P1-A-4

Associations between activity digital measures with sleep and fatigue PROs assessed in the real-world: the IDEA-FAST feasibility study

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Introduction

- Sleep disturbances and fatigue are most commonly reported symptoms in individuals with neurological and immune disorders. Collectively, they impair their daily life activities, reduce quality of life and increase burden on the healthcare system (Figure 1).

Figure 1. *Sleep and fatigue disturbances and their impact on quality of life.*

- Current assessment of sleep and fatigue rely on patient reported outcomes (PROs) which are subjective, prone to recall biases, and do not capture variability over time (Figure 2).
- Advances in wearable technologies offer the opportunity to provide objective and reliable estimates that are sensitive to change over time (Figure 2).

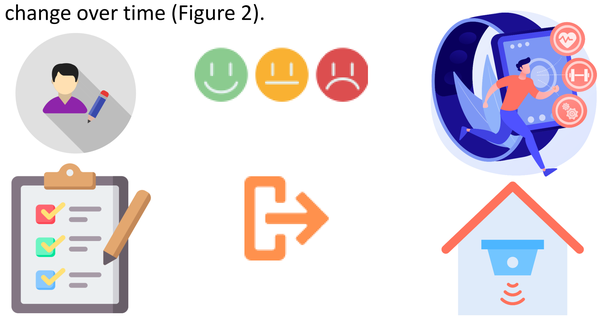

Figure 2. *Moving from subjective assessment to objective assessment with wearable technology*

Aim:

- **We evaluated the performance of four activity monitoring devices to assess feasibility of capturing digital measures of fatigue and sleep in a feasibility study of the IDEA-FAST project from six different disease groups (Parkinson's disease (PD), Huntington's disease (HD), Rheumatoid arthritis (RA), Systemic Lupus Erythematosus (SLE), Primary Sjogren's Syndrome (PSS), and Inflammatory Bowel Disease (IBD)), and healthy controls (HC).**

Methods

- Up to 120 participants in 6 individual disease groups (PD=18, HD=6, RA=17, SLE=16, PSS=17, IBD=12,) and healthy controls (HC=34) wore four wearable devices (i.e. AX6, MoveMonitor, VitalPatch, and Byteflies) continuously for a maximum of ten days at home (Figure 3).

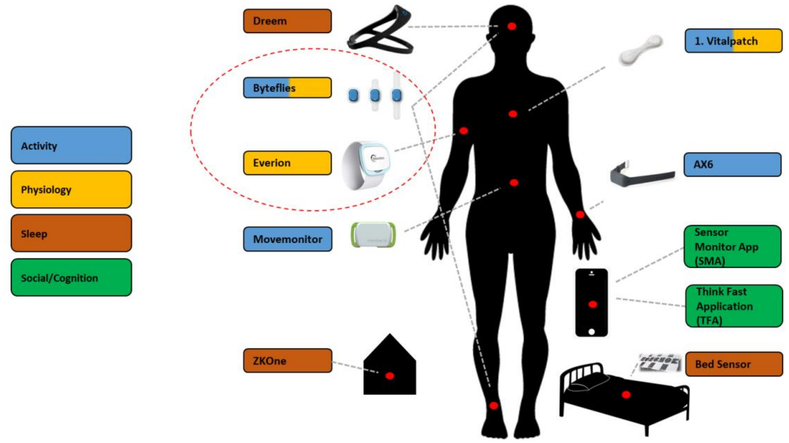

Figure 3. *Devices used in IDEA-FAST feasibility study for data collection and their attachment location on subjects' body.*

- Participants completed sleep-, fatigue- and pain-related PROs up to 4 times a day, using a mobile phone application.
- Performance of different activity monitors was assessed by evaluating the coverage, data quality of the derived features, and their association with PROs in all participants and in individual disease cohorts (Figure 4).

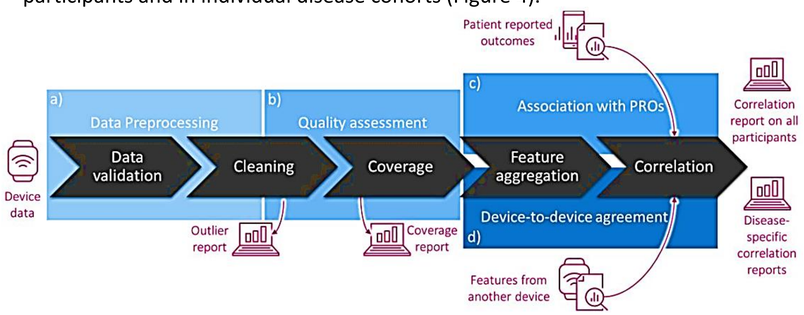

Figure 4 (a-d). *Steps involved in processing and statistical analysis.*

- Activity features were extracted from minute level epochs from the continuous stream of sensor data and then aggregated (2H) for correlation.
- For assessing the quality of the four activity devices, outliers were identified first by plotting the activity measures with box plots and the coverage of each device was calculated as the ratio of the number of days with valid measurement (coverage > 70%) and the expected number of days (i.e. 10).

Results

- Most of the participants wore the AX6 device over 10 days, therefore its coverage was 100%. MoveMonitor and VitalPatch devices had reasonably good coverage (80%). For the MoveMonitor, the daily coverage was relatively low for IBD and SLE cohorts compared to the cohort-specific coverage levels of VitalPatch and AX6 (Figure 5). The Byteflies had the poorest coverage overall.

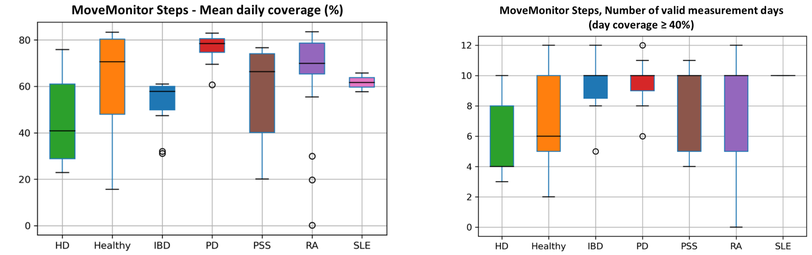

Figure 5. *Mean daily coverage and number of valid days estimated with number of steps from MoveMonitor device attached at the lower back.*

- From the current analysis, MoveMonitor-derived features produced the highest correlations with PROs (*e.g.,* perceived sleepiness, r=-0.33), but AX6 outperformed the other devices in terms of data coverage (100%). Simple features provided by the device manufacturer had a weak correlation with the PROs (Table 1).

Top 3 associations	Reference	Result r, p, coverage	Notes
Steps (2H sum)	Sleepiness index	-0.33, (p<0.001), 53%	63 subjects; quiz 3 x day
Steps (2H sum)	Physical Fatigue	-0.07 (p=0.045), 42%	61 subjects; quiz 4 x day
Steps (2H sum)	Mental Fatigue	-0.03, (p=0.29), 41%	63 subjects; quiz 4 x day

Cohort effects	Results	Notes
PD Coverage	77%	Highest with n=16, (healthy coverage 63% with n=29)
PSS	-0.389 (p<0.001), 65%	Step sum correlation with Sleepiness index, n=10
RA	-0.258 (p<0.001), 67%	Step sum correlation with Sleepiness index, n=10

Table 1. *Score card to assess the MoveMonitor performance*

Conclusions

- **MoveMonitor- and AX6-derived features had the highest correlations with PROs.**
- **The activity device placed on the lower back provided the better data quality and higher correlations, whereas the wrist-worn device provided the highest data coverage.**
- **In future studies, other clinically relevant features of mobility (e.g. gait speed) and specific aspects of mobility (e.g. walking, turning) should be explored to assess their association with sleep and fatigue.**

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