Identification and categorization of older people with functional impairments in scientific studies - Recommendations of the Medication and Quality of Life in frail older persons (MedQoL) Research Group

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Background

When treating older adults, one of the main factors to consider is deterioration of functional status which might result in physical frailty. Deviation from gold standard treatment mostly concerns older adults with impaired function and disability. Because information about functional status in clinical trials has been scarce, a critical appraisal of evidence is still challenging. Our aim was, therefore, to identify and categorize information on functional status used in clinical trials.

Methods

As part of four systematic reviews of the literature (databases: Medline, Embase, Central) of randomized and non-randomized controlled clinical trials in older adults with hypertension, diabetes, depression and dementia, we identified functional assessment scales used in such trials. We analyzed these scales if more than 25% of items represented functional status. An expert group including geriatricians, pharmacologists and epidemiologists reached a consensus on categorizing functional status across the following four levels: functionally not impaired, slightly impaired, significantly impaired, and severely impaired/disabled. Cut-off points of the functional assessments for these four functioning levels were defined by determining the best and worst possible scores that a patient in a given functional category could possibly obtain. For detailed explanation we refer here to the end of table 1.

Results

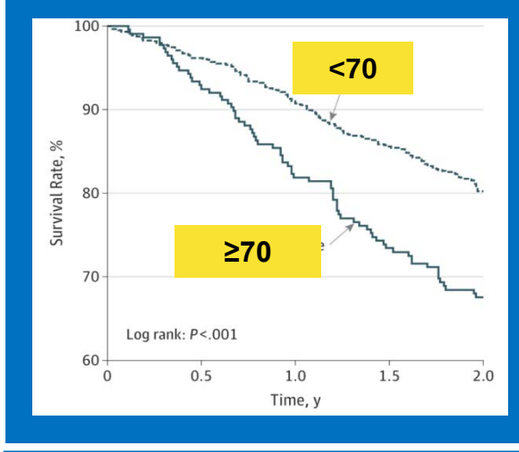
We identified 53 instruments that included measures of functional status with at least 25 % functional items. Only very few of the assessment scales had clearly defined cut-offs for functional status across our predefined categories. In most cases, no cut-offs existed, so that they were determined as described and are presented below in table 1

Conclusion

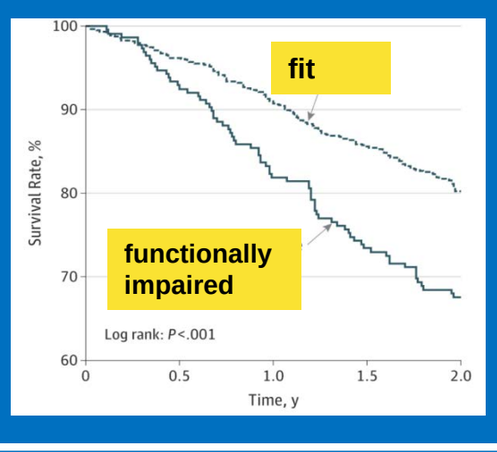
For the retrospective characterization of frail older people in clinical trials, we derived cut-off points for four functional status levels across 53 different assessment scales. The presented list may help to compare studies that include functional parameters for older study participants but that apply different assessments. Future studies should validate our consensus driven results by evaluating the same patients with different assessment scales. Moreover, as general standard, future studies involving older patients should include and explicitly report functional parameters before and during treatment. **Expanding the CONSORT reporting guideline with this item would help to support the search, analysis, synthesis and interpretation of evidence in older adults not just based on chronological age but according to their functional status.**

PROBLEM

How evidence is usually presented in older people



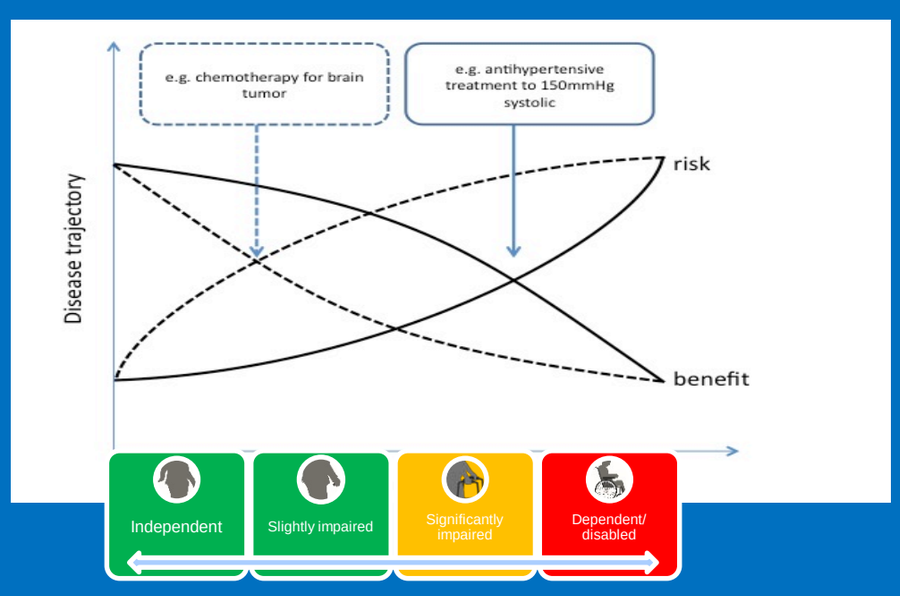
What we consider more appropriate!



Evidence has to be presented according to functional status, but dichotomous categories don't work for all treatments

WHAT WE NEED

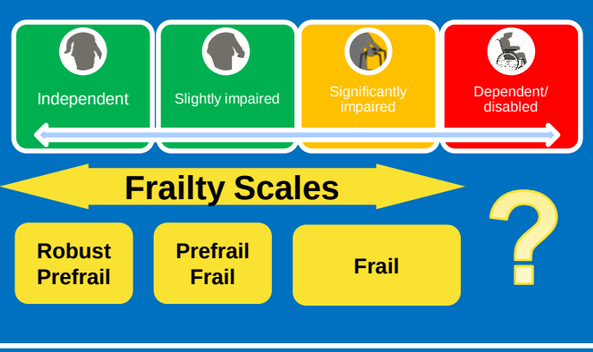
Do we need the full functional range for treatment decisions?



Yes, because adjustments depend on treatment hazards and treatment intensity (e.g. Chemotherapy vs. Antihypertensives)

FRAILTY vs. FUNCTION/DISABILITY

Why not simply use frailty instead of function?



Because frailty scales don't differentiate well in the downstream functional trajectory and are very heterogenous

Table 1: Consensus-based cut-offs to categorize patients according to their functional status*

	Independent	Slightly impaired	Significantly impaired	Dependent/ disabled	Function Quality Category
Barthel ADL-Index	100	75 - 100	40 - 70	0 - 35	**A**
Berg Balance Scale	55 - 56	38 - 54	9 - 37	≤ 8	**A**
Bristol ADL Scale	0	0 - 7	8 - 36	≥ 37	**A**
FIM	126	105 - 126	64 - 104	18 - 63	**A**
Five-Chair-Rise	≤ 15 s		> 15 s	unable	**A**
Gait Speed	≥ 1.0 m/s	< 1.0 and ≥ 0.8 m/s	< 0.8 and ≥ 0.5 m/s	< 0.5 m/s	**A**
GARS	18 - 21	22 - 36	37 - 68	≥ 69	**A**
Katz ADL-Index	6	4 - 6	2 - 3	0 - 1	**A**
Knee extens. strength	≥ 3.0 N m/kg		< 3.0 N m/kg		**A**
Lawton IADL-Index	8	8	4 - 7	0 - 3	**A**
MDS-ADL	0	0 - 3	4 - 18	≥ 19	**A**
MPPT	32 - 36	19 - 31	3 - 18	≤ 2	**A**
NAA-Scale	20	20 - 24	25 - 39	≥ 40	**A**
NAB-Scale	15	15 - 19	20 - 29	≥ 30	**A**
PSMS ADL (range 0-6)	6	3 - 6	1 - 2	0	**A**
PSMS original (obs. r.)	6	6 - 10	11 - 21	≥ 22	**A**
PSMS (self. r.) (8-24)	24	21 - 24	10 - 20	≤ 9	**A**
Six-Minute-Walk	> 300 m		≤ 300 m		**A**
SPPB	11 - 12	9 - 10	3 - 8	0 - 2	**A**
Timed Up and Go	< 10 sec	≥ 10 and < 20 sec	≥ 20 and < 30 sec	≥ 30 sec	**A**
VES-13	0 (3 if participant got 3 points for age!)	1 - 2 (4 - 5 if participant got 3 points for age!)	3 - 6 (6 - 9 if participant got 3 points for age!)	≥ 7 (10 if participant got 3 points for age!)	**A**
IDDD (62)	36 initiation, 0 performance	36 initiation, 0 - 2 performance	36 initiation, 3 - 36 performance	36 initiation, ≥ 37 performance	**A**
ADCS-ADL Scale	78	74 - 78	38 - 73	≤ 37	**B**
DAD	100 %	> 90 % - 100 %	> 47.5 % - 90 %	≤ 47.5 %	**B**
EASYCare	49 - 50	51 - 59	60 - 80	≥ 81	**B**
Handgrip strength	≥ 32 kg ♂ ≥ 20 kg ♀	26 - 31.9 kg ♂ 16 - 19.9 kg ♀	< 26 kg ♂ < 16 kg ♀	≤ 18.9 kg ♂ ≤ 15.2 kg ♀	**B**
MPI	0 - 0.33	0 - 0.33	0.34 - 0.66	0.67 - 1.0	**B**
SF-12 (PCS)	50.5 - 56.6	40.3 - 50.4	29.7 - 40.2	≤ 29.6	**B**
SF-36 (PCS)	48.7 - 64.0	29.6 - 48.6	21.2 - 29.5	≤ 21.1	**B**
SHERPA	0 - 1		≥ 2		**B**
TRST	0	0 - 1	2 - 3	4 - 5	**B**
ASA Score	I	II	III	IV	**C**
ECOG	0		1 - 2	3 - 4	**C**
FES-I	16	17 - 32	33 - 48	49 - 64	**C**
Karnofsky Index	100	80 - 90	60 - 70	10 - 50	**C**
CAF	1 - 10	11 - 25	26 - 35		**A**
Fried Frailty Scale	0	1 - 2	3 - 4	5	**A**
Clinical Frailty Scale	1 - 2	3 - 4	5 - 6	7 - 8	**A**
FORECAST	0 - 4	5 - 7	8 - 13		**A**
Gill Frailty Measure	≤10 s (walk 2x3m) **and** chair stand with arms folded	See left	>10 s (walk 2x3m) **or no** chair stand with arms folded	>10 s (walk 2x3m) **and no** chair stand with arms folded	**A**
PRISMA-7	0	1 - 2	3	4 - 7	**A**
CSHA (Rockwood) Frailty Index (min. 30 items)	0 - 0.1	> 0.1 and ≤ 0.21	> 0.21 and ≤ 0.45	> 0.45	**B**
Edmonton Frail Scale	0 - 5	6 - 7	8 - 11	12 - 17	**B**
FI-CGA		0 - 6	7 - 13	> 13	**B**
FiND Questionnaire	0	0 - 1 (A/B)	2 (A/B) + 0 - 1 (C/D/E) = 2 - 3	2 (A/B) + 2 - 3 (C/D/E) = 4 - 5	**B**
FRAIL Scale	0	1 - 2	3 - 4	5	**B**
Frailty/Vigor Assessment	< 4 frailty criteria, 4 vigor criteria	See left	4 frailty criteria, ≤ 3 vigor criteria	> 4 frailty criteria, ≤ 3 vigor criteria	**B**
FRESH Screening Instrument	0	0 - 1	2 - 3	≥ 4	**B**
Gérontopôle Frailty Screening Tool	0	1	≥ 2		**B**
Groningen Frailty Indicator	0 - 3	0 – 3	4	≥ 5	**B**
MSSA	0 - 1	2 - 3	4 - 5	≥ 6	**B**
SOF	0	1	2	3	**B**
Tilburg Frailty Ind. (B)	0 - 4	2 - 4	5	≥ 6	**B**

- * Cut-offs were identified as follows: If categories existed according to our predefined functional status as shown above, they were used. If not, the following method was used: 1. Critical evaluation of items, taking into account the maximum and minimum item results and item weights, the used scoring system and its clinical interpretation, followed by determining what best possible result a person could optimally obtain in a given functionality category in each item. 2. Determination of the upper cut-off points by counting the results, while the lower cut-offs result from the upper ones of the next lower functional status level. 3. Discussion and review of the results within the expert group and final statement.
- Functional Quality Categories: **A -** Functional status measures contribute to ≥ 50 % of the overall assessment score or are reported separately. Most questions should be related to lower extremity/mobility domains. **B -** Functional measures contribute to < 50 %, but still ≥ 25 % of the overall assessment score or are not mainly related to lower extremity/mobility. **C –** Scales where function is only implicitly included (overall clinical judgment) or which do not allow for separate identification of the functional component. **Excluded** – not A, B, or C

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