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Development of a clinician-administered National Institutes of Health-Brief Fatigue Inventory: A measure of fatigue in the context of depressive disorders

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ABSTRACT

Objective: Fatigue is a complex, multidimensional condition. Although it is often associated with depression, it is not known whether it has a distinct network from depression or whether it can be clinically evaluated, separately. This study describes preliminary findings in the development of a brief, clinician-administered instrument to measure fatigue in the context of depressive disorders using items from existing clinician-administered depression and mania scales.
Methods: Based on items from prior fatigue measurements, items were selected from the Hamilton Depression Rating Scale (HDRS), Montgomery–Asberg Depression Rating Scale (MADRS), Young Mania Rating Scale, and Structured Interview Guide for HDRS with Atypical Depression. The final items composed the NIH-Brief Fatigue Inventory (NIH-BFI). Responses from 89 depressed adults collected pre- and post-antidepressant therapy (ADT) determined the reliability and consistency of the NIH-BFI using Cronbach's alpha and principal components analysis (PCA). Correlations of the NIH-BFI and fatigue items from other scales before and after ADT explored validity.
Results: The 7-item NIH-BFI had Cronbach alphas ranging from 0.81 to 0.88 and PCA indicating a single dimension. The NIH-BFI score was strongly correlated ($r = 0.73$, $p < 0.001$) with fatigue items from Beck Depression Index, with MADRS without fatigue items ($r = 0.77$, $p < 0.001$), and HDRS without fatigue items (pre: $r = 0.69$, $p < 0.001$).
Conclusions: Preliminary findings show support for internal consistency reliability and validity of the NIH-BFI, a clinician-administered measure of fatigue. Further testing in other clinical populations is recommended to obtain additional information on reliability and validity. The NIH-BFI provides a method for clinician-rated fatigue that may be a separate from depression.

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1. Introduction

Fatigue is defined as a subjective sense of persistent tiredness or loss of energy that interferes with the performance of daily life activities and is not relieved by rest (Minton and Stone, 2008). However, this pervasive and debilitating clinical condition is still defined with suboptimal consistency (Alexander et al., 2010; Hardy and Studenski, 2010; Jason et al., 2010; Swain, 2000). Evidence suggests that fatigue is often associated with depression in individuals with Axis 1 psychiatric disorders (Ferrentinos et al., 2010; Fava, 2003), as well as in those with multiple sclerosis (Kroencke et al., 2000), sarcoidosis (de Kleijn et al., 2013), and cancer (Reuter et al., 2006). Oncology patients experiencing fatigue also

Acronyms: ADT, antidepressant therapy; BDI, Beck Depression Inventory; DSM-IV, Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition; ECT, Electroconvulsive Therapy; FACIT-F, Functional Assessment of Chronic Illness Therapy-Fatigue; HDRS, Hamilton Depression Rating Scale; ICC, intra-class correlation; MADRS, Montgomery–Asberg Depression Rating Scale; MDD, major depressive disorder; NIH, National Institutes of Health; NIH-BFI, National Institutes of Health-Brief Fatigue Inventory; NIMH, National Institute of Mental Health; PCA, principal component analysis; PROMIS, Patient Reported Outcomes Measurement Information System; PTSD, Post Traumatic Stress Disorder; rPFS, revised Piper Fatigue Scale; SIGH-SAD, Structured Interview Guide for the Hamilton Depression Rating Scale with Atypical Depression; SD, standard deviation; YMRS, Young Mania Rating Scale.

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report symptoms of depression such as a sense of hopelessness, worthlessness, guilt, and suicidal ideation (Ahlberg et al., 2003). The strong association between fatigue (total or general, physical, and mental) and depressive symptoms (Jacobsen et al., 2003), makes it challenging to obtain measurements that distinguish one from the other (Brown and Kroenke, 2009).

It is suggested that the relationship of fatigue and depression may explain mutual psychological and shared neuroanatomical pathways between these two clinical conditions (Bakshi et al., 2000). Presence of fatigue or loss of energy is one of the core symptoms for the major depressive disorder (MDD) diagnosis (American Psychiatric Association, 1994). The Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria for MDD describes fatigue or loss of energy as a physical manifestation (American Psychiatric Association, 1994). However, fatigue is believed to be multidimensional and includes both physical and psychological (mental or emotional) domains (Zwarts et al., 2008). Physical fatigue is often associated with the reduction of muscle contractions from impaired energy resources (Light et al., 2010), while psychological fatigue is associated with affective, behavioral, and cognitive impairments (Light et al., 2010; Chaudhuri and Behan, 2004).

Although fatigue and depression are strongly associated, there is empirical evidence that they are also distinct entities. Two different studies found that fatigue continued after depression was in remission. Up to 35% of patients with MDD who achieved remission continued to report persistent fatigue (Reuter et al., 2006). In another study, approximately 40% of patients with partial or full remission of MDD after antidepressant therapy still reported persistent physical fatigue (Ferguson et al., 2014). These studies affirm that fatigue and depression are not always linked, which suggests that measures should be able to differentiate them.

There are several valid, self-report measurements to assess fatigue diagnosis and severity, however, the validity of these instruments is often questioned, especially when used as a diagnostic tool for psychiatric patients actively experiencing overlapping symptoms related to their conditions (Nallet et al., 2013; Zimmerman et al., 2011, 2010). The heavy reliance on clinician-administered questionnaires in the mental health field to diagnose psychiatric conditions is influenced by the idea that individuals with psychiatric illness have impaired ability to accurately judge their competence in several quality of life domains, such as social interactions, work performance, and self-care (Schaub et al., 2012), all necessary domains in the assessment of fatigue. Previous reports showed that poor insight and awareness of individuals to their psychiatric illness contribute to poorer ratings of social function and physical performance (Lysaker et al., 2007, 2002). For example, increasing concerns are raised that overreliance on self-report questionnaires can lead to over-diagnoses or underdiagnoses of psychiatric conditions (Nallet et al., 2013; Zimmerman et al., 2011; Goldberg et al., 2012). A recent report suggested that the use of clinician-administered probing can provide more sensitive indicators for diagnosing psychiatric disorders (Schaub et al., 2012), and data obtained from clinician-administered assessments can measure severity of depressive symptoms more accurately than self-report (Rush et al., 1987; Berrios and Chen, 1993). Considering that fatigue items are included in several clinician-administered depression instruments, a clinician-administered fatigue questionnaire could be developed by extracting these items and exploring their reliability and validity to distinguish fatigue from the other symptoms, such as depression.

Recently, a single-item, clinician-administered fatigue questionnaire obtained from the Clinical Global Impression scale was used to assess fatigue in psychiatric patients (Targum et al., 2012). This scale showed good psychometric properties when compared with the Massachusetts General Hospital Cognitive and Physical Functioning Scale (Fava et al., 2009a). However, in addition to the limitation of being a single-item scale, there was inadequate support for its validity, especially the lack of studies comparing it with more established self-report fatigue scales (Ferrentinos et al., 2010). Hence, there is a need to develop a brief, multiple-item tool that can fully assess the concept of fatigue and also be administered by clinicians in practice.

This paper introduces preliminary findings on a clinician-administered scale aimed to measure rapid change in fatigue based on responses obtained from a clinical trial investigating the rapid effect of ketamine on depression. This scale has the potential to be useful in both clinical practice and research. We also explored whether the preliminary findings can provide information on whether this newly developed scale could efficiently evaluate fatigue separately from depression.

2. Methodology

2.1. Design and subjects

All patients included in the analyses were from a series of National Institutes of Health (NIH), institutional review board-approved National Institute of Mental Health (NIMH) clinical studies exploring the efficacy of ketamine as an intervention in reducing depressive symptoms. Informed consents were obtained before study measures were obtained. All of these studies were conducted at the NIH Clinical Center, Bethesda, Maryland.

The presence of clinical depression, based on DSM-IV criteria, was established as the eligibility criterion for participation in these clinical trials. Questionnaire responses at pre- and 230 min post-intervention were used in the analyses, because significant improvements in depressive symptoms were observed between these time points in previous reports (Zarate et al., 2006; Ahern et al., 2015). The strong association of fatigue with depression (Jacobsen et al., 2003), enabled us to expect that the improvements in the levels fatigue would also be correlated with significant improvements in depressive symptoms as observed in a previous study, starting a day following ketamine infusion (Zarate et al., 2006).

2.2. Procedures for item generation

Items pertaining to the concept of fatigue were selected by NIH-credentialed mental health nurses and psychologists experienced in administering existing clinician-administered psychiatric scales used in NIMH clinical trials (i.e., Hamilton Depression Rating Scale [HDRS], Montgomery–Asberg Depression Rating Scale [MADRS], Young Mania Rating Scale [YMRS], and Structured Interview Guide for the Hamilton Depression Rating Scale with Atypical Depression [SIGH-SAD]) to develop a clinician-administered NIH-Brief Fatigue Inventory (NIH-BFI). The psychometric properties of these psychiatric scales from which the NIH-BFI items were selected are as follows:

2.2.1. MADRS

The MADRS is a 10-item, unidimensional instrument used to evaluate psychological aspects of depressive symptoms in adults (Montgomery and Asberg, 1979). A previous psychometric study evaluating the use of MADRS in clinical practice revealed very good internal consistency reliability with a Cronbach's alpha of 0.85 (Bondolfi et al., 2010), very high correlations among all items ($r = 0.95$) (Fava, 2002), good concurrent validity with Pearson's correlation coefficient of 0.81 between the MADRS clinician-administered score and the MADRS self-administered score, and sensitivity to change over a 4-week observation period with