

# Confirmatory Factor Analyses and Differential Item Functioning of the Patient Experience with Treatment and Self-Management (PETS vs. 2.0): A Measure of Treatment Burden

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**Purpose:** To examine the factor structure and differential item functioning (DIF) of the Patient Experience with Treatment and Self-management (PETS version 2.0), a measure of treatment burden.

**Patients and Methods:** Version 2.0 of the PETS has 60 items, extending the previously-validated 48-item version 1.0 by three domains (nine items) and three additional items in an existing domain. We conducted confirmatory factor analyses (CFA) on survey responses of 439 community-dwelling adults living with multiple chronic conditions who completed PETS version 2.0, using R packages, “lavaan” and “semTools.” We tested fit of second-order factors to explore simplifying the reporting of PETS scores. We examined DIF for the two second-order factors with “lordif” R package, testing groups by gender, education, and health literacy, using the McFadden pseudo  $R^2$  change criterion of  $\geq 0.02$  to flag items with DIF. Cronbach’s alpha and the intraclass correlation coefficient (ICC) were used to determine the reliability of PETS domains.

**Results:** The first-order CFA model featuring 12 multi-item domains had an excellent fit (Comparative Fit Index [CFI]=0.989), as did the second-order CFA model (CFI=0.987), specifying two superordinate factors of treatment burden (workload and impact). Items in the workload and impact second-order factors did not show any DIF across gender, education, and health literacy groups as shown by McFadden pseudo  $R^2$  changes  $< 0.02$ . Cronbach’s alphas for all multi-item domain scales were  $\geq 0.80$ , and ICCs of ten scales were  $\geq 0.70$ , meeting the threshold for adequate test-retest reliability.

**Conclusion:** Findings support the construct validity and reliability of PETS version 2.0. The fit of a factor model featuring superordinate (ie, second-order) factors of workload and impact supports index scoring that will simplify reporting of PETS scores. DIF analyses indicate that items from these indices can be interpreted in the same way, regardless of gender, education, or health literacy.

**Keywords:** factor structure, patient-reported outcomes, multi-morbidity, psychometric testing, questionnaire, validation

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## Introduction

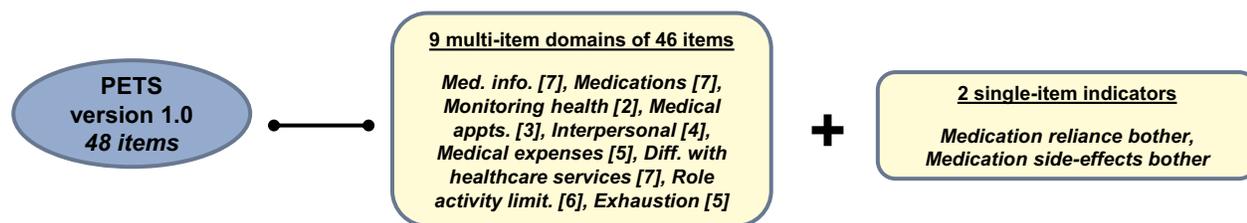
The Patient Experience with Treatment and Self-management (PETS) questionnaire is a comprehensive, multi-domain measure of patient-perceived treatment burden – the workload and associated stressors of treatment and self-management for chronic conditions and their impact on functioning and well-being. Leveraging

a patient-derived conceptual framework of treatment burden,<sup>1</sup> confirmatory factor analysis (CFA) was performed previously on a 48-item version of the PETS (version 1.0) featuring 46 items distributed into nine multi-item domains and two single-item indicators (see Figure 1A).<sup>2</sup> A 9-factor measurement model was supported by the CFA, representing the nine hypothesized multi-item domains with two single-item indicators of medication bother analyzed separately. In this prior analysis, three content domains identified in the original conceptual framework (namely, diet, exercise/physical therapy, and medical equipment) were set aside due to excessive missing data resulting from yes/no screening questions used with each domain. Hence, the full measurement model of the PETS has not yet been empirically tested.

The purpose of the present analyses is to examine the factor structure of the full 60-item PETS measure (version 2.0) in a community sample of people living with multiple chronic conditions (MCCs). As shown in Figure 1B, the PETS version 2.0 includes the domains and

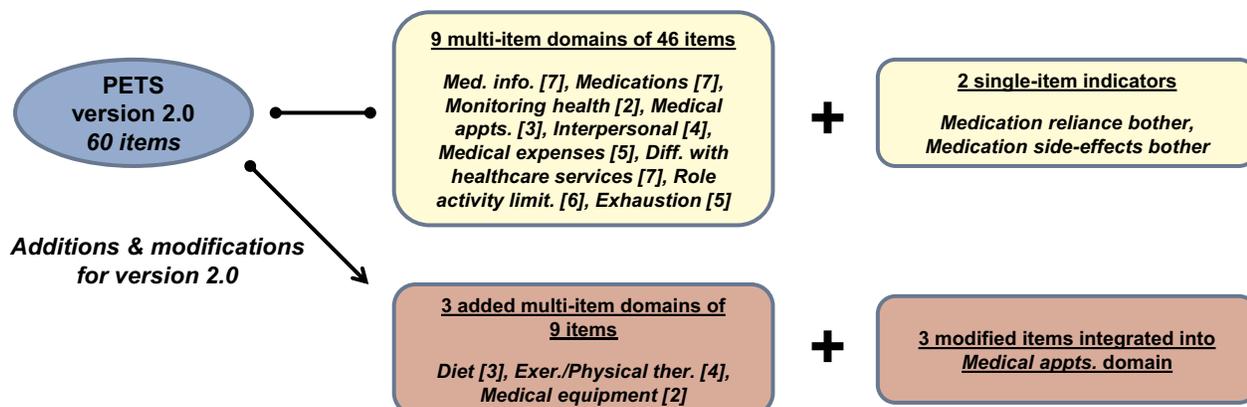
single-item indicators of version 1.0 plus the three previously untested domains of diet, exercise/physical therapy, and medical equipment,<sup>2</sup> representing nine additional items. Furthermore, three other items slightly modified in wording in version 2.0 from PETS version 1.0 were newly integrated into the burden with medical appointments domain and analyzed with the already existing items of that domain. Hence, the current test adds 12 items to the previously confirmed 48-item PETS model. In this analysis we test a 12-factor measurement model consisting of the 12 multi-item domains of the original patient-informed conceptual framework of the PETS.<sup>1,2</sup> To promote parsimony and use of the measure in both research and clinical practice settings, we will also examine a way to simplify the reporting of PETS scores by testing whether certain conceptually-similar content domains reside within common “superordinate” factors. This could support aggregation of certain individual content domains into summary index

**Panel A**



*Eton et al, 2017<sup>2</sup>*

**Panel B**



**Figure 1** Content of PETS version 1.0 (A) and PETS version 2.0 (B).  
**Note:** Additions and modifications for version 2.0 are indicated in the red boxes.  
**Abbreviation:** PETS, Patient Experience with Treatment and Self-management.

scores to facilitate the use and reporting of PETS scores. As differential item functioning (DIF) has never been scrutinized for the PETS measure, we will also test DIF of items when analytically appropriate. Questionnaire items may take on a different meaning across different groups of people with the same latent ability or quality when DIF is present and therefore can reflect measurement bias. Finally, both internal consistency and test-retest reliability will be determined for all domain scales of the PETS.

## Materials and Methods

### Study Population and Sample

Resources of the Rochester Epidemiology Project (REP) research infrastructure were used to identify English-speaking adults ( $\geq 20$  years of age) living with MCCs in Olmsted County, Minnesota, USA between July 1, 2015 and June 30, 2016.<sup>3</sup> The REP links medical records of local healthcare providers for almost all residents of Olmsted County in southeast Minnesota; hence, it can serve as a population-based sampling frame for residents of the region.<sup>4</sup> Surveys were mailed to a random sample of 1,496 persons with MCCs stratified by age (20–49, 50–64, 65+), race (white, non-white), number of medical-record confirmed diagnosed conditions (2–3, 4+), and presence/absence of at least one “incident” condition (a condition diagnosed within the past year). Eligible persons were those who had received an International Classification of Diseases (ICD) diagnostic code from one of their healthcare providers for one or more of 20 chronic conditions identified by the Department of Health and Human Services as public health priorities for the nation.<sup>5,6</sup> Furthermore, persons with ICD codes for anxiety, hearing problems, vision problems, irritable bowel/Crohn’s disease, atopic dermatitis/psoriasis, back problems, or headaches were also included as these conditions were identified by our clinical co-investigators as having high treatment burden. Persons with severe cognitive impairments such as dementia or severe mental illness such as psychotic disorder, as identified by ICD codes, were excluded.

### Study Measures

Version 2.0 of the PETS was used to assess treatment burden. This 60-item version extends the previously-validated, 48-item version 1.0 by nine items, representing three previously untested content domains (diet,

exercise/physical therapy, and medical equipment) and three modified items added to the existing medical appointments domain (having the time, the energy, and transportation to get to medical appointments). The latter items were modified from version 1.0 so that a single response scale could be used for all items within the medical appointments domain. Other PETS content domains include medical information, medications, monitoring health, interpersonal challenges, medical expenses, difficulty with healthcare services, role/social activity limitations due to self-management, physical/mental exhaustion due to self-management, and the two single item indicators of bother with reliance on medication and bother with medication side-effects. Item content is available in the table displaying results of the factor analysis (see below). Note that the two single-item indicators of medication bother were not included in the factor analyses because single items do not represent underlying factors. PETS items use either four- or five-point response scales depending on the content domain. Items querying medical information, medications, medical appointments, monitoring health, medical equipment, and medical expenses use a five-point scale that ranges from “very easy” to “very difficult.” Items querying diet, exercise/physical therapy, and difficulty with healthcare services use a four-point scale that ranges from “strongly agree” to “strongly disagree.” Items querying medication bother, interpersonal challenges, and role/social activity limitations use a five-point scale that ranges from “not at all” to “very much.” Finally, items querying physical/mental exhaustion use a five-point scale that ranges from “never” to “always.” The recall time frame for PETS items is the past 4 weeks.

A validated single-item screener was used to assess subjective health literacy:

How often do you have problems learning about your medical condition because of difficulty understanding written information? (all of the time, most of the time, some of the time, little of the time, none of the time)<sup>7</sup>

Demographic data on age, race/ethnicity, marital, education, and employment status were also collected on the survey. Data on gender as well as the number and types of chronic conditions were extracted from the electronic medical record.

## Procedure

A survey booklet consisting of the PETS and the other measures, a cover letter, and a privacy authorization form (HIPAA) were mailed to the eligible sample of persons along with a stamped envelope for return of the completed survey. The first 100 survey responders were contacted by phone by a research assistant and asked to complete the PETS again within 3 weeks to determine test–retest reliability. Participants were compensated \$10 for completing the full survey battery and an additional \$5 for completion of the PETS re-test. The study was approved as “minimal risk with the use of oral consent” by Institutional Review Boards at the Mayo Clinic (IRB# 14–008629) as well as the Olmsted Medical Center (IRB# 022-OMC-16), institutional co-administrators of the REP. Oral consent was provided in the form of a cover letter describing the survey procedures and consent to participate was implied based on the return of a completed survey (the need for a signed consent form was waived by the IRBs of record). Hence, those who returned a completed survey provided their consent to participate in the study and are represented in this report. A signed HIPAA form was required prior to using any protected health information extracted from the medical record. All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

## Data Analyses

### Confirmatory Factor Analyses (First-Order CFA)

We investigated the factor structure of the full model with 12 hypothesized multi-item factors in two steps. As noted above, the two medication bother items were removed from the CFA. Hence, the measurement model included 58 of the 60 items of version 2.0.

Step 1. We replicated the CFA model in Eton et al<sup>2</sup> with nine multi-item factors, but added the three modified medical appointments items to the existing domain of the same name. Hence, the CFA model tested in this step featured nine correlated factors.

Step 2. We fit a separate CFA model that includes the nine correlated factors of step 1 plus the three multi-item domains excluded in the previous validation (12 factors total).<sup>2</sup> Question sets on diet, exercise/physical therapy, and medical equipment each begin with a yes/no screening question to indicate the relevance to the respondent. These

include the following questions for diet, exercise/physical therapy, and medical equipment, respectively:

- 1) Has a doctor, nurse, or other healthcare provider discussed or given you recommendations for healthy eating, including specific foods to avoid because of your health problems/illnesses?
- 2) Has a doctor, nurse, physical therapist, or other healthcare provider discussed or recommended exercise or physical therapy specifically for your health problems/illnesses?
- 3) Do you currently use any medical equipment or devices?

If the answer to the screening question is “no” then the respondent is asked to skip the domain items.

The CFAs were conducted using the R packages “lavaan” and “semTools,” with polychoric correlation matrices and weighted least squares with adjustments for mean and variance (WLSMV) estimation, which is appropriate for ordered categorical data. We determined model fit using standard criterion and accepted benchmarks: Comparative Fit Index ( $CFI \geq 0.95$ ), Standardized Root Mean square Residual ( $SRMR < 0.08$ ), and Root Mean Square Error of Approximation ( $RMSEA \leq 0.06$ ).<sup>8</sup>

### Confirmatory Factor Analyses (Second-Order CFA)

When factors are highly correlated, a second-order analysis can provide a broader level of generalization than a first-order analysis.<sup>9</sup> Based on construct similarity and inter-domain correlations that have been observed in previous studies using the PETS,<sup>2,10,11</sup> we hypothesized two second-order factors: a workload factor consisting of the medical information, medications, medical appointments, and monitoring health domains (ie, domains assessing difficulty in doing various tasks associated with self-management of health conditions) and an impact factor consisting of the role/social activity limitations and physical/mental exhaustion domains (ie, domains assessing the impact of self-management on daily functioning and well-being).

### Bifactor Model for Workload and Impact Factors

We investigated whether the items in the workload and impact factors fit the confirmatory bifactor graded response models. These models let us investigate the strength of general factor loadings in the presence of group factor loadings, before DIF analyses based on uni-dimensional item response theory can be undertaken with these items. We used maximum likelihood estimation under the item response theory paradigm with the

multidimensional item response theory “mirt” R package.<sup>12</sup> The original designation of items within medical information, medications, medical appointments, and monitoring health domains was used as the group factors for the workload construct. For the impact construct, the group factors were also the original membership of the items, role/social activity limitations, and physical/mental exhaustion. The comparative model fit was evaluated using  $M_2^*$  statistic (ie, a goodness of fit statistic that uses univariate and bivariate residuals, which shows good fit when  $P < 0.05$ ),<sup>13</sup> RMSEA ( $< 0.08$ ), and CFI ( $\geq 0.95$ ).<sup>14,15</sup>

### General Factors in Workload and Impact

In order to justify the use of the DIF methods using item response theory, we tested whether a general factor runs through the second-order factors of workload and impact. When several highly related domains comprise the general construct of interest, the explained common variance (ECV) and coefficient omega hierarchical ( $\omega_H$ ) can be used to index the degree of a general factor<sup>16,17</sup> in workload and impact. Lastly, standardized loadings on the general factor greater than 0.30 in the bifactor model could indicate a well-defined overarching factor even in the presence of the domain factors.<sup>16,18,19</sup>

### Differential Item Functioning

The R software package, lordif,<sup>20</sup> was used to evaluate DIF in workload and impact. Lordif assesses DIF using a hybrid of ordinal logistic regression and item response theory (IRT) framework. The main objective of fitting an IRT model under lordif is to obtain IRT trait estimates to serve as matching criterion. We conducted DIF analyses when factors had at least 10 items in order to have reliable trait estimates as matching criterion. This led to DIF analyses of two second-order factors – the workload factor has 22 items and the impact factor has 11 items, so both are suitable for DIF analyses. The individual content domains consisted of between two and seven items each and were therefore not suitable for this particular type of DIF analysis. In this framework, a base model (model 1) posits that only the trait level predicts responses. A second model (model 2) has both trait level and group as independent variables. If model 2 predicts item responses statistically significantly better than model 1, then DIF has a consistent impact across trait levels (uniform DIF). If the model with an interaction term (model 3) fits significantly better than model 2, then the impact of DIF varies by trait level (non-uniform DIF). If model 3 fits

significantly better than model 1, there is overall or total DIF.

McFadden pseudo  $R^2$  change criterion of  $\geq 0.02$  was used to flag items for DIF.<sup>21</sup> A value of pseudo  $R^2$  less than 0.02 indicates a lack of evidence of differential interpretation of an item across the tested groups. Three groups considered were gender, education (college graduate vs some college or below), and health literacy (no difficulty understanding written medical information vs at least some difficulty understanding written medical information). Gender, education, and health literacy have been used as grouping variables in studies of DIF in PROMIS measures.<sup>22,23</sup>

### Reliability

Two recognized forms of reliability for patient-reported health status measures were determined: internal consistency and test–retest.<sup>24,25</sup> Cronbach’s alpha coefficients were computed for all multi-item domains to determine internal consistency reliability. The intraclass correlation coefficient (ICC) was used to determine test–retest reliability of all PETS domains, including the two single-item indicators, over a brief time interval (no more than 3 weeks). Consistent with current recommendations for patient-reported measures (see Qin et al<sup>26</sup>), to assess test–retest reliability the ICC formula used was derived from the two-way mixed-effect analysis of variance model with interaction for the absolute agreement between single scores.

## Results

### Characteristics of Survey Responders

Of the 1,496 people mailed a survey, two had died prior to its receipt. Of the 1,494 remaining in the sample, 443 returned a completed survey (30% response). In comparison to the 1,053 non-responders, the 443 responders were older, more likely to be white than of a minority race, and had slightly more diagnosed conditions ( $P_s < 0.0001$ ; data not shown). Regarding specific conditions, the following were significantly more prevalent among survey responders than non-responders: arrhythmia, hyperlipidemia, arthritis, cancer, and vision problems ( $P_s < 0.05$ ; data not shown). Hepatitis was slightly less prevalent among responders than among non-responders ( $P < 0.05$ ). Four responders were excluded prior to data analysis due to a diagnosis of an exclusionary condition identified after the original sampling. Hence, the final analyzed sample was 439.

Table 1 shows sample descriptive characteristics. The mean age was 60.3 years (range: 20–98 years), and there were more women than men (62% vs 38%). Most (77%) reported their race as White/Caucasian, were college-educated (73%), married or in a partnered relationship (59%), and currently not employed (57%). The median number of diagnosed conditions was five, with the most commonly observed diagnoses among respondents being hypertension (53%), hyperlipidemia (52%), low back disorder (51%), arthritis (47%), and diabetes (47%). Mental health conditions (depression and anxiety), vision problems, cardiac arrhythmia, and cancer were also common (>25%). Among all diagnoses, only a small proportion (6%) reflected an incident condition that had been diagnosed within the past year. The majority (65%) of the patients reported no problem with health literacy, while 35% had some difficulty with it.

### Confirmatory Factor Analyses (First-Order CFA)

Step 1. The CFA model with nine correlated factors (the first nine domains in Table 2) had excellent fit ( $\chi^2(1,091) = 1,626.5$  with  $P < 0.001$ , CFI=0.991, RMSEA=0.033 [90% confidence interval (CI): 0.030–0.037], and SRMR=0.051). All item factor loadings were at least 0.68.

Step 2. The overall CFA model integrating the three previously untested factors of diet, exercise/physical therapy, and medical equipment with the nine correlated factors of step 1 (ie, 12 factors total) also had excellent fit ( $\chi^2(1,529) = 2,181.8$ .  $P < 0.001$ , CFI=0.989, RMSEA=0.031 [90% CI: 0.028–0.034], and SRMR=0.057). Table 2 shows the content of the items, the factor loadings, and the Cronbach’s alphas for each of the 12 domains. All item factor loadings were at least 0.60. Table 3 shows the variance and correlations among factors supported in the overall CFA model.

### Confirmatory Factor Analyses (Second-Order CFA)

The second-order CFA tests the fit of a model specifying superordinate factors. If supported, this could justify greater parsimony in the reporting of PETS scores by combining closely related domains into aggregated index scores. Relatively high factor inter-correlations from the final first-order CFA model (see Table 3) as well as the similarity of content of these highly correlated domains

**Table 1** Descriptive Characteristics of Survey Responder Sample (N=439)

<b>Age</b>	
Mean (SD)	60.3 (16.7) years
Range	20–98 years
<b>Gender</b>	
Female	274 (62%)
Male	165 (38%)
<b>Race</b>	
White/Caucasian	340 (77%)
Black/AA	38 (9%)
Asian	27 (6%)
Native American	11 (3%)
Mixed	5 (1%)
Other (Filipino, Mid-eastern)	2 (<1%)
Unknown	16 (4%)
<b>Ethnicity</b>	
Hispanic	18 (4%)
<b>Marital status</b>	
Married/partnered	261 (59%)
Not married	161 (37%)
Missing	17 (4%)
<b>Education status</b>	
College educated	319 (73%)
No more than HS	107 (24%)
Missing	13 (3%)
<b>Health literacy</b>	
No problem	284 (65%)
At least some problem	155 (35%)
<b>Employment status</b>	
Not employed	250 (57%)
Employed (full or part)	163 (37%)
Missing	26 (6%)
<b>Total number of diagnosed conditions</b>	
Median	5.0
Range	2–13
2–3 conditions	103 (24%)
4–5 conditions	161 (37%)
6+ conditions	175 (40%)
<b>Types of diagnosed conditions</b>	
Hypertension	231 (53%)
Hyperlipidemia	230 (52%)
Low back disorder <sup>a</sup>	225 (51%)
Arthritis	208 (47%)
Diabetes (Type 1 or 2)	205 (47%)
Depression	188 (43%)
Vision problems	158 (36%)
Anxiety	134 (31%)

(Continued)

**Table 1** (Continued).

Cardiac arrhythmia	115 (26%)
Cancer	115 (26%)
Coronary artery disease	81 (19%)
Hearing problems	69 (16%)
Substance abuse	55 (13%)
Chronic kidney disease	52 (12%)
COPD	49 (11%)
Headache	40 (9%)
Osteoporosis	34 (8%)
Congestive heart failure	34 (8%)
Psoriasis	23 (5%)
Crohn's disease	18 (4%)
Hepatitis	12 (3%)
HIV	2 (<1%)

**Note:** <sup>a</sup>Includes osteopathic conditions such as disc displacement/degeneration, spondylosis, spinal stenosis, sciatica, and post-laminectomy syndromes.

**Abbreviations:** SD, standard deviation; AA, African-American; HS, high school; COPD, chronic obstructive pulmonary disease.

justifies the testing of the two hypothesized superordinate factors of workload and impact. Workload consists of the medical information, medications, medical appointments, and monitoring health domains. Inter-correlations of these four domains ranged from  $r=0.63$ – $0.74$ . Impact consists of the role/social activity limitations and physical/mental exhaustion domains. These domains were correlated at  $r=0.79$ .

The fit of the second-order CFA model was excellent ( $\chi^2(1,561)=2,177.1$ ,  $P<0.001$ , CFI=0.987, RMSEA=0.030 [90% CI: 0.027–0.033], and SRMR=0.060). The item-to-factor loadings were almost identical as those of the first-order 12-factor model. When there were differences in item-to-factor loadings, they were small ( $\leq 0.10$ ). Table 4 shows the second-order to first-order factor loadings, which were at least 0.57 across domains. The final factor model of the PETS version 2.0 featuring both first- and second-order (superordinate) factors appears in Figure 2.

## Bifactor Model for Workload and Impact

The bifactor graded response models were fit as a step toward conducting unidimensional DIF analyses on items within the two factors. For the workload construct, the data were fit to the bifactor model that included a general workload factor and four group factors (medical information, medications, medical appointments, and monitoring health). The preliminary evaluation of model fit suggested that the bifactor model fits the data for the workload construct well, especially with RMSEA and

CFI:  $M_2^*$  (df)=304.41 (121),  $P<0.001$ ; RMSEA=0.060 (90% CI: 0.052–0.068); CFI=0.98. All general factor loadings were at least 0.62, and all group factor loadings were above 0.30 (Table 5). The bifactor model fit statistics for impact were:  $M_2^*$  (df)=2.96 (2),  $P=0.23$ ; RMSEA=0.034 (90% CI: 0.000–0.107); CFI=0.99, with all measures of global fit in an excellent range. All general factor loadings were at least 0.67 (Table 6). All group factor loadings for physical/mental exhaustion were above 0.49. Two items from role/social activity limitation were constrained to load only on the general factor because their group factor loadings were close to 0. The other four items in role/social activity limitation had weaker loadings on their group factor, and stronger general factor loadings compared to the items in physical/mental exhaustion.

## General Factors in Workload and Impact

In both workload and impact, items had salient general factor loadings greater than 0.62 and 0.64, respectively (Tables 5 and 6). The  $\omega_H$  of workload was 0.89, reflecting a strong common factor, and ECV was 0.72, reflecting that the general factor is strong relative to the group factors. Findings were similar for impact, with  $\omega_H$  of 0.88 and ECV of 0.69. This evidence renders support for conducting DIF analyses by these two general factors.

## Differential Item Functioning

For both workload and impact, no uniform, non-uniform, or overall DIF was found for any of the gender, education, and health literacy groups. All items in all analyses had a McFadden pseudo  $R^2$  change below the criterion that indicates DIF ( $<0.02$ ). Given the number of analyses and volume of data produced, these results are available in the Supplementary data file (Section 1: DIF for workload items and Section 2: DIF for impact items).

## Reliability

As shown in Table 2, all 12 multi-item PETS domain scales supported by the CFAs showed good internal consistency reliability with Cronbach's alphas ranging from 0.80–0.94. This exceeds the 0.70 threshold for adequate reliability of health status measures used for group comparisons.<sup>24</sup> Of the 100 initial survey responders, a retest administration of the PETS was received from 65 of them within 3 weeks of the initial survey (Median retest interval=18 days). The ICCs for the 14 PETS scales, including the two single-item indicators of medication

**Table 2** Content of Items Within Each Domain of the Original Model (12 Factors and 58 Items), Standardized Factor Loadings, and Internal Consistency Reliability (Cronbach's Alpha)

Domain and Reliability	Item Content	Factor Loading
Medical information ( $\alpha=0.90$ )	Over the past 4 weeks, how easy or difficult has it been for you to learn about your health problem(s)?	0.83
	Over the past 4 weeks, how easy or difficult has it been for you to learn what foods you should eat to stay healthy?	0.71
	Over the past 4 weeks, how easy or difficult has it been for you to find information on the medications that you have to take?	0.82
	Over the past 4 weeks, how easy or difficult has it been for you to understand any changes to your treatment plan?	0.88
	Over the past 4 weeks, how easy or difficult has it been for you to understand the reasons why you are taking some medicines?	0.89
	Over the past 4 weeks, how easy or difficult has it been for you to find sources of medical information that you trust?	0.86
	Over the past 4 weeks, how easy or difficult has it been for you to understand advice from different healthcare providers?	0.90
Taking medications ( $\alpha=0.92$ )	Over the past 4 weeks, how easy or difficult has it been for you to organize your medicines?	0.88
	Over the past 4 weeks, how easy or difficult has it been for you to take more than one medicine every day?	0.88
	Over the past 4 weeks, how easy or difficult has it been for you to take your medicines several times each day?	0.83
	Over the past 4 weeks, how easy or difficult has it been for you to refill your medicines?	0.89
	Over the past 4 weeks, how easy or difficult has it been for you to adjust your medicines?	0.86
	Over the past 4 weeks, how easy or difficult has it been for you to take your medicines as directed?	0.92
	Over the past 4 weeks, how easy or difficult has it been for you to plan your daily activities around your medicine schedule?	0.83
Medical appointments ( $\alpha=0.93$ )	Over the past 4 weeks, how easy or difficult has it been for you to make or keep your medical appointments?	0.94
	Over the past 4 weeks, how easy or difficult has it been for you to schedule and keep track of your medical appointments?	0.93
	Over the past 4 weeks, how easy or difficult has it been for you to make or keep appointments with different healthcare providers?	0.90
	Over the past 4 weeks, how easy or difficult has it been for you to find the time to get to your medical appointments?	0.87
	Over the past 4 weeks, how easy or difficult has it been for you to find the energy to get to your medical appointments?	0.90
	Over the past 4 weeks, how easy or difficult has it been for you to find transportation to get you to your medical appointments?	0.81
Monitoring health ( $\alpha=0.80$ )	Over the past 4 weeks, how easy or difficult has it been for you to monitor your health behaviors, for example, tracking your exercise, the foods you eat, or medicines you take?	0.94
	Over the past 4 weeks, how easy or difficult has it been for you to monitor your health condition, for example, weighing yourself, checking your blood pressure, or checking your blood sugar?	0.92
Role/social activity limitations ( $\alpha=0.94$ )	In the past 4 weeks, how much has your self-management interfered with your work?	0.90
	In the past 4 weeks, how much has your self-management interfered with family responsibilities?	0.94
	In the past 4 weeks, how much has your self-management interfered with daily activities?	0.95
	In the past 4 weeks, how much has your self-management interfered with hobbies and leisure activities?	0.93
	In the past 4 weeks, how much has your self-management interfered with ability to spend time with family and friends?	0.93
	In the past 4 weeks, how much has your self-management interfered with ability to travel for work or vacation?	0.83

(Continued)

Table 2 (Continued).

Domain and Reliability	Item Content	Factor Loading
Physical/mental exhaustion ( $\alpha=0.93$ )	In the past 4 weeks, how often did your self-management make you feel angry?	0.87
	In the past 4 weeks, how often did your self-management make you feel preoccupied?	0.85
	In the past 4 weeks, how often did your self-management make you feel depressed?	0.90
	In the past 4 weeks, how often did your self-management make you feel worn out?	0.91
	In the past 4 weeks, how often did your self-management make you feel frustrated?	0.93
Medical and healthcare expenses ( $\alpha=0.91$ )	Over the past 4 weeks, how easy or difficult has it been for you to plan for the future because of your medical expenses?	0.90
	Over the past 4 weeks, how easy or difficult has it been for you to pay for healthy foods?	0.91
	Over the past 4 weeks, how easy or difficult has it been for you to pay for all of your medical expenses?	0.92
	Over the past 4 weeks, how easy or difficult has it been for you to pay for your medicines?	0.90
	Over the past 4 weeks, how easy or difficult has it been for you to understand what is and what is not covered by your health insurance?	0.80
Difficulty with healthcare services ( $\alpha=0.86$ )	I have problems with different healthcare providers not communicating with each other about my medical care.	0.68
	I have to see too many different specialists for my health problem(s) or illness(es).	0.75
	I have problems filling out forms related to my healthcare.	0.75
	I have problems getting appointments at times that are convenient to me.	0.86
	I have problems getting appointments with a specialist.	0.79
	I have to wait too long at my medical appointments.	0.74
Interpersonal challenges ( $\alpha=0.85$ )	I have to wait too long at the pharmacy for my medicine.	0.73
	Over the past 4 weeks, how bothered have you been by feeling dependent on others for your healthcare needs?	0.86
	Over the past 4 weeks, how bothered have you been by others reminding you to do things for your health like take your medicine, watch what you eat, or schedule medical appointments?	0.84
	Over the past 4 weeks, how bothered have you been by your healthcare needs creating tension in your relationships with others?	0.87
Diet ( $\alpha=0.80$ )	Over the past 4 weeks, how bothered have you been by others not understanding your health situation?	0.86
	I have to give up too many foods that I like.	0.60
	It is hard to find healthy foods.	0.84
Exercise/physical therapy ( $\alpha=0.81$ )	It is hard for me to follow my healthcare provider's recommendations for healthy eating.	0.93
	It is difficult for me to find the time to exercise or do physical therapy	0.85
	It is difficult for me to follow my healthcare provider's recommendations about exercise or physical therapy	0.91
	It is difficult for me to get motivated to exercise or do physical therapy	0.77
Medical equipment ( $\alpha=0.83$ )	Physical pain or discomfort limits my ability to exercise or do physical therapy	0.72
	Over the past 4 weeks, how easy or difficult has it been for you to use your medical equipment or device?	0.86
	Over the past 4 weeks, how easy or difficult has it been for you to keep your medical equipment or device working correctly?	0.95

bother, were as follows:  $r_{\text{medical information}}=0.71$ ;  $r_{\text{medications}}=0.48$ ;  $r_{\text{bother with med. reliance}}=0.76$ ;  $r_{\text{bother with med. side effects}}=0.60$ ;  $r_{\text{medical appointments}}=0.80$ ;  $r_{\text{monitoring health}}=0.80$ ;  $r_{\text{diet}}=0.80$ ;  $r_{\text{exercise/physical therapy}}=0.90$ ;  $r_{\text{medical equipment}}=0.58$ ;  $r_{\text{interpersonal challenges}}=0.36$ ;  $r_{\text{medical expenses}}=0.77$ ;  $r_{\text{difficulty with healthcare services}}=0.78$ ;  $r_{\text{role/social activity limitations}}=0.79$ ;  $r_{\text{physical/mental exhaustion}}=0.75$ .

Note that the samples available for analysis in the diet, exercise/physical therapy, and medical equipment domains were low due to respondents screening out of the domain items ( $N=11, 18, \text{ and } 25$  for the three scales, respectively). Hence, the ICC estimates for these domains should be interpreted with caution. Test-retest reliability was adequate (above threshold)<sup>24</sup> for all but

the medications, medication side-effect bother, medical equipment, and interpersonal challenges domain scales.

## Discussion

Our analysis provides support for the construct validity of version 2.0 of the PETS treatment burden measure. PETS version 2.0 extends our previously-validated 48-item version by 12 items, including three previously unanalyzed content domains.<sup>2</sup> Overall, our confirmatory factor analyses supported a 12-factor model which is largely consistent with the patient-derived conceptual framework of treatment burden.<sup>1</sup> Reliability of the domain scales supported by the CFA was adequate with good internal consistency observed in all of the multi-item scales. Furthermore, among all 14 scales, including the two single-item indicators, test-retest reliability was found to be acceptable in 10 of them.

In addition to confirming the conceptual structure of treatment burden articulated in the PETS measure, the excellent fit observed in the second-order CFA model along with high inter-domain correlations support the existence of two superordinate factors, representing underlying commonalities in relationships of certain PETS content domains. The ease/difficulty of seeking and understanding medical information, taking medications, monitoring one's health, and making and maintaining medical appointments is reflected in a Workload dimension. The influence of self-management on one's daily functioning and overall well-being is reflected in an Impact dimension. These findings are practically important because they provide justification for calculating and using aggregated index scores that combine scores of related PETS domains. While we do not advocate abandoning the individual domain scores that constitute each index, we do believe that these aggregate index scores will facilitate use of the measure by diminishing the number of scores to report. Furthermore, as with the previous version,<sup>2</sup> since there is no calculated total score, users are free to select whichever PETS scales are best suited to their study or clinical setting. Finally, we also showed that items within workload and impact can be interpreted in the same way regardless of gender (male vs female), formal education status (college graduate vs not), or subjective health literacy (some difficulty understanding written medical information vs no difficulty). Hence, across at least these indicators, there is no evidence of differential item functioning on these PETS items.

There are other ways to improve the usability of the PETS and create a more parsimonious measure. First, the screening questions used for the diet, exercise/physical

therapy, and medical equipment scales tend to produce a considerable amount of missing data. In a recent study to translate the PETS into Norwegian, respondents reported being confused by the screening questions to the extent that they felt uncertain as to whether they had answered the questions in these domains correctly.<sup>27</sup> To alleviate confusion and mitigate the amount of missing data, we will drop these screening questions on future versions of the PETS. Instead, we will include a "not applicable" response option in the rating scale used for these items, similar to several other PETS domain scales. Second, we will set aside two domain scales that appear to be less related to most patients' experience of treatment burden – the interpersonal challenges and medical equipment scales. Interpersonal challenges taps feelings of bother in relating to one's social network regarding one's healthcare needs (eg, "feeling dependent on others for healthcare needs," "healthcare needs creating tension with others"). Problems in these areas are less frequently endorsed by patients. In this study, the selection of "not at all bothered" for the four items of this scale ranged from 54% to 72%. Hence, the range and variability of scores is likely to be restricted. Furthermore, interpersonal challenges are more reflective of a social moderator of treatment burden rather than an indicator of it. Regarding medical equipment, only 45% of respondents replied that they were using some type of medical equipment or device, similar to findings of our prior validation study.<sup>2</sup> The diminished relevance of these domains justifies setting them aside in future versions of the PETS, though we will maintain these as ancillary scales of treatment burden for interested users.

## Study Limitations

There are limitations of this study. First, with a 30% response rate to the survey, there may be selection bias in our sample. It is possible that people with the highest burden were less likely to respond. As treatment burden is inherently subjective, we have no way to know this for certain. However, in comparison to non-responders, survey responders did tend to be older, Caucasian, and diagnosed with more chronic conditions. Other studies of multimorbidity have shown that treatment burden tends to be higher in younger people.<sup>28,29</sup> It will be important for future studies that use the PETS to include younger cohorts of working-aged adults, especially racial/ethnic minorities and persons from socially vulnerable groups such as those with low income, low education, or low health literacy. Second, our psychometric studies of the PETS have focused exclusively on patients living in the

**Table 3** Factor Correlations (Below Diagonal) and Variances (on Diagonal) of the 12-Factor Model<sup>a</sup>

	MINF	MED	MAPP	MH	EX/PT	DIET	RAL	PME	MEXP	HCS	INT	MEQP
MINF												
MED	0.67											
MAPP	0.63	0.74										
MH	0.66	0.69	0.69									
EX/PT	0.28	0.39	0.38	0.50								
DIET	0.46	0.31	0.32	0.55	0.62							
RAL	0.43	0.47	0.54	0.53	0.42	0.22						
PME	0.51	0.53	0.62	0.58	0.43	0.31	0.79					
MEXP	0.54	0.50	0.61	0.55	0.53	0.38	0.61	0.61				
HCS	0.53	0.46	0.65	0.41	0.33	0.38	0.40	0.42	0.52			
INT	0.52	0.57	0.61	0.61	0.36	0.31	0.82	0.79	0.58	0.41		
MEQP	0.57	0.67	0.63	0.69	0.13	0.09	0.49	0.49	0.42	0.51	0.55	

**Notes:** <sup>a</sup>Variances of factors are standardized to 1 and appear in yellow. Correlations of domains making up the workload and impact (second-order) factors appear in red. **Abbreviations:** MINF, medical information; MED, taking medications; MAPP, medical appointments; MH, monitoring health; EX/PT, exercise/physical therapy; RAL, role/social activity limitations; PME, physical/mental exhaustion; MEXP, medical expenses; HCS, difficulty with healthcare services; INT, interpersonal challenges; MEQP, medical equipment.

**Table 4** Standardized First-Order to Second-Order Factor Loadings

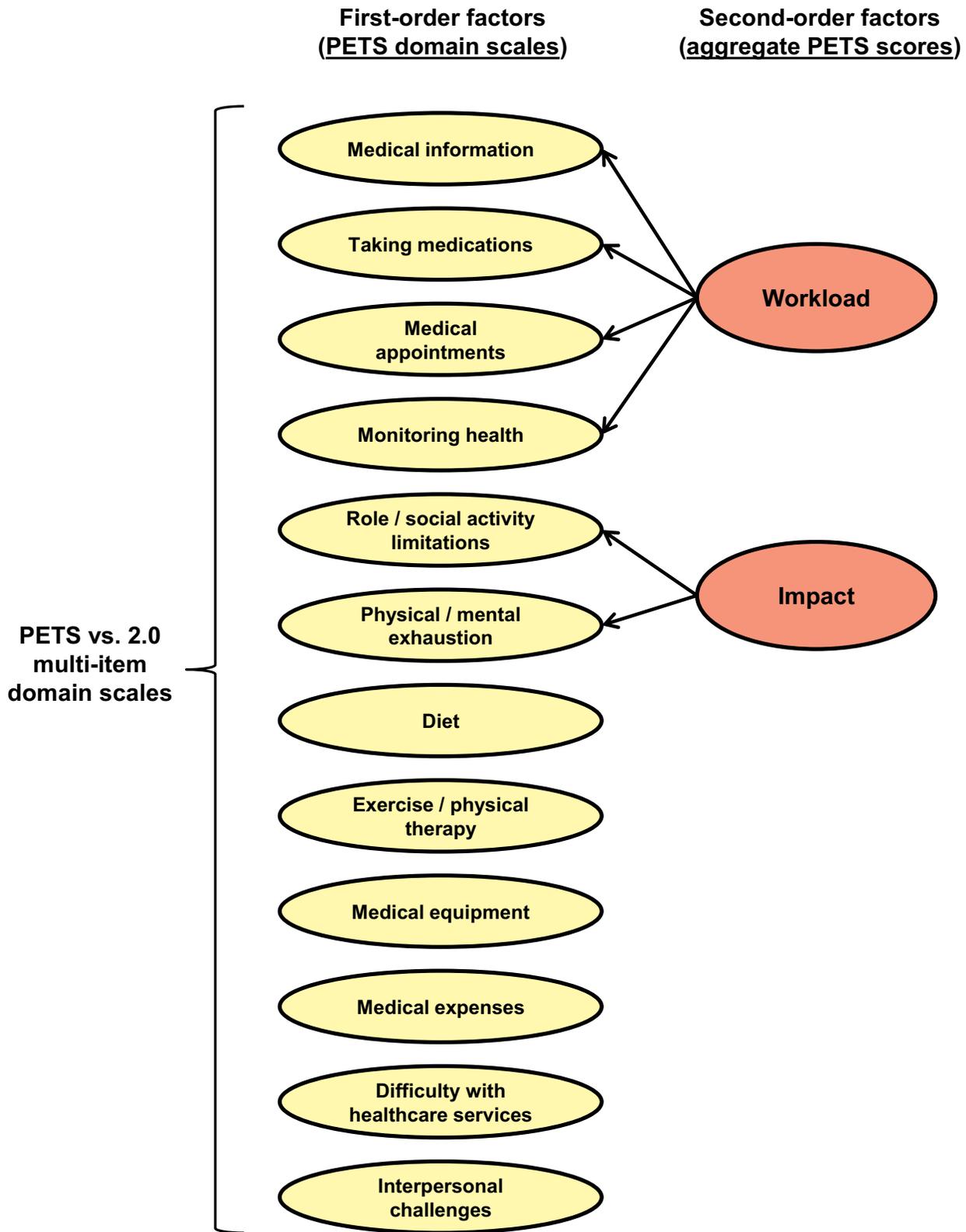
Second-Order Factor	First-Order Factor	Loadings of First-Order Factors on Second-Order Factors
Workload	Medical information	0.57
	Medications	0.82
	Medical appointments	0.89
	Monitoring health	0.81
Impact	Role/social activity limitation	0.86
	Physical/mental exhaustion	0.91

United States. At present, we have limited data from patients in other countries who may have experience with different healthcare systems. However, we are aware of ongoing studies using the PETS in patients across multiple countries and continents, including studies using new translated versions of the measure.<sup>27</sup> Furthermore, the PETS measurement framework<sup>1,30</sup> has informed the content of treatment burden measures developed in the UK and France.<sup>28,29</sup> Third, few patients in this study (6%) had health conditions that were recently diagnosed (within a year of the survey). Responses to questions about perceived treatment burden may be different for those dealing with a new diagnosis. Fourth, the mailed-survey study design prevented us from being able to precisely control the time interval for the retest

administration of the PETS. Some changes in treatment burden over time might have occurred for some which could explain why a few PETS domains featured suboptimal test-retest reliability. Future studies should establish a fixed and briefer interval for retest (eg, 2 days). Furthermore, there may also be value in determining the consistency of PETS scores across various modes of administration (eg, self- vs interviewer-administered) or comparing patient vs caregiver proxy assessments of treatment burden. Finally, conclusions about a lack of DIF on PETS items are limited to only those items analyzed in the present study (ie, items within the workload and impact factors).

## Conclusions

Confirmatory factor analyses of the PETS version 2.0 (60 items: © 2016 Mayo Foundation for Medical Education and Research) supports the factorial construct validity of the measure. DIF analyses support that PETS items do not appear to be differentially interpreted across gender, formal education status, or subjective health literacy (no DIF). Two second-order factors were supported justifying aggregation of certain PETS domain scales into summary index scores for workload and impact. We recommend that investigators use these summary index scores in future reports, and consider using them in clinical trials of the measure, assessing clinical utility of these simplified metrics. The known-groups validity and responsiveness to change of all PETS version 2.0 scales and scores has been supported in



**Figure 2** Second-order model of latent constructs.  
**Abbreviation:** PETS, Patient Experience with Treatment and Self-management.

**Table 5** Confirmatory Bifactor Model Loadings for Workload (Loadings in Blank Cells are 0)

	General Workload Factor	MINF	MED	MAPP	MH
Over the past 4 weeks, how easy or difficult has it been for you to learn about your health problem(s)?	0.70	0.45			
Over the past 4 weeks, how easy or difficult has it been for you to learn what foods you should eat to stay healthy?	0.62	0.44			
Over the past 4 weeks, how easy or difficult has it been for you to find information on the medications that you have to take?	0.70	0.54			
Over the past 4 weeks, how easy or difficult has it been for you to understand any changes to your treatment plan?	0.71	0.58			
Over the past 4 weeks, how easy or difficult has it been for you to understand the reasons why you are taking some medicines?	0.73	0.55			
Over the past 4 weeks, how easy or difficult has it been for you to find sources of medical information that you trust?	0.70	0.56			
Over the past 4 weeks, how easy or difficult has it been for you to understand advice from different healthcare providers?	0.76	0.48			
Over the past 4 weeks, how easy or difficult has it been for you to organize your medicines?	0.82		0.38		
Over the past 4 weeks, how easy or difficult has it been for you to take more than one medicine every day?	0.76		0.57		
Over the past 4 weeks, how easy or difficult has it been for you to take your medicines several times each day?	0.72		0.56		
Over the past 4 weeks, how easy or difficult has it been for you to refill your medicines?	0.78		0.44		
Over the past 4 weeks, how easy or difficult has it been for you to adjust your medicines?	0.79		0.34		
Over the past 4 weeks, how easy or difficult has it been for you to take your medicines as directed?	0.85		0.44		
Over the past 4 weeks, how easy or difficult has it been for you to plan your daily activities around your medicine schedule?	0.75		0.37		
Over the past 4 weeks, how easy or difficult has it been for you to make or keep your medical appointments?	0.80			0.52	
Over the past 4 weeks, how easy or difficult has it been for you to schedule and keep track of your medical appointments?	0.82			0.52	
Over the past 4 weeks, how easy or difficult has it been for you to make or keep appointments with different healthcare providers?	0.79			0.52	
Over the past 4 weeks, how easy or difficult has it been for you to find the time to get to your medical appointments?	0.77			0.48	
Over the past 4 weeks, how easy or difficult has it been for you to find the energy to get to your medical appointments?	0.83			0.32	
Over the past 4 weeks, how easy or difficult has it been for you to find transportation to get you to your medical appointments?	0.78			0.33	
Over the past 4 weeks, how easy or difficult has it been for you to monitor your health behaviors, for example, tracking your exercise, the foods you eat, or medicines you take?	0.80				0.45
Over the past 4 weeks, how easy or difficult has it been for you to monitor your health condition, for example, weighing yourself, checking your blood pressure, or checking your blood sugar?	0.81				0.51

**Abbreviations:** MINF, medical information; MED, taking medications; MAPP, medical appointments; MH, monitoring health.

a companion article to this study.<sup>31</sup> Other modifications to facilitate use of the PETS include the removal of domain screening items and setting aside content that is less frequently endorsed and ancillary to the concept of treatment

burden, such as questions concerning the use of medical equipment and interpersonal challenges with others. While such content can be held in reserve and made available to interested investigators, it will be removed from the base

**Table 6** Confirmatory Bifactor Model Loadings for Impact (Loadings in Blank Cells are Fixed to 0)

	General Impact Factor	RAL	PME
In the past 4 weeks, how much has your self-management interfered with your work?	0.91	0.21	
In the past 4 weeks, how much has your self-management interfered with family responsibilities?	0.93	0.17	
In the past 4 weeks, how much has your self-management interfered with daily activities?	0.96	0.39	
In the past 4 weeks, how much has your self-management interfered with hobbies and leisure activities?	0.93	0.20	
In the past 4 weeks, how much has your self-management interfered with ability to spend time with family and friends?	0.92	~0	
In the past 4 weeks, how much has your self-management interfered with ability to travel for work or vacation?	0.83	~0	
In the past 4 weeks, how often did your self-management make you feel angry?	0.64		0.59
In the past 4 weeks, how often did your self-management make you feel preoccupied?	0.67		0.49
In the past 4 weeks, how often did your self-management make you feel depressed?	0.66		0.63
In the past 4 weeks, how often did your self-management make you feel worn out?	0.74		0.49
In the past 4 weeks, how often did your self-management make you feel frustrated?	0.71		0.60

**Abbreviations:** RAL, role/social activity limitations; PME, physical/mental exhaustion.

PETS measure. Overall, we strive to obtain a valid measure of treatment burden that is both comprehensive in coverage and easy to administer, score, and interpret. Note that while not publicly available, a de-identified dataset of the data analyzed for this study can be made available at reasonable request of the principal investigator of the project (D. Eton). All requests are subject to review by the principal investigator and study co-investigators and must be approved by the Mayo Foundation for Medical Education and Research.

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