Severity Scales for Use in Primary Health Care to Assess Chronic Fatigue Syndrome/Myalgic Encephalomyelitis

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Severity Scales for Use in Primary Health Care to Assess Chronic Fatigue Syndrome/Myalgic Encephalomyelitis

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Chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME) is a physical and cognitive disabling illness, characterized by severe fatigue and a range of physiological symptoms, that primarily affects women. The immense variation in clinical presentation suggests differences in severity based on symptomology and physical and cognitive functional capacities. In this article, we examine a number of severity scales used in assessing severity of patients with CFS/ME and the clinical aspects of CFS/ME severity subgroups. The use of severity scales may be important in CFS/ME because it permits the establishment of subgroups that may improve accuracy in both clinical and research settings.

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Chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME) is a physically and cognitively disabling illness that affects a multitude of bodily systems, including neurological, gastrointestinal, nervous, and immunological systems (Chia & Chia, 2008; Demitrack & Crofford, 2006; Fukuda et al., 1995; Gupta & Vayuvegula, 2006; Jason, Helgerson, Torres-Harding, Carrico, & Taylor, 2003; Klimas & Koneru, 2007; Lyall, Peakman, & Wessely, 2003). CFS/ME affects millions worldwide, with a disproportionately high number of women sufferers (Tuck, 2000). Common symptoms of CFS/ME include cognitive and physical fatigue, headaches, cognitive disorder, dizziness, muscle pain, pallor, abdominal pain, nausea, and swollen or tender lymph nodes. These symptoms can be very diverse and vary greatly over time and in severity (Brenu et al., 2013; Carruthers et al., 2011; Cox & Findley, 1998; Fukuda et al., 1994; Fukuda et al., 1995; Jason, Helgerson, et al., 2003; Straus, 1992; Wiborg, van der Werf, Prins, & Bleijenberg, 2010). The pathogenesis of CFS/ME is unknown; therefore, diagnosis is based on a series of symptom-specific criteria (Carruthers et al., 2011). It can be difficult for practitioners in primary health care to assess women with CFS/ME in a short consultation due to the varying nature of symptom severity in the illness. It may be important for severity scales of mobility and symptoms to be widely used by those in primary health to assist in accurately understanding a patient’s individual condition. In this review, we assess severity scales that may be used in clinical primary health care and research settings to assess severity of CFS/ME patients. The use of these severity scales may also have potential to accompany illness diagnosis for women internationally that are debilitated by the symptoms of CFS/ME.

Criteria have also been developed to allow the assessment of symptom severity of symptoms in patients with CFS/ME based on their mobility, level of self-management, and daily abilities (Straus, 1992). CFS/ME patients may further be categorized into mildly, moderately, severely, or very severely affected by their illness. Mild CFS/ME patients are mobile and often still employed; moderate CFS/ME patients have reduced mobility and are restricted in daily tasks, such as household chores; severe CFS/ME patients are only able to perform minimal necessary hygiene-related tasks and are wheelchair dependant; while those with very severe CFS/ME are unable to carry out any daily task for themselves and are essentially bedridden (Straus, 1992). The International Consensus Criteria for ME (ICC) is the most recent and accurate set of criteria used for CFS/ME diagnosis and contains reference to these severity subgroups of CFS/ME patients, although it is not a necessary component of the guidelines (Carruthers et al., 2011). It may be necessary for primary health care professionals to use the ICC and severity scales to categorize the severity of a CFS/ME patient for a better understanding of their condition.

A variety of severity scales that measure symptoms, quality of life, and functional disability can been effectively used in CFS/ME research to
assess a patient’s levels of severity. Clinically distinct severity subgroups have increasing significance as differences are being found both clinically and physiologically in the illness and in supporting the idea of defining such distinct severity subgroups (Baraniuk et al., 2013; Brenu et al., 2013; Friedberg & Krupp, 1994; Härle et al., 2006; Joyce, Hotopf, & Wessely, 1997; Kerr et al., 2008; Peckerman et al., 2003a; Rangel, Garralda, Levin, & Roberts, 2000; Stringer et al., 2013). A combination of severity scales were used to distinguish a clinically distinct severity subgroup of CFS/ME patients as “house-bound” and confirmed the significance of using severity scales in CFS/ME research (Wiborg, van der Werf, et al., 2010).

It is possible that the lack of recognition or inclusion of these severity subgroups may be a causative factor underlining the inconsistency in research findings. Patients with varying severities or symptomatologies in CFS/ME are typically clustered into a single patient group, hence precluding the specificity and success of clinical maintenance or assistance and also in research settings (Zaturenskaya, Jason, Torres-Harding, & Tryon, 2009).

In this review, we provide an assessment of severity scales in CFS/ME that may be used to assess patient’s severity in clinical primary health care and research settings, focusing on the importance of clinical and physiological studies that have examined CFS/ME patient severity. The implementation of severity scales in CFS/ME may also assist the diagnosis and assessment of many women suffering with the illness internationally.

Determination of Symptom Severity Based on CDC and ICC

The 1994 Centres for Disease Control and Prevention (CDC) definition for CFS/ME is widely used to diagnose CFS/ME patients (Fukuda et al., 1995). This definition requires patients to have persistent chronic fatigue lasting longer than 6 months independent of significant physical exertion that is not alleviated by rest (Cox & Findley, 1998). The CDC requires a CFS/ME patient to have at least four of the following symptoms, including postexertional malaise, impaired memory, unrefreshing sleep, muscle pain, joint pain without redness, tender lymph nodes, sore throat, headaches, or all of these (Cox & Findley, 1998). This does not consider some patients who may experience symptoms with lesser severities while others can be severely affected, such that they are habitually bedridden. In response to the vagueness and commonality of symptoms in the 1994 CDC definition for CFS/ME, further criteria for CFS/ME have been developed, the most recent being in 2011 (Carruthers et al., 2011; Straus, 1992).

The ICC was developed in 2011 to provide enhanced clarity and specificity in CFS/ME diagnosis (Carruthers et al., 2011). The 2011 ICC guidelines incorporate more specific and detailed symptomatologies including fatigue; neurological, gastrointestinal, and immune impairments; and energy production. The application of the 2011 ICC also allows an assessment of symptom
severity and impact based on stages of symptom severity, and it is suggested that symptom severity may frequently fluctuate (Carruthers et al., 2011; Cox & Findley, 1998).

The ICC is a tool that can be utilized to acknowledge severity subgroups of CFS/ME patients, referring to mild as those with reduced activity, moderate as those with a 50% reduction in activity levels, severe as being housebound, and very severe as those who are bedbound and require assistance with daily functions (Carruthers et al., 2011). The recognition of such CFS/ME severity subgroups in research outlines the importance of severity scales in CFS/ME.

The CDC criteria for CFS/ME is still the most commonly used CFS/ME definition regardless of the new enhanced development of the ICC. As a result, those who suffer from severe CFS/ME symptoms are typically pooled as a single CFS/ME cohort regardless of severity as they are difficult to access and typically unable to maintain regular appointments (Jason, Benton, Torres-Harding, & Muldowney, 2009). It is recommended that the ICC criteria for CFS/ME is used in primary health care situations and research as it may increase specificity and identify severe cases of the illness according to extensive new criteria (Carruthers et al., 2011). The best assessment of CFS/ME can be made by using the ICC in conjunction with other valid severity scales to permit the classification of severe CFS/ME patients and patient subgroups according to level of severity.

Severity Scales and CFS/ME

Symptom severity subgroups have been recognized in CFS/ME, although these have not been strictly outlined. Illness severity can be assessed using measures of both physical and cognitive capacities, and this is essential for analyzing illness progression and variations in severity. Alongside CFS/ME case definitions, assessments of CFS/ME patients’ physical functioning are often used to supplement medical information in order to characterize the impact of an illness on a patient and assess variations in symptom severity (Mor, Laliberte, Morris, & Wiemann, 1984). A patient’s severity status can be measured using a variety of scales.

The Karnofsky Performance Scale (KPS) was constructed in 1948 in the absence of a generic scale for clinical characteristics as an assessment tool for performance status in oncology (Abernethy, Shelby-James, Fazekas, Woods, & Currow, 2005; Mor et al., 1984; Wiborg, Knoop, Stulemeijer, Prins, & Bleijenberg, 2010).

The KPS scale comprises a single 11-point rating scale ranging from 0 to 100, where patients are ranked a number interval of 10, with 100 representing normal functioning and 0 representing dead. The KPS allows assessors to rank patients’ mobility and condition based on a one-dimensional numerical scale (Mor et al., 1984; Wiborg, Knoop, et al., 2010).
The reliability of KPS has gained widespread acceptance and it is therefore a valuable tool for rating the functional status of a patient (Mor et al., 1984; Wiborg, Knoop, et al., 2010). While the KPS has limited sensitivity due to the restricted range of scores available, it has been used clinically to establish levels of disability in patients and may be effective in further differentiating severity of CFS/ME (Clapp et al., 1999; Strayer et al., 2012). The use of the KPS has been deemed reliable in evaluating the degree of disability in CFS/ME patients (Clapp et al., 1999). The KPS scale is still used as a predominant measure of functional status in patients, particularly in a recent clinical trial examining 234 patients classified as CFS/ME (Strayer et al., 2012). These severely classified patients scored 40 to 60 on the KPS scale, indicating that they required some daily assistance similar to those who were “disabled” (Strayer et al., 2012). The KPS has also been used to determine impairment of daily activities (a KPS score of below 80) associated with CFS/ME (Sharpe et al., 1996). The KPS as a focal measure of severity highlights its efficiency in classifying severity subgroups of CFS/ME, in particular, this short scale may be beneficial in primary health settings.

The Sickness Impact Profile (SIP) was developed in 1975; it is a generic measure of health status based on changes in behavior that are consequential of illness-related qualities of life (Bergner, Bobbitt, Carter, & Gilson, 1981; Gilson et al., 1975). The SIP allows measures of physical, mental, and social aspects of health-related functions using six subscales including somatic autonomy, mobility control, mobility range, social behavior, emotional stability, and psychological autonomy/communication, which contribute to an overall total score (Post, Gerritsen, Diederiks, & DeWitte, 2001). Clinically, the validity and accuracy of the SIP was confirmed following a study of the relationship between SIP and clinical measures of illness (Bergner et al., 1981; Gilson et al., 1975). Based on the generic nature of the SIP, it is used for a wide range of illnesses and is typically applied in conjunction with other measures of health or functioning (Gilson et al., 1975). A number of items assessed in the SIP, including sleep and rest, daily work, mobility, and bodily movement, allow the SIP to be a beneficial measure of functional performance of a patient with illness, specifically CFS/ME, based on changes in health status, illness progression, and severity over time (Busija et al., 2011; Gilson et al., 1975; Heins, Knoop, Lobbestael, & Bleijenberg, 2011; Wadden & Phelan, 2002; Wiborg, Knoop, et al., 2010). Alongside other severity scales of both physical and emotional function, the SIP has been used in CFS/ME studies to provide an in-depth analysis of functional and cognitive status of patients (Gaab et al., 2002; Petrie, Moss-Morris, & Weinman, 1995; Vercoulen et al., 1994). The SIP has been applied in conjunction with other severity scales to effectively confirm severity subgroups of CFS/ME patients, hence highlighting the ability of those in health care to use the SIP to assess health status and severity of patients with CFS/ME (Wiborg, Knoop, et al., 2010).
One of the most widely used measures of fatigue is the self-rating scale for fatigue severity (FSS; Herlofson & Larsen, 2002; Krupp, LaRocca, Muir-Nash, & Steinberg, 1989; Malagoni et al., 2010). The FSS was generated in 1993 to measure the severity of fatigue-related symptoms of those with CFS/ME. The scale comprises a list of 14 questions related to both physical and cognitive fatigue, with a scale from 1 to 7 correlating with the possible options of “better than usual,” “no more than usual,” “neutral,” “worse than usual,” and “much worse than usual” (Chalder et al., 1993). The use of the FSS provides assessors with a total final score, with higher scores indicating more severe fatigue-related symptomatology (Jason et al., 2011). A proposed limitation of using the FSS is the range of seven optional responses that cannot easily be used as distinctions between fatigue categories, and it has been suggested that reducing the range of options to three (disagree, neutral, agree) may improve the scale overall (Burger, Franchignoni, Puzic, & Giordano, 2010). According to Jason and colleagues (2011), the FSS is the most efficient fatigue-related scale in differentiating CFS/ME patients from healthy controls based on fatigue. The FSS is also more accurate and comprehensive in comparison to most fatigue scales when used to assess fatigue-related severity and disability of CFS/ME symptoms (Taylor, Jason, & Torres, 2000). Overall, this self-reporting scale has been effectively applied when detecting cases of fatigue and is therefore a valid measure of fatigue severity (Chalder et al., 1993; Friedberg & Krupp, 1994; Herlofson & Larsen, 2002; Jason, Benton, et al., 2009; Krupp et al., 1989; Krupp, Sliwinski, Masur, Friedberg, & Coyle, 1994; Malagoni et al., 2010). The recommended “high” level of fatigue using the FSS has been suggested as an average FSS score above 4 or 5, although further validation is required (Lerdal, Wahl, Rustoen, Hanestad, & Moum, 2005). In the future, the FSS may be beneficial in assisting with the characterization of severe cases of CFS/ME into a number of distinct subgroups including mild, moderate, severe, and very severe.

Bell’s CFS Disability Scale (CDS) was developed to clinically assess patients and their response to treatments (Bell, 1995). The scale is a modified version of the KPS, also designed to allow the examination of both physical and cognitive activity alongside a measure of wellness to essentially outline a level of disability. Like the KPS, the scale itself is a numerical score between 0 (severe symptomatology, bedridden and unable to care for self) and 100 (no symptoms at rest). Scores are allocated based on symptom severity, the degree of activity impairment both at rest and during activity and a functional ability regarding full-time work (Bell, 1995). The scale has been effectively applied to assess the disability of CFS patients based on their physical functioning and also to further distinguish severity subgroups. Severity subgroups can be distinguished using this 10-point rating scale that allows physicians to assess patients’ activity levels. A score of 100 on the KPS is related to a person with normal ability and physical functioning. Moderate CFS/ME patients
tend to score between 40 and 70 on the KPS, severe CFS/ME patients tend to score 30, and very severe CFS/ME patients score below 20 on the scale (Myhill, Booth, & McLaren-Howard, 2009). The severity groups we defined and used in this study are similar to the severity subgroups described by the ICC (Carruthers et al., 2011). In effect, the CDS has been utilized to examine functional ability and severity of CFS/ME participants, supporting the notion that it is a simple and adequate tool for assessing the illness (Bell, 1995; Myhill et al., 2009; Tiersky et al., 2001).

The FibroFatigue Scale was developed according to items from the neurasthenia subscale of the Comprehensive Psychopathological Rating Scale (CPRS) and is comprised of 12 observer-rated items (Zachrisson, Regland, Jahreskog, Kron, & Gottfries, 2002). This neurasthenia subscale includes 15 items regarding symptomatology, including aches and pain, fatigability, reduced sleep, muscular tension, and concentration difficulties and was found to be useful when evaluating differences in symptomatology severity in fibromyalgia (FM) and CFS patients (Andersson, Bagby, Dyrehag, & Gottfries, 1998; Zachrisson et al., 2002). This FibroFatigue Scale has since been used as an efficient measure of illness severity in FM and CFS/ME patients in a number of studies (Lucas, Brauch, Settas, & Theoharides, 2006; Maes, Mihaylova, & Leunis, 2006; Maes, Mihaylova, & Leunis, 2007; Maes, Twisk, Kubera, & Ringel, 2012). An analysis of the FibroFatigue scale also found that it is reliable in determining severity of symptoms in both FM and CFS patients and it does require a trained administrator for use, which makes it less appropriate for research studies although it has high potential for health care consultations (Shahid, Wilkinson, & Marcu, 2012).

The ME/CFS Fatigue Types Questionnaire (MFTQ) was developed in 2009 following an analysis of fatigue types in CFS/ME patients that determined distinct variations in fatigue-related symptoms among patients (Jason, Jessen, Porter, Boulton, & Gloria-Njoku, 2009). CFS/ME patients were examined using a combination of fatigue measures, including the FSS and a 1993 Fatigue Scale, to categorize different types of fatigue-related sensations and symptoms. The MFTQ is a 22-item scale designed to measure fatigue duration, severity, and frequency using a number of specific dimensions, including lack of energy, overstimulation of the mind or body, and abnormal exhaustion following physical activity (Jason, Jessen, et al., 2009). The MFTQ has been used to categorize distinct clusters of fatigue state patterns within CFS/ME patients, with results suggesting heterogeneous fatigue patterns in CFS/ME patients that can be classified into fatigue subgroups of low, moderate, and severe (Jason, Boulton, et al., 2010) although the MFTQ has not yet been used to assess CFS/ME. Use of the MFTQ for CFS/ME would require accompanying functional and disability scales as it focuses entirely on fatigue, which is only one of many CFS/ME symptoms experienced by patients; hence the MFTQ is not ideal for primary health.
Clinical Severity of CFS/ME

A subgroup of CFS/ME patients have been identified as housebound patients. These patients experience a high level of daily fatigue, somatic disturbances, and low-level activity. Importantly, the housebound CFS/ME group is less likely to hold a paying job due to the significant impairment in their physical functioning and higher levels of daily fatigue compared with other CFS/ME patients (Wiborg, van der Werf, et al., 2010). It has been suggested that severity may play a role in differentiating dysfunctions in CFS/ME patients and be important for primary health assessment of the illness (Brenu et al., 2013; Rangel et al., 2000; Strayer et al., 2012; Wiborg, van der Werf, et al., 2010).

Fatigue severity has been outlined as one of the most consistent and essential predictors of illness severity with prognostic outcome for a CFS/ME patient (Jason, Corradi, Torres-Harding, Taylor, & King, 2005; Joyce et al., 1997). It has similarly been observed when examined clinically that CFS/ME patients with less severe illness and fatigue were more likely to get a positive prognosis than those who were more severe (Jason et al., 2005).

The rather vague 1991 Oxford criteria for CFS were used in an interview-based study of childhood CFS/ME severity. Severity was assessed using a 0–10 point scale encompassing scales for impairment of school attendance, family and friend relationships, sleep patterns, and physical symptoms (Rangel et al., 2000). The majority of patients recovered within 45 months although, interestingly, those who maintained the CFS/ME symptomatology had significantly further severe differences in fatigue, physical symptoms, and handicap compared with those who recovered (Rangel et al., 2000).

Significant differences have also been examined in CFS/ME compared with other fatigue-related illnesses based on self-reported symptom profiles. It is suggested that the next step is to assess CFS/ME symptom profiles in severity-related subgroups to further determine the pathophysiological mechanisms (Baraniuk et al., 2013). Post-exertional fatigue and infectious-related symptoms are the most characteristic in patients with severe CFS/ME (Peckerman et al., 2003b). Similarly, CFS/ME patients who experience more than the required four symptoms are most likely further affected in their functional ability. There has also been a correlation between the number of severe CFS/ME related symptoms and measures of functional disability, again suggesting potential CFS/ME severity subgroups (Jason, Taylor, et al., 2003).

Severity in CFS/ME symptoms may fluctuate where some patients are able to maintain full-time to part-time jobs while others may be severely affected by symptoms and are completely bedridden. Homebound CFS/ME patients have demonstrated higher levels of fatigue and somatic disturbances combined with significantly lower levels of activity, physical functioning, and ability to maintain a job compared with other CFS/ME patients (Wiborg, van
der Werf, et al., 2010). Undoubtedly, this homebound subgroup of CFS/ME patients is important to CFS/ME research because it accounts for 25% of the CFS/ME patient population. In the majority of studies, classifications of patient variation have been ignored, or severe patients were specifically excluded due to patients' difficulties in keeping appointments (Hooper, 2007; Jason, Benton, et al., 2009).

DISCUSSION

Variation in symptom severity in CFS/ME patients has been established, and a number of severity scales have proven to be effectively applied when assessing CFS/ME patients' severity (Baraniuk et al., 2013; Brenu et al., 2013; Fletcher et al., 2010; Jason et al., 2005; Jason et al., 2011; Jason, Boulton, et al., 2010; Jason, Jessen, et al., 2009). Inconsistency in symptom presentation in CFS/ME advocates the use of severity scales to assess functional ability and quality of life to form an accurate measure of an individual patient's condition. Illnesses such as cancer, multiple sclerosis (MS) and FM have distinct stages of severity based on symptoms and it is likely that CFS/ME patients also require such severity assessments and classification.

MS is a severe inflammatory demyelinating disease that is typically assessed based on stages, predominantly starting with an “attack,” followed by a relapsing–remitting stage and a secondary chronic–progressive stage. The severity of symptoms and activity pattern exhibited in CFS/ME individuals also fluctuates over time, with patients seemingly experiencing improved symptoms or “relapses” (Meeus et al., 2011).

FM is also commonly acknowledged similarly to CFS/ME because it is characterized by chronic widespread pain in conjunction with fatigue, sleep disturbances, and joint stiffness with occasional cognitive dysfunction, bowel and bladder abnormalities, and difficulty swallowing (Saa’d, Many, Jacob, & Ablin, 2012). Unlike the severity of CFS/ME, which is not recognized or assessed in clinical or research settings, FM is usually assessed and diagnosed with the use of severity scales. Scales including the Fibromyalgia Survey Diagnostic Criteria and Severity Scale, Mindful Attention Awareness Scale, Psychological Inflexibility in Pain Scale, Widespread Pain Index, Symptom Severity Scale and the FibroFatigue Scale have been used to examine fibromyalgia patients and assess the severity of the illness (Cebolla, Luciano, DeMarzo, Navarro-Gil, & Campayo, 2013; Fitzcharles et al., 2012; Rogero et al., 2013; Wolfe et al., 2011). The usefulness and benefits of applying a severity scale to assess FM patients in primary health care denote similarly the importance for CFS/ME patients to be examined in the same way.

The SIP is an efficient quality-of-life scale, although it is widely used and does not specifically adhere to CFS/ME. Similarly, the FSS and FibroFatigue
Scales are effectively used when analyzing the symptoms of fatigue; however, they do not include assessment of other important symptoms associated with CFS/ME. The FibroFatigue Scale, SIP, and FSS allow assessment of severity in CFS/ME patients, although they should be used in conjunction with other scales such as the KPS, which assess a broad range of symptoms to encompass CFS/ME (Burger et al., 2010; Gaab et al., 2002; Petrie et al., 1995; Vercoulen et al., 1994; Wiborg, van der Werf, et al., 2010).

The KPS is widely used in a number of illnesses as a measure of functional performance, providing a simple and practical method of scaling a person’s functional abilities and mobility (Clapp et al., 1999; Sharpe et al., 1996; Strayer et al., 2012). The KPS or similarly the adapted SDS may potentially be effective in relation to the severity ranges proposed by the ICC. The numerical scale of the KPS or SDS can be subdivided to correlate with mild, moderate, severe, and very severe descriptions of physical ability in CFS/ME for an overall analysis of a patient’s symptom severity (Carruthers et al., 2011). The simple numerical scale of the KPS or SDS also allows for a quick assessment of a CFS/ME patient’s severity that may easily be used by primary health care professionals as well as in research settings.

Symptom severity of CFS/ME patients has been recognized and acknowledged in the 2011 ICC for ME, although such important severity subgroups continue to be ignored in most research instances (Carruthers et al., 2011; Jason, Evans, et al., 2010). A number of scales, such as the FSS, KPS, and FibroFatigue Scale, can be accurately applied and successful in assessing levels of fatigue, disability, and health status in CFS/ME patients. It is recommended that such scales are utilized in primary health and research to assess patient severity in correspondence with the severity categories suggested in the ICC (mild, moderate, severe, and very severe) for specific distinction and understanding of the multifaceted illness.

CONCLUSION

CFS/ME is a serious illness that predominantly affects women and requires a more accurate assessment to assist those who are suffering. According to the ICC, CFS/ME severity subgroups are present and range between the categories mild, moderate, severe, and very severe (Carruthers et al., 2011). There is an imperative need for these CFS/ME severity subgroups to be widely recognized and consistently distinguished for assessments in clinical primary health care and in research. Severity scales are available and efficient when used to assess CFS/ME patients based on symptoms, quality of life, and functional disability. This is important because it is possible that, like other disorders such as cancer, there are distinct subgroups of CFS/ME (Zaturenskaia et al., 2009). The use of a functional severity scale alongside a simple numerical mobility scale such as the KPS or SDS is highly recommended for
use by health care professionals and in research settings to assess a CFS/ME patient's individual severity and condition.

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