Development of an ICF Core Set for frailty older people – Study Protocol

Diogo Batalha  
dfbatalha@ua.pt

University of Aveiro  https://orcid.org/0000-0002-0111-0135

Joaquim Alvarelhão  
jalvarelhao@ua.pt

University of Aveiro  https://orcid.org/0000-0002-4564-4323

Sara Almeida  
University of Aveiro  https://orcid.org/0000-0002-9516-0298

Joana Pinto  
Instituto Superior Piaget

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Abstract

Frailty is more common as age increases but is not synonymous of ageing. Identifying frail older people should be one of the bases of geriatric care, since this is a complex and important issue associated with aging, with implications for older people and for the functioning of health services. The ICF has the potential to design standardized coding for the various health domains, characterizing the specific functional challenges of individuals, being a first step towards the standardization of the evaluation of results, with several additional advantages. The development of a Core Set allows the creation of practical instruments adjusted to a specific health condition, sufficiently comprehensive and multidisciplinary. It involves formal decision-making and a consensus-seeking process that integrates not only the evidence found in preliminary and already conducted studies but also the creation of a focus group with frail older people, health professionals and experts. We aim to develop an ICF Core Set for frailty and identifying the categories of the ICF most applicable to the weak, according to the frail older people's perspective and based on international consensus.

Introduction

Frailty is defined as an identifiable clinical framework, in which the ability of the person to deal with adversity is compromised by an increased vulnerability, consequent to the declines associated with the physiological and functional reserves of the organic systems (World Health Organization, 2016). The interest in investigating the theme have been witnessing an evolution of the concept, incorporating broader approaches, which address the nutritional, psychological, cognitive and social domains (Duarte & Paúl, 2015). Frailty is more common as age increases but is not synonymous of ageing; evidence suggests increased variability in frailty with ageing, with age only partly explains frailty trajectories (Stolz et al., 2019). Frailty is becoming increasingly recognized as a useful concept for risk stratification in various medical specialties, from oncology to cardiac surgery (Theou et al., 2018). Identifying frail older people should be one of the bases of geriatric care, since this is a complex and important issue associated with aging, with implications for older people and for the functioning of health services (Sutton et al., 2016). Frailty management programs in primary care focus on optimizing the physical and psychological functioning of older people with frail health through early risk identification and intervention (Noten et al., 2021).

This procedure will only be feasible if it is based on a comprehensive, systematized, and multidimensional assessment of functionality, as recommended by the World Health Organization (WHO) and operationalized by the International Classification of Functioning, Disability, and Health (ICF) (Selb et al., 2015). The classification is based on the individual in a specific context, where the interaction between all ICF parts is important. One of the aims of the ICF is to use numerical codes to serve as a common language for health professionals to describe the functioning of individuals with a health condition and thereby make the results of studies (using the ICF) comparable at national and international levels (Karlsson & Gustafsson, 2021). The ICF offers a framework that can be used to assess strengths in addition to impairments and highlights the possible influence of the environment—positive and/or negative—on an individual's outcome. Understanding this modifying role of environmental factors provides the basis for possible adaptation of specific factors to improve outcome (Bölte et al., 2018).

ICF is an exhaustive instrument, so-called "core sets" have been developed. A core set is a shortlist of selected categories from the whole ICF, specified for a specific health condition, circumstance or situation (Karlsson & Gustafsson, 2021). The development of a Core Set allows the creation of practical instruments adjusted to a specific health condition, sufficiently comprehensive and multidisciplinary (Cieza et al., 2004). It involves formal decision-making and a consensus-seeking process that integrates not only the evidence found in preliminary and already conducted studies but also the creation of a focus group with frail older people, health professionals and experts (Selb et al., 2015). An ICF core set is not an instrument, but it can serve as the foundation for developing instruments for clinical settings and research (Karlsson & Gustafsson, 2021).

Thus, we aim to develop an ICF Core Set for frailty and identifying the categories of the ICF that identify those aspects of functioning and environmental and personal factors that are considered the most important to the weak, according to the frail older people's perspective and based on international consensus.
Reagents

Equipment

Procedure

The ICF Core Set will be defined at an ICF Core Set Consensus Conference which will integrate the preparatory phase. To ensure that the core sets covered the most important categories for a given condition, WHO developed a rigorous description of how to proceed in the creation of the core sets (Danermark et al., 2013):

I. an integrative literature review of definitions from frailty, frailty prevention, frailty diagnosis and frailty intervention in older people;

II. a qualitative study (frail older people's perspective of their health conditions);

III. an expert survey to analyze a specialized perspective on frailty (Delphi Method);

IV. a multi-centre, cross-sectional study (professionals' perspective of frailty prevention, diagnosis, and intervention in older people).

Scope Review

A literature review uses explicit methods to systematically search, critically appraise, and synthesize the world literature on a specific issue:

(1) To identify currently developed or used outcome measures for frailty older people, as also the definition of frailty.

(2) To identify and quantify the concepts contained in these measures and definitions using the ICF as a reference. In addition to the literature review, a survey will be conducted to identify currently developed or used measures of functioning, disability and health in hospital departments taking care of the treatment and rehabilitation of frailty older people.

Qualitative Study

Frail older people’s perspective

The focus group technique is a communication process to collect large amounts of information in a short time with peer validation of opinions:

(1) To explore and understand the perspective of frailty older people regarding their health and social condition.

(2) To identify concepts of functioning and health important to frailty older people using the ICF. Individual interviews are an option to identify relevant concepts of functioning and health to individuals who cannot participate in focus groups due the severity of their condition. Although no difference was found in the depth of data generated, more concepts are likely to occur in focus groups compared to individual interviews.

Expert Survey

Delphi Method

A survey involving experts experienced in the treatment and rehabilitation of frailty older people:
(1) To identify relevant problems in frailty older people from the perspective of experts

(2) To quantify the concepts of functioning and health important for frailty older people from the expert perspective using the ICF.

According to the need to maximize the number and range of ideas and opinions gathered, the goal is to include experts from different WHO regions and from different health and social professions.

Empirical Study

Professional’s Perspective

A multi-centre cross-sectional study that involves data collection at one time point:

(1) To describe functioning and health of frailty older people

(2) To identify the most common problems using the ICF

According to the need to involve study centres from different WHO regions, the goal is to involve at least one centre from Eastern Mediterranean, South and East Asia, The Americas and Europe.

The results of each study will be a list of candidate categories that will be consolidated and provided to the participants of the International Consensus Conference to decide on the final set of categories to be included in the ICF Core Set.

PREPARATORY PHASE

Integrative Literature Review

Integrative reviews are the broadest type of research review methods allowing for the simultaneous inclusion of experimental and non-experimental research in order to more fully understand a phenomenon of concern (Dunwoody et al., 2008).

An integrative literature review will be carried out as a guideline (Doolen, 2017), to identify and analyze currently developed or used outcome measures for frailty in older people, as also the definitions of frailty published until 2022. The second task is to identify and quantify the concepts contained in these measures and definitions using the ICF (Cieza et al., 2019). A systematic mixed study review will be used with an integrated design to synthesize findings encompassing qualitative, quantitative and mixed method studies (Doolen, 2017). This twofold review will aim to identify: frailty concept and currently developed or used outcome measures for preventing, diagnosing and intervening in frailty older people; and quantify the concepts contained in these measures and definitions using the ICF.

a) Inclusion and exclusion criteria
A study selection criterion will be determined before the literature search and will show the objective of this review: to identify studies focused on the frailty older people, targeting one or more groups of older people, health and social professionals or students, aiming the knowledge improve of frailty and its impact on older people lives and in the quality of the health care services. Consequently, we will focus on studies that described implemented contents and the evaluation source of the impact.

b) Information sources

This search study will include written/ published work until 2022 in Scopus and Web of Science databases.

c) Search strategy

A comprehensive search limited to English, Portuguese and Spanish documents will be undertaken to mitigate any overlap frailty contents. Studies will be identified using an electronic database systematic search, with additional hand-search of relevant journals and published reference lists and worldwide dissertations as recommended by (Moher et al., 2009).

d) Search

Keywords used for the search will be obtained through MESH and DECs descriptors. Free text terms for searching titles, abstracts and key words will be combined with database-specific subject headings following the structure of [frailty] OR [frail] AND [elderly] OR [older]. After removing duplicates, titles or abstracts will be examined to identify and exclude documents on aspects outside the review scope. In case of ambiguity, documents will be fully read.

e) Appraisal and data extraction

Using a developed and pilot-tested data extraction form, data will be extracted to record key study characteristics and to facilitate quality assessment. All steps in the selection, appraisal and data extraction processes will be performed by the research team (Higgins & Green, 2008).

f) Data synthesis and analysis

When reviewing the articles, the underlying concepts contained in the outcome measures will be linked to the ICF categories adopting the established ICF Linking Rules (Cieza et al., 2005). After this process, frequency analysis will be conducted. Repeated ICF categories in each article will only be counted once. ICF categories identified in 5% of articles will be included in the list of categories.

Qualitative Study (older people's perspective)

A qualitative research approach was considered most appropriate to explore older people's perspectives. A grounded theory approach will be used (Glasser & Strauss, 1967). The qualitative study aims to identify which aspects of functioning, the environment and personal factors are most important to prevent, diagnose and intervene in hospitalized frail older. Focus group and individual semi-structured interviews will be conducted with frail older people in a hospital and continuous care unit context. The methods will be defined according to the Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist (Tong et al., 2007).

a) Interviewing
Semi-structured in-depth interviews will explore the experiences of participants and the meanings they attribute to them. Researchers will encourage participants to talk about pertinent issues to the research question by asking open-ended questions. The interviewer might re-word, re-order or clarify the questions to further investigate topics introduced by the respondent. Sample size with a diverse range of participants will be used to obtain the required level of rich and meaningful data (Jones, 2002), until saturation is reached. Saturation is defined in our study as the point during data gathering when the linking of the qualitative data of 2 consecutive interviews revealed no additional information to the data obtained before.

b) Focus groups

Focus groups are semi-structured discussions with groups of 4–12 people that aim to explore a specific issue set. Moderators will start the focus group by asking broad questions about the topic of interest, before asking the focal questions. Then, participants will individually answer the facilitator’s questions, however, they will also be encouraged to talk and interact with each other.

c) Interviews

All participants will be interviewed by the same interviewer. The interviews will be recorded and transcribed verbatim. A short introduction to the concepts of the ICF will be given in lay terms to all participants at the beginning of each interview. Then, 2 different types of interviews will be performed. Interview type 1 includes open-ended questions formulated around functioning in daily life: participants will be asked about frailty-related problems of their body functions that they experience, which body structures are involved, which limitations of activities and restrictions in participation are significant to them, and which environmental factors and which personal factors are barriers or facilitators for them. In interview type 2, participants will be presented with titles and definitions of all the ICF chapters of which the categories are included in the ICF frailty Core Set. After having presented the title and definition to them, the participants will be asked open-ended questions to describe in their own words any problems they personally experience related to each specific ICF chapter. Each participant will be randomized to be interviewed according to either a type-1 or type-2 schedule. Both interview types will be applied to gather the richest possible data for qualitative analysis and to cover a broad spectrum of possible questions for the participants. The analysis and the results of the 2 types of interviews will be performed and reported together.

d) Qualitative data analysis.

Qualitative data analysis will follow the method of meaning condensation (Flinders, 1997), and will be analyzed by WebQDA software. In the first step, the transcribed interviews will be read through to get an overview of the collected data. In the second step, the data will be divided into meaning units and the theme that dominates a meaning unit will be determined. A meaning unit will define a specific unit of text, either a few words or a few sentences with a common theme. Therefore, a meaning unit division does not follow linguistic grammatic rules. Rather, the text will be divided where the researcher discerned a shift in meaning. In the third step, the concepts contained in the meaning units will be identified. A meaning unit could contain more than one concept. In the final step, every concept will be linked to ICF categories (Cieza et al., 2019).

e) Linking to the ICF

In the ICF classification, the letters b, s, d, and e, which refer to the components of the ICF, will be followed by a numeric code starting with the chapter number (1 digit), followed by the second level (2 digits), and the third and fourth levels (1 digit each). The component letter with the suffix of 1, 3, 4, or 5 digits corresponds to the code of the category. Categories are the units of the ICF classification. Within each chapter, there are 2-, 3-, as well as 4-level categories. Within each component, the categories are arranged in a stem/branch/leaf scheme. Consequently, a lower-level category shares the higher-level categories of which it is a member, i.e., the use of a lower level (more detailed) category automatically implies that the higher-level category is applicable, but not the other way round. Every concept of each meaning unit from the interviews will be linked to the most precise ICF category using the same linking
rule (Cieza et al., 2019). According to these linking rules, health professionals trained in the ICF will be advised to link each concept of a model to the ICF category representing this concept most precisely. If a meaning unit contains more than one concept, it will be linked to more than one ICF category.

f) Procedure to confirm the ICF frailty Core Set categories

A category for the ICF frailty Core Set will be confirmed if an identical or a similar category emerged from the interviews. For the analysis, all third- and fourth-level categories will be moved to the second level. In general, concepts will only be counted once.

g) Accuracy and rigour of the analysis

In addition to the linking by the first author, 15% of the transcribed interview text covering 2 whole interviews and several parts of other interviews will be analyzed and linked by a second researcher. The degree of agreement between the 2 investigators regarding the linked concepts will be calculated by means of Cohen's kappa statistic (Cohen, 1960) and bootstrapped intervals will be calculated (Vierkant, 2004).

Experts Survey (Delphi Method)

In this third project step, the study will be conducted as a national electronic-mail survey applying a three-round Delphi technique with health professionals. The Delphi technique enabled experts to repeatedly access the group, and explore the complex issue aiming to obtain consensus (Sharkey & Sharples, 2001).

a) Recruitment

Professionals with specific training in gerontology and geriatric practice will be eligible to participate in this study. Initially, public and private hospitals, universities, professional Orders, continuous care units and other institutions will be identified by internet search and contacted. To identify experts, author search will be undertaken, and personal recommendations will be followed up. A snowballing technique will also be used, with the included experts being invited to recommend other health and social professionals, and investigators with expertise in gerontology and geriatrics practice. Possible participants will receive an information pack with study details and will give their consent to be included in the study.

b) Delphi process

In the first Delphi round, the experts will receive an open-ended questionnaire. They will be asked to list problems, resources, and aspects of the environment in treating frailty patients, first for the early post-acute and second for the long-term context. Answers will be tabulated and linked to the ICF. In addition, experts will complete questions on demographic characteristics and professional experience. In the Delphi round two, experts will decide whether to agree or not that the respective ICF categories represent frailty in older people's problems, participant's resources or aspects of the environment treated by professionals in frailty intervention.

To maintain the motivation of the participants, only a selection of the ICF categories from the second round will be included in round three. A modified screen test will be applied to identify ICF categories that did not reach sufficient consensus. A graph will be plotted containing the percentages of expert agreement (ordinate) for each ICF category (abscissa). The screen line will be placed onto the downward slope, along the points to see where they approximately form a straight line. Points close to the scree line indicated an insufficient endorsement and will be included in Delphi round three.

In Delphi round three, the ratings will be tabulated with frequencies of answers from the previous round to inform about the decisions other experts made. Experts will be requested to reconsider their answers. Within the Delphi process, experts will return their
responses within 3–5 weeks for each round.

c) Linking

Each response of the first Delphi round will be linked according to the linking rules established in the most precise ICF category by two researchers (Cieza et al., 2019). Each ICF category will be coded with a prefix for the components body functions (b), body structures (s), activities and participation (d) and environmental factors (e) and a suffix of one to five digits. Disagreements will be discussed with the authors and a joint decision will be made. According to the ICF definition, personal factors will be coded as personal factors. Concepts that could not be assigned to ICF categories will be coded as not covered.

d) Data analyses

Descriptive statistics will be used to characterize the sample and frequencies of ratings. k-coefficient will be calculated with bootstrapped confidence intervals to analyze the agreement between the two researchers linking the answers of the participants to the ICF. ICF categories, which reach an agreement of more than 75% among the participants in the final Delphi round, will be considered for comparison with the Comprehensive ICF Core Set for frailty. As no universal agreement on the level of consensus exists, based on experiences from previous studies, this cutoff point will be considered an appropriate consensus to be achieved.

Empirical Study (Professional's perspective)

A cross-sectional study will be conducted to describe the functioning of frailty older people in a clinical setting. Based on information from older people’s records, observations, and semi-structured interviews, clinicians from study centres in at least two different Portugal regions will rate the functioning of their patients using a case record form (CRF) based on the Comprehensive ICF Checklist. Output from the four preparatory studies will be a list of ICF categories with corresponding absolute and relative frequencies. In determining the importance of the aspects to be described by professionals, we should consider: (i) admission (classification); (ii) intervention (clinical procedures); (iii) evaluation and monitoring of results (mortality rate, risk of further hospitalization and reassessment of frailty classification). We will include health and social professionals with 5 years of hospital or continuous care unit intervention experience in frailty older people.

To ensure that the ICF checklist is sensitive to the specific functioning of the health status of frail older people in the hospital setting, it will be extended and supplemented with the categories covered by at least one of the most used measures identified in the systematic review, which are not yet included in the ICF checklist. Experts should also be consulted to ensure that no essential category is lost.

PHASE I

Consensus Conference

The Consensus Conference is very important to the development of an ICF Core Set (Selb et al., 2015). Participants are selected based on their gerontology and/or geriatric experience (at least 10 years) in intervening and studying frail older people. Participants reflect an equal distribution among the five WHO regions and from different health and social professions (Bickenbach et al., 2012).

After the participants are presented to the ICF, to the process of developing ICF Core Sets and the results of preparatory studies (preparatory phase), they will receive the list of candidate categories, identified during the preparatory studies. To help participants know which categories of ICF serves as the basis for discussions and decision-making throughout the conference, they will be asked to do an individually pre-selection of the categories that reflect the most typical problems experienced by frail older people. Then, the iterative decision-making process begins. The decision-making process consists of alternating the working group and plenary
sessions. Experts will be divided into three working groups that reflect a homogeneous distribution among the five WHO regions and from different health and social professions. The sessions of the working groups will allow the participants to discuss the considering factors that are in communion between the candidate categories, the frequency of a category in the population with the state of health under study and the clinical utility, to make the decision. Participants will be invited to consider the results of preparatory studies and to vote on the inclusion of the second level individual ICF categories.

The ICF categories voted by at least 75% of participants in each and all working groups, will be automatically included in the Comprehensive Core Set. ICF categories voted by less than 40% of participants in each and all working groups, will be automatically excluded from the Comprehensive Core Set. All other categories of ICF will be considered "ambiguous", if they are confirmed by only 40%-74% of participants. After session 1 and 2 of the working groups, participants meet in plenary to share the results. Only ambiguous categories will be discussed. The voting of the categories will be done only in each working group session and at 2\textsuperscript{nd} plenary session.

The consensus conference has two objectives: the confirmation of the Comprehensive ICF Core Set and the confirmation of the Brief ICF Core Set. Although the decision-making process of the 2\textsuperscript{nd} plenary session only analyses the 2\textsuperscript{nd} level ICF Categories, the 3\textsuperscript{rd} and 4\textsuperscript{th} plenary sessions will address the relevance of including the 3\textsuperscript{rd} and 4\textsuperscript{th} level ICF categories. Participants are instructed to include a 3\textsuperscript{rd} or 4\textsuperscript{th} level category only if the additional specification provided by this category is essential to comprehensively describe the functionality of frail older people. The first objective, confirming the Comprehensive Core Set, is achieved once a decision is made to add 3\textsuperscript{rd} and 4\textsuperscript{th} level categories to the 2\textsuperscript{nd} level categories already included in the Comprehensive ICF Core Set.

The second part of the decision-making process involves deciding on the Brief ICF Core Set. Participants will be asked to rate the most important Comprehensive ICF Core Set categories in three consecutive ranking sessions. In each ranking session, participants receive a sheet with all categories of the Comprehensive Core Set and are invited to individually classify the ten most essential categories for each Component of the ICF, in order of importance.

Holding three ranking sessions allows participants to share the reasoning for their decision and gives them the opportunity to reassess their decision. The result of the individual rankings will be statistically calculated and thus a common classification arises. After the final session of the ranking, the process of deciding on the "cut-off" for each component of the ICF begins. At that time each participant will be invited to decide how many categories of the ICF component would be important to include in the Brief Core Set. The consensus on the "cut-off" will then be applied to the results of the ranking, and the second milestone will be reached, the Brief ICF Frailty Core Set. The Consensus Conference will be held in 18 months.

PHASE II

Phase II will consist of reliability and validity studies of the ICF Core Sets for frailty in various settings (clinic, school, home, workplace). Specific aims of this phase II study include to: (1) confirm whether categories included in the ICF Core Sets for frailty describe the entire spectrum of typical problems encountered by frailty older people from a global perspective; (2) identify possible relevant categories missing from the ICF Core Sets for frailty; and (3) examine the applicability of the categories of the ICF Core Sets in different contexts, for different purposes, and from different perspectives. An international, cross-sectional, multicenter validation study with frailty older people will be conducted to study the content validity and feasibility of the ICF Core Sets for frailty.

Troubleshooting

Time Taken

Anticipated Results

In this paper, we described the rationale and proposed scientific process for the development of ICF Core Sets for frailty in older people. The ICF Core Sets for frailty will be intended to be used as a guide for making recommendations for the practical use of the
ICF in the prevention, diagnosis, intervention, and monitoring of frailty older people, providing a selection of the most relevant ICF categories that facilitate the description of a patient’s functioning.

Comprehensive and Brief Core Sets will be developed. The Comprehensive Core Set can provide health professionals and investigators a basis for a thorough and interdisciplinary assessment of functioning, for the formulation of prevention and intervention goals, for the evaluation of progress in treatment and for monitoring of the patient’s clinical status after hospital discharge (Bölte et al., 2014). The Brief Core Set can be used when only a brief assessment of functioning is necessary (Noten et al., 2021).

The complex nature of frailty requires a multidisciplinary and multilevel assessment and intervention approach to improve functioning and quality of life for individuals with comorbidities. The ICF Core Sets for frailty can meet this need by providing a common basis for communication across different disciplines in frailty research and clinical practice.

After Phase II, tools for assessment of functioning will need to be derived from the ICF Core Sets for frailty, and these tools will need to be validated and implemented to ensure that the framework of the ICF Core Sets will be widely applied. Applications of the ICF framework include quantifying the effect of frailty on functioning and evaluating the effectiveness of interventions. We envision that the wide application of ICF Core Sets for frailty in research and clinical practice will lead to improved knowledge about functioning in frailty, which in turn will lead to interventions that improve functioning and quality of life for frail older people.

This work has some limitations that need to be acknowledged. At the international consensus phase, we may have as a limitation, the equitable representation of all WHO regions. The understanding of the concept of fragility may vary from country to country, due to its diverse cultural and social meanings.

References


**Supplementary Files**

This is a list of supplementary files associated with this preprint. Click to download.

- Submission1.docx