1	T	he Oswestry Disability Index, confirmatory factor analysis in a sample of
2		35,263 verifies a one-factor structure but practicality issues remain
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34 ABSTRACT

35 Purpose

36 To analyze the factor structure of the Oswestry Disability Index (ODI) in a large symptomatic low back

37 pain (LBP) population using exploratory (EFA) and confirmatory factor analysis (CFA).

38

39 Methods

Analysis of pooled baseline ODI LBP patient data from the international Spine Tango registry of EUROSPINE, the Spine Society of Europe. The sample, with *n* = 35,263 (55.2% female; age 15–99, median 59 years), included 76.1% of patients with a degenerative disease, and 23.9% of the patients with various other spinal conditions. The initial EFA provided a hypothetical construct for consideration. Subsequent CFA was considered in three scenarios: the full sample and separate genders. Models were compared empirically for best fit.

46

47 Results

The EFA indicated a one-factor solution accounting for 54% of the total variance. The CFA analysis based on the full sample confirmed this one-factor structure. Subgroup analyses by gender achieved good model fit for configural and partial metric invariance, but not scalar invariance. A possible twoconstruct model solution as outlined by previous researchers: dynamic-activities (personal care, lifting, walking, sex and social) and static-activities (pain, sleep, standing, travelling and sitting) was not preferred.

54

55 Conclusions

The ODI demonstrated a one-factor structure in a large LBP sample. A potential two-factor model was considered, but not found appropriate for constructs of dynamic and static activity. The use of the single summary score for the ODI is psychometrically supported. However, practicality limitations

- 59 were reported for use in the clinical and research settings. Researchers are encouraged to consider a
- 60 shift towards newer, more sensitive and robustly developed instruments.

61

- 62 Keywords
- 63 Oswestry Disability Index, Confirmatory factor analysis, Patient-reported outcome instrument,
- 64 Validation, Spine Tango, Registry

66 **INTRODUCTION**

67 Measuring and monitoring the individual status and functional change in sufferers of low back pain (LBP) is critical for its overall management ^{1,2}. However, this measurement is not standardized and 68 69 subsequently cannot systematically reflect the effectiveness of evidence-based interventions. There are over 200 PROs available for LBP measurement with the Oswestry Disability Index (ODI) ^{3,4} one of 70 the most commonly used and advocated in clinical guidelines ^{2,4}. First published in 1980 ³, the ODI was 71 72 developed to guide treatment programmes and ensure critical LBP aspects were recorded and 73 progress monitored through measured changes in functional status. However, its development followed a qualitative item-selection process rather than a scientific clinimetric methodology ^{3,4,6,7}. 74 Consequently the ODI presents a scale with 'ordinal' or 'preference-based responses' rather than 75 76 'interval' or 'precise measurement points', which can affect its validity and capacity for standard 77 statistical analysis⁸. Despite its 40 years of wide use, it has still not been conclusively proven whether 78 the ten ODI items can be summated into a single score². The result is a lack of consensus regarding its factor structure ⁹⁻¹¹, an important issue that needs resolution. 79

80 Factor structure is critical and demonstrates the underlying themes or factors present that must be recognized to indicate a parsimonious structure ¹². Factor structure can be singular, enabling a single-81 82 summated score; or two- or multi-factor, which requires separately reported scores ^{12,13}. The ODI has always been reported as singular ^{10,14,15}; however, some researchers suggest a two-factor model of: 83 84 dynamic-activities (personal care, lifting, walking, sex and social) and static-activities (pain, sleep, standing, travelling and sitting) ^{16,17}. With Rasch analysis, which considers the evenness or interval of 85 86 the scores, a suboptimal one-factor structure was found along with psychometric concerns of poor coverage, plus a large floor and small ceiling effect ^{18,19}. If a PRO is to use a single-summated score, a 87 one-factor solution is required to ensure each question reports upon the same underlying construct 88 ¹¹⁻¹³ according to COSMIN standards ⁷. The gold standard to achieve this is confirmatory factor analysis 89 90 (CFA) which requires a large dataset for definitive analysis ^{12,20}. A CFA is validating a preceding 91 exploratory factor analysis (EFA), which expose the underlying traits, and requires 50–100 responsesper-item and consequently a minimum sample of n = 500-1000 for the ODI ¹². There is a gap in the literature as the published studies to date have performed only EFA and only in small samples. In particular, cross-cultural adaptation studies are commonly carried out on samples below n = 100 ^{10,17}.

95 This is inadequate for EFA as the estimates become unstable ^{7,12}.

96 Consequently, to address the existing knowledge gaps a single robust study with a large sample size 97 greater than 10,000, or 1000 per item, would be appropriate to resolve the issue conclusively; whether 98 a one- or a multi-factor model has a better fit. The aims of this study were to analyze the ODI factor 99 structure in a LBP population using CFA in an adequately large sample that allows robust testing of

- 100 competing models, and to determine which model is consistent across genders.
- 101

102 METHODS

- 103 Ethical approval was not required for this post hoc analysis of anonymous data.
- 104

105 Participants

This study was carried out using the Spine Tango data pool. Spine Tango, the international spine registry of EUROSPINE ²¹, the Spine Society of Europe is hosted at the University of Bern's Institute for Social and Preventive Medicine. Completed baseline ODI-PROs (n = 35,263, 55.2% female, age = 15– 99, median 59-years) were obtained from symptomatic LBP patients included in the registry. The study sample comprised patients with degenerative disease (76.1%), non-generative spondylolisthesis (7.8%), pathological fracture (4.2%), repeat surgery (3.8%), deformity and traumatic fracture (2.7% each), tumour and infection (1% each), and patients with other condition (<0.8%).

113

114 Assessment tools

The ODI contains ten pain-related, six responses options questions scored from zero (no pain) to five
 (most severe pain). Scores are expressed as a percentage of total points, with ≤20% indicating minimal

disability, 21–40% moderate disability, 41–60% severe disability, 61–80% crippled, and 81–100%
completely bed-bound ⁴.

119

120 Factor analysis

121 The EFA considers several statistics including: Eigenvalues, a special set of characteristic values 122 associated with a linear system of equations (generally >1.0 = statistically relevant); percentage of 123 variance explained by a particular factor ([10% = relevant); factor loading, a measure of how well any 124 item is represented by a factor (>0.30 = minimum); and 'Scree Plot', a visual representation chart of 125 Eigenvalues versus items (qualitatively assessed). For PRO's to provide a one-factor solution and single total score ^{13,15}, each criteria must be fulfilled and a single-factor solution needs to be obtained ¹². 126 127 When a two-factor solution is argued, the second eigenvalue must be >1 and at least 3–4 items load 128 appropriately on the second factor and also be interpretable. An EFA statistically checks an 129 instrument's dimensionality where the factor structure must be theoretically meaningful ¹². 130 Subsequent CFA clarifies and validates the suggested EFA model/s using significantly larger samples 12. 131

Hence this study investigated the ODI factor structure through EFA from a randomly selected 10% subgroup (n = 3526) using SPSS 22. Then CFA was conducted on the remaining 90% (n = 31,736, 90%) using Mplus 7.11²⁰.

In CFA, model parameters were estimated using the maximum likelihood method which is robust to non-normality ²⁰. The model fit was assessed using the Root Mean Square Error of Approximation (RMSEA) and the Comparative Fit Index (CFI). A RMSEA value of 0.05 or lower suggests excellent fit, and values B0.08 indicate acceptable fit ²². For the CFI, 0.90 is considered acceptable and 0.95 or above reflects excellent model fit ²³. Additionally, modification indices (MI) were analysed to determine if allowing error terms to co-vary would significantly improve the model fit, and during the CFA, errors with MI exceeding 4.00 were allowed to correlate ²⁰.

143 ODI references values (ODI_RV)

144 To fully describe the level of severity of participants' disability, an ODI-RV was created.

145

146 **Sub-group analyses**

Multi-group analyses were conducted to examine whether the identified model through EFA and CFA fits the data equally well for male and female participants. Namely, the degree to which a confirmatory factor model measuring LBP with ten items per six-point response scale exhibited measurement and structural invariance between male and female participants was assessed using Mplus 7.11 ²⁰.

151 The original CFA model was first analyzed using the remaining 90% sample. Then the initial configural 152 invariance model was compared with a series of models with increasing invariance constraints. 153 Specifically: (1) the first configural invariance model constrained the pattern of fixed and free parameters to be equivalent across groups; (2) the second metric invariance model constrained factor 154 155 loadings to be equal across groups; (3) the scalar invariance model constrained all factor loadings and 156 intercepts to be equal across groups; (4) the residual variance invariance model constrained error 157 variance to be equal across groups; (5) the residual covariance invariance model constrained error 158 covariance to be equal across groups; (6) the factor variance invariance model constrained factor 159 variance to be equal across groups; and (7) the factor mean invariance model constrained factor mean 160 to be equal across groups.

161 Invariance between groups on a particular parameter is achieved when non-significant statistical 162 difference is found between a model without a parameter constrained to be equal across groups and 163 the model with the parameter constrained. Then the more parsimonious model is retained and 164 compared to the subsequent model with additional constraints.

165

166 Assessing competing models

The most common method to assess model equivalence is a Chi-square based Likelihood ratio test,
which compares the overall goodness of fit Chi-square values between the two models. However,

169 given Chi-square tests are highly sensitive to trivial differences in large samples ²⁴, other measures, 170 including the Akaike Information Criterion (AIC) and Δ CFI, were also used ²⁵. The Δ CFI was obtained by 171 subtracting the CFI of compared models, where 0.01 indicates a lack of invariance ²⁵. The AIC measures 172 the parsimony of two competing models, where lower values suggest better model fit ²⁶.

173 If a significant, meaningful difference between two compared models exists, then fewer constraints 174 are selected. This indicates a lack of invariance of the parameters in question across groups. The 175 measurement variance across male and female sub-groups was evaluated through multigroup 176 analyses.

177

178 **RESULTS**

179 **Odi_rv**

180 The ODI_RV was calculated from standardized scores classified into five categories: 'minimal',
181 'moderate', 'severe', 'crippling' and 'bed-bound/exaggerated' (Table 1).

182

183 Explanatory factor analysis

The initial EFA showed a one-factor structure which explained 54% of the total variance. The first
eigenvalue was 5.49 and all others were <1.0. Factor loading ranged from 0.58–0.81.

186

187 Confirmatory factor analysis

The CFA confirmed a one-factor structure. Factor loadings ranged 0.53–0.81. The CFI = 0.945 and RMSEA = 0.075, suggesting adequate model fit. However, further examination of modification indices indicated that allowing some error terms to co-vary would significantly improve model fit (Fig. 1). Hence, the model was re-run to depict the second model with correlated errors (Fig. 1; Table 2). The AIC and RMSEA values of the second model decreased, ^CFI increased (~0.04) and the difference in Chi-square values between the two models was significant (Table 2). Consequently the second model, with correlated errors, fit the data significantly better than the first model.

195 Sub-group analyses

196 Multi-group analyses comparing males (n = 14,173) and females (n = 17,507) demonstrated configural 197 invariance and partial metric invariance. The configural invariance model had good fit (CFI = 0.983, 198 RMSEA = 0.046), and partial metric invariance was achieved (Δ Chisquare_{configural vs. partial metric} (2) = 14.022, 199 p>0.05; Δ CFI<0.001; Table 3). Table 4 shows the unstandardized and standardized factor loadings that 200 are statistically similar between male and female (see ODI 2, 4, and 8). However, scalar invariance was 201 not achieved (Δ Chisquare_{partial metric vs. scalar} (2) = 101.005, p<0.001), although the DCFI was<0.01.

202

203 DISCUSSION

204 The findings from both the EFA and CFA confirmed that the ODI's one-factor structure was preferable 205 from both the statistical perspective and parsimony. This is critical as it ensures a valid, single-206 summated score can be used. No appropriate two-factor model was found that is preferred to the 207 one-factor model, but ambiguity is present. Specifically, the two-factor solution, proposed recently of 208 dynamic and static-activities, was not preferred in the total population or either gender sub-group. This study's findings support previous research for EFA in several samples ^{10,15,16}. It also supports the 209 Rasch analysis that found a one-factor structure, but it was suboptimal ¹⁸. In our study, while the Chi-210 211 square test of the model fit was significant (p<0.001), it is heavily impacted by large sample size and 212 further investigations may be optimal. The gender sub-group analysis indicated both configural 213 invariance and partial metric invariance were obtained between men and women specifying the 214 relationships of some items to the latent factor of disability were equivalent in both groups. However, 215 the scalar invariance was not observed. It suggests women tend to have a slightly higher item response 216 than men at the same absolute trait level of disability. The concerns with the ODI's practicality and 217 consequential clinimetric performance aspects affect both the limitations and implications from clinical and research perspectives ^{2,7}. The influence of pain on response options is overwhelming with 218 219 the iteration of similar optional answers in different sections limiting the patients' ability to express

their perceptions of their condition ^{9,11}. This is reflected in the large minimum detectable change (MDC) and minimum clinically relevant difference (MCID), which determine responsiveness and error ^{7,11}. These have been demonstrated in previous studies to be around 20–25% of baseline level ^{1,9,11}. This is insufficient in comparison to several other regional PROs for which the MDC is in the order of 10% or lower, and numerical rating scales have errors of around 15% in the same sample and require only a single question¹⁴.

226 Consequently, the ODI as a modern viable PRO is less practical than simpler PROs that are easier to 227 use and have smaller error scores that reduce the 'number needed to treat' (NTT). This, consequently, 228 determines a smaller sample size and shorter time to provide meaningful results that verifies if true 229 change has occurred and ensures statistically significant outcomes for both the individual and 230 investigative research. The ODI is also unable to include objective parameters which limit postoperative evaluation ^{1,11}. By comparison, recent computer based PROs have such values represented 231 232 or transferred into response options and algorithms that calculate a final single outcome score⁸. The 233 practicality aspect of 'patient demand' to complete a PRO, expound the potential for completion errors and inconsistency ^{10,11}. These include excessive completion time and scoring inaccuracies, a 234 235 consequence of a large number of response options and increased cognitive demand, that leads to respondent uncertainty and reduced precision ^{1,9,11}. Solutions to overcome these issues include 236 237 shortening the PRO, modifications to improve practicality, modern scientific development 238 methodology ^{10,11} and a shift toward digital software systems such as computerized adaptive testing (CAT) or computerized decision support systems (CDSS) ²⁷ in future randomized controlled trials that 239 incorporate objective and individual response options^{1,11}. 240

241

242 LIMITATIONS AND STRENGTHS

This study's limitations are several. As a secondary analysis, diagnostic sub-groups (e.g., spinal stenosis, radiculopathy or disc degeneration) could not be considered due to limited diagnostic codes within the data set. The implications of potential constructs of 'dynamic' and 'static' function, as suggested by some researchers ¹⁷, could potentially have been present within the participants' occupational, social, sporting or daily routine. However, this could not be ascertained from the available data set. It is highly unlikely, from the statistical findings, that such considerations potentially influenced the analysis. If so then this would affect the overall validity of the ODI in terms of the capability of providing a single-summated score.

The dominant strength of this study is the very large sample size. The 10% EFA sample alone was over tenfold larger than all previous factor analysis studies. This is certainly one of the important benefits of registries besides implant tracking, detection of rare adverse events, early warning, benchmarking, real-life perspective and so forth ²¹. Furthermore, a statistician independent of the data collectors is responsible for the data analysis.

256

257 CONCLUSION

The findings are conclusive that the one-factor solution is preferable from the perspectives of both the statistical analysis and parsimony. Consequently, the ongoing use of the ODI summary score is psychometrically supported. However, the ODI, as an outcome instrument, continues to have prominent limitations that include practicality and measurement error. Clinicians must be aware of the completion burden for patients, and that a minimum detectable change is around 20–25% of the baseline level. This may have consequences on the research. Researchers are encouraged to consider a shift towards newer, more sensitive and robustly developed instruments.

265

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298 **Compliance with ethical statement.**

299

300 Conflict of interest

301 None of the authors has any potential conflict of interest.

302

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- 364

365 **TABLES**

366 Table 1

367 Percentiles of Oswestry Disability Index references values (ODI-RV) classified into five categories

	ODI-RV				
	Total $(n = 35,249)$	Male $(n = 15,801)$	Female $(n = 19,448)$	Disability categories	
Percentile					
<20th	-0.902	-1.004	-0.799	Minimal	
<40th	-0.284	-0.387	-0.284	Moderate	
<60th	0.230	0.126	0.229	Severe	
<80th	0.847	0.847	0.949	Crippling	
<99th	2.390	2.390	2.287	Bed-bound/exaggerated	

369 Table 2

- 370 Summary of the one-factor solution with or without error covariance using CFA.
- 371 χ^2 value indicates the difference between observed variance–covariance matrix and the model-implied variance–covariance matrix; *p* value indicates
- 372 probability of the difference; and *df* stands for the degrees of freedom. *RMSEA* the root mean square error of approximation, is a measure of model fit, with
- a value of 0.05 or lower suggesting excellent fit, and values < 0.08 indicating reasonable fit ²⁴; CFI stands for the Comparative Fit Index, with 0.90 being
- 374 considered acceptable, and 0.95 or above reflecting excellent model fit ²⁴. AIC, the Akaike Information Criterion, is a comparative measure of fit, with lower
- 375 values indicating a better model fit²⁵. $\Delta \chi^2$ is the difference in Chi-square values between the first model and the second model with correlated errors.
- 376 Correlated errors in the second model represent that the unique variances of the associated indicators such as pain intensity and sleeping overlap (see Fig. 1

377 for details)

Model	χ^2	df	р	CFI	RMSEA	AIC	Significance of $\Delta \chi^2$
First model	6942.724	35	< 0.001	0.945	0.075	1019349.168	
Second model with correlated errors	2083.422	29	< 0.001	0.983	0.045	1013579.776	P < 0.001

379 Table 3

- 380 Sub-group comparisons of CFA outputs—male vs. female participants
- 381 χ^2 value indicates the difference between observed variance–covariance matrix and the model implied variance–covariance matrix; p value indicates
- 382 probability of the difference; and df stands for the degrees of freedom. RMSEA the root mean square error of approximation, is a measure of model fit, with
- 383 a value of 0.05 or lower suggesting excellent fit, and values < 0.08 indicating reasonable fit 24. CFI stands for the comparative fit index, with 0.90 being
- 384 considered acceptable, and 0.95 or above reflecting excellent model fit 24. Δχ2 (14.022) is the difference in Chi-square values between the configural model
- and partial metric model, and Δχ2 (101.005) is the difference in Chi-square values between the partial metric model and scalar model. Partial metric invariance

386 was achieved (p>0.05), whereas scalar invariance was not achieved (p>0.001)

Model	χ^2	df	р	$\Delta\chi^2$	CFI	р	RMSEA
Configural model	2186.526	58	< 0.001		0.983		0.046
Partial metric model (item 2, 4 and 8)	2200.548	60	< 0.001	14.022	0.983	>0.05	0.045
Scalar model	2301.553	62	< 0.001	101.005	0.982	< 0.001	0.045

388 Table 4

389 Factor loadings from sub-group analyses. * Factor loadings held equal across groups

Item	Unstandardized	l factor loading	Standardized factor loading		
	Males	Females	Males	Females	
ODI 1	0.687	0.661	0.620	0.587	
ODI 2*	0.796	0.796	0.720	0.694	
ODI 3	0.936	1.005	0.694	0.702	
ODI 4*	0.972	0.972	0.690	0.700	
ODI 5	0.743	0.676	0.598	0.552	
ODI 6	0.906	0.963	0.652	0.674	
ODI 7	0.642	0.595	0.565	0.505	
ODI 8*	1.054	1.054	0.788	0.780	
ODI 9	1.195	1.283	0.813	0.813	
ODI 10	1.310	1.412	0.764	0.762	

391 FIGURES

392 Figure 1

- 393 The second model with correlated errors. Disability represents the ODI, and m1–10 stand for pain
- intensity, personal care, walking, lifting, sitting, standing, sleeping, social life, travelling, and sex life

