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Desarrollo de la Escala Multidimensional de Fragilidad (EMFRA), y adaptación transcultural de la Escala FRAIL de 5 ítems: Un diseño de estudio del Proyecto EMFRA

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RESUMEN

Introducción: El concepto de fragilidad en el adulto mayor ha sido ampliamente investigado y se entiende como la vulnerabilidad a eventos relacionados con el deterioro de la salud. Inicialmente, se consideraba dependiente de parámetros físicos, pero ahora incluye influencias físicas, cognitivas, emocionales y sociales.

Justificación: Actualmente no contamos en español con suficientes herramientas para evaluar fragilidad en el adulto mayor, especialmente integrando evaluaciones multimodales.

Objetivos: Desarrollar la Escala Multidimensional de Fragilidad (EMFRA), adaptar transculturalmente la escala FRAIL de 5 ítems, junto con explorar la validez y fiabilidad de ambas escalas.

Métodos: La construcción de EMFRA comenzará con una revisión y síntesis de la literatura. Se identificarán factores relevantes para incluirse en la escala. Se realizará una traducción de la escala FRAIL de 5 ítems. La validación de contenido de ambas escalas comenzará con un panel de expertos, seguida de entrevistas cognitivas a sanitarios y adultos mayores. Se analizará la validez estructural de ambas escalas. Se analizará la validez convergente con el rendimiento físico en la Short Physical Performance Battery, con la función cognitiva global, con los niveles de ansiedad y depresión, nivel de dependencia. Se explorará la validez discriminante de las escalas transversalmente con el nivel de dependencia. Se analizará el tiempo en completar ambas escalas, el efecto suelo y efecto techo. Se realizará un análisis de la consistencia interna, fiabilidad intra-evaluador, error estándar de medición y cambio mínimo detectable de ambas escalas.

Palabras clave: Fragilidad; Validez; Fiabilidad; Adultos mayores; Envejecimiento.

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Development of the Multidimensional Frailty Scale (EMFRA), and cross-cultural adaptation of the 5-item FRAIL Scale: A study design of the EMFRA Project

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ABSTRACT

Introduction: The concept of frailty in older adults has been extensively investigated and is understood as vulnerability to the occurrence of health-related adverse events. Initially, it was considered dependent on physical parameters, but it now includes physical, cognitive, emotional, and social influences.

Justification: Currently we do not count with enough tools in Spanish to assess frailty in the elderly, especially integrating multimodal assessments.

Objectives: To develop the Multidimensional Frailty Scale (EMFRA), to cross-culturally adapt the 5-item FRAIL scale, and to explore the validity and reliability of both scales.

Methods: The construction of the EMFRA will begin with a review and synthesis of the literature. Relevant factors will be identified for inclusion in the scale. A translation of the 5-item FRAIL scale will be performed. Content validation of both scales will begin with an expert panel, followed by cognitive interviews with healthcare workers and older adults. Convergent validity with physical performance will be analysed in the Short Physical Performance Battery, global cognitive function, with anxiety and depression levels, level of dependence. The discriminant validity of the scales will be explored cross-sectionally with the level of dependence. The time to complete both scales, the floor effect and the ceiling effect will be analysed. The internal consistency, intra-rater reliability, standard error of measurement and minimum detectable change of both scales will be studied.

Keywords: Frailty; Validity; Reliability; Older adults; Aging.

INTRODUCTION

Numerous studies have explored the historical origins of the concept of "frailty" (Angulo et al., 2020; Dent et al., 2019) pointing to the last quarter of the 20th century as the date when this concept was originally coined. However, it was not until 2001 that two distinctive conceptualizations of frailty gained prominence.

Mitnitski et al., (2001) developed a "frailty index" based on the accumulation of health-related deficits. Simultaneously, Fried et al., (2001) proposed a "frailty phenotype" based on the presence of a specific set of signs, symptoms and findings.

The "frailty index" assess several health-related deficits, such as physical functioning, cognitive performance, emotional well-being, participation in activities of daily living, sensory perception, and comorbidities.

On the other hand, the "frailty phenotype" is based on the identification of at least one of the following based on the identification of at least 3 out of 5 key findings: unintentional weight loss, exhaustion/fatigue, low level of physical activity, slow walking speed and low hand grip strength.

Since the beginning of this scientific construct, scientists around the world have begun to operationalize the concept of frailty through the development of instruments. This phenomenon has grown significantly; nowadays, we have 51 different measurement tools for the detection and assessment of frailty (Faller et al., 2019). Current data indicate that we have a large number of instruments, due to the varied conceptualization of this construct.

It was initially posed as a physical function-dependent construct, referred to throughout the literature as "physical frailty", Fried's phenotype (Fried et al., 2001) being the best known within the physical frailty framework. However, another body of research has found that not only physical factors contribute to the development of frailty in older adults. Arguably, there is a much broader spectrum of factors involving cognitive functions, emotional status, social interaction and environmental factors that influence the vulnerability of older adults. These factors were first gathered in the "frailty index" following the accumulation of deficits model.

Boers and Cruz Jentoft (2015), provide one of the definitions in the literature that best represents the multidimensionality of the construct of frailty: "the weakening of health, i.e., the resilience or ability to cope with problems and to maintain and restore integrity, balance, and sense of well-being in three domains: physical, mental and social".

We can therefore identify 2 major conceptualization frameworks of "frailty", the first one, unidimensional, where frailty depends on the physical capacities of the older adult (physical frailty), and another that encompasses multidimensional domains (physical function, cognitive functions, capacity for participation, emotional state, and socio-environmental constraints). Furthermore, frailty is framed on a continuum, where older adults undergo a process of transition from non-frail to pre-frail, and finally to frail.

Authors consider prefrailty a clinically silent process that predisposes individuals to frailty (Rasiah et al., 2020). Prefrailty is likewise included within the physical and multidimensional framework (Dent et al., 2019; Rasiah et al., 2020).

Frailty, evaluated both unidimensionally and multidimensionally, is relevant for three reasons: 1) its high prevalence and incidence; 2) its significant healthcare burden; 3) its role as an indicator of being at risk of health-related adverse events.

Epidemiology of frailty.

The prevalence of physical frailty ranges from 11-13%, with pre-frailty having a global prevalence of 44-48% (O'Caoimh et al., 2021). Multidimensional frailty encompasses 26.8% of older adults, rising to 51.5% in hospital settings. Approximately 1 in 4 older adults is frail, with pre-frailty being even more common, reaching 36.4% in older adults, highlighting the importance of early intervention (Veronese et al., 2021).

Worldwide, 13.6% of older adults develop frailty characteristics after 3 years, with an incidence rate of 43.4 per 1000 persons per year. Pre-frail elderly have a higher incidence of frailty reaching 62.7%. The incidence of pre-frailty is also high at 30.9%, or 150 cases per 1000 people per year, an incidence much higher than that of frailty. According to sex, the

incidence of frailty and prefrailty is higher in women than in men (Ofori-Asenso et al., 2019).

Health burden of frailty.

Due to the biopsychosocial factors influencing prefrailty and frailty, it has been observed that these population groups are at a higher risk of being admitted to emergency health departments than non-frail older adults (Kojima, 2019). This entails high costs to healthcare services. In fact, depending on the number of symptoms presented by these frail older adults, the costs can be up to 5 times higher than those of a non-frail older adult. The two characteristics that have the greatest impact on economic expenditures are weight loss and exhaustion (Bock et al., 2016).

Risk of adverse health-related events.

In general terms, frailty detection tools are associated in the long term with the occurrence of events related to health loss. We have several reviews that have identified how multidimensional frailty screening tools are able to detect risk of mortality, hospitalization, disability in activities of daily living, or dependence.

On the other hand, physical frailty identification tools are able to detect the risk of fracture (at 1 year follow-up), fall risk (at 8 years), hospitalization, or even mortality risk (at 1, 2 and 10 years) (Apóstolo et al., 2017; Vermeiren et al., 2016).

In fact, current data seem to indicate that "physical" frailty tools could be more useful to detect some variables related to health deterioration, such as fracture risk versus "multidimensional" frailty tools. On the other hand, "multidimensional" frailty tools are better associated with the risk of mortality and institutionalization than those of physical frailty (Lee et al., 2022; Vermeiren et al., 2016).

JUSTIFICATION

Current data suggest maintaining both the "physical" and "multidimensional" frailty constructs, as they detect different patient profiles and long-term health related adverse events. After a recent search of the literature, it appears that a few frailty scales have been cross-culturally adapted to Spanish, especially to Spanish from Spain. Moreover, few have explored all their psychometric properties in older adults.

The FRAIL proposed by the "European, Canadian and American Geriatric Advisory Panel" (Kan et al., 2008), and subsequently developed by Morley et al., (2012) has been cross-culturally adapted and validated in Mexican Spanish (Rosas-Carrasco et al., 2016). This scale includes 5 items assessing fatigue, ambulation, resistance, illnesses, and loss of weight. These items are patient-reported outcomes, however, in its original development it was not clearly stated whether the measurement was self-administered or through telephone assessment. Items present different categories of responses, but with a total score of 0 or 1 point, with the total scale presenting a score range of 0 to 5 points. Cut-off points were settled by authors at 0, 1-2, and 3-5 for considering robust, prefrail and frail older adults respectively.

Few scales in Spanish assess multidimensional frailty in the elderly, including the Tilburg Frailty Indicator (Vrotsou et al., 2018) or the Frail-VIG Index, both of which assess different dimensions of frailty using dichotomous responses.

The researchers consider that it would be of interest to generate a new multidimensional frailty assessment scale, named as "Multidimensional Frailty Scale" (Escala Multidimensional de Fragilidad, EMFRA), exploring physical, emotional, cognitive and social domains, through a 3-category response system.

OBJECTIVES

The objectives of this research are focused on the following points: 1) translate and cross-culturally adapt the 5-item FRAIL scale into Spanish from Spain; 2) develop a preliminary version of the Escala Multidimensional de Fragilidad (EMFRA); 3) Achieve the content validity in both scales; 4) Explore their structural, convergent and discriminant validity; 5) Analyse the internal consistency; 6) Explore the intra-rater reliability, standard error of measurement (SEM), and the minimally detectable change (MDC) in both scales.

METHODS

Translation, cross-cultural adaptation, and development of the first preliminary version of the 5-item FRAIL scale.

The process of translation and cross-cultural adaptation of the scale will be carried out in a blinded and independent manner by 2 native Spanish speaker researchers from Spain. To perform this procedure, the researchers will respectively rely on both the original English scale (Morley et al., 2012; Rolfson et al., 2006) and the previous validation to Mexican Spanish of this scale (Rosas-Carrasco et al., 2016).

Once the independent translations are obtained, both in conjunction with 2 other native Spanish speaker researchers, will resolve by consensus the final translation and cross-cultural adaptation of the scale.

This version of the scale mentioned as FRAIL – Preliminary version 1 (FRAIL–P1) will be reported.

Review and synthesis of literature for the development of EMFRA.

A review of the literature in the PubMed and Google Scholar databases (in English and Spanish) will be carried out with the following objectives:

1) identify previous multidimensional frailty assessment tools and other tools that assess physical function, cognitive function, emotional status and social status; 2) identify the measurement procedure for these variables; 3) based on the frailty progression model proposed by Angulo et al., (2020), select variables that present a cross-sectional or longitudinal association with disability (conceived as "dysfunction at one or more of the following levels: impairments, activity limitations and participation restrictions") (*The International Classification of Functioning, Disability and Health: ICF*, 2001), suffering any event related to health deterioration, and mortality.

Development of the first preliminary version of EMFRA.

Based on this information, items will be generated stablishing the measurement method (external evaluator, self-reported or hetero-completed) and establish the 3-category score system based on the synthesized information.

Develop a preliminary scale with 4 assessment domains (physical function, cognitive function, emotional status, social situation), with 6 assessment items each. The scale will include functional tests where a participant's performance will be evaluated, and another set of items evaluated in a hetero-completed form. This preliminary version of EMFRA will be reported as EMFRA – Preliminary version 1 (EMFRA–P1).

Content validity.

Both scales will undergo a content validation process in Spain, by experts, followed by clinicians and patients. After each validation process, modifications will be conducted in both scales. The methodological procedures will be based on the COSMIN recommendations (Vet et al., 2011).

Content validation by an expert panel.

The expert panel will include 10-15 Spanish professionals, specialized in health sciences, involving various fields of knowledge, such as physiotherapy, occupational therapy, podiatry, medicine, nursing, and physical activity and sport sciences. An online validation panel will be conducted through the *Cognitoforms* platform.

The following information will be extracted from experts: 1) sociodemographic data including age, sex, nationality, native language, country of residence, autonomous community of residence, academic level, profession, and current job; 2) years of clinical and research experience with older adults, other frail populations, managing assessment tools, with frailty assessment tools; 3) the number of ongoing research projects related with frail older adults currently working on; 4) the number of previous validation process previously participated in; 5) previous knowledge and use of the 5-item FRAIL scale.

An initial presentation will be made to the experts presenting the justification and aims of the study, along with the informed consent for participation.

The online *Cognitoform* will include in both scales the following points: 1) The title / question of each item; 2) scoring / response system of each item. Additionally, in EMFRA we will include: 3) measurement procedure of each item; 4) justification

of the measurement procedure; 5) justification of the scoring / response system.

The level of "comprehension", "coherence" and "relevance" of each item will be assessed among experts employing a 5-category Likert scale of agreement:

- *"Completelly disagree"*
- *"Disagree"*
- *"Neither agree nor disagree"*
- *"Agree"*
- *"Completelly agree"*

The authors will evaluate each item of both scales quantitatively in terms of "comprehension", "coherence" and "relevance" of the items and response systems.

1) Item comprehension.
2) Score / Response options' comprehension.
3) Measurement procedure suitability (EMFRA).
4) Item coherence to assess physical frailty (5-item FRAIL scale).
5) Item coherence to assess multidimensional frailty (EMFRA).
6) Score / Response options' coherence to assess their respective item
7) Item relevance to assess physical frailty (5-item FRAIL scale)
8) Item relevance to assess multidimensional frailty (EMFRA).

Experts will be requested to provide comments, indications and suggestions for improvement or modification for each item in both scales. They will be asked an open question about the "item", and the "response system" for both scales with the following questions.

Additionally, an open-ended question will be asked for the measurement procedure of EMFRA items.

The level of agreement across items will be explored with the Aikens' V (Aiken, 1985):

$$Aiken's\ V = \frac{S}{[n\ (c-1)]}$$

The number of ordinal categories is denoted "c", the number of evaluators "n". "S" refers to the sum of the scores of the total number of evaluators. To calculate "S", the score for the category with the level of agreement selected "c_i" is subtracted from the value of the category with the lowest level of agreement "c_{low}".

$$S = \sum_n (c_i - c_{low})$$

Categorizing the Likert scale of Level of Agreement with the following scores:

- *"Completelly disagree" = 1 point (c_{low})*
- *"Disagree" = 2 points*
- *"Neither agree nor disagree" = 3 points*
- *"Agree" = 4 points*
- *"Completelly agree" = 5 points*

Aiken's V will be reported for every question of "comprehension", "coherence" and "relevance" in each item.

Second preliminary version of 5-item FRAIL scale and EMFRA after the validation by experts.

Based on the previous statistical analysis of agreement, a low level of agreement across authors will be considered when V<0.7. Items will be excluded if at least 1 question in each item presents a low level of agreement across authors. Only items with all questions presenting a V≥0.7 will be maintained.

Maintained items will be modified based on the suitability of the retrieved suggestions by authors.

The list of suggestions by every author will also be reported, indicating which suggestions were considered suitable for conducting modifications. A second preliminary version of both scales will also be presented, named as FRAIL–P2, and EMFRA–P2, highlighting the modifications conducted.

Content validation by clinicians and older adults.

The FRAIL-P2 and EMFRA-P2 will be administered and validated by clinicians and older adults, employing cognitive interviews (Estefania & Zalazar-Jaime, 2018). This procedure will serve to identify the comprehension and coherence of items for both clinicians, who will administrate the scale, and older adults, who will be assessed.

A total of 10 clinicians, and 10 older adults will be interviewed. A non-probabilistic sampling will be conducted for including clinicians, and older adults.

No selection criteria will be applied for clinicians, but presenting a native or C2 level of Spanish, as we want to explore their level of comprehension and the coherence of the scales despite their level of expertise. Nevertheless, we will include older adults with the following criteria:

- Native or presenting a C2 level of spanish from Spain.
- ≥65 years

The following exclusion criteria will also be applied for older adults:

- Any medical or health condition that poses a risk when conducting physical tests or physical exercise (e.g., heart failure, pulmonary hypertension, dilated or hypertrophic cardiomyopathy or non-idiopathic cardiomyopathy).
- Inability to stand without the assistance of the hands.
- Inability to walk independently even with assistive walking devices (participants unable to walk if not with assistance from another person assisting them during walking are excluded).
- Inability to transfer from sitting to standing even with the aid of assistive walking devices (participants unable to stand other than with the assistance of another person assisting them are excluded).
- Inability to read or understand the investigators' commands.
- Inability to observe clearly.

To participate in the interviews, clinicians and older adults will have to sign the informed consent. After that, the clinicians will be asked for the following information: 1) sociodemographic data including age, sex, nationality, native language, country of residence, autonomous community of residence, academic level, profession, and current job; 2) years of clinical experience, years of clinical experience with older adults, years of clinical experience with other frail populations, years of experience employing tests and assessment tools.

Older adults will be characterized with sociodemographic data including age, sex, body mass index, completed educational level, years studied, marital status, and employment status.

The audio in each interview will be recorded, and the methodology of interviews will vary for clinicians and older adults.

At the start of the interview for clinicians, the investigator will mention the procedure of administration the clinicians should conduct for assessing the scales FRAIL-P2 and EMFRA-P2 (which items are functional tests, self-reported or hetero-completed). Based on this information, clinicians will read every item with its score/response options.

They will be asked to retrieve any comments, suggestions, or modification requirements they consider. Finally, they will be asked for:

- *How much difficulty would it be administrating the scale?*
- *How much difficulty would it be to rate the final score?*

They will respond to these questions for each scale, following a 5-category Likert scale of difficulty:

- *"Very difficult"*
- *"Quite difficult"*
- *"Somewhat difficult"*
- *"Slightly difficult"*
- *"Not difficult at all"*

The order of administration for both clinicians and older adults will be first with the FRAIL-P2, indicating the comments, and responding to the level of difficulty, and then performing the same with the EMFRA-P2.

Interviews to older adults will be conducted by a researcher. In this case, the researcher will administer the scales to the older adults following the stablished procedure (functional tests, self-administered, or hetero-completed). After reading each item, older adults will be requested to indicate any comment, suggestion or modification requirement they consider. Additionally, the drop-out rate (ability / inability to

respond the item) will be indicated, and older adults will rate their perceived level of difficulty with the aforementioned Likert for:

- *Level of difficulty for comprehending the task/question.*
- *Level of difficulty for comprehending the response options.*

Third preliminary version of 5-item FRAIL scale and EMFRA after the validation by clinicians and older adults.

The information from clinicians and older adults will be summarized. Their level of difficulty and drop-out rate will also be summarized. Interviews' audiotapes will be checked, extracting the comments suggested by every participant.

Remaining items will be modified based on the suitability of the suggestions retrieved. A third preliminary version of the scales, FRAIL-P3 and EMFRA-P3, will be presented highlighting the modifications conducted.

Psychometric analysis of FRAIL-P3, and EMFRA-P3.

Aims.

The FRAIL-P3 and EMFRA-P3 will be further analysed in a sample of older adults to test their psychometric properties in terms of structural validity, convergent validity, discriminant validity, intra-rater reliability, floor-ceiling effect, SEM, and MDC in both scales. These aims will be achieved following the COSMIN recommendations (Vet et al., 2011).

Sampling and selection criteria.

A non-probabilistic sampling will be conducted, searching for older adults in day-care centres and nursing homes in the Autonomous Community of Madrid.

The inclusion of older adults will be based on the age criteria of ≥65 years. Older adults will be excluded if they present:

- Any medical or health condition that poses a risk when conducting physical tests or physical exercise (e.g., heart failure, pulmonary hypertension, dilated or hypertrophic cardiomyopathy or non-idiopathic cardiomyopathy).
- Inability to stand without the assistance of the hands.
- Inability to walk independently even with assistive walking devices (participants unable to walk without the assistance of another person during walking are excluded).
- Inability to transfer from sitting to standing even with the aid of assistive walking devices (participants unable to stand other than with the assistance of another person are excluded).
- Inability to read or understand the investigators' commands.
- Inability to observe clearly.
- Confirmed dementia.

Outcome measures and measurement time-points.

Two sessions of evaluation will be conducted leaving 2-10 days between measurements.

On the first day, we will extract sociodemographic variables including age, sex, nationality, native language, country of residence, autonomous community of residence, academic level, profession, and current job will be extracted, and the presence of any musculoskeletal, traumatological, neurological, psychological, psychiatric, metabolic, pain, or other disorders will be compiled.

Additionally, the following outcome measures will be explored:

- FRAIL: total punctuation, time for completion.
- EMFRA: total punctuation, time for completion.
- Global cognitive function: this outcome will be explored with the MoCA. This scale evaluates executive function, identification, working memory, attention, language, abstraction, delayed recall and orientation, attention, language, abstraction, delayed recall and orientation (Gómez-Moreno et al., 2020; Nasreddine et al., 2005; Ojeda et al., 2016).
- Level of dependence: the Barthel Index will be used to establish the level of independence of the participants (Cabañero-Martínez et al., 2009).

- Anxiety and depression signs and symptoms: this variable will be measured with the Hospital Anxiety and Depression Scale (HADS). This scale counts with 14 items, of which 7 items assess anxiety and depression signs and symptoms respectively (Herrero et al., 2003; Herrmann, 1997).
- Functional performance: this variable will be assessed with the Short Physical Performance Battery (SPPB). This test assesses physical functioning across three levels, including postural stability in normal, semi-tandem and tandem bipodal stance, gait performance (2.4 linear walk), and Five times sit-to-stand test (FTSTS). Postural stability and FTSTS tests are conducted with no aids, while gait performance can be conducted with assistive gait devices.

The aforementioned assessments will be conducted with face-to-face interviews or tests respectively with a clinician.

FRAIL and EMFRA will be assessed again in 2-10 days, for assessing its intra-rater reliability.

These procedures will be followed based on the recommendations of the Strengthening the Reporting of Observational Studies in Epidemiology on a cross-sectional study design (von Elm et al., 2007).

Structural validity.

Structural validity will be analysed by means of an exploratory factor analysis (EFA) and a confirmatory factor analysis (CFA), with the aim of confirming the theoretical factor structure of the items of both scales.

To determine whether the Pearson correlation matrix is factorizable, Bartlett's and Kaiser-Meyer-Olkin tests will be used (Izquierdo et al., 2014). To determine the optimal number of factors we will use the Kaiser eigenvalue criterion (≥1) and a sedimentation plot analysis (Ferguson & Cox, 1993). These data will be confirmed with the parallel analysis method (Horn, 1965; O'connor, 2000).

In the EFA, we will use the principal axis extraction method with factor loadings > 0.4 to include items in the factors. The CFA will employ a more rigorous model for factor determination. We will use the weighted least squares mean, variance-adjusted estimate and several goodness-of-fit indices, including the comparative fit index (CFI), the Tucker Lewis index (TLI), the root mean square error of approximation (RMSEA) as a parsimony fit index, and finally the chi-square and the weighted root mean square residual (WRMR) as absolute fit indices.

To determine whether the model fit is acceptable, Hu and Bentler's criteria (TLI ≥ 0.95, CFI ≥ 0.95, RMSEA ≤ 0.06, WRMR ≤ 1.0) will be used (Hu & Bentler, 1998). Likewise, modification indices will be calculated to detect local misspecified areas of the model not sensitive to the general goodness-of-fit indices mentioned above (Brown, 2015).

Convergent validity.

Correlation analysis with Pearsons' r coefficient will be employed for assessing convergent validity of FRAIL and EMFRA with the other assessed variables. Additionally, the correlation between FRAIL and EMFRA will also be assessed.

Authors expect a small correlation between FRAIL, and MoCA or HADS, and a moderate correlation with SPPB or the Barthel index.

Additionally, we expect a small correlation between the EMFRA and SPPB, MoCA, or HADS, as EMFRA will only include a subset of items assessing physical functions, cognitive functions, and emotional status respectively. EMFRA will correlate moderately with the Barthel index.

FRAIL and EMFRA will be expected to present a moderate correlation.

Discriminant validity.

Initially, in the 5-item FRAIL scale, cut-off values were deliberately established by setting the frailty-free status at 0 points, pre-frailty at 1-2 points and frailty at 3 to 5 points. However, we did not proceed with a discriminant validity on that scale, where appropriate cut-off points would be established cross-sectionally for the presence and appearance of the dependency in basic activities of daily living (ADL) (Morley et al., 2012).

This analysis will serve to differentiate at which cut-off, the FRAIL and EMFRA scales are already detecting dependency in ADL.

Therefore, the researchers of the present project will establish discriminant validity by generating 2 cut-off points to differentiate non-frail from pre-frail status and pre-frail from frail status.

The discriminant tool will be the Spanish version of the Barthel Index, initially translated by Baztán et al., (1993) and psychometrically analysed by González et al., (2018). The scale presents 10 assessment items with a total score fluctuating from 0 to 100, indicating respectively total dependence and independence in basic activities of daily living. This scale will be taken as a reference to perform the discriminant validity of the 5-item FRAIL scale and EMFRA.

Baztán et al., (1993) are the only ones to have translated and cross-culturally adapted the scale into Spanish (Cabañero-Martínez et al., 2009). The scale has levels of dependency classification:

- 0-19 points: Total dependence
- 20-35 points: Severe dependence
- 40-55 points: Moderate dependence
- ≥ 60 points: Mild dependence

An area under the curve analysis will be performed to establish 3 cut-off values in both frailty scales, exploring with an area under the curve (AUC) < 70, the cut-off value in the scale to detect mild dependence in the Barthel Index (equivalent to pre-frail status), and to detect moderate dependence in the Barthel Index (equivalent to frailty status).

Time for completion.

The process of administration and completion of both scales will be timed.

Internal consistency.

Internal consistency will be explored with Cronbach's α, considering a criterion of α > 0.70, to determine a good internal consistency (Cronbach, 1951).

Intra-rater reliability.

Intra-rater reliability will be assessed only for the 5-item FRAIL scale, and EMFRA leaving a period of 2-10 days between measurements.

The intra-rater reliability will be evaluated by means of the intraclass correlation index (ICC), considering a value above 0.70 as acceptable (Kline, 2013). ICC will be analysed in terms of 2-way mixed effects, absolute agreement, for a single measurement, employing the ICC (2,1) model (Koo & Li, 2016).

Standard error of measurement.

The standard error of measurement (SEM) following the formula (Vet et al., 2011):

$$SEM = SD \times \sqrt{(1 - ICC)}$$

Minimum detectable change.

In addition, the minimum detectable change (MDC) with an observed magnitude of change between 2 and 10 days will be analysed (Haley & Fragala-Pinkham, 2006).

The MDC will be provided with 90% (MDC_{90}) and 95% (MDC_{95}) confidence interval, calculated respectively by:

$$MDC_{90} = SEM \times \sqrt{2} \times 1.65$$
$$MDC_{95} = SEM \times \sqrt{2} \times 1.96$$

Floor-ceiling effect.

The floor and ceiling effect will be evaluated by calculating the percentage of participants obtaining the minimum or maximum scores in both questionnaires. A floor or ceiling effect is considered to be present if 15% or more of the participants obtain the minimum or maximum score respectively.

Sample size calculations.

The sample size calculation will be focused on both the exploratory factor analysis and intra-rater reliability.

For the exploratory factor analysis, the sample size should reach 200 to 300 cases, considering a moderate condition where communalities in the range of 0.40 to 0.60 are expected and the presence of at least 4 factors, each with between three and four items, as indicated by Lloret-Segura et al., (2014).

This estimation is in line with the methodological recommendations of experts who argue that, even in ideal situations with high communalities and well-defined factors, the sample size for studies involving factor analysis should exceed 200 cases (Ferrando

Piera & Anguiano Carrasco, 2010; Lloret-Segura et al., 2014).

In addition, we considered the classic rule for factor analyses that states the following: 50 cases are considered very poor; 100 cases are considered poor; 200 cases are considered acceptable; 300 cases are considered good; 500 cases are considered very good; and 1000 cases or more are considered excellent (Lloret-Segura et al., 2014).

Having this considered, and adjusting the sample size to meet project deadlines, a sample range between 250 and 300 cases was established.

The sample size calculation for intra-rater reliability, we will be based on the proposal by Walter, et al., (1998), which is based on estimating the sample size from assumptions related to the intraclass correlation coefficient (ICC).

For the intra-rater evaluations (two measurements), we set a minimum acceptable ICC of $P_0 = 0.75$, following theoretical recommendations (Koo & Li, 2016). However, we expect to obtain an ICC higher than $P_1 = 0.82$, considering the reliability demonstrated in previous studies using the FRAIL scale (Rosas-Carrasco et al., 2016).

With a power of 90% ($\beta = 0.1$) and an alpha error level of 0.05, the sample size calculation has been estimated at 86 participants. To account for possible losses of up to 20% of the sample, a total sample size of 107 participants is recommended. This calculation was performed using Power Analysis and Sample Size software (PASS 12; NCSS Statistical Software, Kaysville, UT, USA).

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