Floor and ceiling effects of the World Health Organization Disability Assessment Schedule 2.0 (WHODAS 2.0) amongst patients with chronic musculoskeletal pain

Short title: **WHODAS 2.0 floor and ceiling effects**

Niina Katajapuu MSc[1], Katri Laimi PhD, MD[2], Ari Heinonen PhD[1], Mikhail Saltychev PhD, MD[2]

[1] Faculty of Health and Sport Sciences, University of Jyväskylä, Jyväskylä, Finland

[2] Department of Physical and Rehabilitation Medicine, Turku University Hospital and University of Turku, Turku, Finland.

ADDRESS FOR CORRESPONDENCE

Niina Katajapuu, Email: niina.katajapuu@turkuamk.fi

Turku University of Applied Sciences

Joukahaisenkatu 3, 20520 Turku, Finland

CONFLICT OF INTEREST

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ABSTRACT

Objective of this study was to investigate the floor and ceiling effects of 12-item World Health Organization Disability Assessment Schedule 2.0 (WHODAS). This was a cross-sectional survey study at a university's Physical and Rehabilitation Medicine (PRM) outpatient clinic amongst 1988 patients with chronic musculoskeletal pain. Floor and ceiling effects were calculated as relative frequencies of the lowest or the highest possible scores for each item. Probit plotting method was used to detect the non-normality of distribution of total score graphically. A significant floor effect of 15% to 79% was observed in all twelve WHODAS 2.0 items. A substantial floor effect for total score was detected as well graphically. No ceiling effects were observed. In this study, significant floor effect was found for all WHODAS 2.0 items amongst patients with chronic musculoskeletal pain associated with mild or no disability.

KEYWORDS

Musculoskeletal pain, WHODAS 2.0, floor effect, ceiling effect, validity

INTRODUCTION

In an ideal situation, a scale is able to measure the entire spectrum of a phenomenon. However, scales commonly perform better around their mid area displaying a poorer discrimination ability at their tails producing so called floor and ceiling effects. Statistically speaking, 'floor effect' is a level below and 'ceiling effect' a level above which variance within an independent variable is no longer measurable (Velozo et al., 2012, De Vet, 2011). For example, when using a pain numeric rating scale, estimates might cluster around zero demonstrating a significant floor effect in a sample predominated by patients with mild pain severity or without pain. In other words, in that hypothetical case, a numeric rating scale may fail to distinguish people with very mild pain from those with no pain at all – both will mark zero.

Floor and ceiling effects are common findings when measuring functioning restrictions amongst people with musculoskeletal disorders (McHorney et al., 1994, Pellicciari et al., 2016). Modest to substantial ceiling effects have been found for the 36-item Short Form Health Survey (SF -36) in chronic medical and psychiatric conditions (McHorney et al., 1994). Small average scores of Neck Disability Index in patients with acute neck pain have probably been related to a floor effect in primary care population (Vos et al., 2006). A 36% floor effect of Neck Disability Index has also been observed in patients with neck pain in a university spinal clinic (Hung et al., 2015). Floor effects of Daily Activity Questionnaire have been detected in patients with different musculoskeletal conditions, the worst floor effect being observed in ankylosing spondylitis and Sjögren syndrome (Hammond et al., 2018).

WHODAS 2.0. is a generic tool to assess health and disability across all diseases and cultures in both clinical and general population settings (World Health Organization, 2018, Chiu et al., 2014, Carlozzi et al., 2015, Younus et al., 2017). While the WHODAS 2.0 psychometrics have extensively been studied, only a few inconsistent reports on its floor and ceiling effects have been published so far. Federici et al. have observed strong 75% floor effect in 'self-care' and 60% in 'getting around' domains amongst healthy volunteers and, respectively, 50% and 40% amongst disabled patients (Federici et al., 2009). Significant floor effects in "understanding and communicating" and "getting along with people" domains and a milder floor effect in 'self-care' domain amongst patients with rheumatoid arthritis have been reported (Meesters et al., 2010). In

turn, when studying patients with spinal cord injury, a floor effect has not been observed but, instead, a large 54% ceiling effect in “understanding and communicating” domain and milder ceiling effects in “self-care” and “getting along with others” domains (Wolf et al., 2012). Similar results amongst patients with spinal cord injury have been seen: significant ceiling effects in items “understanding and communication”, “self-care”, and “getting along with others” (van der Zee et al., 2014). The recent review has reported a floor effect within ”self-care” domain explaining the finding by cultural differences (Federici et al., 2017). Both floor and ceiling effects across most of the domains of a modified 36-item WHODAS 2.0 have been observed (Yen et al., 2014). Previous research has suggested further evaluation of floor and ceiling effects of WHODAS 2.0 within different patient groups. Knowledge on how well WHODAS 2.0 performs across the entire spectrum of restricted functioning amongst patients with chronic musculoskeletal pain may improve its usability in different situations as e.g., screening, clinical evaluation, or attaining rehabilitation goals. The aim of this study was to assess the ceiling and floor effects of WHODAS 2.0 amongst patients with chronic musculoskeletal pain.

METHODS

This was a cross-sectional study of consecutive patients with chronic musculoskeletal pain who were seen in an outpatient Physical and Rehabilitation Medicine (PRM) clinic of university hospital between April 2014 and February 2017. The survey was sent to the patients and filled up before a physician appointment. The survey included the WHODAS 2.0 questionnaire and questions on demographics, pain intensity, perceived general health, and working ability among others. A university hospital ethics committee approved the study.

The self-administered WHODAS 2.0 contains 12 items covering the most common limitations of functioning appearing in general population. The questionnaire covers limitations during the last 30 days. A Likert-type scale is used to define the severity of limitation with 0 denoting “no limitation” and 4 denoting “extreme limitation or inability to function”. For the calculations employed in this study, the total score was the sum of all 12 responses divided by 48 and multiplied by 100 and presented as a percentage where 100% represents the worst possible restriction.

Age was defined in full years at the time of visiting the clinic. Pain intensity was assessed using an 11-point numeric rating scale (NRS) 0 denoting “no pain” and 10 denoting “worst possible pain”. Educational level was dichotomized “high school” vs. “no high school”. Body mass index (BMI) was calculated as a body mass divided by a squared body height (kg/m^2).

Statistical analysis

The basic characteristics were presented as means, standard deviations (SDs), and percentage when appropriate. In case of a rough 5-point Likert-type scale used in WHODAS 2.0 individual items, the ceiling and floor effects of WHODAS 2.0 were calculated numerically as a relative frequency of lowest or highest possible score achieved by the respondents (McHorney et al., 1994, Coster et al., 2014, Carlozzi et al., 2015). The cut-off for a significant floor or ceiling effect was set at >=15%. Instead, the distribution of a continuous WHODAS 2.0 total score was analyzed graphically. To detect the nonnormality of WHODAS 2.0 total score’s distribution, the probit plotting method was used as described by Miller.(Miller R.G, 1997) This method demonstrates how the sample is differing from normality and presents irregularities in the tails rather than only in the

middle of the distribution. All the analyses were conducted using Stata/IC Statistical Software: Release 15. College Station (StataCorp LP, TX, USA).

RESULTS

Of 3150 patients visiting the clinic, 1988 (63%) returned a questionnaire. The patients were 47.6 (15.0) year-old and 1,297 (65%) were women (Table 1). The average intensity of pain was 6.3 (2.0) points. Most of the patients (n=1746, 88%) had a main diagnosis 'M' - 'Diseases of the musculoskeletal system and connective tissue' - according to the International Classification of Diseases version 10. The most frequent diagnoses were 'M54 Dorsalgia' (n=781, 39%) and 'M79 Other soft tissue disorders' (n=202, 10%). A significant floor effect was observed in all twelve WHODAS 2.0 items varying from 15% to 79% (Table 2). Figure 1 displays the substantial floor effect for a total score as well. No ceiling effect was detected for any of WHODAS 2.0 items.

DISCUSSION

This cross-sectional study amongst 2000 patients with chronic musculoskeletal pain showed a significant floor effect for all twelve items of WHODAS 2.0 and for its total score.

The sample represented a population of patients referred to a university PRM outpatient clinic supposing to receive high-end examination and treatment and, thus, they probably differ from patients treated in primary healthcare. The sample was predominated by women. As the patients experienced mostly mild disability, the generalization of the results over populations with more severe disability levels (e.g., in in-patient settings) may be problematic. However, the sample was large enough to achieve credible results for the population of interest – mildly disabled patients with chronic musculoskeletal pain.

The results were in line with some previous studies that detected floor effects for several WHODAS 2.0 items or for its overall score (Federici et al., 2009, Meesters et al., 2010, Schneider M et al., 2015). On contrary, the results differed from previously observed ceiling effect in 'self-care' domain without any significant floor effects amongst patients with spinal cord injury (Wolf et al., 2012, van der Zee et al., 2014). In other words, the results of the present and previous studies pointed the possibility that WHODAS 2.0 may have a substantial floor effect when disability is mild and ceiling effect in situations where disability is severe. This conclusion raises a question if WHODAS 2.0 is sensitive amongst people with midrange disability levels only?

Further research is needed especially amongst populations with midrange disability severity and amongst mixed samples containing patients of all grades of disability.

Amongst mildly disabled patients with chronic musculoskeletal pain, significant floor effect was found for all WHODAS 2.0 items.

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TABLES AND FIGURES

Figure 1. Floor and ceiling effects of WHODAS 2.0 total score

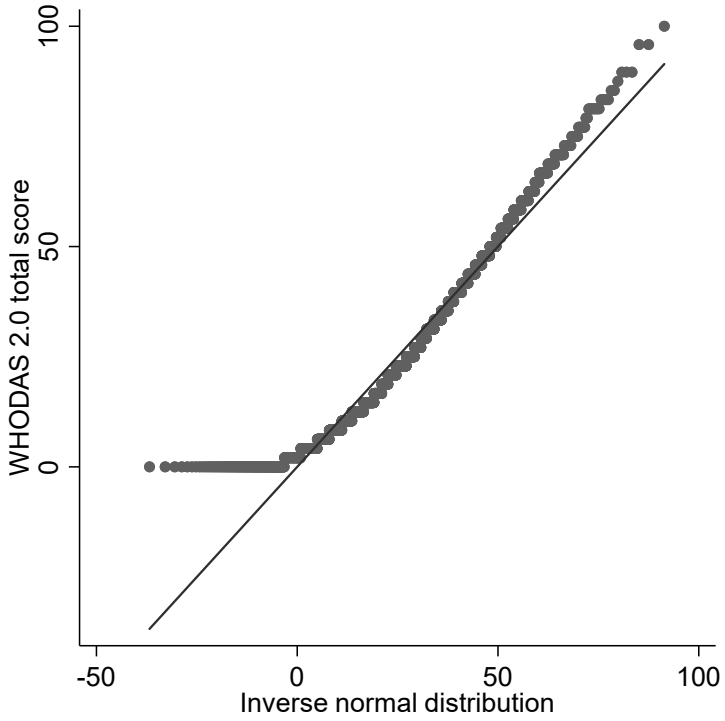

Table 1. Demographic characteristics of participants

Variable	Estimate
Age, years	47.6 (15.0)
WHODAS 2.0 total score, points	27.3 (19.5)
Body mass index, kg/m^2	27.4 (5.7)
Pain, points 0–10	6.3 (2.0)
Educational level, n	
High school	609 (33%)
No high school	1258 (67%)
Gender, n	
Women	1297 (65%)
Men	691 (35%)

Table 2. Floor and ceiling effects of WHODAS 2.0 individual items

Item	Lowest score '0'	Highest score '4'
Standing for long periods	29%	0%
Taking care of household responsibilities	21%	0%
Learning new task	74%	1%
Joining in community activities	46%	6%
Emotional affection by health problems	15%	3%
Concentrating doing something for 10 min	56%	2%
Walking long distance as 1 km	37%	14%
Washing whole body	51%	2%
Getting dressed	42%	1%
Dealing with people you do not know	79%	2%
Maintaining friendship	62%	2%
Day-to day work/school	18%	0%