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Development and Validation of New Disease-Specific Measures of Somatization and Comorbidity in IBS

Elizabeth W. MacLean, B.A.,
Medical Student, University of North Carolina at Chapel Hill

Olafur S. Palsson, Psy.D.,
Associate Professor of Medicine (Gastroenterology & Hepatology), University of North Carolina at Chapel Hill

Marsha J. Turner, M.S., and
Research Coordinator, Department of Medicine, University of North Carolina at Chapel Hill

William E. Whitehead, Ph.D.
Professor of Medicine and Adjunct Professor of Obstetrics and Gynecology, University of North Carolina at Chapel Hill

Abstract

Objective—To create and validate empirically derived questionnaires that measure non-gastrointestinal symptoms and disorders that co-exist with irritable bowel syndrome (IBS).

Methods—A systematic review of the world literature identified all non-GI symptoms and diagnoses known to have excess frequency in IBS patients. This data was used to create the Recent Physical Symptoms Questionnaire (RPSQ), which measures somatization (the psychological tendency to report multiple physical symptoms), and the Comorbid Medical Conditions Questionnaire (CMCQ). The psychometric properties of these questionnaires were assessed in two studies: 109 IBS patients in Study I; 286 IBS patients and 67 healthy controls in Study II.

Results—In Study I, the RPSQ and CMCQ showed high test-retest reliability (r=.88 and .95) and good internal consistency (Cronbach alphas: .86 and .70, respectively). In Study II, principal components analysis demonstrated that the RPSQ is a homogeneous somatization scale, but the CMCQ could be divided into 4 subscales: one for psychiatric disorders and 3 for different types of somatic disorders. Concurrent validity was shown by strong correlations of both the RPSQ and the CMCQ with the Cornell Medical Index (CMI) and the Brief Symptom Inventory-18 (BSI-18) somatization scales. Discriminant validity was modest: the BSI-18 anxiety and depression scales

Corresponding author: William E. Whitehead, PhD, Professor of Medicine and Adjunct Professor of Obstetrics and Gynecology, Center for Functional GI & Motility Disorders, Campus Box 7080, University of North Carolina at Chapel Hill, Chapel Hill, NC27599-7080, William_Whitehead@med.unc.edu, Telephone: 919-966-6708, Fax: 919-966-7592.

Authors' involvement:
Elizabeth W. MacLean, BA, contributed to study design, analysis and interpretation of the data, and drafting of the manuscript. She approved the final draft of the manuscript.
Olafur S. Palsson, PsyD, was responsible for the study concept and contributed to study design, data acquisition, data analysis and interpretation, and drafting of the manuscript. He approved the final draft of the manuscript.
Marsha S. Turner, MS, contributed to study design, data acquisition, and interpretation of data. She approved the final draft of the manuscript.
William E. Whitehead, PhD, contributed to concept, study design, data analysis, interpretation of results, and drafting of the manuscript. He also approved the final draft of the manuscript.

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were less strongly correlated with the RPSQ than the BSI-18 somatization scale. The RPSQ and CMCQ scores of IBS patients were significantly higher than the scores of healthy controls ($P < .001$).

Conclusions—The RPSQ and CMCQ are highly reliable and valid measures of somatization and medical comorbidities in IBS.

Keywords

Irritable Bowel Syndrome; Comorbidity; Somatization; Validity

BACKGROUND

Irritable bowel syndrome (IBS) is characterized by an excess incidence of non-gastrointestinal medical diagnoses and symptoms, and patients who score high on somatization have more severe gastrointestinal (GI) symptoms, greater impairment in quality of life, incur more healthcare costs and use healthcare resources at higher rates (1–5). Thus, identifying patients with high rates of comorbid symptoms and offering them adjunctive psychological treatment may improve outcomes and reduce costs (6).

No validated disease-specific measures for assessment of comorbid symptoms and medical conditions in IBS have been developed to date. Typically, investigations have used somatization subscales of general psychological symptom inventories. A problem with these generic somatization scales is that they include GI symptoms, confounding the measurement of somatization with the case selection criteria. Even more problematic is the fact that studies addressing medical diagnoses co-existing with IBS have typically only studied the occurrence of one or a few other disorders. The lack of comprehensive, IBS-tailored measures of somatization and comorbidity has made it difficult to reliably quantify or compare extra-intestinal symptoms and disorders in IBS across studies and settings.

The aim of the present work was to create empirically derived disease-specific questionnaires to assess comorbid medical conditions and somatization in IBS patients in a comprehensive, reliable and valid manner. This process involved 4 steps:

1. A literature review to identify comorbid diagnoses and symptoms that occur significantly more often in IBS patients than in controls; these formed the draft questions for our scales.
2. A test of the understandability of the two draft scales.
3. Study I: Test of the concurrent validity, internal consistency, and test-retest reliability of the scales.
4. Study II: Comparison of IBS patients to healthy controls to test predictive validity

Literature Review

The published world literature available on comorbid symptoms and medical conditions in IBS was reviewed by searching all publications in any language published from 1965 to 2011. This resulted in the identification of 41 studies showing excess overlap of IBS with psychiatric disorders, 38 studies reporting excess overlap with other (non-psychiatric) medical conditions, and 20 studies reporting an excess of one or more non-gastrointestinal symptom in IBS (7;8). This review led to the identification of 16 comorbid medical conditions and 26 non-gastrointestinal physical symptoms that are significantly more common in IBS patients. This information was used to construct two questionnaires, one for self-reported medical diagnoses and the other for symptoms.

The Comorbid Medical Conditions Questionnaire (CMCQ) was created by listing all 16 non-gastrointestinal medical diagnoses that had been found in past work to be significantly more frequent in IBS patients (see Table I). IBS itself was added as the 17th listed diagnosis in order to make it possible for the questionnaire to be used to survey patients with the other listed conditions to assess the reciprocal overlap of those other disorders with IBS. (Responses to question 17 were not included in analyses for this report.)

For each listed diagnosis on the CMCQ, patients were instructed to indicate whether they had "ever been diagnosed by a physician" with the listed diagnosis. Response options were "yes," "no" or "don't know". The questionnaire was scored by totaling the number of "yes" responses to obtain an index of the respondent's number of medical comorbidities. Responses of "don't know" were equated with "no" responses because we assume that a subject who did not know what a diagnostic term meant was unlikely to have received this diagnosis from a physician. This sum score is referred to below simply as the CMCQ score.

The Recent Physical Symptoms Questionnaire (RPSQ) was constructed by listing all 26 symptoms identified by at least one past study as having a statistically higher prevalence in IBS patients compared to healthy control subjects (Table I). The respondent is asked to indicate "how frequently you have experienced each symptom in the past month". Response options are 0="never or only once", 1="less than one day a week", 2="at least 1–2 days a week", 3="most days", and 4="every day". The RPSQ score is the number of different symptoms experienced with higher frequency than "never or only once" in the past month. In addition to this simple count of the number of different symptoms present, we also created a measure of physical symptom burden (RPSQ-freq),which is the sum of the numerical ratings (0–4) that correspond to the frequency responses for all questions.

Testing draft questionnaires for understandability

Twenty IBS patients seeking care in the Gastroenterology Outpatient Clinic at UNC-Chapel Hill (60% females, mean age=41.2 years) were asked to rate the understandability of each item on both questionnaires on a scale in which 0="poor", 1 ="fair", 2="good" and 3="excellent". The understandability was rated as "good" or "excellent" for all questions except the following three questions on the CMCQ where more than 10% of patients reported not knowing the nature of the diagnoses listed: interstitial cystitis, dysmenorrhea and prostatitis. It was decided to keep these particular diagnostic terms unchanged because (1) no alternative commonly used diagnostic terms could be identified for these conditions, and (2) subjects who had received these diagnoses by their physician would be likely to recognize the diagnosis.

Study I: Test of concurrent validity, internal consistency, and test-retest reliability

Subjects—One hundred and nine patients with IBS who met the Rome II criteria and had been diagnosed by a physician were recruited through posted advertisements at UNC-Chapel Hill Hospitals and the university campus as well as through the website of the UNC Center for Functional GI and Motility Disorders.

Study design—The Cornell Medical Index (CMI) (11) was administered to assess the concurrent validity of the CMCQ and the RPSQ with an existing measure of somatization. The CMI was originally developed as a structured review of systems for medical evaluation of new patients, but it was quickly recognized that it reflected somatization (12). The CMI separates symptoms into categories (subscales), including one category for gastrointestinal symptoms, 6 categories for psychiatric symptoms, and 11 categories for non-psychiatric, non-GI symptoms. For these analyses the CMI items related to the psychiatric and GI

subscales were excluded, and the sum of all remaining items was used as a measure of physical symptom reporting.

As additional tests of concurrent validity, subjects were asked how many outpatient clinic visits they had made in the last year for any cause and they were asked to rate their health using a 4-point scale (1=excellent, 2=good, 3=fair, 4=poor). We predicted that both the number of clinic visits and the subject's self-rated health would be correlated with the subject's CMCQ and RPSQ scores.

Results—Seventy-one percent of the patients in Study I were female. Age was 18 to 74 years (mean 41.5 years). Self-reported race was 89% White, 7% African-American, 2% Hispanic, and 2% other or undisclosed. The vast majority of patients in the study were classified as having moderate (41.3%) or severe (47.7%) IBS, and patients reported an average duration of 8.7 years (range=1–34 years) with IBS symptoms.

Psychometric properties—The psychometric properties of the RPSQ and CMCQ scales are shown in Table III. Concurrent validity was shown by significant correlations of both scales with the number of physical symptoms endorsed on the Cornell Medical Index, number of doctor visits, and self-rated health scores.

The RPSQ and CMCQ were not significantly correlated with patient age or years since diagnosis, indicating that the questionnaires can be used without adjustment for age or chronicity of IBS. However, mean CMCQ scores were higher in women than men (3.5 vs. 1.8, $P<.01$). This difference was expected, as several of the conditions on the CMCQ questionnaire (including fibromyalgia, headaches and depression) are known to occur at higher rates in women in the general population. No significant gender differences were found in RPSQ and RPSQ-Freq scale scores.

The intercorrelation between CMCQ and RPSQ was relatively modest (r=.44), suggesting that the two scales quantify partly different phenomena. In contrast, the RPSQ main scale score and RPSQ-Freq scale were highly intercorrelated (r=.91), indicating that they reflect the same characteristic and produce similar results, and therefore probably do not need to be reported separately for most purposes.

The investigators concluded that psychometric properties of the 2 questionnaires were acceptable in all regards, and that no changes were needed in the questionnaire structure or content prior to further validation in a large sample of IBS patients and healthy controls.

Study II: Comparison of IBS patients to healthy controls and additional tests of psychometric properties

The second study was conducted to further evaluate the psychometric properties of the RPSQ and the CMCQ by (1) testing the correlation of the RPSQ with the somatization subscale of the Brief Symptom Inventory-18 (13), a widely used scale of psychological symptoms, (2) performing a principal components analysis of both scales to determine whether the items clustered into subscales, and (3) confirming that IBS patients score higher than control subjects. The study was reviewed and approved by the Institutional Review Board at UNC-Chapel Hill prior to beginning subject recruitment.

Methods

Subjects: Study II was conducted as part of a larger study that examined pain sensitivity and colonic motility in IBS patients (14). The subject population consisted of 286 IBS patients and 67 healthy controls, recruited by physician referrals (some IBS patients) or

advertisements. All subjects were screened by telephone. In order to be included in the study, IBS patients were required to (1) fulfill Rome II criteria for IBS, (2) have received a physician diagnosis of IBS, and (3) have current symptoms.

Study design: Subjects completed the CMCQ, the RPSQ, and the Brief Symptom Inventory-18 (BSI-18) (15) on a computer during a visit to the Clinical and Translational Research Center at the University of North Carolina. The BSI-18 is a validated questionnaire for measuring the degree of psychological distress over the past week. Subjects are asked how much they were bothered over the past 7 days by each of 18 symptoms, and they respond on a 5-point scale from "not at all" to "extremely." The BSI-18 can be scored on 3 subscales – anxiety, depression, and somatization. Scores for each subscale were converted to standardized scores, which allowed BSI-18 scores for men and women to be pooled together for analysis (15). The BSI-18 somatization scale includes one item related to GI distress, which asks about "nausea or upset stomach." We included this item in our calculations of BSI-somatization scores because these symptoms are different from the abdominal symptoms that characterize IBS[1].

Data analysis: Principal Components Analysis was used to assess the internal consistency of the CMCQ and the RPSQ. Analysis of covariance adjusting for age and sex was used to compare IBS patients to healthy controls. The Spearman correlation coefficient was calculated to assess the correlation of the BSI-18 somatization scale with both the RPSQ and CMCQ scores as further measures of concurrent validity. No adjustment was made for age or sex because they all compare paired observations made within the same subjects. Spearman correlation coefficients were also calculated to assess the correlation between the RPSQ and the BSI-18 anxiety scales and between the RPSQ and BSI-18 depression scales to explore discriminant validity. We predicted that the correlation would be stronger between the RPSQ and the BSI somatization subscale than the correlations of the RPSQ with the depression or anxiety subscales.

Results—Two hundred eighty-six subjects who met Rome II criteria for IBS and 67 healthy subjects were analyzed. Average age was significantly different (34.6 years (Standard Deviation (SD) 11.7) for IBS vs. 39.3 years (SD 12.9) for healthy controls, $p<.01$), and was included as a covariate in subsequent between-group analyses. Neither sex (82% females for IBS vs. 88% for controls) nor race (71% white for IBS compared to 67% for controls) differed significantly. IBS symptom severity was 15.2% mild, 44.2% moderate, and 40.6% severe.

Factor analyses of the CMCQ and RPSQ: For the CMCQ, four factors were identified that accounted for 47.2% of the variance in subject responses. Following varimax rotation, factor 1, accounting for 14.2% of the variance, included the genitourinary disorders interstitial cystitis, prostatitis, and dysmenorrhea. Factor 2 accounted for 13.7% of the variance and included the central nervous system disorders tension headache, migraine, chronic fatigue, insomnia, and temporomandibular joint disorder. Factor 3 was a psychiatric factor which includes anxiety disorder, panic disorder, depression, PTSD, and back pain; it accounted for 11.6% of the variance. The fourth factor, accounting for 7.7% of the variance, included chronic pelvic pain and fibromyalgia. For the RPSQ, we identified only one factor, somatization, which accounted for 26.8% of the variance.

In order to verify that the item tapping GI distress did not have a large effect on the somatization scores in the IBS patient population, we also calculated these Spearman Rho values using BSI-somatization scores that did not include the item related to GI distress. In these calculations, all values were still statistically significant, and the Spearman Rho values changed little from those listed.

Comparison of IBS patients to healthy controls: CMCQ scores were significantly higher in IBS patients (mean 2.31 comorbid conditions [95% confidence interval, 2.07, 2.55] compared to healthy controls (mean 1.23 comorbid conditions [95% confidence interval 0.73, 1.74]; $F(1,332)=14.33$, $p<.001$). RPSQ scores were also significantly higher in IBS patients (mean 11.12 symptoms [95% confidence interval 10.53, 11.71]) compared to healthy controls (mean 4.72 symptoms [95% confidence interval 3.50, 5.94]; $F(1,341)=85.59$, $p<.001$).

In addition to analyzing the total CMCQ scores of IBS patients and healthy controls, we looked at the frequency with which each CMCQ item was reported in the IBS patient and healthy control samples. In all but one of the conditions (prostatitis) listed on the CMCQ, a higher proportion of IBS patients reported having been previously diagnosed with that condition than did healthy controls. These results are displayed in Figure I.

Correlation of the RPSQ with the Brief Symptom Inventory-18: The RPSQ scores of Study II subjects were strongly correlated with scores on the BSI-18 somatization subscale (rho=.70), providing furtherevidence for the concurrent validity of the RPSQ with another commonly accepted somatization scale. The Spearman correlation coefficient for the CMCQ with the BSI-18 somatization subscale was rho=.34, which is statistically significant but lower than the correlation between the BSI-18 somatization scale and the RPSQ, indicating a less robust correlation between CMCQ scores and BSI-somatization scores.

As measures of discriminant validity, we also calculated the Spearman correlation between the RPSQ scores and scores on the BSI anxiety (rho=.569) and depression subscales (rho=. 511). These values were slightly lower than the correlation between the RPSQ score and the BSI somatization scale (rho=.697).

DISCUSSION

As detailed above, the RPSQ and CMCQ are new comprehensive empirically derived questionnaires that are internally consistent, unaffected by age or chronicity of IBS, and have high test-retest reliability in clinical IBS patients. The results of our two studies suggest that these questionnaires, each of which is typically completed in 2–3 minutes by patients, are valid measures of comorbidity and somatization in patients with IBS. As addressed in Study 1, RPSQ and CMCQ scores also show evidence of associations with self-rated health and number of doctor visits. Thus, the RPSQ and CMCQ are likely to be useful tools for research on somatization and multiple medical comorbidities in IBS.

Research has demonstrated that somatization, which can be measured by the RPSQ, responds to targeted psychological treatment for IBS. Both hypnosis treatment and cognitive-behavioral therapy of IBS patients can produce substantial and lasting reduction in somatization scores, with corresponding bowel symptom relief (18;19). The RPSQ might therefore be of use in screening patients for high somatization tendency who are likely to require such a therapy approach to have a reasonable chance at substantial clinical improvement. The RPSQ is also likely to be valuable in IBS research on further investigating the roles that trait somatization plays in this disorder.

The BSI-18 measures psychiatric distress due to symptoms (i.e., “how much were you bothered by X”), which may suggest that the RPSQ is simply an alternative measure of general distress. Based on our findings that the RPSQ and RPSQ-Freq scales are strongly correlated, however, we believe that the RPSQ is in fact quantifying physical symptoms and not simply a reflection of a patient’s tendency to report distress. The degree to which the

RPSQ remains correlated with BSI anxiety and depression scores confirms prior findings that somatization ratings are often correlated with anxiety and depression (20)

The CMCQ, which quantifies the co-presence of multiple other medical conditions in IBS, might be of clinical use by alerting healthcare providers to the necessity to take a broader medical approach to treatment. If healthcare providers target bowel symptoms but fail to address other disorders, treatment may be less successful. The CMCQ may also be valuable as an epidemiological instrument to assess comorbidity in IBS in large patient cohorts, once the accuracy of patient self-reports of diagnoses is established. Evaluation of CMCQ scores may require gender-specific norms, as Study 1 revealed that women had significantly higher scores than men on the CMCQ.The CMCQ has been criticized for its use of the phrase "Anxiety Disorder" as opposed to the formal DSM-IV term "Generalized Anxiety Disorder." We felt constrained by our methodology to use the exact terms found in the literature when we created this questionnaire. The term "Anxiety Disorder" may, however, be confusing to some because of the DSM-IV's subclassification system, where multiple disorders exist under the heading of anxiety disorders. We propose to change this term to "Generalized Anxiety Disorder" for future applications of the CMCQ in order to avoid this confusion.

In the version of the CMCQ tested in these studies, no space was provided for patients to record additional, unlisted diagnoses. This was a deliberate decision as our goal was to create a disease-specific measure of comorbid conditions, and our criteria for including items was that one or more published study identified the disorder as significantly more common in IBS patients compared to control subjects. For clinical use, however, it may be more appropriate to include an open-ended question with the CMCQ, as this can help physicians tailor treatment to a patient's individual needs. Similarly, some clinicians may want to modify the CMCQ so that patients only endorse recent or current diagnoses in their responses. For research purposes, however, lifetime diagnoses of the conditions listed may be more appropriate because most CMCQ items refer to chronic or recurring conditions.

One limitation of the studies presented in this paper relates to the unknown accuracy of self-reports on the CMCQ. This instrument has not been validated against objective evidence of recorded medical diagnoses. Even though our data show that patients reliably answer the same way when retested on this questionnaire, it is unknown how correctly those self-reports correspond to the diagnoses they have actually been given. There is, however, evidence that patients can accurately assess their comorbidities, and that self-report measures are often a suitable alternative to chart reviews (21).

Another limitation of our work is that it has only involved IBS healthcare consulters in the IBS patient population. In both studies, subjects were seeking clinical care or participation in research studies. It is unknown whether IBS non-consulters would also have higher CMCQ and RPSQ scores than healthy controls.

One of the limitations of Study II was the small size of the control patient sample. The small healthy control sample in contrast with the much larger IBS sample makes comparisons between these patient groups imprecise. Specifically, the probability of sampling bias increases for conditions with low base rates, such as fibromyalgia or interstitial cystitis. This inaccuracy applies to individual conditions identified on the questionnaires, however, and is therefore less likely to have a significant impact on the overall score differences.

In summary, we have developed psychometrically sound, disease-specific scales that measure somatization and comorbidity in IBS. These scales should prove useful in future research on the causes and consequences of comorbidity in this disorder.

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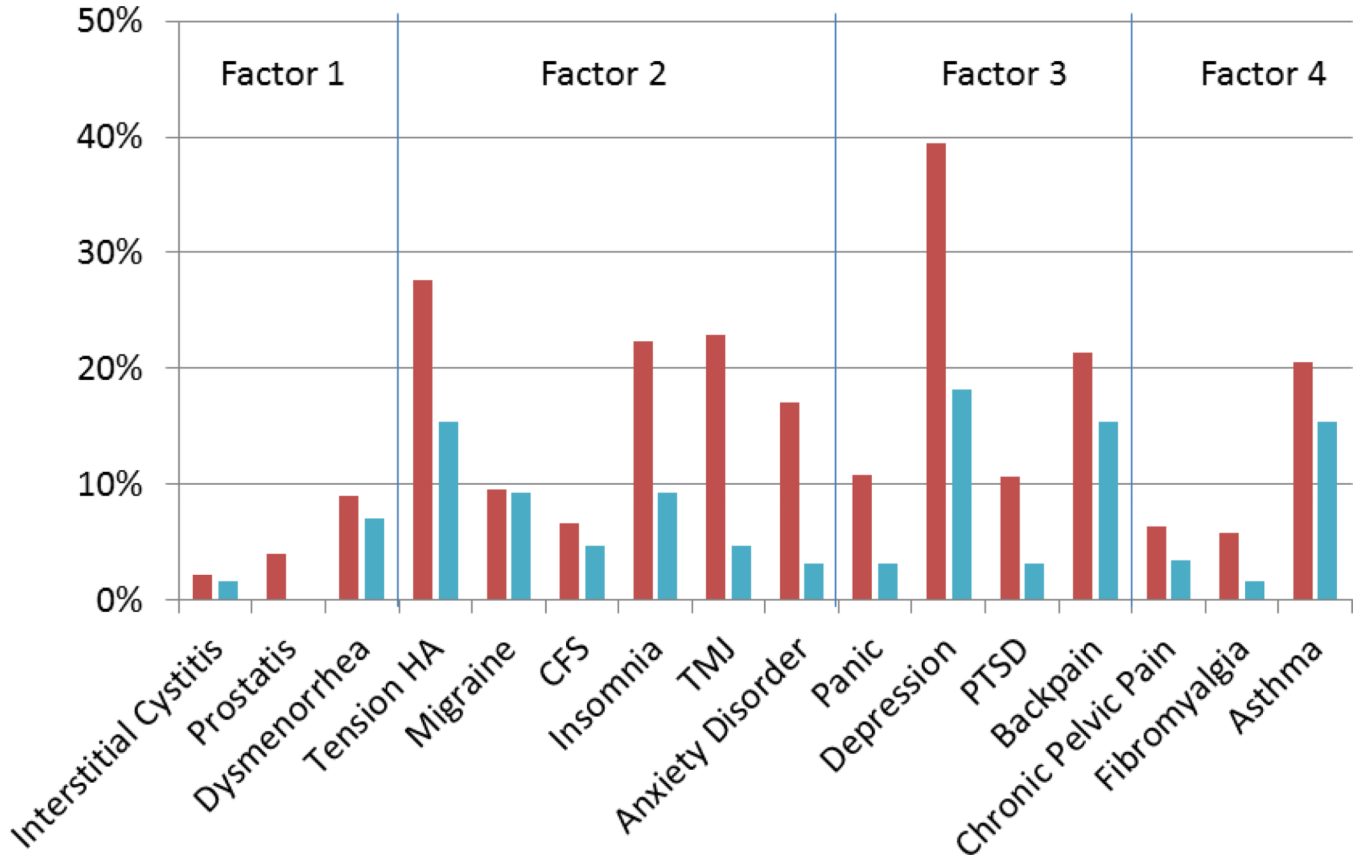

Figure I.
Frequency of comorbid disorders in Study II subjects
* indicates disorders with statistically significant differences (*P*<.*05*).

Table I

Medical diagnoses included on the CMCQ

1. Fibromyalgia
2. Asthma
3. Temporomandibular joint disorder (TMJ or TMD)
4. Chronic fatigue syndrome (CFS)
5. Migraines
6. Tension headaches
7. Insomnia
8. Depression
9. Back pain
10. Panic disorder
11. Post-traumatic stress disorder (PTSD)
12. Anxiety disorder
13. Chronic pelvic pain
14. Interstitial cystitis
15. Prostatitis
16. Dysmenorrhea
17. Irritable bowel syndrome (IBS)

Table II

Physical symptoms included on the RPSQ

1. Headache
2. Dizziness
3. Heart palpitations or racing heart
4. Back pain
5. Shortness of breath
6. Muscle aches
7. Frequent urinating
8. Difficulty urinating
9. Sensitivity to heat or cold
10. Constant tiredness
11. Pain during intercourse (sex)
12. Trembling hands
13. Sleeping difficulties
14. Bad breath/unpleasant taste in mouth
15. Grinding your teeth
16. Jaw pain
17. Flushing of your face and neck
18. Dry mouth
19. Weak or wobbly legs
20. Scratchy throat
21. Tightness or pressure in the chest
22. Low sex drive
23. Poor appetite
24. Eye pain
25. Stiff muscles
26. Eye twitching

Table III

Study I psychometric results for the RPSQ and CMCQ scales

	RPSQ:	**RPSQ-Freq**	**CMCQ:**
Cronbach's Alpha:	0.86	0.88	0.70
Two-week test-retest reliability:	0.88	0.86	0.95
Correlation with CMI physical symptom count:	0.80	0.73	0.60
Self-reported number of doctor visits in the past 12 months:	0.50		0.37
Self-rated health over the past 12 months:	0.31		0.28

Main scale scores are indicated in bold face.