DEVELOPMENT AND VALIDATION OF PATIENT REPORTED OUTCOMES MEASUREMENT SCALES FOR CROHN’S DISEASE: THE INFLAMMATORY BOWEL DISEASE IMPACT AND SYMPTOM SCALES (IBDIMSYS)
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OBJECTIVES: According to recently published guidelines, treatments effects on patient’s health status should be measured by validated disease-specific Patient Reported Outcomes concepts. The aim of this study is to develop and validate a PRO questionnaire based on a conceptual framework for Crohn’s disease. METHODS: An item pool of 77 items was generated through in focus groups and validated in a German sample (n = 104). Other data included the SF-36 and IBDQ. RESULTS: A principal component analysis revealed 7 independent factors: impact, intimacy, abdominal pain, bowel movements, nausea, extraintestinal problems and night sweat. The impact factor was shown to comprise further three interpretable domains: emotional, social, and physical. CONCLUSION: Symptoms and consequences of Crohn’s disease need to be measured separately, since their constituent items do not load on the same factors. Further investigation could reduce the amount of items of one concept or find further items for relevant aspects such as problems with intimacy.