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Statistical power of a smartphone app to objectively monitor performance outcomes in degenerative cervical myelopathy: power analysis of a simulated research trial using data from an observational study

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Title: Statistical power of a smartphone app to objectively monitor performance outcomes in degenerative cervical myelopathy: power analysis of a simulated research trial using data from an observational study

Background: Developing new clinical measures for degenerative cervical myelopathy (DCM) is an AO Spine RECODE-DCM Research priority.

Research question: To assess the statistical power of a battery of performance outcome measures, performed using a mobile phone application, in a simulated research trial.

Design: Quantitative modelling of prospective data from an observational study in decentralised secondary care.

Methods: Sample size was modelled using a validated power calculator (Sealed Envelope Ltd) and benchmarks from peer-reviewed DCM literature (alpha: 5%, power: 80%, standard deviation of the modified Japanese Orthopaedic Association Score, mJOA: 2.7). The primary outcome was the sample size required by the simulated clinical trial to demonstrate superiority of a treatment or intervention using a continuous outcome measure.

Results: 27 adults aged 60 (SD: 11) who live with DCM, possess an approved smartphone, and participated in the decentralised EMPOWER study. Digital performance outcomes reduced the sample size of the simulated trials by two-thirds, on average. Power analysis found that a simulated trial using the mJOA to detect a one-point decrease in control vs. experimental group would need to recruit 230 patients (115 per arm) to demonstrate superiority. Preliminary results found that endpoints from a Fast Tap, Hold, Typing, and Stand and Walk Tests could detect the equivalent point decrease with 118 (59 per arm), 22 (11 per arm), 16 (8 per arm), and 146 (73 per arm) patients, respectively.

Discussion: Improving measurement of DCM is an AO Spine research priority. In silico analysis of preliminary EMPOWER findings suggest digital endpoints could reduce trial recruitment importantly. The potential to transform trials could be significant.