Restless legs syndrome (RLS) severity symptoms in relation to environmental and habitual conditions- the Mediterranean example

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Background: It is known that RLS is one of the most "frustrating" syndromes affecting approximately 4-10% of the otherwise healthy population, while when it co-exists with other chronic conditions it affects up to 40% of the suffering patients. RLS affects many aspects of daily living and has an important impact on quality of life: sleep quality, fatigue and mental health are all affected. Moreover, treatment with L-dopa or dopamine agonists could result in augmentation of symptoms, a phenomenon with still unknown aetiology. The syndrome's severity varies from mild to severe while the frequency fluctuates from once a month to almost every day. The aetiology for such inconsistency between RLS patients is still unknown. However, anecdotal data from patients' forums and blogs suggest that factors such as moon phase, environmental temperature, sunlight exposure, levels of physical activity, quality of diet etc., could influence not only the syndrome's severity but also the frequency and the time that symptoms start.

Only a few "Cost of illness" studies have assessed the economic burden that RLS imposes on society. Considering the high prevalence of RLS and its effect on health-related quality of life, it is expected that RLS poses an important social and economic burden. Indeed, it was calculated that each RLS patient costs an average of 700 euro per month due to drugs, rehabilitation, hospitalisation, physician time, physical therapy, cost for early retirement, time off work and productivity loss. In addition, the greater the severity of RLS symptoms, the greater the increase in indirect costs while other parameters such as gender (RLS in males caused higher indirect costs than in females), quality of sleep (the worse the sleep, the higher

the indirect costs) and depression seem to increase the overall cost. In 2009 the population of Europe was estimated to be 852.4 million, bringing the number of patients with RLS to 34 million (4%). Using the 700 euro/month as cost of illness, the total figure is translated to 23.8 billion. In addition, RLS is also associated with cardiovascular risk factors and higher mortality rates due to sympathetic overactivity often observed in RLS patients increasing even further the overall cost of health care.

So far, there are no available scientific data on whether environmental or habitual factors could influence the severity of the symptoms or alter medication effectiveness. Even though patients' experiences can be very helpful in optimizing therapeutic regimes and improving care, there is a significant dearth of scientific evidence to support patients' personal accounts. A large-scale epidemiological study is crucial in order to address the issue of environmental factors on severity of RLS. In this light, it is vital for the EURLSSG to act immediately and invest some time and resources to assess the "unknown" factors that can influence RLS severity and jeopardize patients' care.

Objectives: The aim of this proposal is to investigate the interconnections between (1) the exposure to natural sunlight, (2) the level of physical activity and (3) the Mediterranean diet in the severity of RLS and health related quality of life in different European Countries.

The proposed project (HappyFeet) is an epidemiological survey that will assess the level of exposure to elements that characterize the "traditional Mediterranean living" (sun light, temperature, physical activity, diet etc.) on RLS severity and augmentation.

Methods: In the proposed hospital-based study, epidemiological data related to RLS severity and augmentation phenomena in conjunction with the various environmental and habitual factors, from countries with various geographical and cultural backgrounds, will be recorded in the form of a structured questionnaire. Data will be then analysed in order to investigate any possible associations between RLS aspects and the habitual or environmental factors.

The knowledge gained will set the basis for the development of a pan-European consensus on the various factors influencing the severity and frequency of symptoms of RLS. In addition, data from the current project will help us design a multicentre clinical trial in order to investigate non-pharmacological interventions that could ameliorate RLS symptoms and improve patients quality of life.

Expected Results: The expected results include (1) a robust evidence base on the interconnections between exposure to various environmental / habitual factors and health and well-being of RLS patients. Moreover, we expect to gain a better understanding on (2) augmentation pathogenesis and (3) on factors contribute to symptom variability between patients and time.

Phases of Work: 1) Project preparation (end of Nov 2011); 2) Project presentation at EURLSSG 2011 (Dec 2011); 3) Data collection (March 2012 – Feb2013); 4) Data analysis (March 2013-June 2013); 5) Drafting a papers (Sept 2013).

Participants: The HappyFeet network will include all interested parties from EURLSSG.