



## Study Protocol: Outcome Measurement

**Primary Outcome:** The primary outcome will be the Physical Function Test for ICU-scored (PFIT-s) measured at 3 days after ICU discharge by assessors blinded to treatment allocation. PFIT-s is a reliable and valid 4-item scale (arm and leg strength, ability to stand, and step cadence) with a score range from 0 to 10 (higher scores = better function).<sup>78,79</sup> It was developed in an ICU population, includes functional items, and, unlike the 6MWT, can be measured serially over time (as few patients can walk at ICU awakening).<sup>80</sup> We chose the PFIT-s because we expect all ICU patients will be able to complete part of the assessment if they cannot stand (e.g., arm or leg strength), limiting floor effects, and strong psychometric properties (reliability range = 0.996 to 1.00;<sup>79</sup> convergent validity with the 6MWT and muscle strength<sup>78</sup>). We selected 3 days after ICU discharge because it is proximal to the intervention, and some patients may be discharged before 7 days. Also, prior studies documented variable delivery of rehabilitation post-ICU<sup>81</sup> that may contaminate later evaluations.

**Secondary Outcomes:** Secondary outcomes include muscle strength<sup>48,49</sup> and function (e.g., 30-second sit to stand,<sup>50,51</sup> 2 minute walk test).<sup>52</sup> These measures have age- and sex- based reference values, and good reliability in critically ill or frail elderly populations.<sup>51,52</sup> We will also collect patients' perception of physical function (Patient-reported functional scale- ICU, PRFS-ICU),<sup>53,54</sup> Katz activities of daily living (ADL) scale,<sup>55</sup> frailty,<sup>56</sup> critical care-related psychological distress (Intensive Care Psychological Assessment Tool (IPAT))<sup>57,58</sup>, Hospital Anxiety and Depression Scale (HADS))<sup>59</sup>, HRQoL (EQ-5DL<sup>TM</sup>),<sup>60-62</sup> Quality-Adjusted Life Years (QALYs), mortality, hospital discharge location, healthcare utilization (e.g., length of MV, LOS and mortality (ICU, hospital)), and intervention and healthcare costs.

All strength and physical function outcomes assessors will receive a 3-hour in-person training session and support materials. At each site, we will train multiple assessors to ensure a blinded outcomes assessor is always available despite planned or unplanned absences. This interactive training session includes didactic lectures, and use of the strength and physical function outcome measures with simulated patients. The assessors will receive paper copies of each outcome measure, administration instructions, and normative values (where available).