HHS Public Access

Author manuscript

J Psychosom Res. Author manuscript; available in PMC 2020 November 01.

Published in final edited form as:

J Psychosom Res. 2019 November ; 126: 109821. doi:10.1016/j.jpsychores.2019.109821.

Effects of a comprehensive self-management intervention on extraintestinal symptoms among patients with IBS

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Abstract

Objective: Adults with irritable bowel syndrome (IBS) often report extraintestinal pain, fatigue, and sleep disturbances in addition to abdominal pain. Few interventions have sought to reduce these extraintestinal symptoms within the IBS population. To address this, we compared the effects of a comprehensive self-management (CSM) intervention to a control intervention (usual care) on extraintestinal pain, fatigue, and sleep disturbances among patients with IBS.

Method: Data were obtained from 243 IBS patients participating in two CSM intervention trials. Daily symptom diaries were collected at baseline, 3 and 6 months post-randomization. Daily

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Declarations of interest: none

symptoms of headache, backache, muscle pain, joint pain, fatigue, sleepiness during the day, sleep quality, and refreshed by sleep were analyzed. Linear regression models were used to determine the effects of the intervention on each symptom at 3 and 6 months controlling for study and baseline symptom levels.

Results: Patients in the CSM intervention group reported decreased symptoms of fatigue, sleep disturbances, backache and headache compared to usual care at 3 and 6 months. The CSM group also reported significantly decreased joint pain at 3 months compared to usual care, but not 6 months. No significant difference was found for muscle pain.

Conclusions: An existing CSM intervention is effective in reducing fatigue and sleep disturbances. However, mixed results for extraintestinal pain indicates a need to better differentiate between underlying mechanisms. Addressing such symptoms is important to decrease the overall burden of IBS, reduce health care expenditures, and improve patients' quality of life.

Trial Registration: ;

Keywords

irritable bowel syndrome; self-management; pain; fatigue; sleep

Introduction

Irritable bowel syndrome (IBS) is a gastrointestinal (GI) disorder that affects 10-20% of adults in the United States [1] and globally [2], and is characterized by abdominal pain and alterations in bowel habit function: diarrhea, constipation, or both. Patients with IBS have a significant use of healthcare resources, and account for nearly 40% of primary care and gastroenterology visits [3]. The pathophysiology of IBS is complex and not fully understood, although proposed mechanisms include dysregulation of the gut-brain axis [4]. IBS often co-occurs with extraintestinal symptoms such as pain, fatigue, and self-reported sleep disturbances [5]. Such co-existing symptoms may contribute to the overall burden of IBS, leading to a decrease in work productivity and an increase in activity impairment [6-9].

In addition to abdominal pain, IBS patients report extraintestinal pain including headache, backache, muscle pain, and joint pain [10, 11]. For some patients, their IBS is part of a chronic overlapping pain condition [12]. When multiple pain-related comorbid symptoms are present, there is an even greater reduction in quality of life, increase in life interference, and increase in health care expenses for those with IBS [7].

Adults with IBS also report greater symptoms of fatigue and sleep disturbances compared with the general population [13]. A meta-analysis of the prevalence of fatigue in patients with IBS identified a pooled rate of 54.2% [14]. The prevalence of sleep disturbances in patients with IBS has been reported as 37.6% [15]. Fatigue and sleep disturbances have been associated with increased GI symptoms, reduced quality of life, and increased healthcare costs in patients with IBS [7, 16]. Therefore, it is important to address symptoms of fatigue and sleep disturbances within the IBS patient population.

Although many interventions (e.g., low Fermentable Oligo-, Di-, Mono-saccharides And Polyols [FODMAP] diets, hypnosis, psychotherapy) exist to reduce GI symptoms among IBS patients [17], few interventions have examined their potential concurrent effects among other commonly reported symptoms associated with IBS. Due to the high prevalence of extraintestinal symptoms, it is important to determine if interventions designed for GI symptom reduction are also effective in reducing extraintestinal symptoms. We previously published the beneficial effects of a Comprehensive Self-Management (CSM) intervention among patients with IBS for GI symptoms (abdominal pain, abdominal distention, bloating, constipation, diarrhea, intestinal gas, and urgency) as well as symptoms of anxiety and depression [18, 19]. The CSM intervention focuses on improving IBS symptom management and covers four broad topics: education, diet, relaxation, and cognitive-behavioral strategies [20]. Recent interest in extraintestinal pain, fatigue, and sleep raised additional questions regarding the effectiveness of the CSM intervention on these outcomes which we have not previously examined [21]. Although the CSM intervention was designed to reduce GI symptoms, many of the self-management strategies such as cognitive restructuring and relaxation strategies may also influence extraintestinal symptoms [22, 23]. Therefore, this secondary data analysis had two aims: 1) to compare the effects of a CSM intervention to a control intervention (usual care) on extraintestinal pain (e.g., headache, backache, muscle pain, and joint pain) in patients with IBS and 2) to compare the effects of a CSM intervention to a control intervention (usual care) on extraintestinal symptoms of fatigue and sleep disturbances in patients with IBS.

Materials and Methods

Study Design and Sample

The patient population and study design of two randomized controlled trials (RCT), upon which this secondary data analysis was performed, have been previously described [18, 20]. This investigation evaluated data from 243 individuals with IBS (RCT-1 = 161; RCT-2 = 82). RCT-1 () occurred from 2003 to 2008 and RCT-2 () occurred from 2009 to 2012. The primary study aims included an IBS symptom score and quality of life. Briefly, individuals met inclusion criteria if they were 18-70 years old, had a history of IBS symptoms for at least 6 months prior to IBS diagnosis by a healthcare provider, experienced symptoms for at least 6 months after diagnosis, and met the Rome research criteria at the time of the study (for study eligibility, Rome-II for RCT-1 and Rome-III for RCT-2 were used; for study measures, Rome-III was used for both studies).

Participants were excluded from study participation if medication use or comorbidities would influence the measurement of symptoms or influence the participants' ability to complete the study. Participants taking the following medications were excluded: antibiotics, corticosteroids, anticholinergics, tricyclic antidepressants, and calcium-channel blockers. Participants were also excluded if they had a history of abdominal surgery (except appendectomy, Caesarian section, tubal ligation, laparoscopic cholecystectomy, hysterectomy, or abdominal wall hernia repair), organic GI disease, diabetes, current mental health disorders, cardiac valve or conduction defects, immune-compromised disorders, or women who were pregnant, breastfeeding, and/or planning to become pregnant in the next

year. Human subjects' institutional review board approval was obtained prior to recruiting participants and renewed annually.

Procedures

Both studies used similar recruitment strategies including local community advertisements and direct mailing to IBS patients. Interested individuals were screened over the phone. Those interested in participating completed an informed consent process and then began a 5-week baseline assessment that included an initial in-person interview and a 4-week daily symptom diary. Participants were instructed to complete the daily symptom diary each evening. Participants were randomized into CSM or usual care (UC) group via a customized computer adaptive randomization procedure to ensure groups remained balanced regarding age, sex, predominant stool consistency, and severity of abdominal pain at baseline. Follow-up data collection occurred at 3 and 6 months post-randomization.

Intervention

The study design was a two-armed RCT. Study staff who collected outcome data were blinded to treatment assignment. Briefly, participants in the CSM received 8 individual sessions with an advanced practice psychiatric nurse practitioner, and could elect to complete the intervention in-person, over the telephone, or a mixture of telephone and in-person sessions. Sessions were based on an "IBS Managing Symptom Workbook" [24]. The CSM intervention includes: education (i.e., introduction to IBS, healthy sleep behaviors), diet (i.e., size and frequency of meals, trigger foods), relaxation (i.e., abdominal breathing, active/passive progressive muscle relaxation, and visualization), and cognitive behavioral-strategies (i.e., healthy thought patterns, problem solving, and identifying and changing/challenging false beliefs). Participants had worksheets and homework assignments each week. The session's also included practical discussions on applying the strategies to managing IBS pain control, traveling, and eating out. Participants in the UC group were notified to continue the treatment recommended by their healthcare provider. At the end of the study, participants in the UC group were provided with intervention materials [18, 20].

Measures

Participant Characteristics.—Age, gender, race, marital status, education, and IBS predominant bowel pattern based on Rome III definition were obtained.

Daily Diary Measures.—Participants completed a daily symptom diary for four weeks. Participants responded to twenty-six symptoms on a scale of not present (0) to very severe (4). The scores for individual symptoms were summarized as the percent of days rated as 'moderate' to 'very severe'. Symptoms analyzed for this report include extraintestinal pain (e.g., headache, backache, muscle pain, and joint pain), fatigue, and sleepiness during the day.

In addition, participants reported the overall quality of sleep as 'poor', 'fair', 'good', 'very good', or 'excellent' and responded to the statement "*I felt refreshed by last night's sleep*" as 'not at all refreshed', 'somewhat', 'moderately', or 'very refreshed'. For these two sleep variables, the percent of days participants reported poor or fair (diminished sleep quality) or

not at all or somewhat refreshed (unrefreshed sleep) is reported; a higher number indicates worse sleep.

Statistical Analysis

The data were analyzed using SPSS for Window version 19 (SPSS, Inc. Chicago, IL). Analysis was completed among participants who had follow up on at least one of the time points (3 or 6 months). Descriptive statistics were calculated using counts and percentages for categorical variables and means and standard deviations for continuous variables.

Since the original intervention was aimed at reducing IBS symptoms, the inclusion criteria included presence of more than minimal IBS symptoms at baseline. Analogously, the analysis of each extraintestinal symptom will include only individuals with whom that symptom is present at baseline. For example, participants were included in the analysis of fatigue if they reported moderate to severe fatigue for at least 10% of the days during daily diary assessment at baseline. For quality of sleep, participants reporting ‘poor’ or ‘fair’ quality of sleep for at least 10% of days at baseline were included in the analysis. For the item refreshed by sleep, participants reporting ‘not at all refreshed’ and ‘somewhat refreshed’ for at least 10% of days were included in the analysis.

Due to the distribution of the data, symptom variables were square root transformed for analysis. Analysis of covariance was used to determine the effects of the intervention on each symptom at 3 and 6 months, controlling for baseline levels of symptoms and ‘study’ in which subjects participated (RCT 1 vs. 2). Signed effect sizes (Cohen’s Effect Size d) were reported with the p-values to enhance interpretability. We also conducted a sensitivity analysis to determine whether controlling for age influenced the conclusions.

Results

Participant Demographics

Participants with IBS had a mean age of 43.1 years (SD=14.7). The sample was 88% female and 83% white. Participants reported a predominant IBS bowel pattern of diarrhea (n=105, 43.2%), mixed (n=74, 30.5%), and constipation (n=43, 17.7%). See Table 1 for additional demographic information.

Baseline Extraintestinal Symptoms

Participants reported ‘moderate’ to ‘very severe’ fatigue (81%, n=197), sleepiness during the day (67%, n=162), backache (41%, n=100), muscle pain (41%, n=100), headache (40%, n=97), and joint pain (37%, n=86) on at least 10% of days (see Table 2). Ninety-one percent reported waking up not at all refreshed or somewhat refreshed on and eighty-nine percent of participants reported poor or fair sleep quality at least 10% of days. The symptoms with the greatest severity were: unrefreshed sleep (M=48.7, SD=27.2), diminished sleep quality (M=44.0, SD=26.0), joint pain (M=41.6, SD= 27.2) and fatigue (M=41.5, SD=26.1). Baseline symptom severity did not differ based on IBS subtypes (see Table, Supplemental Digital Content, symptom severity at baseline based on IBS Subtypes: constipation, diarrhea, and mixed).

Extraintestinal Pain

Table 3 reports the mean change scores from baseline to 3 and 6 months for extraintestinal pain (backache, headache, muscle pain, and joint pain), fatigue, and sleep disturbances. A significant difference of backache ($p = .024$ and $p = .019$, respectively) and headache ($p = .055$ and $p = .039$, respectively) scores existed between CSM and UC at 3 and 6 months, although muscle pain scores ($p = .45$ and $p = .85$, respectively) did not. Participants in the CSM group experienced a significant reduction in joint pain at 3 months ($p = .029$) but not 6 months ($p = .92$). Controlling for age did not substantially change the conclusions (results not shown).

Fatigue and Sleep

At 3 and 6 months post-randomization, participants in the CSM experienced a statistically significant decrease in both fatigue ($p < .001$ and $p = .01$, respectively) and sleepiness during the day ($p < .001$ and $p = .016$, respectively) compared to UC. Participants in the CSM group had improved sleep quality compared to UC at 3 months ($p = .039$) and 6 months ($p = .011$). Finally, participants in the CSM group reported an increase in refreshed sleep at 3 months ($p = .009$); the relationship had marginal significance at 6 months ($p = .058$). Controlling for age did not substantially change the conclusions (results not shown).

Discussion

This study examined the effects of an advanced practice nurse-delivered comprehensive self-management intervention, designed for GI symptoms, on participant daily self-reports of extraintestinal pain (headache, backache, muscle pain, and joint pain), fatigue, and sleep disturbances. In comparison to UC, the CSM intervention was efficacious in reducing fatigue and sleep disturbances up to 6 months, although mixed results were noted for extraintestinal pain symptoms.

Our CSM intervention, designed for IBS GI symptoms, focused on relaxation techniques, diet, and cognitive restructuring about IBS. While strategies learned in the CSM intervention can be transferred to other symptoms, it may be that extraintestinal pain such as headache, backache, muscle pain, and joint pain have different perpetuating mechanisms than abdominal pain in IBS. Abdominal pain is multifactorial and may be due to visceral hypersensitivity, autonomic nervous system imbalance, bacterial dysbiosis, immune activation, or hypothalamic-pituitary-adrenal axis dysregulation [25, 26]. Our previous work indicates that the CSM intervention had a greater effect on abdominal pain among IBS individuals with greater nighttime vagal modulation and lower sympathovagal balance compared to IBS patients with decreased nighttime vagal modulation and increased sympathovagal balance [18]. Therefore, the efficacy of the CSM intervention in reducing symptoms of abdominal pain, fatigue and sleep but not symptoms of muscle and joint pain may partly be attributed to the relevance of autonomic functioning and vagal tone in symptom manifestation. As the effect of the CSM intervention on extraintestinal pain may also be moderated by various mechanisms, future research could apply biomarkers to investigate the underlying mechanisms among abdominal pain and extraintestinal pain.

Controlling for age did not influence the effectiveness of the intervention on extraintestinal pain, fatigue, and sleep. Therefore, identifying mechanisms that differentiate abdominal from extraintestinal pain in IBS, may be key to developing efficacious interventions for the reduction of extraintestinal pain. Future trials focusing on pain management may incorporate the biopsychosocial model, which involves the use of cognitive, affective, and interpersonal factors in addition to underlying biology to guide treatment [27]. This analysis also examined the direct effect of the CSM intervention on symptoms of fatigue and self-reported sleep quality, finding a significant improvement in both fatigue and sleep among the intervention group compared to control. However, indirect effects may also occur such that reductions in fatigue and sleep disturbances may also lead to decreased IBS symptoms [16, 28]. For instance, vital exhaustion (i.e., excessive fatigue) has been associated with the symptoms of heartburn [29] and, therefore, may also be associated with other GI symptoms.

Although the intervention was disease-specific, the results seem to suggest the intervention had elements of a transdiagnostic framework in which reductions occurred not only in GI symptoms but also among symptoms of fatigue, sleep, headache, and backache [30, 31]. The magnitude of the CSM intervention effect on extraintestinal symptoms (Effect size = 0.39 - 0.67 was nearly as large as the effect on IBS symptoms (Effect size = 0.47 – 0.91) [18, 20]. The transdiagnostic approach, although typically examined in the context of comorbid anxiety and depression [32 - 34], may have applications to multiple pain-related symptoms and fatigue. For instance, our previous research identified that 12 months after beginning the CSM program, the most commonly used intervention strategies included: relaxation, diet recommendations, and identifying thought distortions [35]. Such self-management strategies may have relevance for patients with other functional pain and sleep disorders. In summary, the CSM intervention, although designed for IBS symptoms, provided individuals with self-management skills that may be transferable to other co-occurring symptoms.

This study has several limitations, including the analysis of pooled data from two randomized controlled studies. Eligibility criteria for enrollment included mild to severe abdominal pain or discomfort at least two days per week during the baseline assessment, however, participants in study 1 were screened using Rome II criteria whereas study 2 participants were screened using Rome III criteria. Although we controlled for study number in the analysis, other differences may exist between study participants in these two cohorts. A second limitation is the homogeneity of participants that were included in the overall study analysis. The beneficial effects noted from the CSM intervention on fatigue, sleep and extraintestinal pain, may not be extended to more diverse populations in terms of sex, ethnicity, level of education, or other subtypes of IBS. Extraintestinal symptoms were measured using a unidimensional daily symptom diary items; future work incorporating validated multidimensional extraintestinal symptoms is needed. Since symptoms of fatigue and sleep disturbances were more common, we may have experienced a greater ability to detect change than among extraintestinal pain symptoms. Furthermore, study criteria excluded persons with a mental health disorder; therefore, findings from this investigation may not be extrapolated to patients with IBS with such comorbid conditions.

In conclusion, an established nurse-delivered CSM intervention designed for reducing IBS GI symptoms, also reduced fatigue and sleep disturbances, and had mixed effectiveness on

reducing extraintestinal pain. As previously described, prevalence rates of extraintestinal symptoms in patients with IBS warrants attention, as does the recognition of their relevance to manifestations of IBS [28]. Implementing the CSM to specifically target sleep, fatigue and extraintestinal pain symptoms in addition to GI symptoms, may prove efficacious in diminishing the burden of IBS, reducing health care expenditures, and improving patients' quality of life.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

Conflicts of Interest and Source of Funding: The authors have no conflicts of interest to disclose. The parent studies were supported by the National Institutes of Health, National Institute of Nursing Research (Grant Nos. NR004142 and P30 NR04001). Kendra Kamp was also supported in part by the National Institutes of Health, National Institute of Nursing Research Aging and Informatics Training Program at the University of Washington (Grant No. T32NR014833). Kristen Weaver was supported by the National Institutes of Health, National Institute of Neurological Diseases and Stroke at Johns Hopkins University (Grant No. T32NS070201). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Glossary

IBS	irritable bowel syndrome
CSM	comprehensive self-management
UC	usual care

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Highlights

- Sleep disturbances, joint pain, and fatigue are commonly reported by persons with IBS.
- A nurse-delivered CSM intervention reduces fatigue and sleep disturbances at 6 months.
- Backache and headache symptoms, but not musculoskeletal pain, are reduced by the CSM intervention.

TABLE 1.

Demographics and Bowel Patterns of Individuals with Irritable Bowel Syndrome

	CSM (n=148)	**UC (n=95)**	**Total Sample (n=243)**
	M (SD)	***M (SD)***	***M (SD)***
Age	44.0 (14.4)	41.6 (15.1)	43.1 (14.7)
	n (%)	*n (%)*	*n (%)*
Gender, female	131 (88.5)	83 (87.4)	214 (88.1)
Race, white	126 (85.1)	75 (78.9)	197 (82.8)
Married/partnered	72 (48.6)	39 (41.1)	111 (45.7)
Education, college or greater	105 (70.9)	59 (62.8)	164 (67.8)
Predominant bowel pattern[*]			
IBS-Constipation	29 (19.6)	14 (14.7)	43 (17.7)
IBS-Diarrhea	63 (42.6)	42 (44.2)	105 (43.2)
IBS-Mixed	42 (28.4)	32 (33.7)	74 (30.5)
IBS-Unclassified	14 (9.5)	7 (7.4)	21 (8.6)

[*] Based on Rome III criteria

UC = usual care; CSM = comprehensive self-management

TABLE 2.

Symptom Severity at Baseline among Individuals with Irritable Bowel Syndrome

	Subjects with more than minimal symptoms[a]	Symptom severity[b]
	n (%)	*Mean (SD)*
Extraintestinal Pain		
Backache	100 (41.2)	34.4 (25.4)
Headache	97 (39.9)	27.7 (19.1)
Muscle pain	100 (41.2)	39.9 (26.2)
Joint pain	89 (36.6)	41.6 (27.2)
Fatigue and Sleep Disturbances		
Fatigue	197 (81.0)	41.5 (26.1)
Sleepiness during the day	162 (66.7)	37.2 (24.9)
Diminished sleep quality	216 (88.9)	44.0 (26.0)
Unrefreshed sleep	220 (90.5)	52.0 (25.4)

[a] minimal symptoms indicates that participants reported <10% of days with ‘moderate’ to ‘very severe’ symptom rating (headache, backache, muscle pain, joint pain, fatigue, and sleepiness during the day), ‘poor’ or ‘fair’ sleep quality (diminished sleep quality), or ‘not at all refreshed’ or ‘somewhat refreshed’ sleep (refreshed sleep)

[b] mean symptom score among those with more than minimum symptoms, where symptom score is defined as percent of days with ‘moderate’ to ‘very severe’ symptom severity.

TABLE 3.

Mean Change from Baseline of Extraintestinal Symptoms in UC vs CSM among Individuals with Irritable Bowel Syndrome

	Baseline		3 months				6 months			
	M(SD)	***n***	**M (SD)**	***n***	**E.S. (d)**	***p*-value**[a]	**M (SD)**	***n***	**E.S. (d)**	***p*-value**[a]
Extraintestinal Pain										
Backache[b]										
UC	37.0 (29.1)	38	−4.6 (24.3)	35	−.50	.02	1.32 (22.1)	34	−.54	.02
CSM	32.8 (23.0)	62	−11.1 (24.4)	59			−8.8 (25.6)	54		
Headache[b]										
UC	27.2 (20.4)	35	0.07 (20.1)	30	−.45	.055	−0.7 (21.5)	32	−.48	.04
CSM	28.0 (18.5)	62	−7.1 (20.8)	56			−8.0 (20.2)	54		
Muscle pain[b]										
UC	42.3 (28.9)	39	−8.7 (25.8)	36	−.17	.45	−11.7 (29.5)	35	.04	.85
CSM	38.3 (24.5)	61	−12.3 (28.6)	58			−8.5 (22.5)	55		
Joint pain[b]										
UC	45.8 (28.2)	38	−7.4 (30.2)	36	−.50	.03	−15.1 (30.8)	35	.02	.92
CSM	38.4 (26.4)	51	−13.5 (29.3)	47			−8.0 (32.5)	46		
Fatigue and Sleep Disturbances										
Fatigue[b]										
UC	40.4 (24.8)	77	−4.0 (22.4)	69	−.55	<.001	−4.0 (23.2)	71	−.40	.01
CSM	42.3 (26.9)	120	−15.3 (27.1)	113			−14.6 (25.7)	108		
Sleepiness during the day[b]										
UC	35.5 (22.1)	63	−3.2 (23.5)	57	−.67	<.001	−3.1 (25.5)	60	−.41	.02
CSM	38.2 (26.6)	99	−15.0 (23.8)	91			−14.1 (23.9)	90		
Diminished sleep quality[c]										
UC	43.4 (25.5)	81	−1.9 (18.6)	73	−.32	.04	−1.8 (17.5)	74	−.39	.01
CSM	44.3 (26.5)	135	−6.0 (23.9)	126			−9.3 (21.7)	95		

	Baseline		3 months				6 months			
	M(SD)	***n***	**M (SD)**	***n***	**E.S. (d)**	***p*-value**[a]	**M (SD)**	***n***	**E.S. (d)**	***p*-value**[a]
Unrefreshed sleep[d]										
UC	50.5 (24.1)	80	−2.1 (18.4)	77	−.39	.009	−2.4 (17.3)	78	−.28	.058
CSM	53.0 (26.2)	122	−8.6 (23.7)	125			−8.5 (19.9)	122		

UC = usual care; CSM = comprehensive self-management; M = mean; SD = standard deviation; E.S. (d) = Cohen's effect size d, defined as the difference in mean change score between group divided by the within group standard deviation of change score, adjusted for baseline and 'study'.

[a]P-value is based on a model built with square root transformed variable controlling for baseline and 'study'.

[b]Diary symptom severity was summarized across all days for each person as the mean percent of days that participants reported 'moderate' to 'very severe' symptoms, range 10–100.

[c]Diminished sleep quality was summarized across all days for each person as the mean percent of days that participants reported 'poor' or 'fair' sleep quality, range 10–100.

[d]Unrefreshed by sleep was summarized across all days for each person as the mean percent of days that participants reported 'not at all refreshed' or 'somewhat refreshed', range 10–100.

J Psychosom Res. Author manuscript; available in PMC 2020 November 01.