Perception of pain self-efficacy and fatigue in Greek patients with multiple sclerosis: a study protocol

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Abstract

The examination of the perception of pain and fatigue in patients with various health problems has received increased research attention in recent years. The aim of the present study protocol is to examine levels of pain self-efficacy and fatigue in a sample of Greek patients suffering from multiple sclerosis. The association of years and severity of diagnosis with the perception of pain self-efficacy and fatigue will be also investigated. Forty patients from the 2nd Neurological Department, Aristotle University of Thessaloniki (Greece) will participate in this study. The measurement tools include i) the Fatigue Assessment Scale, ii) the Pain Self Efficacy Questionnaire and iii) the Expanded Disability Status Scale. Test-retest reliability of the first two questionnaires will be assessed with the same patients rating their situation in a 10 days interval from the first examination in order to examine consistency over time.

Background

Multiple sclerosis (MS) is a neurodegenerative disease characterized by chronic inflammation, demyelination, and scarring of the central nervous system. Symptoms include weakness, fatigue, sensory loss, vertigo, lack of coordination, impotence or sexual dysfunction, urinary incontinence, optic atrophy, dysarthria, and mental problems.1,2 The average age at onset of MS is 30 years, and the disease runs its course for the remainder of the patient’s life frequently causing disability of varying degrees.3 The prevalence of MS varies with both geography and ethnic background with women twice as likely to be afflicted as men.3

Multiple sclerosis has a major impact on the lives of patients.4 The disease substantially interferes with daily activities and family, social and working life, disturbs emotional well-being, and reduces quality of life (QOL).5

Other symptoms related to MS are weakness, paresthesia, visual changes, spasticity, cognitive dysfunction, ataxia, pain and fatigue. Fatigue remains one of the most common and debilitating symptoms in MS and is quoted as one of the single most disabling symptoms.13 Forty percent of MS patients state fatigue as their most disabling symptom.14 It has been reported to cause profound disruption of QOL in MS patients.15 Approximately 20% of patients evaluated in primary care clinics experience fatigue.16 In contrast, 96% of MS patients experience fatigue, 88% of whom report fatigue as a moderate to high problem.15,17

The cause of fatigue in MS remains unclear. Suggested etiologies of fatigue in MS have included an increase in nervous system conduction time, alterations in the function of monoamine transmitters, deconditioning, reduction in melatonin levels, increase of cytokines or immune system dysregulation, neuromuscular transmission defects, psychological factors, increased energy demands for muscle activation due to spasticity, central brain neuronal injury, damage to the brainstem reticular activating system, respiratory muscle weakness and sleep disturbances.18-24

In response to the presence of these symptoms, the study of self-efficacy is very crucial. Social cognitive theory yielded the concept of self-efficacy as the perceived capability of a person to perform a specific action required to achieve a concrete goal.25 The concept is competence-based, prospective and action-related.25 In general, self-efficacy is conceptualized task-specific, for example self-efficacy in managing diabetes self-care tasks like blood sugar testing, keeping to diet and doing physical exercises regularly or pain self-efficacy in MS patients. Self-efficacy is a prerequisite of effective self-management.26 Patients with higher self-efficacy levels are more likely to start or maintain a specific task even in face of existing barriers. Several self-management programs successfully targeted self-efficacy resulting in improved health outcomes.27,28

The aim of the present study protocol is to examine levels of pain self-efficacy and fatigue in a sample of Greek patients suffering from multiple sclerosis. Physical disability will be also investigated. Test-retest reliability of two questionnaires used i) the Fatigue Assessment Scale (FAS), ii) the Pain Self Efficacy Questionnaire (PSEQ) will be assessed with the same patients rating their situation in a 10 days interval from the first examination in order to examine consistency over time.

Methodology

Forty patients diagnosed with MS will be recruited from hospitals located within the broader area of Thessaloniki. The inclusion criteria are: i) >18 years of age; ii) ability of communication in Greek; iii) diagnosed with MS; iv) satisfying level of cooperation and perceived ability; v) no history of primary psychiatric disease that may interfere with conduct of study; vi) clinically stable with no evidence of chronic or acute infections, inflammatory disorders, malignancy.

All subjects will be informed of their rights to refuse or discontinue participation in the study according to the ethical standards of the Helsinki Declaration. Ethical permission for the study will be obtained from the scientific committees of the participating hospitals.

The psychometric tools that will be included in the study are presented below.

Instruments

The FAS is a fatigue questionnaire consisting of 10 items.29 Five questions of the FAS reflect physical fatigue and five assess mental fatigue. Although these two aspects of fatigue are represented in the questionnaire, the FAS has shown to be unidimensional in various populations,29,30 as well as in sarcoidosis patients.31,32 The unidimensional structure indicates that the FAS total score should be used. The response scale is a 5-point scale (1, never to 5, always). Scores on the FAS range from 10 to 50. The Chronbach alpha of the FAS in a random sample of the Dutch working population was 0.90 and in a sarcoidosis population 0.89. In addition, the FAS had the highest factor loading in a factor analysis incorporating five fatigue questionnaires.33 Correlations between the FAS and the Beck Depression

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Key words: Pain; fatigue; pain self-efficacy; disability; multiple sclerosis.

Contributions: the authors contributed equally.

Conflict of interest: the authors declare no potential conflict of interest.

Received for publication: 1 April 2014. Accepted for publication: 7 April 2014.

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Inventory were 0.59 and between the FAS and the CES-D 0.65. The PSEQ is a 10-item questionnaire developed to assess the confidence people with ongoing pain have in performing activities while in pain. It consists of two domains, physical and psychological. The PSEQ is applicable to all persisting pain presentations. It covers a range of functions, including household chores, socializing, work, as well as coping with pain without medication.

The Expanded Disability Status Scale (EDSS) is a method of quantifying disability in multiple sclerosis and monitoring changes in the level of disability over time. It is widely used in clinical trials and in the assessment of people with MS. The scale was developed by a neurologist called John Kurtzke in 1983 as an advance from his previous 10 step Disability Status Scale (DSS). The EDSS scale ranges from 0 to 10 in 0.5 unit increments that represent higher levels of disability. Scoring is based on an examination by a neurologist. EDSS steps 1.0 to 4.5 refer to people with MS who are able to walk without any aid and is based on measures of impairment in eight functional systems (FS): i) pyramidal - weakness or difficulty moving limbs; ii) cerebellar - ataxia, loss of coordination or tremor; iii) brainstem - problems with speech, swallowing and nystagmus; iv) sensory - numbness or loss of sensations; v) bowel and bladder function; vi) visual function; vii) cerebral (or mental) functions; viii) other.

Each functional system is scored on a scale of 0 (no disability) to 5 or 6 (more severe disability). EDSS steps 5.0 to 9.5 are defined by the impairment to walking.

Demographic and clinical characteristics of all patients will be collected as baseline information at the beginning of the study.

**Data analysis**

A P value of 0.05 or less will be considered to indicate statistical significance. All analyses will be performed with the Statistical Package for the Social Sciences (SPSS 13.0 for Windows).

**Discussion**

This study aims to demonstrate fatigue and pain self-efficacy issues in MS patients. The findings of the present study can be used in the development of health care services and in-patient management. The role of fatigue and pain self-efficacy in particular may play an important role in the course of illness and treatment outcomes and could therefore be identified as a new area for psychological intervention in people diagnosed with MS.
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