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Measuring Substantial Reductions in Activity

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Abstract

The case definitions for Myalgic Encephalomyelitis/chronic fatigue syndrome (ME/CFS), Myalgic Encephalomyelitis (ME), and chronic fatigue syndrome (CFS) each include a disability criterion requiring substantial reductions in activity in order to meet diagnostic criteria. Difficulties have been encountered in defining and operationalizing the substantial reduction disability criterion within these various illness definitions. The present study sought to relate measures of past and current activities in several domains including the SF-36, an objective measure of activity (e.g. actigraphy), a self-reported quality of life scale, and measures of symptom severity. Results of the study revealed that current work activities had the highest number of significant associations with domains such as the SF-36 subscales, actigraphy, and symptom scores. As an example, higher self-reported levels of current work activity were associated with better health. This suggests that current work related activities may provide a useful domain for helping operationalize the construct of substantial reductions in activity.

Keywords

Substantial Reductions; Activity; Myalgic Encephalomyelitis/chronic fatigue syndrome; Myalgic Encephalomyelitis; chronic fatigue syndrome

In order to be diagnosed with Myalgic Encephalomyelitis/chronic fatigue syndrome (ME/CFS) (Carruthers et al., 2003), Myalgic Encephalomyelitis (ME) (Carruthers et al., 2011), or chronic fatigue syndrome (CFS) (Fukuda et al., 1994), individuals must experience substantial reductions in functioning. A crucial problem with the disability requirement within these case definition criteria involves the lack of specification regarding what constitutes substantial reductions in functioning. For instance, the Fukuda et al. (1994) case definition for CFS requires that individuals experience substantial reductions in previous levels of occupational, social, and family activities. The wording within the Fukuda et al. (1994) criteria is vague and does not provide specific instructions regarding the severity of reductions and how they should be measured. Similarly, the Canadian Clinical Case Definition for ME/CFS requires that a person have key symptoms of ME/CFS and that these symptoms are severe enough to cause substantial reductions in activity levels by at least 50%, compared to premorbid activity levels (Carruthers et al., 2003). While Carruthers et al. (2003) provided a cutoff point to measure substantial reductions in individuals with ME/CFS, it is unclear how to measure this 50% reduction.

Additionally, in the Myalgic Encephalomyelitis International Consensus Case Criteria (ME-ICC), Carruthers et al. (2011) specifies that individuals must experience symptoms severe enough to cause substantial reductions in pre-illness activity. Furthermore, the ME-ICC criteria designates three levels of activity reduction severity (mild, moderate, and severe), with the mild level signifying an approximate 50 percent reduction in activity levels, the moderate level signifying individuals who are unable to function outside of the home, and the severe level signifying individuals who are confined to their beds and who have difficulties caring for their own basic needs. Following the development of the ME-ICC, Carruthers et al. (2012) developed a primer to be used by medical practitioners as a guide for diagnosing ME in adults and children/adolescents. The primer also provides specifications regarding the assessment of substantial reductions, which deviate slightly from the original guidelines mentioned in the ME-ICC (Carruthers et al., 2011). Similar to ME-ICC, the primer designates severity levels for the assessment of activity reduction; however, instead of three levels of severity indicated in the ME-ICC, the primer includes four severity categories (mild, moderate, severe, and very severe): the mild level signifies that a person “meets criteria” and is experiencing “significant” reductions in activity, the moderate level signifies that a person has experienced approximately a 50 percent reduction in pre-illness activity level, the severe level signifies individuals who are unable to function outside of the home, and the very severe level signifies individuals who are confined to their beds and who have difficulty caring for their own basic needs. It is unclear why the ME primer (Carruthers et al., 2012) implemented four severity levels of activity reduction as compared to the three that are specified in the ME-ICC (Carruthers et al., 2011). Most importantly, the mild level signifies an approximate 50 percent reduction in activity levels for the Carruthers et al. (2011) criteria, but the moderate level signifies that a person has experienced approximately a 50 percent reduction for the Carruthers et al. (2012) criteria. Furthermore, the language that is used in both the ME-ICC (Carruthers et al., 2011) and the ME primer (Carruthers et al., 2012) is vague and lacks specific steps or assessment tools for consistently and accurately assessing substantial reductions and severity level in individuals with the illness. For instance, it is unclear how to determine whether someone is experiencing “significant” reductions in activity versus a 50 percent reduction in activity. Without clearly defined criteria and adequate assessment tools, the method for determining whether an individual meets the required severity level of reductions in pre-illness activity is left to clinical discretion, which may differ greatly across clinicians.

In order to improve the diagnostic reliability and validity of measuring disability within ME/CFS, ME, and CFS, it is necessary to develop clearly defined, explicit, and systematically derived case criteria that differentiate individuals with the illness from those who are unaffected. In an effort to operationalize and standardize the CFS criteria, Reeves et al. (2005) developed the empiric CFS case definition. In their operationalization of the disability domain, Reeves et al. (2005) utilized the Medical Outcomes Study Short Form-36 Health Survey (SF-36; Ware, 2000). This instrument is a 36-item, broadly based, self-report measure of functional status that includes eight different subscales. In their operationalization of the disability criterion, Reeves et al. (2005) selected four out of a total eight SF-36 subscales to measure substantial reductions. According to Reeves et al. (2005), the disability CFS criterion would be met by scoring at or below the 25th percentile of

published U.S. population data on at least one of the following four selected sub-scales: Physical Functioning (= 70), Role-Physical (= 50), Social Functioning (= 75), and Role-Emotional (= 66.7). Although Reeves and colleagues developed explicit guidelines for assessing substantial reductions; it was unclear why individuals were required to meet only one of the four subscales to meet the disability criterion, particularly the Role-Emotional subscale (which would be met by any person with a Major Depressive Illness). Ware et al. (2000) found that the mean for Role-Emotional for a clinical depression group was 38.9, indicating that almost all those with clinical depression would meet the CFS disability criterion, as they would be within the lower 25th percentile on this subscale.

The inclusion of the Role Emotional subscale in the Reeves et al. (2005) CFS criteria has been questioned by Jason, Najjar, Porter, and Reh (2009), who pointed out that a person could meet the disability criterion without any reductions in the key areas of physical functioning and only have impairment in role emotional areas. In fact, Jason et al. (2009) found that 38% of individuals who had primarily a Major Depressive Disorder (MDD) were misclassified as having CFS using the Reeves empiric CFS case definition (2005). In further support of this critique by Jason et al. (2009), Jason et al. (2011) found that the Role Emotional subscale had the worst sensitivity and specificity of all the SF-36 subscales using responses from both a community-based sample and a tertiary care sample.

In order to test the diagnostic validity of the Reeves et al. (2005) disability criterion, Jason and colleagues (2010) used a Receiver Operating Characteristic (ROC) curve analysis to assess how well the SF-36 scales and the proposed cutoff scores discriminate between those with CFS and those without CFS within a community-based sample. Jason et al. (2010) found that the Reeves et al. (2005) cutoff scores had adequate sensitivity (.96), meaning they could correctly identify individuals with CFS 96% of the time; however, the cutoff scores had very low specificity (.17) suggesting that individuals without the illness would only be identified 17 percent of the time (Jason et al. 2010). In other words, the disability criterion recommended by Reeves et al. (2005) is at risk for erroneously including individuals who do not have the diagnosis.

In a separate study, Jason et al. (2011) administered the SF-36 to individuals with CFS and controls in both a community-based population and a tertiary care population. Rather than only focusing on the four subscales selected in the Reeves et al. (2005) disability criterion, Jason et al. (2011) investigated the sensitivity and specificity of all eight subscales, again using ROC analysis. Overall, Jason et al. (2011) found that the following subscales and cutoff scores had the highest sensitivity and specificity across the two samples: Vitality (= 35), Social Functioning (= 62.5), and Role Physical (= 50). In order to investigate this issue further, Jason et al. (2011) also examined published studies using the SF-36 that contrasted individuals with CFS with controls. The largest differences emerged for the Role Physical, Social Functioning, and Vitality SF-36 subscales, providing further evidence that these three subscales are the best at differentiating individuals with CFS from those without the diagnosis.

As is demonstrated in the above studies, considerable care is needed when determining the appropriate measures, scales and cutoff points for assessing disability within the ME/CFS,

ME, and CFS populations. While the SF-36 scale has been utilized in the past to assess disability and substantial reductions, there may be other methods for validating this construct, involving both objective measures of activity as well as additional self-report measures. The present study sought to investigate the potential of using several self-report questions that attempt to capture substantial reductions in activity in work, social and household areas. Responses to the current and past activity questions were correlated with objective and subjective measures of disability and functioning. As this is an exploratory study, it was hypothesized that the number of past and current hours in the three key areas would be highly correlated with critical markers of disability and illness severity.

Method

Participants

The present investigation utilized baseline data derived from a larger longitudinal study of nonpharmacological treatment interventions for CFS (Jason et al., 2007). Participants were recruited from physician referrals, media advertisements, and CFS support groups. Participants were required to be at least 18 years of age, not pregnant, able to read and speak English, and considered to be physically capable of attending scheduled appointments. Participants were included if they met the Fukuda et al. (2004) criteria for CFS as diagnosed by the study physician (see Jason et al., 2007 for details on diagnostic procedures). A total of 114 participants were recruited and enrolled in the original study and their baseline data was used for the present study. All procedures were approved by the DePaul University Institutional Review Board. Informed consent was given by all participants.

Sample Characteristics

In regards to sociodemographic characteristics, 83.3% of the 114 participants were female and the average age was 43.8 years ($SD = 11.6$). Concerning ethnicity, 87.7% of the participants were White, 4.4% were African American, 4.4% were Latino, and 3.5% were Asian American. Regarding marital status, 49.1% of the participants were married/living with a partner, 33.3% were single, and 17.6% were either divorced or separated. As for work status, 40.4% of the participants were working or full-time students, and 59.6% were not working or were part-time students. Concerning education, 47.4% of the participants had earned a standard college degree, 21.8% had a graduate or professional degree, 21.1% had partial college, and 9.7% had a high school/GED degree or less.

Procedures

A semi-structured psychiatric interview (the Structured Clinical Interview for DSM-IV) was administered to establish Axis I psychiatric diagnoses and rule out exclusionary psychiatric diagnoses according to the Fukuda et al. (1994) criteria. Next, an in-depth medical and laboratory evaluation similar to that which was given in the community-based sample was conducted. One hundred and fourteen individuals were diagnosed with CFS based on the Fukuda et al. (1994) criteria and enrolled in the study (see Jason et al. (2007) for more details regarding recruitment, procedure, and evaluation).

Measures

DePaul University Fatigue Questionnaire—The DePaul University CFS Questionnaire (Jason, Ropacki, Santoro, Richman, Heatherly, Taylor, et al. 1997) evidences good inter-rater and test-retest reliability, and is able to sensitively distinguish among individuals with CFS, individuals with Major Depressive Disorder, and healthy controls (Hawk, Jason & Torres-Harding, 2006). The DePaul CFS Questionnaire assesses for frequency and severity over the past 6 months. For the current study, we focused on the following questions: “In the past month, how many hours a week have you spent doing: household related activities, social-related activities, work-related activities?” There was space on the form to indicate number of hours spent on each of the three domains. Next, respondents responded to the following questions: “In the past 6 months, have you had to reduce the number of hours you previously spent on occupational, social, or family activities because of your health or problems with fatigue?” If the participants responded affirmatively that activities had been reduced, the respondents responded to a question asking “How many hours per week you used to spend in occupational, social, and family areas.”

Actigraph—Participants wore an actigraph for a one-week period at baseline and at the end of the treatment. An actigraph is a small, lightweight, cost-efficient activity monitor that can be worn on the waist. It has a long battery life and can continuously collect data over the 24-hour period for 22 days before its memory reaches capacity (Tryon & Williams, 1996). Unlike most activity monitoring devices, the actigraph is capable of recording movement intensity. The actigraph transduces activity using an accelerometer. An 8-bit analog-to-digital converter quantifies these measurements into 128 levels of positive acceleration and 128 levels of negative acceleration 10 times each second. Integration over the resulting sampling time of 0.1 s in combination with other details provided by Tryon and Williams (1996) would result in measurements of 1.664 milli-g/activity activity count. For simplicity, analog-to-digital (A/D) counts are retained as activity units. The average of 600 absolute A/D values is stored in memory at the end of every minute. Participants wore the actigraph on their waist at all times except when bathing or sleeping.

Fatigue Severity Scale (FSS)—The FSS (Krupp, LaRocca, Muir-Nash, and Steinberg, 1989) was used to measure fatigue. This scale is a subjective questionnaire containing nine questions that the participant rates on a scale from 1–7. Scoring is done by calculating the average response to the questions. A higher score relates to severe fatigue. A study by Taylor, Jason, and Torres (2000) compared the Fatigue Scale (Chalder, Berelowitz, Pawlikowska, Watts, & Wessely, 1993) with the FSS (Krupp et al., 1989) with a sample of healthy controls and a CFS-like group. Within a CFS-like group, the Fatigue Severity Scale (Krupp et al., 1989) was more closely associated with severity ratings for the eight Fukuda et al. (1994) CFS symptoms as well as with functional outcomes related to fatigue.

Beck Depression Inventory (BDI-II)—Since depression is the most commonly diagnosed psychiatric disorder in CFS (Friedberg, 1996), a quantitative measure of depression severity was used. The BDI-II (Beck, Steer, & Brown, 1996) is a self-report measure that consists of 21 items to assess the intensity of depression in clinical and normal patients. Higher scores indicate higher intensity of depression. The BDI-II is the only

depression rating scale to be empirically tested and interpreted for both individuals with CFS who were depressed and those that were not depressed (Johnson, DeLuca, & Natelson, 1996). Also the BDI-II has shown sensitivity to treatment changes in two cognitive behavioral treatment studies of CFS (Deale et al., 1997).

Perceived Stress Scale (PSS)—The PSS is a four-item revised version of a previous 14-item measure of global perceived stress. This instrument measures stress in the previous month (Cohen, Kamarck, & Mermelstein, 1983). It has a range from 0–16, with higher scores measuring more stress.

Pittsburgh Sleep Quality Index (PSQI)—Sleep disturbances were assessed using The Pittsburgh Sleep Quality Index, which was developed to measure sleep quality in psychiatric research (Buysse, Reynolds, Monk, Berman, & Kupfer, 1989). This Index is a 24-item, self-administered questionnaire which assesses sleep quality and disturbances over a 1-month time interval (0 = not during the last month; 1 = less than once a month; 2 = once or twice a month; 3 = three or more times a week). Nineteen individual items generate seven “component” scores: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. The sum of these seven component scores yields one global score. Higher scores indicate less sleep quality. Three items were identified as central to CFS, i.e. trouble staying awake while driving, eating meals, or engaging in social activities.

Beck Anxiety Inventory (BAI)—Anxiety symptoms were measured with the BAI, a self-report measure that consists of 21 items to assess severity of anxiety in psychiatric populations. Higher scores indicate higher intensity of anxiety. Anxiety symptoms at intake were a predictor of treatment outcome in two cognitive behavioral treatment studies of CFS (Sharpe et al., 1996). Also, there is a high frequency of anxiety disorders reported in psychodiagnostic studies of CFS (e.g., Pepper et al., 1993).

Brief Pain Inventory (BPI)—The BPI (Cleeland & Ryan, 1994) was administered to measure the intensity of pain (pain severity) and the inference of pain in the individuals’ life (pain inference). Higher scores indicate more severe levels of persistent pain and higher levels of inference with functioning. It also evidences good concurrent validity with other generic pain measures and has been shown to be sensitive to changes in pain status over time (Keller et al., 2004).

Quality of Life (QOL)—The Quality of Life Scale measures satisfaction with different life activities for individuals with various chronic illnesses (Burckhardt & Anderson, 2003). The scale consists of 16 items answered on a Likert type scale, from one to seven, which measures six conceptual domains of quality of life: material and physical well-being, relationships with other people, social, community and civic activities, personal development and fulfillment, and recreation, and independence. Higher scores mean more overall life satisfaction.

Medical Outcomes Study- Short Form-36 (SF-36)—The SF-36 is a 36 item broadly-based self-report measure of functional status related to health (Ware & Sherbourne, 1992).

A higher score indicates better health or less impact of health on functioning. An example of a question on this form follows: Does your health now limit you in these activities? Walking one block (Yes, limited a lot; Yes, limited a little; No, not limited at all). Test construction studies for the SF-36 (McHorney, Ware, Lu, & Sherbourne, 1994) have shown adequate internal consistency and substantial differences between patient and non-patient populations in the pattern of scores. The SF-36 has also demonstrated sufficient psychometric properties as a measure of functional status in a CFS population (Buchwald, Pearlman, Umali, Schmalting, & Katon, 1996). The MOS Physical Functioning Scale was utilized in the present study as it has been used in several other outcome studies (Deale et al., 1997).

Results

Correlational analysis

Table 1 presents Pearson correlation coefficients between self-reported current activities (within the social, work, and household domains) and past activities (within the social, occupational, and family domains) and objective measures (actigraphy) and additional self-report measures. Past occupational and current work were significantly associated with objective and subjective markers of better health. For instance, past occupational activities was positively associated with actigraphy and negatively associated with self-reported pain. Current work activities was also positively associated with actigraphy and negatively associated with fatigue severity, sleep, and pain.

Table 2 presents Pearson correlation coefficients between self-reported current activities (within the social, work, and household domains) and past activities (within the social, occupational, and family domains) and the eight SF-36 subscales (Physical Functioning, Role Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role Emotional, Mental Health). Results showed that higher reports of current social activities, past and current occupational activities, and current household activities were markers of better health on the SF-36. For instance, past occupational activities were positively associated with Physical Functioning, Vitality, and Social Functioning. Current work activities were positively associated with Physical Functioning, Bodily Pain, and Vitality. Lastly, current household activities were positively associated with Physical Functioning, Role Physical, Vitality, and Social Functioning.

Table 3 presents Pearson correlation coefficients between current and past self-reported activities and the eight case-defining symptoms of CFS as defined by the Fukuda et al. (1994) case criteria (post exertional malaise, unrefreshing sleep, impaired memory, muscle pain, headaches, joint pain, lymph nodes, sore throat). Activity items were negatively associated with multiple CFS symptoms, indicating that these items were markers of better health, as lower scores on symptoms are associated with less severity. Past occupational activities were negatively associated with post exertional malaise, impaired memory, and lymph node pain. Current work activities were negatively associated with post exertional malaise, impaired memory, muscle pain, headaches, and joint pain. Past family activities were positively correlated with headaches. Current household activities were negatively associated with post exertional malaise and lymph node pain.

Discussion

Utilizing the CFS questionnaire (Jason et al., 2007), the present study examined the relationship of current and past activities in three domains with a sample of individuals with CFS. The findings suggest that past occupational and current work related activities may provide a helpful marker of disability and functioning in the ME, ME/CFS, and CFS populations. Our data revealed that past activity levels were less associated with both the objective and subjective measures of disability and functioning as compared to current activity levels across the household, social, and work domains. Given the significant associations found between current levels of activity and the various measures of functioning, it may be more effective for surveys to specifically ask about activity levels in the last week or month. This might reveal a more accurate picture of how ME/CFS, ME, or CFS affects these patient groups.

Work activities were associated with the most Fukuda et al. (1994) symptoms, SF-36 subscales, self-report measures, and objective measures of functioning. Similarly, current household activities were also associated with several SF-36 subscales, including positive associations with Vitality, Social Functioning, and Role-Physical. Notably, these three SF-36 subscales were found by Jason et al. (2011) to have the best sensitivity and specificity towards assessing substantial reductions in individuals with CFS. Impaired past occupational, current work, and current household functioning may be more strongly associated with worse ME/CFS, ME, or CFS symptomology overall. It appears that the fewer hours that an individual is able to physically work at home or for a job, the more impaired he or she may be. However, current social activity was only significantly associated with Physical Functioning on the SF-36.

Future research applying objective measures of activity such as actigraphy may be a useful approach to corroborating substantial reductions, especially compared to self-report measures that may be influenced by patient interpretation. Because of the fluctuating nature of ME/CFS, ME, or CFS, utilizing actigraphy may reveal a more precise and reliable picture of the disability and impaired functioning caused by this illness. As shown in Table 1, actigraphy was only positively correlated with past occupational and current work activities. This shows that self-report measures can be significantly correlated with an objective measure.

There are several limitations to this study. Regarding activity across the social, family, and work domains, questions were worded slightly differently between the past and current time frames. Our questionnaire assessed past occupational but current work-related activities, but both terms are relatively synonymous. In addition, we asked about current household-related activities but past family activities. This may potentially assess two different aspects within the family domain because “household-related” may be interpreted as chores around the house whereas “family” may be interpreted as recreational family activities. Both would still fall under the general family domain, but future studies should use similar terms for both time periods. Finally, the Fukuda et al. (1994) CFS criteria require substantial reductions in levels of occupational, family, and social activities. Clearly, we did not have a question regarding what the participants level of activities were prior to illness onset, so we were not

able to calculate an overall reduction in activities from pre-illness onset to the present time. Whether this construct of substantial reductions can be reliably measured with all the problems inherent with recalling from events that occurred years ago is still unclear, however, it does appear that current reductions is a construct that can be measured.

In summary, our study suggests that current work activities are associated with better health in different areas of functioning. Therefore, those with lower work activities might be considered as evidencing more substantial difficulties with many areas of functioning, and this domain might be an excellent one for further investigation. Undoubtedly, great care needs to be exercised when determining which activities might be substantially reduced. Rather than ambiguously asking about substantial reductions, this construct needs to be carefully measured with standardized instruments. Efforts to measure substantial reductions in different domains of life continues to be a challenge for researchers, and by tackling this complex measurement issues, ultimately we will be able to reduce reliability issues when using the ME/CFS, ME, or CFS case definitions.

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Table 1Substantial Reductions with Actigraphy and Self-Reported Scales¹

	Actigraphy	FSS	PSS	PSQI	BAI	BDI	BPI	QOL
Past Social	.14	.10	-.16	.15	.13	.16	-.11	.05
Current Social	.08	.02	-.13	-.02	-.09	.01	-.18	-.12
Past Occupational	.33**	-.15	-.14	-.15	-.22	-.12	-.24*	-.06
Current Work	.26**	-.24*	-.02	-.23*	-.14	-.11	-.33**	-.01
Past Family	.04	.15	.04	.00	.21	.28*	.03	.19
Current Household	.17	-.20	.02	-.03	-.03	-.15	-.07	-.13

¹ Hours per Week

* P value < .05

** p value < .01

Table 2

Substantial Reductions with SF-36 Subscales¹

	Physical Functioning	Role Physical	Bodily Pain	General Health	Vitality	Social Functioning	Role Emotional	Mental Health
Past Social	.13	.01	.10	.07	-.03	.11	.12	.06
Current Social	.21**	.01	.16	.06	.09	.15	-.14	-.05
Past Occupational	.31**	.04	.21	.13	.24*	.39**	-.03	.05
Current Work	.36**	.10	.28**	.04	.25**	.10	.08	-.15
Past Family	-.04	-.06	-.05	-.09	-.09	-.02	-.11	-.09
Current Household	.26*	.22*	.08	-.01	.24*	.38**	.13	.09

¹ Hours per Week
* P value < .05
** p value < .01

Table 3Substantial Reductions with Fukuda symptoms[/]

	Post Exertional Malaise	Unrefreshing Sleep	Impaired Memory	Muscle Pain	Headaches	Joint Pain	Lymph Nodes	Sore Throat
Past Social	.04	.13	-.04	-.03	.01	.01	-.17	-.10
Current Social	.07	-.09	-.03	-.16	-.19	-.09	-.18	-.16
Past Occupational	-.30*	.00	-.26*	-.09	-.01	-.20	-.30*	-.09
Current Work	-.28**	-.16	-.21	-.25**	-.25**	-.23	-.11	-.07
Past Family	.24	.02	.16	.10	.36**	.01	-.07	.08
Current Household	-.22*	-.16	-.17	-.04	-.04	-.07	-.20*	-.09

[/] Hours per Week

* P value < .05

** p value < .01