



Functional limitations in functional somatic syndromes and well-defined medical diseases. Results from the general population cohort LifeLines



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ABSTRACT

Objective: Functional somatic syndromes (FSS), defined as physical syndromes without known underlying organic pathology, are sometimes regarded as less serious conditions than well-defined medical diseases (MD). The aims of this study were to evaluate functional limitations in FSS, and to compare the results to MD patients with the same core symptoms.

Methods: This study was performed in 89,585 participants (age: 44.4±12.4 years, 58.5% female) of the general-population cohort LifeLines. Quality of Life (QoL) and work participation were examined as indicators of functional limitations. QoL was assessed with two summary scales of the RAND-36: the physical component summary (PCS) and the mental component summary (MCS). Work participation was assessed with a self-reported questionnaire. QoL and work participation were compared between FSS and MD patients, using Chi-squared tests and ANCOVA-analyses, adjusted for age, sex, educational level, and mental disorders.

Results: Of the participants, 11.0% (n=9861) reported a FSS, and 2.7% (n=2395) reported a MD. Total QoL, PCS and MCS were significantly lower in all separate FSS and MD compared to controls ($P \leq .001$). Clinically relevant differences in QoL were found between chronic fatigue syndrome and multiple sclerosis patients, and between fibromyalgia syndrome and rheumatoid arthritis patients. Compared to controls, FSS and MD patients reported a comparably reduced working percentage, increased sick absence, early retirement due to health-related reasons, and disability percentage ($P \leq .001$).

Conclusion: Functional limitations in FSS patients are common, and as severe as those in patients with MD when looking at QoL and work participation, emphasizing that FSS are serious health conditions.

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Introduction

The experience of physical symptoms in the general population is common [1]. When medical evaluation does not reveal sufficient explanatory pathology, these symptoms are referred to as functional somatic symptoms. Functional somatic symptoms often occur together resulting in functional somatic syndromes (FSS). Chronic fatigue syndrome (CFS), fibromyalgia syndrome (FMS), and irritable bowel syndrome (IBS) are the most well-known FSS. CFS is mainly characterized by fatigue without sufficient explanatory pathology [2], FMS patients suffer from musculoskeletal pain with unknown etiology [3], and IBS

patients suffer from bowel complaints with unknown underlying pathology [4]. These core symptoms are typically accompanied by various additional symptoms. The etiology of all FSS is assumed to be multifactorial involving biological, psychological, and social factors [5].

Because physicians cannot find a disease-based explanation for these syndromes nor always offer appropriate treatment, they find it often difficult to deal with FSS. Physicians might also be frustrated as a result of difficulties in controlling the symptoms and the patients' emotional responses to the syndromes [6]. Furthermore, it is often assumed that functional limitations in FSS patients are less severe than those in patients with well-defined medical diseases (MD). To date, relatively little is known about functional limitations in FSS patients compared to MD patients. FSS patients have been shown to suffer from productivity loss in daily activities, and from social isolation [7,8]. Several studies suggest that Quality of Life (QoL) is impaired in FSS patients [9–11]. For instance, overall QoL scores in CFS patients were significantly lower than in other chronic illness groups [12]. QoL and functional disabilities among patients with FMS have been found to be similar to or worse than QoL in patients with rheumatoid arthritis (RA), Parkinson's disease, and other pain conditions [11,13–15]. Significantly lower QoL scores were found in IBS patients as compared to the general population

Abbreviations: CFS, chronic fatigue syndrome; FMS, fibromyalgia syndrome; FSS, functional somatic syndromes; IBD, inflammatory bowel disease; IBS, irritable bowel syndrome; MCS, mental component summary; MS, multiple sclerosis; PCS, physical component summary; QoL, Quality of Life; RA, rheumatoid arthritis; MD, well-defined medical diseases.

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[16,17]. QoL appeared to be similarly reduced in IBS and inflammatory bowel disease (IBD) [18]. While previous studies only compared one FSS and MD, we aimed to compare multiple FSS and MD in one cohort, thereby avoiding differences in selection procedure or measurement.

FSS are associated with relevant indirect costs [8]. A recent study showed that costs for healthcare services use and work-related costs in functional somatic symptoms were estimated to be €6815±10,923 per patient per year [19,20]. Work-related costs are predominantly caused by productivity loss at work (56%), early retirement (29%), and sickness absence (14%) [21]. Moreover, high levels of somatic symptoms are a determinant of long-term sickness absence, health-related job loss, and work disability [22]. FSS patients often encounter difficulties at work, as a result of the somatic symptoms [8,23]. For instance, fatigue is significantly influencing work participation in FSS patients resulting in more productivity loss at work and sickness absence [24, 25]. Because there are no studies that compare work participation between FSS and MD patients, it is unknown to what extent work participation is affected in FSS patients compared to MD patients.

The aim of the current study was to compare functional limitations in FSS patients, MD patients, and controls (defined by the absence of self-reported FSS or MD). We hypothesize that FSS and MD are both associated with functional limitations. This study is based on data of LifeLines, a large population-based cohort study. To the best of our knowledge, there are no studies that evaluate functional limitations in both FSS and MD patients in one cohort. CFS patients were compared with patients who suffer from multiple sclerosis (MS), because fatigue is the most common symptom experienced by persons with MS [26]. FMS patients were compared with RA patients, because they share similar symptoms including pain and sleep disorders [27]. Lastly, IBS patients were compared with IBD patients, consisting of Crohn's disease and ulcerative colitis, because they share many of the clinical symptoms of IBS [28].

Methods

Sampling frame

This study was conducted within the sampling frame of the LifeLines cohort study. LifeLines is a multi-disciplinary, prospective (three-generational) population-based cohort study examining health and health-related behaviors of 165,000 persons living in the North East part of The Netherlands. LifeLines employs a broad range of investigative procedures in assessing biomedical, socio-demographic, behavioral, physical and psychological factors which contribute to the health and disease of the general population, with a special focus on multimorbidity and complex genetics [29].

Recruitment

Participants of LifeLines were recruited in two ways. First, a number of general practitioners from the three northern provinces of the Netherlands invited all their listed patients between 25 and 50 years of age to participate. If they agreed to participate, these participants were asked to invite their partner(s), parents, parents in law, and children to participate as well. In this way participants of all ages were included. Eligibility for participation was evaluated by general practitioners. To ensure the reliability of the study, persons with severe psychiatric or physical illness, and those not being able to visit the general practitioner, to fill in the questionnaires, and/or to understand the Dutch language were excluded. Parents and children were not excluded in case of the mentioned criteria when a representative was willing to assist these participants in the performance of the study. Inclusion of pregnant women was rescheduled until 6 months after pregnancy or 3 months after breastfeeding. Second, persons who were interested to participate could register themselves via the LifeLines website.

All participants received written information on the purpose and methods of the study and written informed consent was obtained after the procedure was fully explained. All data are kept confidential and are only used for medical research. Approval by the Medical Ethical Committee of the University Medical Center Groningen was obtained for the study.

Measures

Functional somatic syndromes and well-defined medical diseases

FSS and MD were assessed by questionnaire, including a list of chronic disorders with three FSS (irritable bowel syndrome, fibromyalgia syndrome, chronic fatigue syndrome) and four MD (Crohn's disease and ulcerative colitis, multiple sclerosis and rheumatoid arthritis). Participants were asked to indicate which of these diseases they have or have had, with more than one answer allowed. IBD was defined as the presence of Crohn's disease or ulcerative colitis. Controls were defined by the absence of the self-reported FSS or MD on which this study focused. To define a more strict diagnosis, FSS patients with a comorbid MD were excluded, including CFS patients who reported comorbid MS (N=6), FMS patients who reported comorbid RA (N=196), IBS patients who reported comorbid IBD (N=103), and other combinations (N=258). Furthermore, participants who reported more than one FSS (N=1281) (for more details, see (30)) or MD (N=29) were excluded, so that the different groups present their own corresponding core symptom.

Functional limitations

The RAND-36 was used to evaluate health-related QoL [31]. The RAND-36 consists of 36 closed-ended, structured questions that measure QoL in eight subscales (physical functioning, role limitations due to physical health, role limitations due to emotional problems, energy/fatigue, emotional well-being, social functioning, pain, general health). The subscales were summarized in two components: the physical component summary (PCS) and mental component summary (MCS). The PCS includes physical function, role physical, bodily pain, and general health, while the MCS includes vitality, social function, role emotional, and mental health. The PCS, MCS, and total QoL score were calculated as recommended by the RAND-36 guideline [32], to generate a score from 0 to 100, with 0 being the lowest score and 100 being the best score for QoL. The outcome measures were transformed in T-scores performing a Z-score transformation ($[Z*10]+50$). The T-score with the mean of 50 and an SD of 10 is the average for the Dutch population. Thereafter, summary score coefficients of the RAND-36 were used to calculate the PCS, MCS and total QoL score [32]. A minimum difference of three points on any given RAND-36 scale was considered clinically relevant [31]. The RAND-36 is validated in the general population and for patients suffering from several medical conditions [31].

Work participation was assessed with a self-reported questionnaire, including the following questions: "Which situation applies to you?" (answer categories: working, retired; early retired; unemployed/looking for work; disabled for work; welfare; homemaker; study), and "On average how many hours per week do you spend on paid work?". Participants who indicated they were early retired, the reason for stop working was asked (answer categories: retirement; illness/unfit for work; dismissal/unemployment; other). Participants who indicated that they were disabled for work were asked for what percentage they were disabled for work (ranging between 0–100%). According to the definition of Statistics Netherlands, the working population was defined working ≥ 12 h per week [33]. Sick leave was assessed by the following questions: "In the past 3 months, how many days did you not work because of an illness or health problems?", and "In the past year, how often did you stay home from work because of an illness or health problems?". Sick leave frequency was dichotomized (<4 and ≥ 4 days).

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