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Predicting the course of persistent physical symptoms: Development and internal validation of prediction models for symptom severity and functional status during 2 years of follow-up

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ABSTRACT

Objective: Increased knowledge about predictors of the course of persistent physical symptoms (PPS) is needed to identify patients at risk for long-term PPS in clinical settings.

Therefore, we developed prediction models for the course of PPS in terms of symptom-severity and related functional status during a 2-year follow-up period.

Methods: We used data of the PROSPECTS cohort study, consisting of 325 PPS patients from several health care settings. Symptom severity (PHQ-15), physical functioning (RAND 36 PCS) and mental functioning (RAND 36 MCS) were assessed at baseline and 6, 12 and 24 months afterwards.

We applied mixed model analyses to develop prediction models for all outcomes, using all follow-up measurements. Potential predictors were based on empirical and theoretical literature and measured at baseline.

Results: For symptom severity, physical functioning and mental functioning we identified predictors for the adverse course of PPS included physical comorbidity, higher severity and longer duration of PPS at baseline, anxiety, catastrophizing cognitions, embarrassment and fear avoidance cognitions, avoidance or resting behaviour and neuroticism. Predictors of a favourable course included limited alcohol use, higher education, higher levels of physical and mental functioning at baseline, symptom focusing, damage cognitions and extraversion. Explained interpersonal variance for all three models varied between 70.5 and 76.0%. Performance of the models was comparable in primary and secondary/tertiary care.

Conclusion: The presented prediction models identified several relevant demographic, medical, psychological and behavioural predictors for adverse and favourable courses of PPS. External validation of the presented models is needed prior to clinical implementation.

1. Introduction

In all health care settings, patients present with physical symptoms such as fatigue, dizziness and pain for which no sufficient explanation is found after thorough medical examination. Such symptoms are called medically unexplained physical symptoms. They are very common. In primary care, around 30% of the symptoms that patients present to their general practitioner are unexplained [1,2]. In specialist care, up to 70% of the presented symptoms are unexplained, depending on the specialty [3,4]. Most unexplained symptoms are transient and mild [5]. However, when they persist, they can become severe and disabling [1,6]. Patients with persistent physical symptoms (PPS) have a greater risk of psychosocial disability and experience more psychological distress than patients with explained physical symptoms [7]. Additionally, PPS are associated with high health care and societal costs [8–10].

1.1. Predictors of the course of PPS

Because of the described consequences of PPS, it may be helpful to identify patients at risk for long-term PPS as early as possible in order to offer

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them treatment aimed at improving their prognosis. Several studies aimed to identify factors that predict an unfavourable course of PPS. A higher number and longer duration of symptoms at baseline repeatedly emerged as a predictor of an unfavourable course [11–14]. Female sex was also reported as a predictor in some studies [13,15,16], but another study did not confirm these findings [17]. Studies evaluating the role of affective disorders showed conflicting results [11–13,18,19]. Authors of a systematic review about course and prognosis of PPS concluded that the body of evidence is too little to draw conclusions about relevant prognostic factors [20].

1.2. Theoretical models of PPS

In addition to the described empirical studies (mainly assessing the predictive value of demographic and symptom-related factors), literature provides a wide range of theories aiming to explain which factors influence the development and persistence of physical symptoms. The cognitive behavioural model is seen as a meta-model, incorporating many of these theories [21,22]. It provides various explanatory elements for the development and persistence of physical symptoms, including somatic causes and illness predispositions, cognitions, emotions and behaviours.

Although the described explanatory elements form the basis for various PPS therapies, such as cognitive behavioural therapy [22], there is very little empirical evidence for their role in the course of PPS. There are a few studies that evaluated the temporal relation between individual explanatory elements and outcomes in PPS populations [11,12,18,23]. However, subsets of studied elements varied and some of the studies showed contradictory results [11,12].

We can conclude that increased knowledge about predictors of the course of PPS is needed in order to identify patients at risk for long-term PPS in clinical settings. Furthermore, in addition to demographic and medical characteristics, the predictive value of characteristics based on theoretical PPS models needs to be assessed.

1.3. Study aim

Our research group is currently performing the PROSPECTS study, a multi-center prospective cohort study on the course and prognosis of PPS. For this study we aimed to assess which baseline characteristics of patients with physical symptoms predict severity of symptoms, physical functioning and mental functioning during a 2-year follow-up period. For this aim, data of the PROSPECTS study was used. Assessed baseline characteristics included demographic and medical characteristics (based on empirical literature), and also a large subset of characteristics based on theoretical PPS models.

2. Methods

2.1. Study design and subjects

In the PROSPECTS study PPS were defined as the presence of physical symptoms, which had lasted at least several weeks and for which no sufficient explanation was found after adequate medical examination. PPS patients aged between 18 and 70 years were recruited in general practices and in specialized PPS programs of secondary and tertiary care organizations across the Netherlands in 2013–2015.

In primary care, electronic medical records were searched to select patients who visited their general practitioner (GP) twice or more in the last 3 months with one or more physical symptoms without a matching diagnosis. The list of selected patients was checked for exclusion criteria by the GP. In secondary and tertiary care all newly referred patients with PPS as the reason for referral were screened for exclusion criteria by the physician performing the intake consultation.

Exclusion criteria were: a sufficient medical explanation for the symptoms (according to the physician); incomplete diagnostic evaluation of the symptoms (according to the physician); insufficient command of the Dutch language; a significant cognitive or visual impairment; severe psychopathology (psychotic disorder, bipolar disorder, substance related disorders or severe personality disorders); pregnancy; cancer diagnosed in 5 years prior to inclusion; or another life threatening condition or a short life expectancy.

In all setting, patients who did not meet exclusion criteria received by mail the Patient Health Questionnaire 15 (PHQ-15 [24,25]). Patients who returned the questionnaire and had a score of 2 for at least one symptom (indicating that the symptom was bothering a lot) were considered eligible and were approached for informed consent. The Medical Ethics Committee of the VU University Medical Center Amsterdam approved the study protocol. Details about the study design have been published elsewhere [26].

2.2. Measures

A detailed description of all questionnaires used at all time points of the PROSPECTS study has been published elsewhere [26]. In this section we describe the questionnaires that we used for the analyses in this paper. We used data collected at baseline, and at 6, 12 and 24 months of follow-up. An overview of all questionnaires used is given in Appendix 1. Almost all potential predictors were assessed at baseline. Only the assessment of perfectionism and personality was postponed until the first follow-up measurement (T1) in order to reduce participant burden. We deem this choice justified as these factors are considered to be relatively stable over time [47].

2.2.1. General characteristics

The baseline questionnaire included questions about general characteristics (i.e. gender, age, length, weight, country of origin, educational level, occupation) and medical characteristics (medical history, chronic medical conditions and life style parameters). Specific questions about PPS related diagnostics and treatments were included at all time points.

2.2.2. Outcome measures

We used PHQ-15 scores as an indicator for the severity of PPS and RAND-36 scores (Physical Components Summary (PCS) and Mental Components Summary (MCS)) as an indicator for functional status [28]. These three outcome measures were assessed at all time-points.

2.2.3. Potential predictors

All described general characteristics, including characteristics identified as predictors in previous empirical studies, were taken into account as potential predictors. Furthermore, we based the choice of additional potential predictors on the cognitive behavioural model as described in the introduction [22]. Potential predictive illness predispositions were covered by the incorporation of questionnaires about personality (NEO Personality questionnaire- Five Factor Inventory [31,32]), perfectionism (Multi-dimensional Perfectionism Scale [29,30]), psychiatric co-morbidity (medical chart), depression (Quick Inventory of Depressive Symptomatology [39]), anxiety (Beck Anxiety Inventory [40,41]), positive affect (subscale of Positive And Negative Affect Schedule [34]), life events (Life Events Questionnaire [43]) and social support (Social Support scale [44]).

Potential predictive illness emotions, cognitions and behaviours were covered by incorporating questionnaires about illness anxiety (Whitely Index for hypochondria [36,42]), hypervigilance (SomatoSensory Amplification Scale [35,36]), negative illness perceptions (Illness Perception Questionnaire [37,38]), illness cognitions and behaviours (Cognitive and Behavioural Responses to symptoms Questionnaire [33]) and physical activity (International Physical Activity Questionnaire [45,46]).

2.2.4. Statistical analysis

Data analyses were performed using SPSS (version 20.0) and STATA (version 14) software packages. Descriptive statistics were used to summarize background characteristics and PPS characteristics of the study population.

Prior to the development of the prediction models we checked for