

An Assessment of the ALSFRS-R by the ALS Community: A Mixed-Methods Study

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Background

The Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised (ALSFRS-R) total score is the most used outcome measure in pivotal ALS clinical trials. Additionally, several ongoing initiatives directly collect ALSFRS-R data from people with ALS online. Anecdotal reports of scale completion by the people with ALS and their caregivers have expressed concerns regarding some items of the ALSFRS-R. The aim of this study is to identify potential scoring difficulties in the ALSFRS-R from the perspective of people with ALS and caregivers of people with ALS.

Methods

- A web-based survey developed with people with ALS and ALS caregiver advocates
- IRB reviewed and determined exempt
- Mixed methods study design
 - Quantitative analysis performed with SPSS version 27
 - Qualitative data analyzed NVivo
- Participants were asked questions about their personal characteristics, then presented with each section of the ALSFRS-R and asked **4 questions about each item**:
 1. Can you think a situation where you might not be able to answer this item accurately or that your answer might not reflect your abilities? Please describe.
 2. Do you understand the descriptions of each choice?
 3. Is there any way that this item can be improved?
 4. Please share any additional thoughts about this item.

Conclusions

Nearly half of the patients indicated concerns that parts of the ALSFRS-R do not accurately reflect their ability. Though improving language may address some of these concerns, there is need to critically revise items to accurately capture the functioning of the person with ALS. Co-development with people with ALS and/or caregivers could benefit to define better fitting questions and refine standard operating procedures to reduce potential variability in data collected.

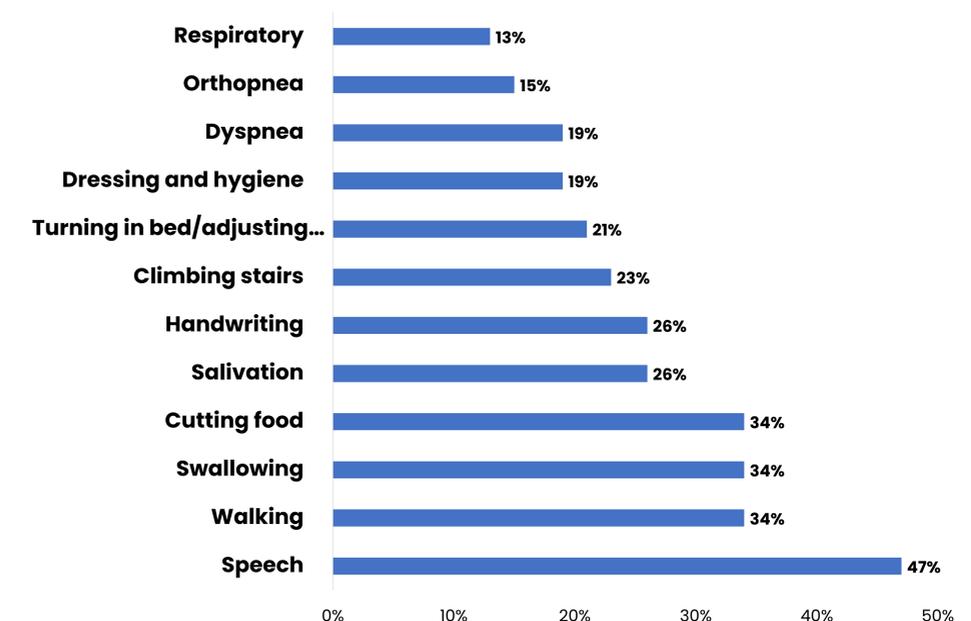
Results

- 103 Participants: originated from 17 countries with 32 (31%) from USA
- 67% people with ALS, 33% caregiver
- 53% female; 47% male
- 95% White/Caucasian
- Mean age: 50
- Most recent mean ALSFRS-R total score, if known, was 31.4 (SD 11.8; range 1 to 48).
- 46% individuals expressed concerns about their ability to accurately answer at least one item of the scale.
- Most individuals had concerns about: item 1 (speech), item 8 (walking), and item 5 (cutting food)
- Majority of comments fell into one of the following categories:
 - language used in the question is of a *literacy level too high* for most people with ALS
 - language used is of appropriate literacy level but *needs clarity*
 - the question is *answered differently depending on the situation or equipment used*
 - it is *difficult to distinguish the difference between choices* on the scale;
 - the *structure and/or underlying assumptions of the question makes it difficult to answer*
 - *Example response (study participant):*

“It's far too subjective. It might change daily. We need to allow for a range.”

Can you think a situation where you might not be able to answer this item accurately or that your answer might not reflect your abilities? Please describe.

% of critiques by domain (n=47)



Discussion

- Several study limitations: cross sectional, unable to verify with clinical documentation, recall bias, missing data
- Original ALSFRS-R administration manuals are not available; therefore, there is no consensus training and procedural manual that is followed globally. Though certification and training programs do exist for clinicians and researchers, they vary in their interpretations of how the scale should be used (e.g., recall period, cueing to facilitate response selection, etc.)