To develop and validate a patient-reported questionnaire assessing disease activity and health-related QoL compared to PBO.*

PRM144

CULTURAL ADAPTATION INTO SPANISH (PA) OF THE QUESTIONNAIRE “OVERACTIVE BLADDER - FAMILY IMPACT MEASURE (OAB-FIM)”

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OBJECTIVES: To carry-out the cultural adaptation into Spanish (for Spain) of the questionnaire “Overactive Bladder - Family Impact Measure (OAB-FIM)”.

METHODS: The adaptation included linguistic validation through forward and back translations and cultural adaptation discussions by a panel of experts including 16 OAB patients, and a phase of preliminary measurement of psychometric properties in OAB patients and their relatives of habitual coexistence, of both genders, ≥18 years of age, newly diagnosed and on treatment for their symptoms (with Conceptual and linguistic equivalences, internal consistency (α-Cronbach), content validity (the inter-rater Rovinelli-Hambleton index of item congruence) and construct validity were measured. Construct validity included included correlation coefficients with validated scales, with ZARIT and OAB-SF, and validity of known groups according to the benefit of treatment on TBS scale. Feasibility and burden of administration were also measured.

RESULTS: 25 couples of patients [mean (SD): 57.2 (16.0) years, 60% women] and their relatives (43.3%) were enrolled; 48% were enrolled from secondary health care and 52% from primary care. The OAB-FIM was equivalent conceptually and linguistically to the original, remaining the same initial domains: activities, travel, concern, irritation, sleep and sex. Missing items was ≤5% in all domains, and missing effects were still considered significantly relevant, between 0% and 5% (SD: 0.0-16.0). The average time of completion was 5.2 (2.8) minutes. 24% needed some help to complete the questionnaire. The Rovinelli-Hamblen index ranked correctly all items in its domain, except for the item 10 which ranked on domain irritation and fatigue, the item 10 compared well between the English version and the Spanish version of the OAB-FIM with ZARIT were high-to-moderate (0.407-0.753) and moderate-to-small with the OAB-SF (0.004-0.423). Relatives whose patients showed treatment benefit showed scores lower on the scale (lowest impact). CONCLUSIONS: A Spanish version of the OAB-FIM conceptually and linguistically equivalent to the original has been obtained. The questionnaire has shown good internal consistency, content validity and construct validity, together with feasibility in the Spanish culture.

PRM145

DEVELOPMENT AND VALIDATION OF A QUESTIONNAIRE ASSESSING THE FEARS AND HARMFUL BEHAVIOR IN PATIENTS SUFFERING FROM MENTAL HEALTH DISORDERS

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OBJECTIVES: To develop and validate a patient-reported questionnaire assessing the fears and avoidant behavior of patients suffering from a mental health disorder, specifically for patients suffering from major depressive disorder (Spa), that could improve educational methods. METHODS: Step 1: Qualitative research (individual patient interviews: 25 RA, 25 axial Spa [asSpA]). Step 2: All fears and beliefs appearing in more than 15% of interviews rephrased as questions (TBS scale) and an expert panel (20 patients and 20 partners). Each question score 0-10 (higher scores higher/beliefs). Step 3: Preliminary questionnaire tested by cognitive debriefing (5 RA, 5 asSpA patients), and reproducibility through a test-retest procedure among 28 patients (13 RA, 15 asSpA). Step 4: Psychometric validation through a cross-sectional study of 226 patients. Internal consistency assessed by Cronbach’s alpha.

principal components analysis and descending hierarchical classification. RESULTS: Step 1: Development and adaptation of a self-reported 44-item questionnaire on a 0-10 scale of fears and beliefs. 5 domains established: 1st origin of the disease, flares, treatments, disease progression and consequences of disease. Step 2: In the study of 226 patients (161 RA, 65 asSpA), all dimensions were ≥0.79 and ≥0.79, apart from fear of medication (FMD: 0.67). Step 3: The hypothetical patient identified 6 axes (63.7% of variance explained) and the descending hierarchical analysis identified 9 clusters (63.7% of variance). 2 clusters were highly correlated (≥0.80) and combined into a single cluster. Based on the psychometric validation, the following domains were identified: fears of the disease progression/consequences (18 items) and fears about treatment (5), beliefs related to: psychological influence (2), genetic influence (2), physical influence (4), diet influence (4), lifestyle (3) and diverse opinions. CONCLUSIONS: This study confirms the internal consistency of the questionnaire developed. The scoring results should help physicians to understand their patients’ perceptions of their disease better and eventually lead to improved adherence to treatment.