c of 8.4% (range: 7 to 10%; 53 to 85.8 mmol/mol). The average BMI was 32.8kg/m2 (range: 24.1 to 37).

Study Quality

There was mixed reporting across studies demonstrating a moderate to high risk of bias, particularly in performance and detection bias, however this was mostly due to a lack of clear reporting or disclosure. Many studies did not clearly state their randomisation processes or describe methods of concealment or if allocation concealment was even performed, as such, it was unclear whether bias truly existed between studies.

Meta-analyses

Primary analyses: DSD

Thirty-two studies [e1-e32], with a total of 5206 participants, used a control group and reported baseline and follow-up data for DSD. Overall DSD scores were significantly lower in the intervention group with a greater change from baseline compared to the control group (p=0.034) [Fig 2]. Heterogeneity was high I^2 = 77.4% with meta-regression analyses identifying one potential confounder in study year (p=0.043). Egger's test (p=0.593) and a funnel plot suggested publication bias was absent [Supplementary Fig 2].

Subgroup analyses to determine the impact of different intervention characteristics on DSD [Table 2] demonstrated no significant differences, although findings on the

cusp of significance were seen in interventions that used digital platforms (SMD -0.378 vs. -0.098, p=0.056) or self-management education (SME) (SMD -0.191 vs. 0.127, p=0.064) compared to those that did not. Substantial effects were also seen when comparing interventions that adopted a collaborative care model (CCM) (SMD -0.303 vs. -0.083), defined as structured care involving a large number of non-medical specialists working together with a primary care physician and mental health professionals to deliver stepped interventions, of varying intensity with the overall aim of improving patient outcomes [27], or included self-monitoring of blood glucose (SMBG) (SMD -0.266 vs. -0.038) with those that did not.

Secondary analyses: HbA1c

Of the thirty-two studies in the primary analyses, twenty-three (n= 3818) reported data for HbA1c, demonstrating that overall, interventions significantly reduced HbA1c compared to controls with a significant weighted mean difference (WMD) of -0.279 (95% CI = -0.480, 0.079, p=0.006) [Fig 2]. Heterogeneity was high, I^2 = 70.6%, which was not explained by meta-regression analyses. Egger's test (p=0.150) and a funnel plot suggested publication bias was absent [Supplementary Fig S2].

Subgroup analyses to determine the impact of different intervention characteristics on HbA1c [Table 2] demonstrated no significant differences. Substantial effects were seen, however, when comparing interventions that adopted digital platforms (WMD -0.647 vs. -0.207), SMBG (WMD -0.449 vs. -0.102), or individualised goal setting (WMD -0.314 vs. -0.083) with those that did not.

Discussion

Key findings

The overall effect of thirty-two psychoeducational interventions in reducing DSD in people with T2DM was significant compared to controls. Of these, twenty-three

studies reported data for HbA1c, with a significant overall reduction in HbA1c by interventions compared to controls. Further meta-analyses and meta-regression analyses to explore the effect of specific intervention characteristics on DSD and HbA1c yielded no significant results, although this is a likely consequence of disparate numbers of studies being compared.

Strengths and limitations

This is the first known systematic review and meta-analyses of existing literature examining interventions aimed to improve DSD and HbA1c specifically in people with T2DM, augmented by an additional focus on specific intervention characteristics that mediate this effect. As such, it addresses a gap in the literature with novel information.

A large proportion of existing research combines people with T1DM and T2DM when exploring DSD; this can be problematic due to the way in which psychological comorbidity may manifest differently in these populations. The PAID scale can be used for people with either T1DM or T2DM, however it has been previously noted that the data collected is likely to be intrinsically different between populations, with recommendations to assess DSD separately with the DDS for people with T2DM and the recently developed T1-DDS for those with T1DM [28]. As such, the current review is focused specifically on individuals with T2DM and thus provides novel insight into potential factors for consideration in treating DSD in this population.

The methods used to undertake this review were robust, adopting strategies to gain all relevant outcome data. The study quality was strong in relation to study design and data collection methods, suggesting that the likelihood for bias due to allocation processes was small. All studies were randomised and controlled, demonstrating low risk, however few employed or disclosed the use of allocation concealment meaning

that overall selection bias was moderate. Similarly, few studies discussed the use of blinding meaning that the potential for performance and detection bias were high. When assessing outcome-specific quality within the GRADE approach, the quality for DSD was low, namely due to unexplained and considerable heterogeneity. The majority of studies in this review sought glycaemic control as a primary outcome with the overall quality for HbA1c being moderate. This highlights a distinct need for further research into DSD and more targeted and focussed studies seeking DSD as a primary outcome measure to improve quality.

While a potential strength for this review is that it is the first of its kind in published literature, this meant that data were limited, with the vast majority (78%) of studies testing interventions that were neither specifically designed for, nor targeted towards DSD. The findings of this review should therefore be interpreted with caution. There was considerable heterogeneity between studies, both in intervention design and participant demographics, reinforcing tentative interpretation of the findings. Although stringent efforts were made to obtain missing data from authors, this was not always successful and certain data were imputed from existing data. In many instances this was not possible, resulting in thirteen studies requiring exclusion from the analyses due to missing, incomplete or inappropriate data.

Surrounding evidence and implications

The only intervention characteristic that demonstrated substantial effect sizes in reducing both DSD and HbA1c was the use of digital platforms, such as mobile phone and/or web-based interfaces. Four interventions utilised digital platforms [29-32], demonstrating reductions in DSD and HbA1c three to four times larger than interventions that did not, with a very near significant effect on DSD ($p=0.056$). Of these studies, the Reducing Distress and Enhancing Effect Management (REDEEM)

study [29] was specifically designed for DSD; utilising a web-based computer-assisted behavioural self-management support program, with or without DSD-specific problem solving training, compared to a minimal support and education control. In the REDEEM study, all three conditions were web-based and demonstrated significant improvements in DSD, which may have affected the findings in the current review, since we sought to compare interventions against controls and their findings favoured both.

With as much as 17% of the UK's National Health Service's (NHS) budget anticipated to be attributable to diabetes care [33] there continues to be a pressing need to find cost-effective interventions offering patient-centred and tailored care; such cost-effective potential could be realised in the use of digital platforms. Despite an increasing call for such interventions, data is limited, particularly when exploring DSD, as demonstrated in the paucity of studies in the current review. Despite current low numbers of studies, they show promising findings, further corroborated by studies [34-36] excluded from our review due to an over-representation of T1DM, demonstrating significant positive effects of digital platforms for reducing DSD, and other psychological and physiological outcomes.

Interventions that incorporated SME demonstrated a near significant positive impact upon DSD ($p=0.064$). SME content varied across interventions and analyses were further delineated by physical activity, nutritional intake and SMBG. SMBG was the only variable that demonstrated substantially larger SMD/WMDs in both DSD and HbA1c. While showing merit in reducing HbA1c, SMBG has been shown to hold the potential to actually increase DSD and depression due to the burden of self-management, although findings do vary. Research has demonstrated either no effect on blood glucose or a negative impact on both HbA1c and psychological wellbeing

[37,38], while other research has demonstrated improved blood-glucose with no impact on wellbeing [39]. The latter study emphasised the importance of *appropriate* use of structured SMBG. The authors emphasised the importance of adequate training for HCPs and endorsed the used of SMBG within an individualised and collaborative programme to improve outcomes.

The American Diabetes Association and the European Association for the Study of Diabetes have together stressed the importance of individualising treatment targets and strategies, emphasising the value of patient centred care and shared decision making in the management of people with T2DM [40]. The current findings demonstrated a nearly four-times larger reduction in HbA1c in studies that used individualised goal setting compared to those that did not, although no substantial differences were seen in DSD. Patient-centred care has been proven effective and is encouraged across all UK health disciplines by the National Institute for Health and Care Excellence (NICE) [41]. Specific research into individualised goal setting in newly diagnosed people with T2DM demonstrated that, alongside educational and surveillance support, it reduced diabetes-risk factors and complications for the entire six-year follow-up period [42]. Seventy-five percent of studies included in the analyses discussed the use of individualised goal setting, showing promise in the overall recognition of the importance of patient-centered and individualised targeting in intervention design.

Lastly, interventions that adopted a CCM demonstrated a nearly four-times greater reduction in DSD compared with those that did not, although this effect was not seen in reduced HbA1c. Current NICE guidelines for the treatment of comorbid depression in adults with a chronic physical comorbidity, such as diabetes, recommend collaborative care within a stepped framework, beginning with the least intrusive but

most effective intervention, and progressing in treatment intensity as required [43].

The literature on the CCM and DSD is limited, with more research focused on depression and HbA1c. A recent systematic review and meta-analysis of studies reporting interventions for depression in patients with T2DM [13] demonstrated that interventions were effective at reducing symptoms, with particular merit given to the CCM. However, the review noted that improvement of glycaemic control required further research, since treatments targeted at depression alone did not improve diabetes outcomes. This corroborates other findings that interventions targeted at solely treating depression fail to improve physical outcomes, or vice versa [44-46] [45-47]. Notable among these studies utilising the CCM for the treatment of people with diabetes was the Pathways Programme study [45,47], which incorporated a motivational interviewing counseling-style approach to support patients with problem solving and goal setting for people with comorbid diabetes and depression. The study demonstrated significantly greater improvements in depressive symptoms over 12 months, but did not report statistically significant reductions in HbA1c. A later study examining effects of a CCM intervention on depression but including a measure of DSD, found that the CCM was effective in reducing both depression and DSD but again showed no significant effects on HbA1c [48]. This is consonant with our findings and warrants further research into the management of these comorbid conditions.

Conclusion

Results from this review, along with the existing literature on interventions for depression and distress, suggest a need for greater scrutiny of interventions that improve depression, distress and glycaemic control.

The number of studies that came forward in this review shows promise for both the recognition of DSD as a construct and its importance within diabetes literature. While there were areas that showed promise in our findings, these should be interpreted tentatively, since few studies in the analyses were specifically targeted towards DSD. This highlights a need for further research to design interventions that specifically target DSD, both to understand better the effect of interventions on DSD in people with T2DM, and to shape best practice in treating this population.

Acknowledgements

We acknowledge Navneet Aujla and Shaun Barber for their support as second reviewers.

We acknowledge support from the National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care – East Midlands (NIHR CLAHRC – EM), the Leicester Clinical Trials Unit and the NIHR Leicester-Loughborough Diet, Lifestyle and Physical Activity Biomedical Research Unit which is a partnership between University Hospitals of Leicester NHS Trust, Loughborough University and the University of Leicester

Conflict of interest

None declared

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