



**Living with Chronic Illness Scale: International validation through classic test theory and Rasch analysis among Spanish-speaking population with long term conditions**

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## Living with Chronic Illness Scale: International validation through classic test theory and Rasch analysis among Spanish-speaking population with long term conditions

### Abstract

*Background:* The Living with Chronic Illness (LW-CI) scale is a comprehensive **patient reported outcome measure** that evaluates the complex process of living with long term conditions.

*Objective:* To analyse the psychometric properties of the LW-CI scale according to the classic test theory and Rasch model among individuals living with different long term conditions.

*Design:* Observational, international and cross-sectional study.

*Methods:* A total of 2753 people from six Spanish-speaking countries living with type 2 diabetes mellitus, chronic obstructive pulmonary disease, chronic heart failure, Parkinson's disease, hypertension, and osteoarthritis were included. **Acceptability, internal consistency, and validity of the LW-CI scale were analysed using the classical test theory and fit to the model, unidimensionality, person separation index, item local independency and differential item functioning using Rasch model.**

*Results:* Cronbach's alpha for the LW-CI scale was 0.91 and correlation values for all domains of the LW-CI scale ranged from 0.62-0.68, except for domain 1 that showed correlation coefficients <0.30. The LW-CI domains showed a good fit to the Rasch model, with unidimensionality, item local independency and moderate reliability, providing scores in a true interval scale. **Except for two items**, the LW-CI scale was free from bias by long term condition type.

*Discussion:* After some adjustments, the LW-CI scale is a reliable and valid measure showing a good fit to the Rasch model and is ready to be used in research and clinical practice. Future implementation studies are suggested.

*Patient and public contribution:* **PPI was conducted prior to this study, during the piloting phase.**

**Keywords.** Living with, long term condition, psychometric properties, Rasch analysis, classic test theory, person-centred tool, **Spanish.**

## Introduction

Nowadays, long term conditions (LTCs) are the leading causes of disability and costs worldwide.<sup>1</sup> It is estimated that by 2030, LTCs will account for the three-quarters of deaths globally, with considerable social and economic impact due to the exorbitant costs that implies for the system.<sup>2,3</sup> In particular, cardiovascular and respiratory diseases, as well as diabetes, are the LTCs that account the most deaths all worldwide.<sup>1</sup>

Based on previous studies, living with an LTC is defined as a complex, dynamic, cyclical and multidimensional process, that involves five different attributes, namely, acceptance, coping, self-management, integration and adjustment.<sup>4</sup> Living with an LTC is influenced by social and personal factors, leading the process of living with an LTC to be a unique, individual and unrepeatabe process.<sup>4,5</sup> Health and social professionals need to have an in-deep understanding of what it means to live with an LTC from the person's perspective, focusing on the psychosocial and spiritual areas of the person and not just on the condition as has been done thus far.<sup>1,4,6</sup> In this sense, using patient-reported outcome measures (PROMs) is paramount to evaluate how the person is living with his/her condition.<sup>7,8</sup> Consequently, interdisciplinary team could design individualized and comprehensive care pathways and recommendations to achieve a positive living with an LTC as a final desired target.<sup>7,8</sup> Currently, most relevant available PROMs in clinical practice and research evaluate specific aspects of the LTC (e.g., stage, symptoms or severity) or outcomes of the process of living with LTCs (e.g. quality of life, satisfaction with life or well-being).<sup>9</sup> The Long-Term Conditions Questionnaire<sup>10</sup> is the only PROM that potentially evaluates how a person is living/managing an LTC. However, this scale seems to evaluate quality of life outcomes and does not tackle items related to acceptance, which is an essential attribute when living with an LTC.<sup>4</sup> Inevitably, this left a gap regarding person-centred measures that could evaluate the process of living with an LTC. To fill this gap and based on previous empirical studies<sup>11,12</sup> and conceptual works,<sup>4,13</sup> the Living with Chronic Illness (LW-CI) scale was designed.<sup>14</sup>

The LW-CI scale is a comprehensive PROM that evaluates the complex process of living with an LTC.<sup>14,15</sup> It is a 26-item self-reported scale with direct applicability in people living with LTCs. It was originally designed for Spanish-speaking population living with an LTC.<sup>15</sup> The LW-CI Scale has been previously published for Spanish-speaking population in a pilot study carried out in patients living with different LTCs<sup>15</sup>. Until now, the LW-CI scale has been tested separately in several LTCs namely Parkinson's disease (PD),<sup>16,17</sup> osteoarthritis,<sup>18</sup> chronic heart failure,<sup>19</sup> type 2 diabetes mellitus<sup>20</sup> or chronic obstructive pulmonary disease.<sup>21</sup> The results from each validation study showed that the LW-CI scale is a feasible, reliable and valid measure to evaluate separately the process of living with an LTC in a Spanish-speaking population. According to those validation studies<sup>16-21</sup>, potential modifications were proposed to achieve a better version of the LW-CI scale for each LTC in particular, such as simplifying the response scale, deleting some items or redesigning the domains. However, could those previous specific-disease validation results be extended across LTCs population? There is an opportunity to test psychometric properties of the LW-CI scale in a sample representing

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3 diverse chronic health conditions to validate the measurement properties across persons  
4 living with different LTCs.  
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6 All LW-CI scale validation studies were conducted using a classical test theory (CTT) approach  
7 to evaluate reliability, validity and sensitivity to change along with acceptability and other  
8 parameters, mostly based on correlations and mean difference analyses. Only the LW-CI for  
9 people with PD was additionally tested using Rasch measurement analysis.<sup>17</sup> The application  
10 of the Rasch model,<sup>22</sup> one of the most used applications of item response theory, combined  
11 with the classic test theory approach is recommended for evaluating PROM.<sup>23-25</sup> The Rasch  
12 model<sup>22</sup> completes the information provided by the classic test theory because it provides  
13 additional and relevant information about the measurement properties of a scale, such as  
14 unidimensionality and Differential Item Functioning (DIF) by individual groups including LTC  
15 type. In addition, it also allows for the calculation of scores on a linear scale.<sup>26</sup>  
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18 Therefore, the aim of this study is to analyse the psychometric properties of the LW-CI scale  
19 according to the classic test theory and Rasch model among people living with different LTCs.  
20 Suggestions for modification of the LW-CI scale are presented accordingly.  
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## 23 24 25 26 27 28 **Methods**

29 *Design.* International and cross-sectional study. This study is part of a multicentric and  
30 multidisciplinary research programme led by nurses (ReNACE Programme)  
31 (<https://www.unav.edu/web/programa-renace/proyectos>) aimed at achieving an in-depth  
32 understanding of the complex process of living with an LTC from the person and family/carers  
33 perspectives through the development of individualized interventions and comprehensive  
34 PROM.<sup>11,12</sup> In particular, this study has the general aim of achieving a unique and standardized  
35 international Spanish-speaking self-reported scale to evaluate how the person is living with  
36 his/her LTC in several Spanish-speaking countries.  
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39 *Setting.* Participants were recruited from different healthcare systems from six Spanish-  
40 speaking countries, namely, Spain, Cuba, Argentina, Ecuador, Mexico, and Colombia. More  
41 concretely, private and public primary and specialized healthcare services attending  
42 outpatients with LTCs were included. Additionally, individuals living with LTCs from the  
43 community were also approached, mainly from LTC organizations in Spain, such as the  
44 Parkinson's Disease Association.  
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50 *Participants.* Consecutive cases sampling<sup>27,28</sup> was applied to select participants. The sample  
51 was composed of individuals living with different LTCs, namely, type 2 diabetes mellitus  
52 (T2DM), chronic obstructive pulmonary disease (COPD), chronic heart failure (HF), PD,  
53 hypertension, and osteoarthritis. The following criteria were applied: 1) diagnosed with an  
54 LTC by a general practitioner or consultant (T2DM, COPD, HF, PD, hypertension and  
55 osteoarthritis); 2) adult person ( $\geq 18$  y); 3) be able to read, understand, and answer written  
56 questionnaires; 4) native Spanish-speaking person; and 5) be able to provide written informed  
57 consent. The applied exclusion criteria were as follows: 1) have cognitive deterioration or  
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3 psychiatric disorders, or any other disorder that could interfere with or impede the  
4 appropriate development of the study (e.g., blindness); 2) hospitalized patients; and 3) not  
5 meeting established inclusion criteria.  
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8 According to international criteria, the sample size was estimated to fulfil the rule of 10  
9 participants per item<sup>29</sup> which exceeds the minimum of 100 subjects required for classical test  
10 theory. Therefore, considering that the LW-CI scale is a 26-item scale, the minimum sample  
11 size estimated was 260 participants per condition, aiming for a total of 1,560 participants.  
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14 *Assessments.* Sociodemographic data, such as age, gender, marital status, employment  
15 situation and educational level, were collected. In addition, LTC related information was  
16 collected namely, age at disease and disease duration. In addition to sociodemographic and  
17 LTC related data, the Spanish version of the following self-reported validated PROMs was  
18 used:  
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22 - Living with Chronic Illness Scale (LW-CI scale).<sup>15</sup> The LW-CI scale is a self-reported scale  
23 that evaluates the complex process of living with an LTC. The LW-CI scale is a 26-item scale  
24 grouped into five domains: Domain 1: Acceptance (4 items); Domain 2: Coping (7 items);  
25 Domain 3: Self-management (4 items); Domain 4: Integration (5 items); Domain 5:  
26 Adjustment (6 items).<sup>15</sup> All items are answered using a 5-point Likert scale from never or  
27 nothing (0) to always or a lot (4), except for Domain 1: Acceptance, that is reversely scored  
28 from never or nothing (4) to always or a lot (0). The LW-CI scale has total score value from  
29 0 points, indicating negative living with the condition, to 104 points, reflecting positive  
30 living with the condition.  
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32 - Duke-UNC Functional Social Support Questionnaire (DUFSS).<sup>30</sup> The DUFSS is a self-  
33 reported measure that comprises 11 items evaluating diverse dimensions of social  
34 support as confidant, affective and instrumental support. The score for each item varies  
35 from 1 (much less than I would like) to 5 (as much as I would like). Total total score ranges  
36 from 11 (lowest level of support 'much less than I would like') to 55 (highest level of  
37 support 'as much as I like'). According to the Spanish validation study,<sup>31</sup> the DUFSS  
38 presented adequate psychometric properties, showing a Cronbach's alpha value of 0.9  
39 and satisfactory construct validity.<sup>30,31</sup>  
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41 - Modified version of the Satisfaction with Life Scale (SLS-6). Originally, this is a 7-item self-  
42 reported questionnaire.<sup>32</sup> For this study, the modified version of the Satisfaction with Life  
43 Scale was used because the original version and in particular, one of the items was specific  
44 for a student population.<sup>33</sup> In this way, a modified version with a 6-item scale was used to  
45 evaluate the degree of overall satisfaction with life and regarding to six areas: whole life,  
46 physical, psychological wellbeing, social relations, leisure, and financial situation. Each  
47 item was rated on a 0 (totally unsatisfied with life) to 10 (totally satisfied with life) point  
48 Likert scale. According to the Spanish validation study,<sup>33</sup> the SLS-6 presented satisfactory  
49 psychometric properties, with a Cronbach's alpha of 0.8 and internal validity values  
50 ranging from 0.4 to 0.7.<sup>32,33</sup>  
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3 - Patient-Based Global Impression of Severity Scale (PGIS). This is an adaptation of the  
4 clinical global impression of severity<sup>34</sup> adapted for patients as a self-reported scale.<sup>35</sup> It is  
5 a global index that may be used to assess self-perception of disease severity of the person  
6 living with a disease. The PGIS is a 6-point Likert scale, ranging from 0 (not ill at all) to 5  
7 (extremely ill). It has excellent construct validity and has been widely used in studies of  
8 chronic diseases.<sup>36</sup>  
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12 *Data collection.* For people living with PD, data were collected between January and June  
13 2015 and for people living with T2DM, COPD, HF, hypertension, and osteoarthritis, data were  
14 collected between November 2018 and May 2019, among the different healthcare centres  
15 and community settings of the six Spanish-speaking countries. Although data collection was  
16 taken at different times, a detailed and standardized protocol was performed to ensure data  
17 collection homogeneity and reduce possible errors during the process.<sup>37</sup> According to the  
18 established protocol, potential participants were approached through a health professional  
19 (nurse or physician) or member of the research group. An invitation letter and a participant  
20 information sheet as well as verbal information were provided to explain the study.  
21 Participants who agreed to participate signed the consent form and were asked to complete  
22 the sociodemographic and LTC-related data as well as PROM when they agreed with his/her  
23 health professional or researcher. Hence, participants completed the scales during the  
24 consultation with the GP, specialized clinician, nurse specialist or primary care nurse.  
25 Participants who required help to complete the scales (e.g., due to vision problems) were  
26 supported by a researcher. Once the participants finished answering the scales, a researcher  
27 reviewed the answers to identify possible missing data. Hence, no missing data was expected.  
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35 *Ethical aspects.* The study was approved by the research ethics committee of the principal  
36 investigator centre (reference numbers: BLINDED FOR REVIEW) and all the included centres.  
37 This validation study was adjusted to the principles outlined in the Declaration of Helsinki  
38 (1964) of Law 14/2007 on Biomedical Research and Law 15/1999 on the Protection of  
39 Personal Data. All participants gave their signed consent to participate voluntarily after  
40 receiving verbal and written information related to the study. Signed consent was given in  
41 front of the health professional or a member of the research group before completing the  
42 surveys.  
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47 *Data analysis.* Descriptive statistics, namely central tendency measures and proportions,  
48 were used to determine the sociodemographic and LTC characteristics of the participants.  
49 The main data were ordinal or did not fit a normal distribution. Therefore, nonparametric  
50 statistics were used.  
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53 According to the CTT, the following psychometric attributes were analysed:

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55 - Feasibility and acceptability. The quality of the data was considered satisfactory if 95% of  
56 the data were computable. The limit for missing data was <5%<sup>38</sup> and mean, median and  
57 standard deviation was estimated to be roughly equivalent ( $\leq 10\%$  maximum  
58 punctuation).<sup>39</sup> Floor and ceiling effect were deemed acceptable if they were < 15%<sup>39</sup> and  
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the skewness was expected between -1 to +1.<sup>40</sup>

- **Reliability.** Internal consistency was tested by Cronbach's alpha coefficient (criterion value  $\geq 0.70$ ),<sup>41</sup> item-total correlation (corrected for overlap; criterion value,  $r_s \geq 0.30$ ),<sup>23</sup> inter-item correlation (criterion value,  $r \geq 0.20$  and  $\leq 0.75$ ),<sup>38,42</sup> and item homogeneity (criterion value  $> 0.30$ ).<sup>43</sup>
- **Construct validity.** For convergent validity, a moderate ( $r_s \geq 0.35-0.50$ ) or strong relationship ( $r_s > 0.50$ )<sup>44-46</sup> was hypothesized between LW-CI scale and DUFSS and SLS-6, according to previous studies. A weak ( $r_s = 0.20-0.34$ ) or insignificant ( $r_s = 0.00-0.19$ ) relationship with age at diagnosis and disease duration was also hypothesized. These hypotheses were established to corroborate previous LW-CI scale validation study results in specific LTCs.<sup>16,18-21</sup> Spearman rank correlation coefficients were obtained for this purpose. Internal validity, defined as the intercorrelations between the LW-CI scale dimensions (standard,  $r_s = 0.30-0.70$ )<sup>40,47</sup> was determined. For known-groups validity, differences in LW-CI scale scores in the participants grouped by gender and PGIS scores were analysed.<sup>47,48</sup> Mann-Whitney and **Kruskal-Wallis with Bonferroni corrections tests were used for group comparisons.**

For the Rasch model, the following measurement properties were analysed: fit to the Rasch model, reliability (**Person Separation Index, PSI**), adequacy of the response scale, item local independence and unidimensionality. In addition, DIF was analysed by the following person factors: sex, age groups (70 years or lower vs. more than 70 years old), disease duration (categorised by the median; up to 6 years vs. 7+ years) and LTC type; **DIF by country was not possible due to an unequal distribution of data from different countries, precluding comparisons.**

According to the Rasch model, the response to a certain item is a function of the person's ability (or experienced level of the construct) and the item's difficulty (or the measured level of construct by that item), expressed in logits.<sup>22</sup> Fit to the Rasch model is observed when there is a nonsignificant chi-square difference between the data and the Rasch model, with Bonferroni correction by number of items.<sup>26</sup> In addition, residuals should follow a normal distribution (mean of 0; standard deviation, SD of 1) and fall within the  $\pm 2.5$  range. Large sample sizes might result in a high statistical power to detect small model deviations and unnecessary modifications. Therefore, for Rasch analysis we took a random sample of 300 individuals.<sup>49</sup>

**Reliability is expressed by the PSI, interpreted similarly to Cronbach's alpha.** A threshold is the point of equal response probability between two adjacent categories. Its order is analysed and in the case of disordered thresholds, adjacent categories are collapsed. For items to be locally independent, we expect low correlations ( $<0.30$  of the average correlation) between item residuals.<sup>50</sup> Unidimensionality is measured through a principal component of the residuals, and person estimates are compared by t-tests. A lower bound of the associated binomial 95% confidence interval (CI)  $<5\%$  indicates unidimensionality.<sup>51,52</sup> For DIF, analyses of variance (ANOVA) with Bonferroni correlation are conducted for all person factors.<sup>53</sup> When

several items present significant DIF by a certain factor, a top-down purification procedure is followed by creating two groups of items, with or without DIF, and comparing the person estimates in an ANOVA to see if DIF remains.<sup>54</sup> Model modifications were evaluated iteratively.

SPSS 22.0 (Armonk, NY: IBM Corp) was used for all CTT analyses, and RUMM2030 was used for Rasch analysis.

## Results

A total of 2,753 people living with different LTCs were included in the sample. Osteoarthritis presented the lowest sample size (n=291), and T2DM presented the highest (n=582). Demographic information it is shown in Table 1. The age range was 20-98 years, with a mean age of 68.21 (SD: 12.21 years). More than half of the sample was female (n=1,441; 52.3%), was married (n=1,555; 56.5%) and had basic/primary education levels (n=1,596; 58.1%). The employment status of the sample was mainly distributed between retired (n=934, 34%) and housekeeper (n=827, 30.1%). All of the participants present at least one LTC, with a duration of 9.80 years (SD: 8.65; range: 0-67 years) and a mean age at diagnosis of 58.37 years old (SD:  $\pm 13$ ; range: 3-91 years).

### *CTT analysis*

The results related to feasibility and acceptability showed that, the LW-CI scale was fully completed by 2,738 participants, with 99.46% of the data computable. Levels of missing data were low and broadly uniform across domains, ranging from 0 missing data (domain 1: Acceptance) to 6 (domain 5: Adjustment). The floor effect was absent in all domains and in the total score, whereas domains 1: Acceptance and 4: Integration showed ceiling effects (19.1% and 15.6%, respectively). For the five domains and the LW-CI total scale, the difference between the mean and the median was less than 10%, the theoretical and observed ranges were coincident, and the skewness values were between -1 and +1. Table 2 presents further feasibility and acceptability results.

The results related to internal consistency showed that Cronbach's alpha for the LW-CI scale was 0.91 and that for domains ranged between 0.76 (domain 3: Self-management) and 0.87 (domain 1: Acceptance). All domains reached the present 0.30 threshold value for item-total correlation and item homogeneity index values were higher than 0.30 for all domains. Interitem correlation coefficient values ranged from 0.20 to 0.73 (Table 2).

Regarding convergent validity (Table 3), the LW-CI scale showed strong positive correlation coefficients with DUFSS ( $r_s = 0.62$ ) and SLS-6 ( $r_s = 0.54$ ).

Regarding internal validity, correlation values for all domains of the LW-CI scale ranged from 0.62-0.68, except for domain 1: Acceptance, which showed correlation coefficients  $<0.30$  (Table 3).



LW-CI scale scores were significantly different for each category of PGIS (normal, mild, moderate, severe), gender and LTC (Table 4), with significantly higher scores for people with normal severity, women and individuals with hypertension ( $p < 0.05$ ). Comparisons between subgroups of PGIS and type of LTC are included in Table 4.

### *Rasch analysis*

The first Rasch analysis, with all items, showed a significant model deviation:  $\chi^2(234)=560$ ,  $p < 0.00001$ . Because the total scale was multidimensional (19% significant t-tests, 95% CI: 0.165-0.215), each domain was analysed separately. Table 5 presents the goodness of fit of the LW-CI domains and Table 6 presents the individual item fit.

For the Acceptance domain, item 2 showed disordered thresholds, and categories 2-3 were collapsed. This dimension showed a good model fit,  $\chi^2(16)=18.772$ ,  $p = 0.281$ , with unidimensionality,  $PSI=0.763$ , locally independent items, and absence of DIF by age, sex, disease duration or LTC. The person-Item threshold distribution shows a ceiling effect close to 20% (Figure 1).

When performing a Rasch analysis of the Coping domain, three items (2, 11 and 12) showed a significant misfit: item 8 presented a low fit residual (-2.501) and items 11 and 12 presented high fit residuals (3.506 and 2.957, respectively). All Coping items were rescored due to disordered thresholds. The resulting scale presented an adequate fit to the Rasch model,  $\chi^2(20)=23.790$ ,  $p = 0.252$ ,  $PSI=0.648$ , unidimensionality, and item local independency. Item 7 presented DIF by LCT type and item 5 showed uniform DIF by disease duration (people with more recent diagnosis underestimated scores).

The Self-management domain presented a good fit to the Rasch model, with ordered thresholds, unidimensionality,  $PSI=0.703$ , locally independent items, and absence of DIF:  $\chi^2(16)=13.783$ ,  $p = 0.615$ .

To obtain fit in the Integration domain, the following modifications were performed: rescoring of all items due to disordered thresholds, and deletion of items 18 (fit residual 3.454) and 21 (fit residual 2.848). The modified scale presented a good fit to the Rasch model,  $PSI=0.576$ , unidimensionality, and item local independency,  $\chi^2(12)=15.493$ ,  $p = 0.216$ . Item 20 presented uniform DIF by LCT type. The person-item threshold distribution showed a high (26.7%) ceiling effect (Figure 1).

In the Adjustment domain, all items but one (item 24) were rescored due to disordered thresholds. After this, the domain presented a good fit to the Rasch model,  $\chi^2(20)=33.994$ ,  $p = 0.0262$ ,  $PSI=0.743$ , unidimensionality and item local independency. Although item 26 showed a marginally high fit residual (2.603), it was nonsignificant. The initial DIF by LCT type in items 24 and 26 cancelled out in the top-down purification procedure.

## **Discussion**

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3 This is the first study that analyses the psychometric properties of the LW-CI scale in a **large**  
4 **sample** of individuals with different LTCs in several Spanish-speaking countries. Currently, the  
5 LW-CI scale is the only **PROM** available in clinical practice and research to evaluate in a  
6 comprehensive manner how a person is living with an LTC.  
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### 9 *Feasibility and acceptability*

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11 In general, all acceptability parameters fulfilled the standard criteria. **Floor and ceiling effects**  
12 **could be explored using both CTT and Rasch analysis.** The two domains with the highest ceiling  
13 effect at the item level, Acceptance and Self-management, also showed a ceiling effect at the  
14 threshold level in the Rasch analysis. This could be explained because individuals involved in  
15 this study participated voluntarily, potentially implying some degree of acceptance as well as  
16 good management of the LTC and hence, in some cases, also a positive living with the disease.  
17 A large percentage of individuals tend to score in the highest levels of these domains, which  
18 might prevent observing changes after an intervention in people with initial high scores. To  
19 verify this result, group comparisons in the Acceptance and Self-management domains should  
20 be made with caution.  
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24 The quality of the data was satisfactory, exceeding the 95% of computable data, due to the  
25 close supervision performed by researchers during data collection and the standardized  
26 protocol established for the data collection.  
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### 29 *Reliability*

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31 **Reliability was also explored using both to the CTT and Rasch approaches.** Internal consistency  
32 of the LW-CI scale is satisfactory, with all domains exceeding the criteria of  $\geq 0.70$  for  
33 Cronbach's alpha. However, Integration and Coping domains showed lower reliability (**PSI**) in  
34 Rasch analysis, which may be due to a small number of items and ceiling effect. A lower  
35 reliability might hinder the ability of these domain scores to discriminate between two  
36 individual groups.<sup>55</sup> In this sense, further studies are recommended to verify the reliability of  
37 both domains.  
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### 40 *Convergent validity*

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42 Regarding convergent validity, the results corroborate the strong relationship between living  
43 with an LTC and perceived social support of the person as well as satisfaction with life. Living  
44 with an LTC presents low correlations with disease-related factors, namely duration.  
45 Congruently, all items but one were unbiased by disease duration in Rasch analysis. Further  
46 studies are needed to confirm whether DIF by duration in item 5 (I try to cope and fight the  
47 disease) remains, as it was not identified in a study **with PD population.**<sup>17</sup> In addition, two  
48 items showed bias by LTC type: coping item 7 (I try to see the positive side of the disease) and  
49 Integration item 20 (Although I have the disease, I feel satisfied with my life). In item 20,  
50 people with hypertension tended to overestimate scores whereas for item 7, there was no a  
51 clear pattern. Further studies are needed to confirm these DIF results, and the results at the  
52 item level should be interpreted cautiously when comparing individuals. However, these two  
53 items represent less than 10% of the scale. Even though a previous study had found that one  
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3 item was biased by age, we did not replicate this finding in the present study, showing the  
4 absence of DIF by age for all items.<sup>17</sup> Therefore, the LW-CI scale could be useful across a  
5 general adult ( $\geq 18$  y) population living with at least one LTC in clinical practice.  
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8 Convergent validity findings were also identified in previous validation studies<sup>16,18-21</sup> and  
9 additionally were confirmed through linear regression models performed with an LTC  
10 population such as PD.<sup>5</sup> According to these results, there is clearly a need to place the  
11 emphasis on the person and in his/her daily living with the condition, and not just on the  
12 disease. Each person with an LTC must be seen as a **unique person**, independent of the stage  
13 or the severity of the disease. Therefore, it is necessary to incorporate multidisciplinary and  
14 individualised interventions in current health and social services, focusing on the factors that  
15 directly influence in living with an LTC, namely, social support and satisfaction with life.  
16 Consequently, possible negative aspects of the daily living with an LTC, as lack of support,  
17 loneliness or dissatisfaction with life, could be prevented, and a more positive living achieved.  
18 In this sense, person-centred interventions or individualised health and social pathways could  
19 be implemented in clinical practice, incorporating nonpharmacological or disease-specific  
20 measures that address the factors that are paramount in the daily living with an LTC.  
21 Therefore, LTC programmes that mobilize and optimize the use of community resources and  
22 increase social networks and support seem to be the direction for the management of LTCs.  
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### 30 **Internal validity**

31 Internal validity for LW-CI scale domains was excellent, except for domain 1: Acceptance, with  
32 correlation coefficients under 0.30 with the rest of domains. **This result is consistent with**  
33 **previous validation studies<sup>16</sup> and conceptual work<sup>4</sup> showing that Acceptance is always the**  
34 **first domain to achieve a positive living. Only when the person has accepted and assumed**  
35 **his/her illness, can move on to the other domains, such as coping or self-management.**  
36 Therefore, according to the poor correlation that Acceptance showed with other dimensions  
37 of the LW-CI scale and based on the aforementioned conceptual framework, these findings  
38 were expected because Acceptance is considered an internal, illness-independent, process  
39 through which the person recognizes and assumes the reality. Interval validity was also  
40 supported by Rasch analysis, showing that each domain is unidimensional, and providing  
41 support for the calculation of domain scores.  
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### 48 **Known-groups validity**

49 The LW-CI scale demonstrated satisfactory known-groups validity, yielding significantly  
50 different scores between men and women, patient-based global impression of disease  
51 severity and LTC type. Result related to differences among types of LTC is understandable, as  
52 each condition has its particular symptoms and evolution. For example, PD is defined as a  
53 complex and disabling disorder characterized by being a neurodegenerative and progressive  
54 disorder while hypertension is a cardiovascular condition that could be coped and managed  
55 with healthy lifestyle patterns. In this sense, the individual may have a better or worst process  
56 based on the LTC characteristics. However, further studies are suggested to verify this result.  
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3 Regarding gender differences, existing evidence also justifies the identified results. For  
4 example, Crispino and colleagues<sup>56</sup> stated that in general, women with PD showed more positive  
5 disease outcomes than men. Besides, other studies performed in individuals with T2DM<sup>57</sup>  
6 showed that women with T2DM are at greater risk than men of psychosocial maladjustment,  
7 a poorer cardiovascular profile and/or noncompliance with treatment goals. The observed  
8 significant differences by gender are not due to a bias, as no item presented DIF by gender.  
9 However, the significantly lower scores in hypertension individuals should be interpreted  
10 cautiously, since two items were biased by LCT type. Therefore, LW-CI scores may be  
11 interpreted similarly across LCT types, thus allowing group comparisons except for two items.

### 16 *Rasch analysis*

18 To achieve model fit in Rasch analysis, some modifications were performed. First, the  
19 response scale was simplified for some items, similar to a previous study with only **PD**  
20 **population**.<sup>17</sup> This result suggests that individuals have difficulty in setting apart from some  
21 response options, and that the response scale should be codified differently than what it was  
22 initially proposed. This does not modify the scale administration. Another modification  
23 suggested by Rasch analysis was the deletion of certain items. Again, they might be  
24 maintained in the scale administration, as they can provide useful clinical information.  
25 However, when calculating linear scores, these items should not be considered, as they are  
26 either redundant or they measure a different construct.<sup>26</sup> In both the present study and the  
27 previous study,<sup>17</sup> item 8 was found to be redundant, and item 18 measured a different  
28 construct.

34 Recently, other measures have been designed and validated as the Long-Term Conditions  
35 Questionnaire<sup>10</sup> with Rasch analysis<sup>58</sup> in a wide and representative sample of people living  
36 with LTCs in three regions of England with the general aim of evaluating how people  
37 live/manage their LTC. **However, despite the potential relevance of the Long-Term Conditions**  
38 **Questionnaire, this scale seems to evaluate quality of life outcomes instead of living with an**  
39 **LTC and excluding aspects related to acceptance, which is an essential attribute when living**  
40 **with an LTC.<sup>4</sup> Moreover, currently there are multiple measuring scales that seem to evaluate**  
41 **the phenomena of living with an LTC<sup>9</sup>. However, existing scales evaluate the process in a**  
42 **fragmented way by measuring some elements of the process or related processes, such as**  
43 **quality of life<sup>9</sup>. Consequently, to our knowledge the LW-CI scale could be considered the only**  
44 **available person-centred measure available that evaluates the complex process of living with**  
45 **an LTC in a comprehensive manner. Through this scale, healthcare professionals could identify**  
46 **aspect/s of the process that the patient finds more challenging and consequently, referrals,**  
47 **interventions or signposting to services or resources could take place based on the**  
48 **assessment and identified needs. For example, the scale itself could be part of interventions**  
49 **through which patients could complete the scale at home, increasing their awareness of how**  
50 **they live with the LTCs and in their annual or periodic review with the GP, nurse or specialist**  
51 **the results from the assessment could also be discussed for further support. This could be**  
52 **equally applied to research projects. At present, a cross-culturally adapted version of the scale**

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3 has been produced in the UK (called the Living with Long term condition scale, LwLTC scale)<sup>59</sup>  
4 and full validation study is ongoing, which would allow health and social care professionals,  
5 to implement person-centred care pathways and referral processes.  
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8 This validation study is novel because the LW-CI scale is the first validated rating scale for  
9 assessing the phenomena of living with an LTC. Moreover, this scale has been used for the  
10 first time to assess several highly prevalent LTCs in different Spanish-speaking countries, using  
11 two complementary analytical approaches to ascertain its psychometric properties.  
12 Therefore, considering the results, the LW-CI scale could be used in clinical practice to  
13 evaluate the degree of living with several highly prevalent LTCs in different Spanish-speaking  
14 countries.  
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### 18 *Limitations*

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20 We acknowledge that the limitations of the study are mainly related to the convenience  
21 sample, with a heterogeneous representation of LTCs and countries. Additionally, although  
22 country-based samples were not large enough to produce any country-based (cultural)  
23 analysis, further international studies are needed to test item bias by country as well as  
24 cultural differences within countries. Besides, considering the sample diversity, including  
25 people from six different countries, sociodemographic data related to ethnicity were not  
26 collected. Additionally, for this validation study patient and public involvement (PPI) was not  
27 conducted, as the aim of this study was to statistically analyze the psychometric properties of  
28 the LW-CI scale. However, PPI was a key aspect during the development of the scale and  
29 piloting phase before the main validation studies. Finally, data collection was performed at  
30 different times for PD and the rest of the LTCs. However, to ensure homogeneity of the  
31 process and avoid errors, a clear and standardized protocol was followed, and data quality  
32 was equally valid for the purpose of this study. On the other hand, the strengths of this study  
33 are related to the sample diversity, including the highly prevalent and prototypical LTC  
34 population as well as the large age range population which led to the real value of the LW-CI  
35 scale psychometric properties for a general LTC population. Finally, the combined application of  
36 the classic test theory approach and Rasch analysis is highly recommended for evaluating  
37 patient outcome report measures such as the LW-CI scale.  
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### 48 **Conclusion**

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50 This study fulfils an important gap in the literature regarding person-centred measures to  
51 evaluate the process of living with an LTC. After some adjustments, the LW-CI domains  
52 showed a good fit to the Rasch model, with unidimensionality, item local independency and  
53 moderate reliability, providing scores on a true interval scale. This last feature is key for using  
54 the scale in clinical trials. Except for two items, the LW-CI scale was free from bias by LCT type.  
55 In this sense, although cautious use is suggested, the LW-CI scale is ready to be used in clinical  
56 practice and research in Spanish-speaking population living with different LTCs, which could  
57 lead to a more person-centred care and individualized psychosocial interventions. Therefore,  
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future implementation studies are suggested to assess the usefulness of the LW-CI scale in clinical practice.

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**Table 1. Participant characteristics (n=2753).**

<b>Demographical variable</b>	<b>Response option</b>	<b>N (%)</b>
Country	Argentina	60 (2.2%)
	Colombia	1329 (48.3%)
	Cuba	50 (1.8%)
	Ecuador	60 (2.2%)
	Mexico	53 (1.9%)
	Spain	1201 (43.6%)
Long term condition	Type 2 diabetes Mellitus	582 (21.1%)
	Chronic obstructive pulmonary disease	612 (22.2%)
	Chronic Heart Failure	603 (21.9%)
	Parkinson's disease	324 (11.8%)
	Hypertension	341 (12.4%)
	Osteoarthritis	291 (10.6%)
Gender	Male	1312 (47.7%)
	Female	1441 (52.3%)
Marital status	Single	316 (11.5%)
	Married	1555 (56.5%)
	Widower	612 (22.3%)
	Separated/ divorced	261 (9.5%)
	Others	6 (0.2%)
Employment situation	Active working	501 (18.2%)
	Housekeeper	827 (30.1%)
	Retired	937 (34%)
	Other	487 (17.7%)
Educational level	Basic/ primary studies	1596 (58.1%)
	Secondary studies	709 (25.8%)
	University studies	359 (13.1%)
	Others	83 (3%)
	<b>Range</b>	<b>Mean (Standard deviation)</b>
Age	20-98	68.21 (12.21)
Age at diagnosis	3-91	58.37 (13.00)
Long term condition duration	0-67	9.80 (8.65)

**Table 2. Feasibility, acceptability and reliability of the LW-CI scale**

	LW-CI scale					
	Domain 1. Acceptance	Domain 2. Coping	Domain 3. Self- management	Domain. 4 Integration	Domain 5. Adjustment	Total
<b>Missing data/Fully computable data</b>	0/2753	2/2751	5/2748	2/2751	6/2747	15/2738
<b>Mean</b>	10.66	18.54	10.62	14.69	14.99	69.52
<b>Median</b>	11	19	11	15	15	70
<b>Standard Deviation</b>	4.40	6.07	3.72	4.04	5.94	18.37
<b>Observed range</b>	0-16	0-28	0-16	0-20	0-24	0-104
<b>Floor effect (%)</b>	2.4	0.5	0.4	0.2	0.5	0.1
<b>Ceiling effect (%)</b>	19.1	6.2	12.9	15.6	12.6	1.6
<b>Skewness</b>	-0.59	-0.43	-0.36	-0.66	-0.17	-0.21
<b>Cronbach's alpha</b>	0.87	0.81	0.76	0.79	0.85	0.91
<b>Item-total correlation</b>	0.61 – 0.80	0.41 – 0.65	0.48 – 0.60	0.38 – 0.67	0.49 – 0.68	--
<b>Inter-item correlation</b>	0.48 – 0.73	0.23 – 0.53	0.30 – 0.55	0.20 – 0.62	0.29 – 0.61	--
<b>Item homogeneity</b>	0.62	0.38	0.44	0.42	0.48	--

LW-CI scale: Living with Chronic Illness Scale. SEM: Standard error of measurement.

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**Table 3. Convergent validity and internal validity of LW-CI scale**

		LW-CI scale					
		Domain 1. Acceptance	Domain 2. Coping	Domain 3. Self-manag.	Domain 4. Integration	Domain 5. Adjustment	Total score
<b>Convergent validity</b>	<b>Age</b>	0.00	-0.10**	-0.10**	-0.05*	-0.12**	-0.10**
	<b>Age at diagnosis</b>	0.02	-0.06**	-0.10**	-0.03	-0.09**	-0.08**
	<b>Disease duration</b>	-0.02	-0.06**	-0.01	-0.02	-0.06**	-0.04*
	<b>DUFSS</b>	0.30**	0.54**	0.47	0.54	0.50**	0.62**
	<b>SLS-6</b>	0.40**	0.40**	0.40**	0.48**	0.50**	0.54**
<b>Internal validity</b>	<b>Domain 2. Coping</b>	0.15	-	-	-	-	-
	<b>Domain 3. Self-management</b>	0.14	0.66	-	-	-	-
	<b>Domain 4. Integration</b>	0.27	0.68	0.67	-	-	-
	<b>Domain 5. Adjustment</b>	0.23	0.64	0.62	0.63	-	-

LW-CI scale: Living with Chronic Illness Scale. DUFSS: Duke-UNC Functional Social Support Questionnaire; SLS-6: Satisfaction with Life Scale.  
 \* p<0.05; \*\* p<0.01

**Table 4. Known-groups validity**

Categories	LW-CI scale total Mean (SD)	p
<b>PGIS-based severity levels<sup>†</sup></b>		<b>&lt;0.001<sup>a</sup></b>
Normal	75.06 (17.20)	
Mild	69.84 (17.11)	
Moderate	71.12 (18.23)	
Severe	59.73 (18.51)	
<b>Gender</b>		<b>&lt;0.001</b>
Male	68.09 (18.13)	
Female	70.83 (18.50)	
<b>Long-term condition</b>		<b>&lt;0.001<sup>b</sup></b>
Type 2 diabetes mellitus	71.53 (16.45)	
Chronic obstructive pulmonary disease	67.84 (18.86)	
Chronic heart failure	72.92 (20.14)	
Parkinson's disease	62.45 (18.57)	
Hypertension	75.20 (15.37)	
Osteoarthritis	63.19 (15.30)	

SD standard deviation. LW-CI scale: Living with Chronic Illness Scale. PGIS: Patient-Based Global Impression of Severity Scale.

<sup>†</sup>PGIS-based severity levels: normal, 0 points; mild, 1-2 points; moderate, 3 points; severe 4-5 points.

Kruskal-Wallis test with Bonferroni correction for PGIS and long-term condition, Mann-Whitney test for gender.

<sup>a</sup> Except for mild-moderate comparison, not significant; <sup>b</sup> Except for Parkinson's disease with osteoarthritis, and chronic heart failure with type 2 diabetes mellitus and with hypertension comparisons, all not significant.

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**Table 5. Goodness of fit to Rasch model of LW-CI scale domains.**

Attribute		Criteria	Domain 1. Acceptance	Domain 2. Coping	Domain 3. Self-manag.	Domain 4. Integration	Domain 5. Adjustment
<b>Item fit residual</b>	Mean	0	0.067	0.545	0.441	0.634	0.371
	SD	1	0.753	0.734	0.999	0.594	1.496
<b>Person fit residual</b>	Mean	0	1.189	0.650	1.322	1.256	0.444
	SD	1	1.730	1.224	1.544	1.490	1.362
<b>Item-trait interaction</b>	$\chi^2(df)$	Low	18.771 (16)	23.790 (20)	13.783 (16)	15.493 (12)	33.994 (20)
	p-value	NS	0.281	0.251	0.615	0.216	0.0262
<b>PSI</b>		>0.70	0.763	0.648	0.703	0.576	0.743
<b>Unidimensionality</b>	Independent t-tests	<5%	1.33%	1.33%	0%	1.33%	3.00%
	CI 95% Binomial	*	(-0.011, 0038)	(-0.011, 0038)	-	(-0.011, 0038)	(0.005, 0.055)

\* Lower bond should be  $\leq 0.05$ .

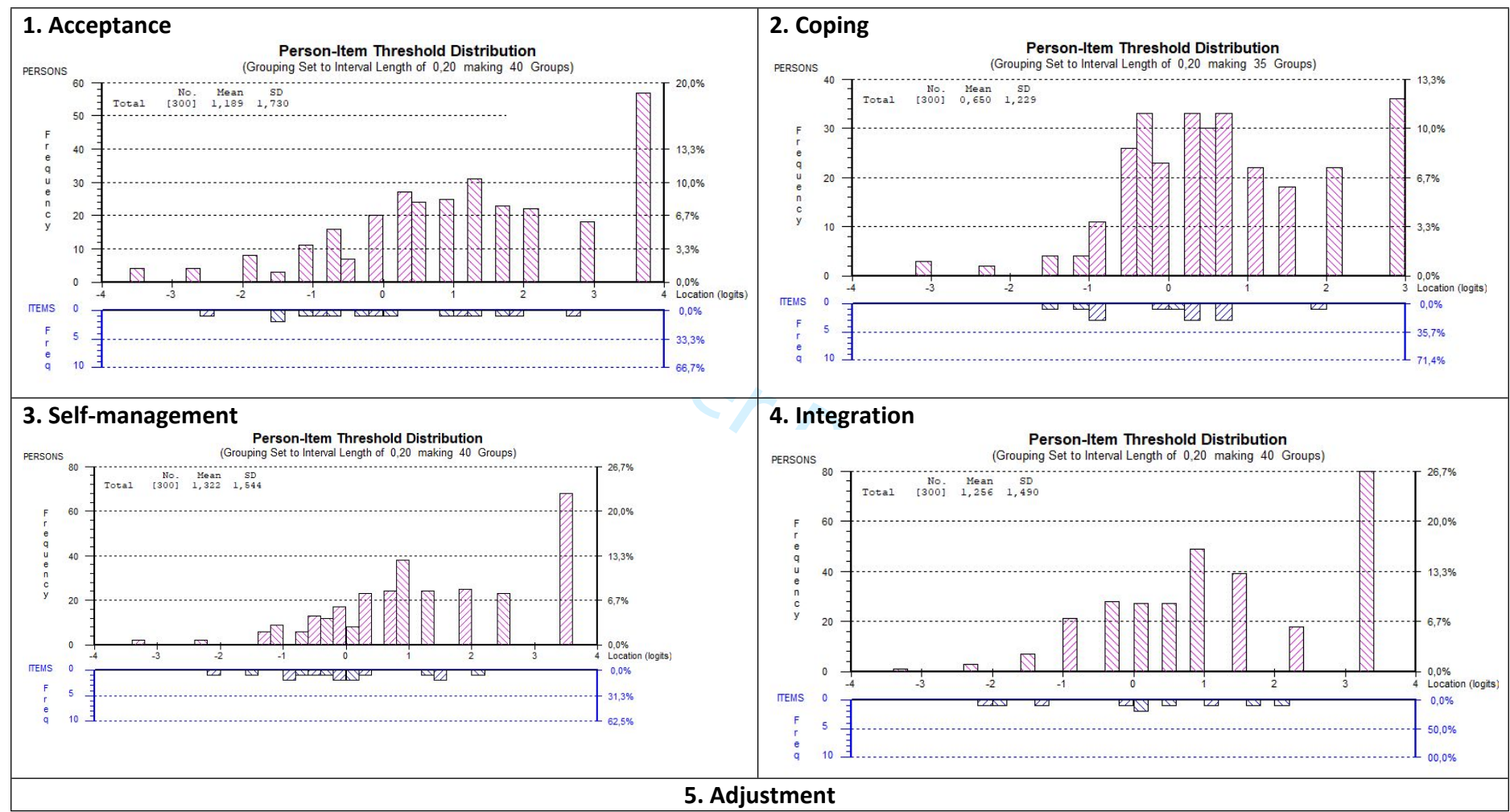
LW-CI scale: Living with Chronic Illness Scale. SD: Standard Deviation. NS: non-significant. PSI: Personal Separation Index.



**Table 6. Individual item fit.**

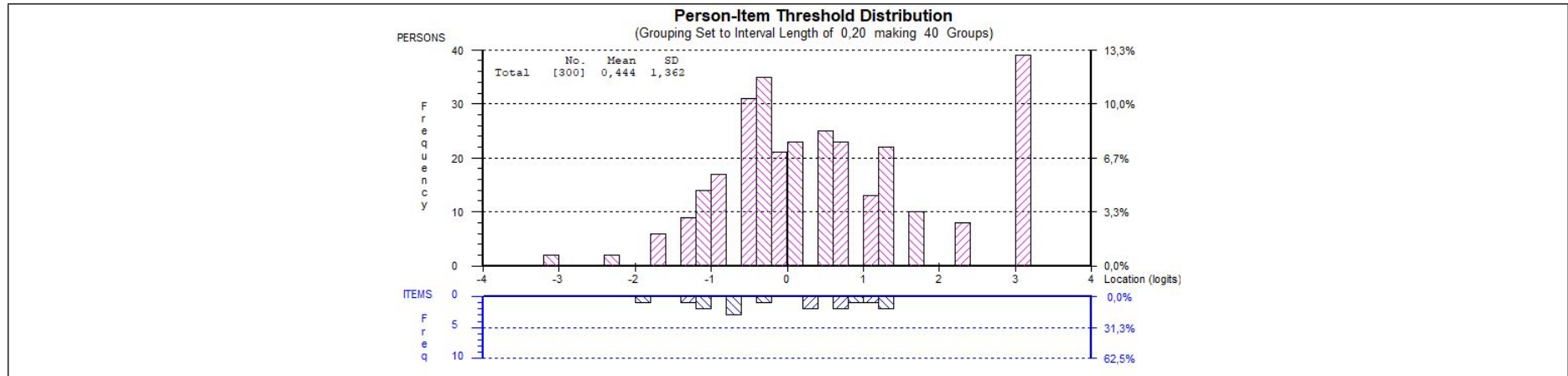
Item (response categories)	Location	Standard error	Fit residual	DF	Chi-square (df=4)	p-value
<b>Domain 1. Acceptance</b>						
Item 1. (0-4)	0.212	0.078	-0.283	175.75	6.051	0.195
Item 2. (0-3)	-1.299	0.111	0.605	175.75	6.326	0.176
Item 3. (0-4)	0.312	0.079	-0.825	175.75	5.827	0.212
Item 4. (0-4)	0.775	0.079	0.77	175.75	0.566	0.967
<b>Domain 2. Coping</b>						
Item 5. (0-3)	-0.075	0.074	0.096	206.2	2.828	0.587
Item 6. (0-3)	-0.072	0.075	0.048	206.2	7.006	0.136
Item 7. (0-2)	0.472	0.109	1.654	206.2	9.113	0.058
Item 9. (0-3)	0.038	0.073	-0.018	206.2	2.542	0.637
Item 10. (0-3)	-0.362	0.076	0.948	206.2	2.301	0.681
<b>Domain 3. Self-management</b>						
Item 13. (0-4)	0.436	0.075	1.731	168.75	0.937	0.919
Item 14. (0-4)	-0.418	0.083	-0.471	168.75	5.131	0.274
Item 15. (0-4)	0.202	0.073	0.711	168.75	2.934	0.569
Item 16. (0-4)	-0.220	0.08	-0.209	168.75	4.781	0.311
<b>Domain 4. Integration</b>						
Item 17. (0-3)	-0.322	0.094	1.261	143	2.981	0.561
Item 19. (0-4)	0.365	0.078	0.078	143	4.211	0.378
Item 20. (0-3)	-0.043	0.096	0.564	143	8.301	0.081
<b>Domain 5. Adjustment</b>						
Item 22. (0-3)	0.467	0.08	0.38	204.2	1.281	0.865
Item 23. (0-3)	-0.235	0.082	0.775	204.2	6.801	0.147
Item 24. (0-4)	-0.806	0.066	-0.553	204.2	6.175	0.186
Item 25. (0-3)	0.233	0.078	-1.347	204.2	13.897	0.008
Item 26. (0-3)	0.341	0.082	2.602	204.2	5.839	0.212

Figure 1. Person item-threshold distributions for the LW-CI domains.



5. Adjustment

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This document certifies that the manuscript

## **Living with Chronic Illness Scale: International validation through classic test theory and Rasch analysis among Spanish-speaking population with long term conditions**

prepared by the authors

**Carmen Rodriguez-Blazquez, Maria João Forjaz, Alba Ayala, Mari Carmen Portillo, Leire Ambrosio, on behalf of the EC-PC validation group**

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