Title

Moderating the relationship between diabetes distress and mastery: the role of depression and empowerment

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Abstract

Type 2 diabetes is a chronic condition primarily self-managed by the individual. Mastery is a recognised protective factor linked to better control of chronic conditions, more effective self-management and improved medication adherence. The importance of mastery may become more acute as treatment regimens and self-management demands on those living with type 2 diabetes become more complex and burdensome. Diabetes distress is associated with poor self-management, inadequate glycaemic control and issues with treatment adherence. Understanding more about the relationship between diabetes distress and mastery would provide insights for clinicians tasked with improving condition management and adherence in those living with type 2 diabetes. However, this relationship may not be simple with other factors such as depression and disempowerment impacting the sense of control an individual perceives they have over their condition. This study tested the moderating role of diabetes empowerment and depression in the relationship between diabetes distress and mastery. Data was drawn from participants in a randomised controlled trial of adults with type 2 diabetes transitioning to injection therapy. A sample of 131 adults completed measures of diabetes distress (Problem Areas in Diabetes scale), mastery (Perlin Mastery Scale), depression (Hospital Anxiety and Depression Scale) and empowerment (Diabetes Empowerment Scale). Diabetes distress and depression were negatively associated with mastery. Diabetes empowerment was positively associated with mastery. A moderation model confirmed a significant interaction effect (b=.024, t(112) = 3.79, p=<.005) with the relationship between diabetes distress and mastery is moderated by depression. Findings highlight the additive deleterious effects of depression. Interventions to improve mastery among those living with type 2 diabetes may need to address diabetes distress and depression to optimise outcomes.

Keywords

Moderating the relationship between diabetes distress and mastery: the role of depression and empowerment

Introduction

Type 2 diabetes (T2D) is a condition predominantly managed by the individual (McSharry et al., 2019). To be effective self-managers, those with T2D need to make decisions regarding medication, diet, exercise and blood glucose monitoring (Skinner et al., 2006). Effective self-management is necessary to ensure appropriate glycaemic control and reduce diabetes related complications (Wilkinson et al., 2014). Treatment advice for T2D advocates lifestyle and dietary change as the first option to achieve optimal glycaemic control; if control remains poor, oral medications are prescribed, progressing to injection therapy, i.e. GLP-1 receptor agonists or insulin (Edelman & Pettus, 2014). However, approximately 1 in 3 express a reluctance to commence prescribed injection therapy, with up to 80% discontinuing or interrupting treatment relatively quickly following initiation (Perez-Nieves et al., 2016; Perez-Nieves et al., 2017; Peyrot et al., 2012). Poor engagement with injectable therapies corresponds to concerns around the impact of injectables on daily living, treatment complexity and the restrictive nature of injectable regimens (Allen et al., 2017). Individuals who feel they have little control over their T2D and are unable to reach treatment targets report less motivation to manage their condition often irrespective of other factors (Gonzalez et al., 2016).

Mastery is recognised as a health-related protective factor, with higher levels of mastery related to better control of chronic conditions (Roepke & Grant, 2011). Mastery is considered: the extent to which individuals perceive aspects of their lives to be under their control, their ability to manage these aspects in light of the challenges they bring and their capacity to take appropriate action to affect associated positive outcomes (Forgeard & Benson, 2019). Mastery is positively associated with improved health behaviours (O'Kearney

et al., 2020). Individuals with higher levels of mastery are more likely to engage in better self-management, adherence to diabetes treatment plans and medication management (Daniel et al., 2001; Roepke & Grant, 2011). Therefore, understanding more about factors which contribute to an individual's level of mastery, particularly when changes in medication regimen are demanded, may provide insight to improve engagement and adherence.

Whilst mastery may serve as a positive protective factor, other factors can adversely affect adherence and self-management (Assari & Lankarani, 2017; Gonzalez et al., 2016; Linetzky et al., 2017; Spain et al., 2016). Diabetes distress refers to the negative psychological effects of living with diabetes and is linked to poor self-management, poor glycaemic control and difficulties with adherence (Dennick et al., 2016; Linetzky et al., 2017). Due to this link interventions targeting diabetes distress are receiving further attention as potential methods to improve outcomes for those living with diabetes (Hessler et al., 2020). Understanding the impact of diabetes distress on mastery among a population of those transitioning to injection therapy would provide insights for clinicians tasked with improving condition management and adherence among this group. This cannot be explored as a simple direct relationship; other factors should be considered. Depression often presents as a comorbid condition in those living with T2D and is associated with poorer clinical outcomes, initiation of injectable therapies, medication adherence and motivation which impacts negatively on effective self-management behaviours (Lee, 2015; Nefs et al., 2013). Feelings of disempowerment associated with their diabetes is a further indicator of medication resistance and poorer outcomes (Linetzky et al., 2017).

Mastery is important for effective self-management and may be more potent as management of T2D becomes more complex. Thus, understanding more about mastery and factors that impact this among a T2D population transitioning to injectable therapies has potential to provide additional insights for clinicians and educators aiming to improve engagement with and adherence to injectable therapies. With this in mind, the aim of this study is to examine

the role of depression and diabetes empowerment as moderators in the relationship between diabetes distress and mastery among a sample of those with T2D as they transition from oral medications to injectables. Based on the existing literature it was hypothesised that the relationship between diabetes distress and mastery would be moderated by depression and empowerment, with the interaction between patients' distress levels at high levels of depression and low levels of diabetes empowerment reflecting greater reductions in mastery.

Materials and Methods

This study used baseline data drawn from a randomised controlled trial (RCT) of a structured diabetes education intervention. Individuals were eligible to participate in the trial if they: had a diagnosis of T2D for one year or more; were aged over 25 years; had HbA_{1c} level of 58-100 mmol/mol; and required transfer from oral hypoglycaemic treatment to injectable therapies as judged by the diabetes healthcare team. Exclusion criteria meant individuals: newly diagnosed with T2D; with $HbA_{1c} >100$ mmol/mol; undergoing retinal photocoagulation therapy or renal dialysis treatment; in receipt of psychiatric support or clinical psychology input; within 3 months of a major event including MI, stroke or major surgery; within 3 months of diagnosis or treatment of a major coexisting medical condition, were not eligible for inclusion. All participants attended a secondary care diabetes service in Northern Ireland delivered by a consultant-led, multidisciplinary team comprising Diabetologists/Endocrinologists, Diabetes Specialist Nurses and Diabetes Specialist Dietitians. Eligible participants were identified by a member of this multi-disciplinary care team. Participants provided informed consent to participate. Ethical approval was granted by the Office of Research Ethics Committee in Northern Ireland, with governance from the Trust Research Governance Committee prior to the commencement of participant recruitment [15/NI/0091].

Participants

The sample comprised 131 participants diagnosed with T2D transitioning to injectable therapies for effective management of the condition. Mean diabetes duration was 10.4 years, (HbA$_{1c}$ M=70.3 mmol/mol; SD=12.31). Age ranged from 39 to 85 years (M=62.3; SD=8.8); 59.5% of participants were male.

Measures

Once eligible participants were identified and informed consent obtained, participants were asked to complete and return two questionnaires, one providing demographic information (see supplementary online materials for sample characteristics) and the second consisting of the following measures taken at baseline.

Diabetes distress

The Problem Areas in Diabetes Scale (PAID: Polonsky et al., 1995), comprising 20 statements, is a reliable and valid measure of emotional distress specific to diabetes (Huang et al. 2010; Welch et al. 2003; Polonsky et al.1995). Scored on a 5-point Likert scale (0=not a problem; 4=serious problem), scores range from 0-100, with higher scores indicative of higher levels of emotional distress (Welch et al., 1997).

Mastery

The Pearlin Mastery Scale (PMS: Pearlin & Schooler, 1978) is a reliable and valid, unidimensional measure used to assess the extent to which individuals feel they have control over stressful events in their lives (Turner & Noh,1988; Pearlin et al., 1981; Pearlin & Schooler, 1978). The scale comprises 7 items, with higher scores are indicative of greater levels of mastery (Brady, 2003).

Depression

The Hospital Anxiety and Depression Scale (HADS: Zigmond & Snaith, 1983) is a reliable and valid measure for assessing anxiety and depression among hospital out-patients, including adults with diabetes (Bjelland et al., 2002; Lloyd et al., 2000). Comprising 14 items

(7 items in each subscale) assessing the severity of anxiety and depression; scored on a 4-point Likert scale. Subscale scores range from 0-21, with scores of 0-7 considered normal, and scores ≥11 moderate to severe (Collins et al., 2009).

Diabetes Empowerment

The Diabetes Empowerment Scale - Short Form (DES-SF: Anderson et al., 2003) is a brief, reliable and valid measure assessing overall diabetes-related self-efficacy (Anderson et al. 2003). The scale comprises 8 items, scored on a 5-item scale (1=strongly disagree; 5=strongly agree). Higher scores are indicative of greater empowerment.

In the current sample, the reliability of the scores on each scale was found to be acceptable with Cronbach's alpha ranging from 0.95 (PAID) to 0.84 (HADS-D).

Analysis

The aim of this study is to examine the role of diabetes empowerment (M_1) and depression (M_2) in the relationship between diabetes specific distress (X) and mastery (Y). To test this, a moderated model (Figure 1) was specified and tested in SPSS using PROCESS (Hayes, 2014). PROCESS "uses logistic regression-based path analytical framework for estimating direct and indirect effects in simple and multiple moderation models" (Hayes, 2018,p.1). In PROCESS, R^2 is used to assess model fit (Hayes, 2013).

Figure 1 near here

Results

Model Summary

The model was found to be a good fit for the data, with included variables accounting for approximately 54% of the variance in mastery among the group: $R^2 = .539$, $F(5, 112) = 26.22$, p=<.0001.

Main Effects

Regression coefficients (Table 1) for the model indicate diabetes distress (b=-.249, t(5,112) = -3.71, p=<.005), diabetes empowerment (b=.280, t(5,112) = 3.02, p=<.005) and depression (b=-.980, t(5,112) = -5.73, p=<.005) are all statistically significant predictors of mastery. The main effects show diabetes distress and depression are negatively associated with mastery. Diabetes empowerment is positively associated with mastery.

Interactions

A significant interaction between diabetes specific distress and depression was found, (b=.024, t(112) = 3.79, p=<.005), indicating the magnitude of the effect of diabetes distress on mastery depends on level of depression. No significant interaction effect was found for diabetes distress and empowerment. PROCESS provides additional outputs on the change in the variance explained in the outcome due to the addition of the interaction. Results show no significant change in variance explained in mastery due to the addition of the diabetes distress x diabetes empowerment interaction: F(1,112) = .46, p=.50, ΔR^2=.001. There was a significant increase in variance explained due to the interaction of diabetes distress x depression: F(1,112) = 14.40, p=<.005, ΔR^2=.06.

Figure 2 illustrates the interaction between diabetes distress and depression more clearly: increasing levels of distress, at increased levels of depression, are indicative of lower levels of mastery, regardless of the level of diabetes empowerment.

Discussion

This study used data drawn from an RCT of adults living with T2D transitioning to injectable therapies to examine the role of diabetes empowerment and depression in the relationship between diabetes distress and mastery. It was hypothesised that the relationship between diabetes distress and mastery would be moderated by depression and empowerment, in essence individuals experiencing diabetes distress, high levels of depression and low levels of empowerment would report the lowest levels of mastery. Using Hayes' (2014) PROCESS moderation model, this study evidenced that diabetes distress, diabetes empowerment and depression significantly impact levels of mastery. Direct relationships indicated diabetes distress and depression were negatively associated with mastery, in essence in this cohort, as diabetes distress or depression increase, mastery decreases. These relationships are consistent with the existing literature that highlights the negative impact of distress and depression (Dennick et al., 2016; Lee, 2015; Linetzky et al., 2017). Diabetes empowerment was positively associated with mastery, i.e. as diabetes empowerment increases in this grouping, so too does mastery.

The significant interaction between diabetes distress and depression highlights how the negative impact of diabetes distress on mastery is heightened by increasing levels of depression with this interaction creating greater reduction in mastery. Additionally, there was no significant interaction for diabetes empowerment and distress. Further findings confirmed any positive effect of diabetes empowerment on mastery appears to be eroded in the presence of diabetes distress and depression.

The literature evidences the importance of mastery in chronic conditions, positively impacting self-management and treatment adherence (Roepke & Grant, 2011). The results from the current analysis provide insight into the mechanisms by which mastery is impacted, with contributing factors possibly more salient for the cohort involved in this study. Evidence suggests that diabetes distress is chronic, in that if it remains unresolved it can become more pervasive as the condition progresses (Hessler et al., 2020). Those with T2D transitioning to

injection therapy are a unique population as they usually have been living and coping with the condition for a longer duration, therefore diabetes distress may be more prominent among this group. The current findings provide a basis for a more comprehensive understanding of the relationship between distress and mastery, recognising the impact of depression which presents as a common diabetes comorbidity (Lee, 2015; Nefs et al., 2013). Unpacking these associations may allow for development of better self-management promotion, strategies and interventions for this population. Indeed, calls for interventions to address diabetes distress to improve self-management and associated outcomes for those with diabetes may not offer effective solutions for this population if efforts are not made to tackle depression also. There are some limitations with this study which should be recognised. This study utilises baseline data from an RCT, as such provides a snapshot of the population. A lack of longitudinal assessment limits our understanding of the changing nature of distress, depression, empowerment and mastery among this population as they navigate the challenges of injectables. Although a cross-sectional approach is suitable for this type of moderation study, a longitudinal study would have allowed for evidencing of injectable therapy adherence as a covariate in the model. Secondly, the study relies on self-report measures for data collection and therefore may be more influenced by participants' subjective views. Overall, this study identified the relationship between diabetes distress and mastery is moderated by depression, undermining the impact of diabetes empowerment. These findings have important implications for those involved in the care of those with T2D requiring injectables to achieve optimal glycaemic control. Within the diabetes specialist services, diabetes distress and empowerment may be modulated through specific education to promote understanding about managing the injections and the implications of this additional treatment or through conversations to help resolve individual worries. However, these results indicate depression moderates the relationship between distress and mastery, accordingly it is not enough to simply target distress; if the individual also presents with depression then this must

also be treated before mastery improves. As treating depression falls beyond the current remit

of the diabetes clinicians and educators, a multi-disciplinary approach may be merited.

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None

Declaration of Interest Statement

No potential conflicts of interest were reported by the authors.

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Table 1. Model summary: path coefficients for estimated model using PROCESS

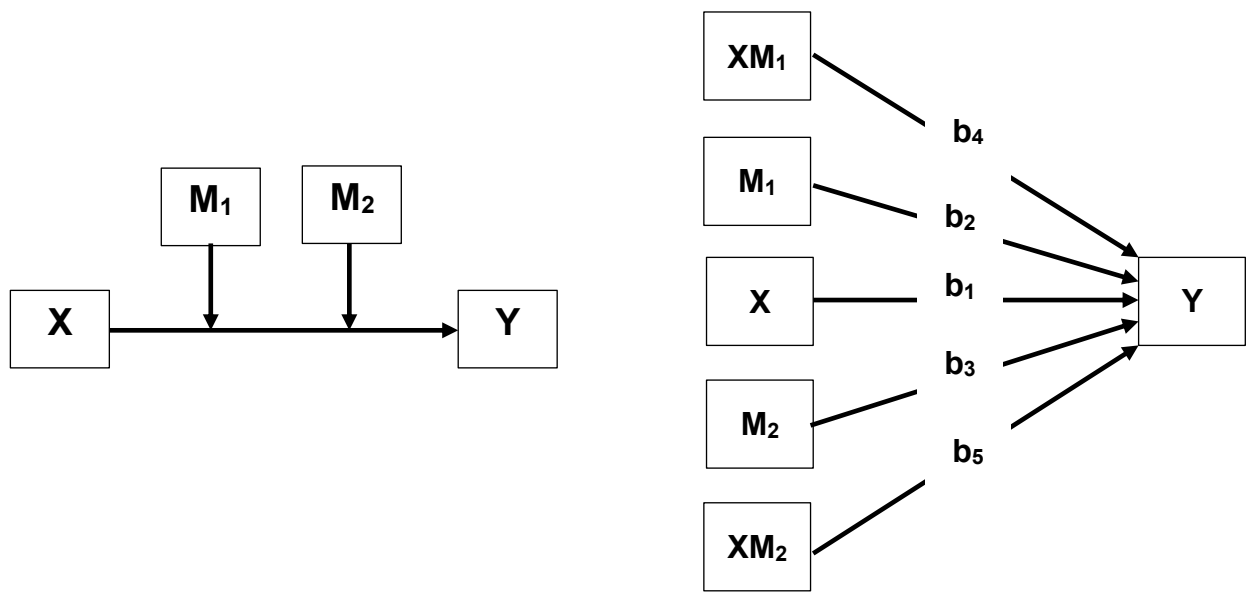|	Coefficient (std error)	T	P	LLCI;ULCI
Constant	30.213 (1.53)	19.71	p=.000	27.18;33.25
Diabetes specific distress (X)	-.249 (.07)	-3.71	p<.001	-.38;-.12
Diabetes empowerment (M_1)	.280 (.09)	3.02	p<.001	.10;.46
Diabetes specific distress x Diabetes empowerment (X M_1)	.003 (.004)	.68	p=.500	-.00;.01
Depression (M_2)	-.980 (.17)	-5.73	p<.001	-1.32;-.64
Diabetes specific distress x Depression (XM_2)	.024 (.01)	3.79	p<.001	.01;.04

Figure 1. **Conceptual and statistical diagram of proposed moderation model (Hayes, 2013)**
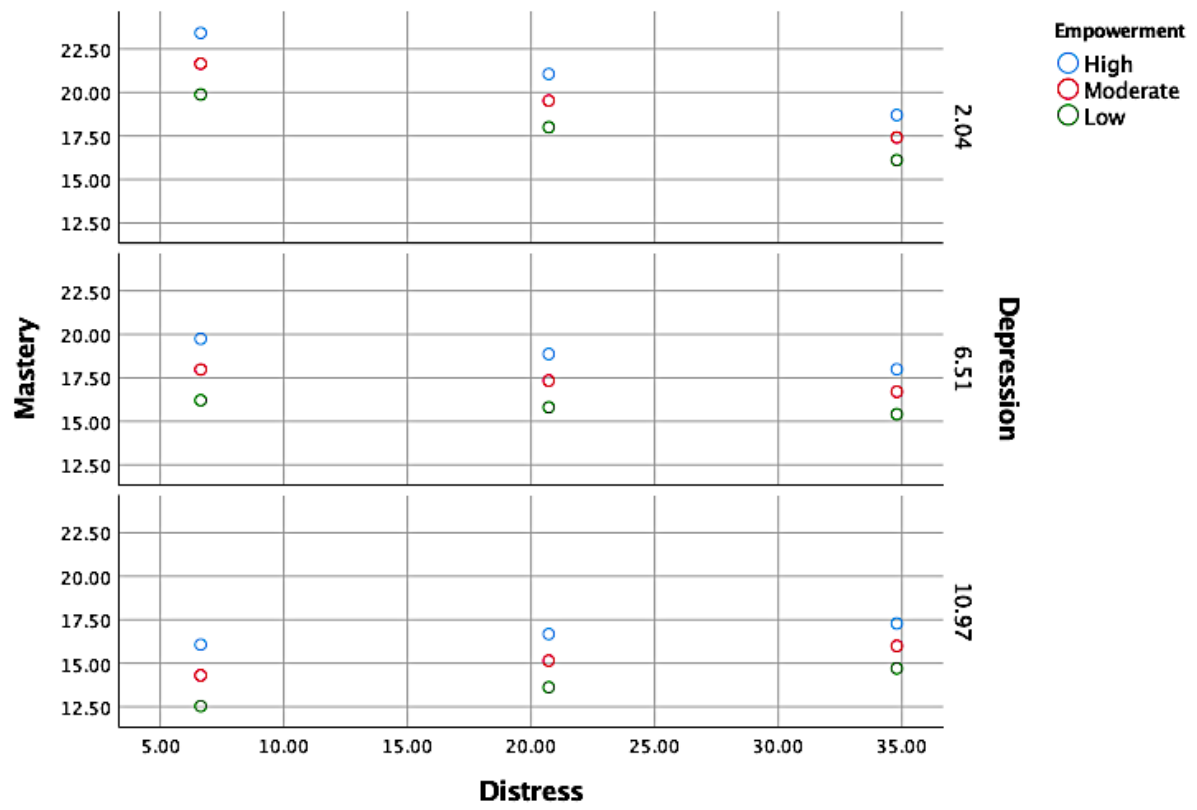
Figure 2. Relationship between diabetes distress and mastery at different levels of the moderators