The Impact of Emotional Regulation on Treatment Burden

in the Primary Care Population

Sigma Grant Recipient Report

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ABSTRACT

Background: For the 60% of the US population living with one or more chronic conditions, understanding how emotional regulation contributes to treatment burden is an unstudied, yet potentially important dynamic affecting self-management adherence.

Objectives: To examine the relationship between emotional regulation and treatment burden within the primary care population diagnosed with one or more chronic conditions.

Methods: We used a descriptive, cross-sectional, cohort study design to collect data from 149 men and women diagnosed with one or more Center for Medicare and Medicaid defined chronic conditions. Participants were enrolled from a single primary care clinic affiliated with a tertiary hospital system within an urban setting in a large Midwestern city in the United States with data collected from September 2019 through December 2019. We used correlation and multivariate analyses to examine the association/influence of emotional dysregulation, measured using the Dysfunction in Emotional Regulation Scale-16, on treatment burden, measured using the Treatment Burden Questionnaire-15, controlling for known co-variates of treatment burden (age,

the number of chronic conditions, the diagnosis of diabetes, and self-efficacy) as well as variable potentially affecting an individual's capacity to effectively self-manage (income, employment, and number of children living at home).

Findings: Based on our correlation analyses, patients experience higher emotional dysregulation and associated treatment burden when interfacing with the healthcare system, performing self-management tasks, within their social relationships, and in relation to the burden of constantly needing care due to their conditions as compared to medication, exercise, and dietary related burden. Our multivariate analyses demonstrate emotional regulation is an independent factor contributing to cumulative, medication, and dietary treatment burden, with model effect sizes ranging from large (.43) to moderate (.21), when controlling for other known antecedent factors, but was not a factor influencing exercise burden.

Discussion: Our findings indicate emotional regulation appears to be an important factor in determining the level of cumulative, medication and dietary treatment burden a patient experiences when engaging in their daily self-management regimen. Most importantly, findings demonstrate that improving emotional regulation can reduce the amount of burden a patient experiences thereby improving subsequent adherence to a self-management regimen.

Keywords: Self-Management Adherence, Emotional Regulation, Treatment Burden, Primary Care, Chronic Conditions

INTRODUCTION

For the 60% of the US population diagnosed with at least one chronic condition, adherence to prescribed medication, exercise, and dietary self-management regimens are essential in maintaining optimal health (CDC, 2019). Adherence to this self-management regimen is a complex process in which individuals must balance their self-management needs with other important life demands (e.g. work, family) (Shippee et al., 2012; Sav et al., 2017). The capacity to meet these health related needs and other life demands is determined by personal, social, and clinical factors (Shippee et al., 2012; Sav et al., 2017). Those individuals who lack the capacity to optimally self-management their chronic conditions within the context of their other life demands are at higher risk for experiencing treatment burden. Treatment burden, or the burden associated with adhering to a specific self-management regimen and its subsequent impact on the individual's health and well-being, is a contributing factor to sub-optimal adherence (Tran et al., 2012; Sav et al, 2017; Schreiner et al., 2019; Schreiner et al., 2020blinded for peer review). A personal factor that is potentially associated with treatment burden and subsequent sub-optimal adherence is emotional regulation, or the ability to adapt one's emotional response to various stimuli, though this concept has gone unstudied in the chronic condition population. The purpose of our study was to examine the relationship between emotional regulation and treatment burden.

Emotional regulation is an adaptive psychological, neurocognitive driven process in which individuals modify their emotional responses to best contend with contextual stimuli (Aldo, 2013; Barrerios et al., 2019). Poor adaptive responses to a specific stimulus, known as emotional dysregulation, can reduce one's ability to effectively self-manage chronic conditions (Wierenga, Lehto, & Given, 2017; Appleton et al., 2013). For instance, if an individual

experiences emotional dysregulation due to waiting an additional hour at a provider's office for his/her appointment, this can increase the experience of treatment burden, subsequently affecting future appointment adherence. Additionally, this dysregulation may impact future self-management adherence decision making. After leaving the provider's office, this individual might need to eat a meal or still may need to participate in daily exercise, but due to emotional dysregulation might choose a "more convenient" unhealthy option for a meal or might choose to skip exercise that day. Supporting this example, research indicates individuals with better "adaptive" emotional regulation (e.g. individuals who can better assess internal and external cues in order to make logically informed decision) have better adherence to diet (Micanti et al., 2017) and medication (Huerta et al., 2016) regimens.

Building on the Cumulative Complexity Theory (Shippee et al., 2012) we hypothesize that individuals diagnosed with one or more chronic conditions who exhibit greater emotional dysregulation will experience higher levels of treatment burden. Treatment burden, or the burden associated with adhering to a specific self-management regimen, is an antecedent factor predictive of lower medication, exercise, and dietary self-management adherence (Schreiner et al., 2019; Schreiner et al., 2020blinded for per review; blinded for per review) and lower quality of life (Eton et al., 2017) in persons diagnosed with chronic conditions. We posit emotional regulation influences treatment burden via two different pathways. First, a stimulus not related to a self-management task (e.g. having a stressful day at work) elicits a maladaptive emotional response. Due to the maladaptive emotional response to this stimulus, the act of adhering to future tasks of a self-management routine (e.g. eating healthy, exercising, remembering to take medications) can become increasingly burdensome. Secondly, a self-management task itself (e.g. giving oneself an injection) can be the negative stimulus that elicits a maladaptive emotional

response, thus causing the individual to perceive the task as burdensome or difficult, thereby increasing potential sub-optimal adherence. In both examples, the process of emotional regulation is antecedent to treatment burden.

Findings of this study will have important scientific and nursing-related clinical implications. First, findings will illustrate how stressful or emotionally charged situations can contribute to treatment burden within the context of chronic condition self-management. Secondly, they will inform clinicians, including nurses, how incorporating known emotional regulation interventions/training into self-management education (e.g. self-awareness of emotionally distressing events, employment of techniques known to improve emotional regulation such as deep breathing or daily meditation) has the potential to decrease cumulative and/or task-specific treatment burden.

PURPOSE

The purpose of our study was to test the relationships between emotional regulation and treatment burden. Our specific hypotheses were:

H1: emotional dysregulation and treatment burden will be positively associated,

H2: emotional dysregulation will significantly explain a portion of treatment burden's variance in a multivariate model controlling for known antecedent factors of treatment burden (age, total number of chronic conditions, diagnosis of diabetes, and self-efficacy) and factors potentially contributing to burden (income, employment, and the number of children living at home).

MATERIALS AND METHODS

Design

We used a descriptive, cross-sectional, cohort study design in order to test our study hypotheses.

Ethical Considerations

We received IRB approval from the participating hospital IRB (UHCMC 2019069) prior to contacting, screening and enrollment of participants.

Participants

We enrolled and collected data from 149 men and women diagnosed with at least one chronic condition. We selected potential study participants from a primary care clinic-provided list of patients who had clinic appointment scheduled in the following month. Eligibility criteria for participants were: (1) ≥ 18 years of age, (2) diagnosis of one or more Center for Medicare and Medicaid (2019) defined chronic conditions, (3) understood written or spoken English.

We conducted a sensitivity analysis in G Power 3.1 (Erdfelder et al. 2009) based on our sample size of 149 with statistical parameters of $\alpha = .05$, $\beta = .80$, enabling us to detect statistical significance in a multivariate regression model consisting of 8 independent variables at a small effect size of .11.

Setting

We recruited our sample from a single primary care clinic affiliated with a tertiary hospital center located in an urban academic setting located in a large Midwestern city with a metropolitan population of approximately 2 million people (Census profile: Cleveland-Elyria, OH Metro Area, 2018blinded for peer review). The city's demographic is representative of other large Midwestern cities found within the United States.

Data Collection

We used convenient sampling to select potential participants for enrollment into the study. We collected participant data beginning September 2019 through December 2019. We first contacted potential participants via mail two weeks prior to their scheduled clinic visit using

a scripted, IRB approved letter briefly explaining why they were selected for the study, study details, and that they would be contacted by phone by study staff in approximately a week. We then contacted these patients approximately one week later, explained the study, answered any study related questions, and asked if they would like to participate. If participants verbally agreed to participate via phone, study staff would meet the participant at a scheduled time 1 hour before their clinic visit. We experienced a refusal rate of approximately 40% of patients who we contacted. Potential participants stated not being interested or not having enough time as the main reasons for refusal to participate.

During the study visit, after obtaining written consent, we collected all data in-person at the clinic in a private room. Participants took approximately 25 minutes to complete the self-report study survey and received $20 for their participation. Research staff transcribed all data from paper surveys into an electronic REDCap database of the participating health system.

Measures

Emotional Dysregulation. We measured emotional dysregulation using a psychometrically validated, self-report survey, The Difficulties in Emotional Regulation Scale-16 (DERS-16) (Bjureburg et al., 2016). This scale is comprised of 16 self-report questions with participant responses ranging from 1 (almost never) to 5 (almost always) measuring 5 domains of emotional dysregulation. For example, Item 4 of the DERS-16 measures participant difficulties controlling impulsive behaviors when distressed by asking: "When I am upset, I become out of control". Higher scores indicate greater emotional dysregulation. This scale demonstrates high internal reliability (α= .92), test-retest reliability (Pearson's r= .85; p < .0001) and strong construct validity (Bjureburg et al., 2016). We calculated a Cronbach's alpha of .92 for this instrument within this study sample. The DERS-16 has been used in previous studies examining the

influence of emotional dysregulation in chronic condition populations (Wierenga, 2017, Tull et al. 2018). Total item scores were summed and used for our planned analyses.

Treatment Burden. We selected the Treatment Burden Questionnaire-15 (TBQ-15) to measure treatment burden among our sample participants. It measures multiple domains of treatment burden, including burden related to prescribed medication regimens, self-management tasks, the interface with healthcare system, finance, as well as meeting the requirements of exercise and a healthy diet. The TBQ-15 is a widely used measure of treatment burden displaying strong psychometric properties including good internal reliability (Cronbach's Alpha= .80) in a previous study within chronic condition samples (Sav et al., 2016,- Schreiner et al., 2018; Schreiner et al., 2020blinded for per review, blinded for peer review). This measure consists of 15 items with scores for each item ranging for 0 (no burden) to 10 (high burden) with all items summed for a total treatment burden score ranging from 0 to 150. Within this scale, we made adjustments to the dietary burden item, removing the language about reducing smoking and alcohol intake, increasing the accuracy of measuring burden associated with eating a healthy diet. Internal reliability (Cronbach's Alpha= .90) between items remained very strong following the adaptation of the question. We used four variations of treatment burden items as our dependent outcome variables in our regression models: a summed total of all treatment burden items, a summed score of medication related treatment burden items (items 1-4), exercise specific treatment burden, and dietary specific treatment burden.

Covariates

We controlled for known antecedent factors of treatment burden in our multivariate regression analyses: age, the diagnosis of diabetes, the total number of Center for Medicare and Medicaid defined chronic conditions, and self-efficacy. Those individuals younger in age

experience higher levels of treatment burden potentially due to increased life responsibilities competing with the need for self-management and/or the lack of adapting to a newly diagnosed condition (Sav et al., 2016). Age was self-reported and doubled checked via patient electronic medical record (EMR).

The number of total chronic conditions and the specific diagnosis of diabetes are antecedent factors contributing to higher levels of treatment burden related to an increased number of self-management activities (e.g. polypharmacy, increased self-monitoring tasks) (Tran et al., 2012; Sav et al., 2016; Schreiner et al., 2018; Schreiner et al., 2019; Schreiner et al., 2020blinded for peer review; blinded for peer review, blinded for peer review). Total chronic condition diagnoses, as defined by the Centers for Medicare and Medicaid (CMS, 2019), and the diagnosis of diabetes (Type I and II) were abstracted from the clinics EMR.

We measured self-efficacy using the Partners-In-Health Scale, a psychometrically tested scale specifically developed measuring a patient's ability to self-manage his/her chronic conditions. This scale consists of 11 items with individual item scores ranging from 0 (poor self-management) to 8 (excellent self-management), demonstrating good internal consistency with a Cronbach's Alpha= .82 (Battersby et al., 2003). We calculated a Cronbach's Alpha= .92 for the Partners-In-Health scale within our sample.

In addition to those known predictors treatment burden, we also controlled for the impact of other personal factors (e.g. income, employment, # of children living in the household) which could impact the level of treatment burden. Those individuals with lower income might have fewer resources to self-manage their conditions (Koch, Wakefield & Wakefield, 2015) thereby increasing treatment burden (Tran et al., 2014). Additionally, the responsibilities of work and taking care of dependent children could reduce the capacity for self-management adherence

(Shippee et al, 2012). We dichotomized income status into two groups for our planned multivariate analyses: those at or below the poverty level vs. those above the poverty level. We also dichotomized employment into two groups: those who were working (part and full time) vs. those who were not working (unemployed and retired).

Analysis

All analyses were conducted using SPSS, Version 27. We examined univariate statistics for all variables assessing for normality, potential outliers, and miscodes. We conducted correlation analyses using Pearson's Product-Moment Correlation after testing to ensure our variables met correlational assumptions. Prior to multivariate regression testing, we ensured variables met primary and secondary assumptions of regression while also testing for multicolinearity. We also examined correlations between all variables prior to conducting our multivariate regression analyses. *A priori* statistical significance for all tests was set at α= .05, though we adjusted for multiple comparisons using a Bonferroni method for both correlational analyses.

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RESULTS

~~**Findings**~~

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Sample Demographic Characteristics

Sample demographics are presented in Table 1. Our sample was predominantly over the age of 50, female, and Black. The majority of our sample was high school educated, had an income of $25,000 or less, unemployed or retired, and did not have children living in the home. Participants averaged 3.06 (SD= 1.09) chronic conditions and 71 participants (47.7%) were diagnosed with diabetes.

Correlation Analyses between DERS-16 and Individual Treatment Burden Items

Based on our correlation analyses, we found emotional dysregulation correlated with many TBQ-15 items (Table 2) supporting our first hypothesis. Bonferroni method adjustment for multiple comparisons set statistical significance at $\alpha= .003$ for these analyses. Our analyses demonstrated small to moderate correlations between the DERS-16 and medication ($r= .19$; $p< .01$ to $.39$; $p < .001$), exercise ($r= .29$; $p< .001$), and dietary ($r= .38$; $p< .001$) burden. Larger correlations were found between the DERS-16 and test related burden ($r= .47$; $p< .001$), provider visit related burden ($r= .49$), burden affecting social relationships ($r= .48$; $p< .001$), the burden of self-management tasks ($r= .43$; $p< .001$), and global impact of burden ($r= .51$; $p <.001$). An unexpected finding is that emotional dysregulation has no association with financial burden ($r= .17$; $p <.05$).

Correlational Analyses between Multivariate Regression Variables

We examined correlation between all model variables (Table 3) prior to conducting multivariate analyses. Bonferroni method adjustment for multiple comparisons set statistical significance at $\alpha= .006$ for these analyses. Our analyses revealed a significant, moderately strong correlation between emotional dysregulation and total treatment burden ($r= .51$; $p< .001$), and significant, moderate correlations between emotional dysregulation and self-efficacy ($r= -.39$; p, $.001$), diet burden ($r= .38$; $p< .001$), and medication burden ($r= .33$; $p< .001$). Smaller, significant correlations were observed between emotional dysregulation and exercise burden ($r= .29$; $p< .001$). There were not significant correlations between emotional dysregulation and other sample demographic characteristics.

Multivariate Regression Models

Findings associated with our multivariate regression analyses found emotional dysregulation is explanatory of cumulative treatment burden, as well as medication and diet specific treatment burden, supporting our second hypothesis. Our first multivariate model explained 30% of total treatment burden's variance [$F_{(8, 140)}= 8.93$, $p< .001$], with emotional dysregulation (standardized beta coefficient$= .4$, $p < .001$) and total number of chronic conditions (standardized beta coefficient$= .17$, $p =.05$) as significant variables in the model. Our second multivariate model explained 18% of medication burden's variance [$F_{(8, 140)} = 5.16$, $p < .001$], with the diagnosis of diabetes (standardized beta coefficient$= .2$, $p = .02$) and emotional dysregulation (standardized beta coefficient$= .23$, $p = .007$) as significant variables in the model. Our third multivariate model explained 17% of diet burden's variance [$F_{(8, 140)} = 4.83$, $p < .001$), with emotional dysregulation (standardized beta coefficient$= .28$, $p = .002$) as the only significant variable in the model. Our fourth multivariate model explained 20% of exercise burden's variance [$F_{(8, 140)}= 5.58$, $p < .001$], with the total number of chronic conditions (standardized beta coefficient$= .28$, $p = .002$) as the only significant variable in the model.

DISCUSSION

Due to the known impact of sub-optimal adherence on health-related outcomes and their associated economic costs, researchers and healthcare practitioners need a more complete understanding of the complex, dynamic self-management paradigm. Our findings add significant understanding to the science of self-management as well as suggesting practical implications applicable to the clinical setting. The testing of our hypotheses demonstrated that (1) emotional dysregulation was positively associated with treatment burden and (2) emotional dysregulation is a significant explanatory factor of treatment burden controlling for other antecedent factors.

Examining how emotional regulation is associated with each individual treatment burden item increases scientific understanding of which self-management tasks are most impacted by emotional regulation. Based on our findings, patients experience higher emotional dysregulation and associated treatment burden when interfacing with the healthcare system (e.g. lab testing, scheduling/waiting at provider appointments), performing self-management tasks (e.g. monitoring blood sugars), within their social relationships (e.g. feeling like a burden to others), and the burden of constantly needing care due to their conditions as compared to specific medication, exercise, and dietary related burden. These associations suggest that patients are at risk for lower adherence from the burden of attending provider appointments (Distelhorst et al., 2018; Horstman et al., 2010; Schectman, Schorling, & Voss, 2009), poor self-monitoring (Henderson et al., 2014; Crowe et al., 2017; Tucker et al., 2017), and strained social relationships (Meek et al., 2018; Gallant, 2003), all of which can lead to worsening health outcomes. Indirectly, these associations could contribute to a feeling of greater cumulative burden further decreasing the effectiveness of patient self-management on a day-to-day basis.

When these findings are applied within the clinical setting, improving/streamlining delivery of care within a health system, findings ways to help patients improve daily self-management tasks/monitoring, and helping patients maintain some independence or providing additional care-oriented and/or social support, can decrease emotional dysregulation in relation to these specific areas. By decreasing emotional dysregulation, the burden associated with these areas of self-management, as well as the impact of cumulative burden, is potentially reduced, thereby subsequently improving adherence.

Our multivariate analyses demonstrates emotional regulation is an independent factor contributing to cumulative, medication, and dietary treatment burden when controlling for other

known antecedent factors. Contrary to previous findings, self-efficacy (Eton et al., 2019), age and diagnosis of diabetes (Sav et al., 2016) were not explanatory factors contributing to cumulative treatment burden in the presence of emotional regulation, and the number of chronic conditions was not a significant factor associated with medication and dietary burden (Schreiner et al., 2019; Schreiner et al., 2020blinded for peer review; blinded for peer review). This finding signifies the importance of this unique psychological process in determining successful self-management among those diagnosed with one or more chronic conditions. It also provides support for use of potential mindfulness interventions that have been shown to improve emotional regulation (e.g. situation selection, situation modification, attentional deployment, cognitive change, and response modulation) in order reduce cumulative, medication, and dietary burden and improve adherence (Quoidbach, Mikolajczak, & Gross 2015; Cameron & Lago, 2008; Farb et al., 2014). Identifying potential interventions reducing treatment burden presents a promising, unexplored pathway aimed at improving self-management adherence.. Further research is needed combining the measurement of emotional regulation in conjunction with tests of executive functioning to determine the extent of the influence of neurocognitive functioning within the context of treatment burden and self-management adherence.

From a clinical prospective, being cognizant of patient traits that may predispose them to emotional dysregulation or using the DERS-16 a tool to screen patients at higher risk for treatment burden and potential sub-optimal adherence can improve the effectiveness of care for this population. Interventions exploring the education and training of clinicians to use the DERS-16 as a screening tool and/or recognizing traits of emotional dysregulation to identify at risk patients are additional areas of future research.

Our study was not without limitations. Our sample demographic was homogenous in many aspects including gender, race, education, and income, decreasing the generalizability of our results to the chronic condition population as a whole as well as our ability to detect the influence of these variable within our proposed statistical models. Our sample size was relatively small, though adequately powered, demonstrating moderate (.21) to large (.43) multiple regression effect sizes (Cohen, 1988). Conducting this study within a larger, heterogeneous sample representing different geographic areas (e.g. urban, suburban, rural) would improve the strength and generalizability of findings. Additionally, a more complex model using hierarchical multivariate regression models with measures of medication, exercise, and dietary adherence as dependent outcomes would represent a more comprehensive examination of self-management adherence. Controlling for both emotional regulation and treatment burden within a comprehensive model would also allow for the testing of treatment burden as a mediating factor within this paradigm. Lastly, while all participants had decision capacity, we acknowledge other sub-clinical diagnoses (e.g. anxiety) or executive dysfunction could confound the influence of emotional dysregulation on treatment burden. Future studies examining the influence of emotional dysregulation on treatment burden should control for these potential confounding variables.

CONCLUSION

Our study findings filled important gaps in previously unexplored self-management literature, and suggested relevant clinical applications aimed at improving adherence. Multiple avenues of future research have been identified by providing preliminary evidence for subsequent studies examining the influence of psychological processing within the paradigm of self-management adherence. Our findings suggest that emotional regulation appears to be an

important factor in determining the level of cumulative, medication and dietary treatment burden

a patient experiences when engaging in their daily self-management regimen. Most importantly,

findings demonstrate that improving emotional regulation can reduce the amount of burden a

patient experiences.

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