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Background

Amyotrophic Lateral Sclerosis (ALS) is a progressive, neurodegenerative disease that leads to severe disability and loss of voluntary muscle control. The progression of the disease makes it challenging for ALS patients to visit clinics regularly or participate in clinical trials. Remote monitoring and the development of digital outcome measures can help overcome these barriers by enabling remote monitoring, participation in clinical trials, and meaningful measurement of outcomes.

Aim of this study

Aparito's Patient Group Accelerator and ALS Liga Belgium have collaborated to develop digital endpoints that capture the meaningful aspects of health (MAH), concepts of interest (COI), and outcomes to be measured for ALS patients. We aim to test the usability and clinical utility of these digital outcome measures using the Atom5™ software platform.

Study design

To explore the MAH and COI, a survey was conducted with ALS patients (n= 16) in France and Belgium (Table 1).



The survey was divided into three parts:

- Part I – defining the meaningful aspect of health.
- Part II – defining the concepts of interest.
- Part III – willingness to use digital remote technology.

A focus group was held with two ALS patients (F, 68 and M, 62) who responded to the survey and two representatives of ALS Liga Belgium. The focus group content was developed based on key topics identified from the survey, including:



- Independence
- Fatigue
- Upper/Lower limb function
- Psychological/ emotional impacts

Table 1 – Sample demographics

Gender	N, (%)
Male	12, (75%)
Female	4, (25%)
Country	N (%)
France	9
Belgium	7
Age (years)	Range, (median)
	31–70, (61)
Type of onset	N (%)
Bulbar onset	2
Spinal onset	14
Time since diagnosis (months)	Range, (median)
	1–528, (21)
Severity of symptoms	N, (%)
Mild	1
Moderate	6
Severe	9

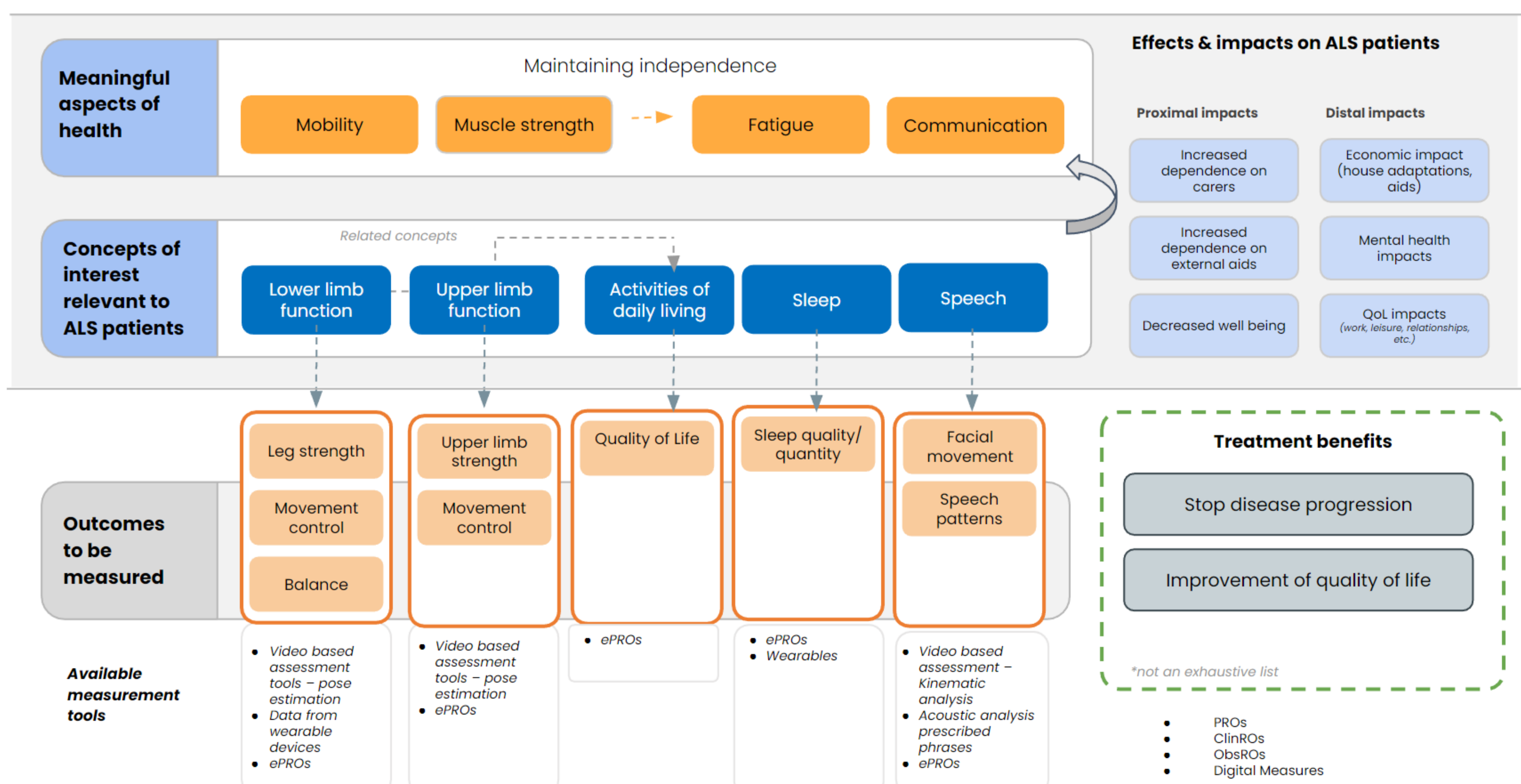
Results & Conclusions

Qualitative analysis was conducted, showing ALS patients experience a significant psychological impact due to loss of independence, dependence on caregivers, and the inability to carry out daily activities. Loss of motor function, muscle strength, and fatigue were identified as important COIs. Bulbar-onset patients specifically reported the impact of speech loss on independence, which will be further investigated due to their underrepresentation in the study sample. These findings, alongside a literature review informed the development of a conceptual model (Figure 1). Most respondents expressed confidence in using an app to remotely capture their symptoms, although opinions were mixed regarding video assessments.

The co-creation process involving ALS patients is crucial for developing digital outcome measures that capture the aspects most relevant to their health. The study highlights the importance of understanding the MAH and COI of ALS patients in developing fit-for-purpose digital outcome measures. By utilizing remote monitoring and digital technologies, such as the Atom5™ platform, it is possible to improve data collection, facilitate participation in therapeutic clinical studies, and ultimately enhance health outcomes for ALS patients.

Meaningful Aspects of Health for ALS Patients: A Conceptual Model

Figure 1 – Conceptual model



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