

Applications of Daily Life Sampling in Clinical Populations

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Spotlight: Digital Health Regulatory Science Research Opportunities

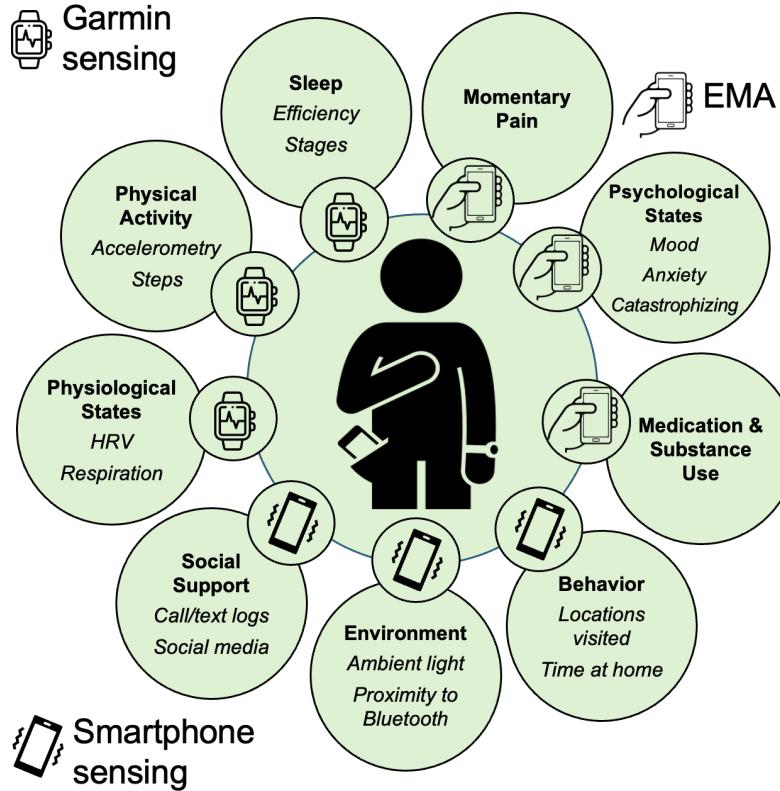


www.fda.gov/digitalhealth

Definition of a digital biomarker

As defined in the Biomarkers, EndpointS and other Tools (BEST) glossary developed by U.S. Food and Drug Administration (FDA) and National Institutes of Health Biomarker Working Group, a biomarker is “a defined characteristic that is measured as an indicator of normal biological processes, pathogenic processes, or biological responses to an exposure or intervention, including therapeutic interventions”¹ (e.g., blood pressure). In line with this definition and in a guidance document², FDA defines a digital biomarker to be a characteristic or set of characteristics, collected from digital health technologies, that is measured as an indicator of normal biological processes, pathogenic processes, or responses to an exposure or intervention, including therapeutic interventions. The use of ‘characteristic or set of characteristics’ in the definition of digital biomarkers stems from the ability to derive one or more biomarkers from one or more DHTs simultaneously. In some instances, the characteristics of the host and disease or medical condition can be simultaneously collected and consolidated from multiple DHTs to derive a biomarker. This ability to derive biomarkers from multiple DHTs can potentially provide additional context to enrich normal values for the population, patient-specific baseline values, and assess changes in health status relevant for healthcare applications.





Why digital biomarkers?

- Retrospective recall of symptoms is biased by the individual's most recent and most severe experiences (Horowitz et al., 2023; Stone et al., 2004; Stone et al., 2000)
- Self-report tends to have low agreement with objective measurement (Collins et al., 2025; Lauderdale et al., 2008; Prince et al., 2008; Varallo et al., 2022)
- Longitudinal monitoring facilitates investigation of symptom dynamics



1,533 | 50

17

Views

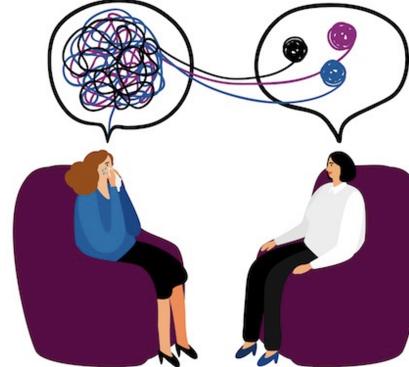
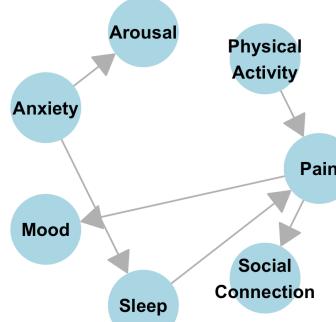
CrossRef citations to date

Altmetric

Empirical Papers

Feasibility and utility of idiographic models in the clinic: A pilot study

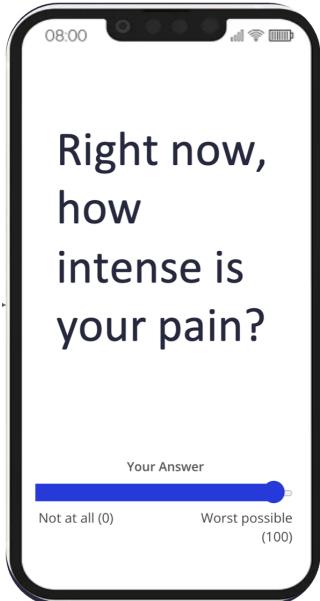
Madelyn R. Frumkin  , Marilyn L. Piccirillo, Emorie D. Beck, Jason T. Grossman & Thomas L. Rodebaugh



Paper



Digital assessment is highly feasible

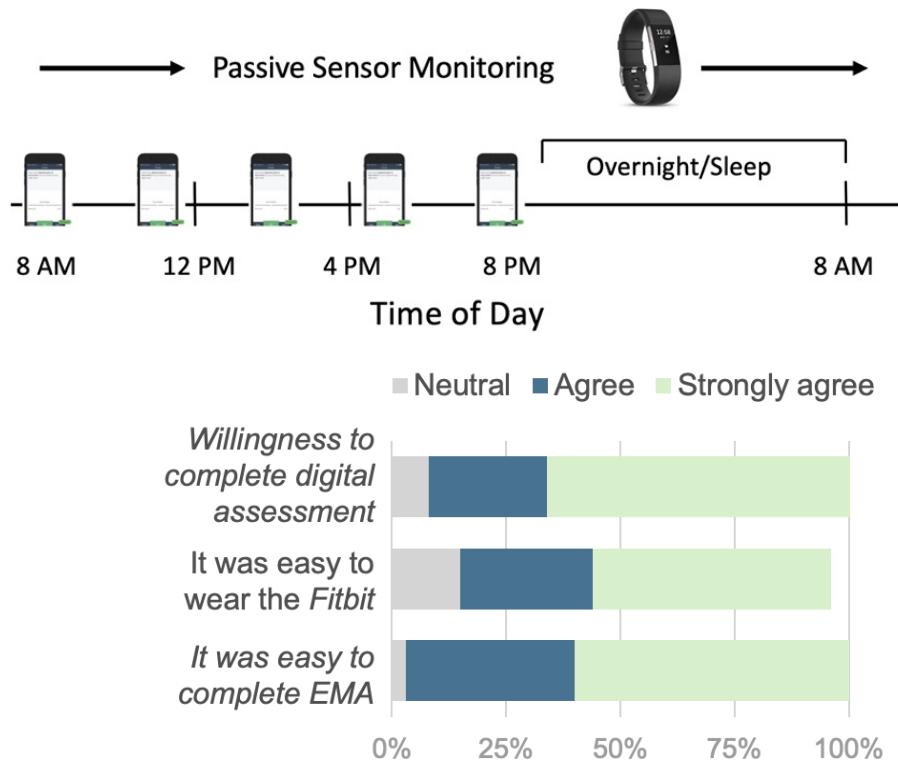


- 2,500 patients undergoing surgery (30% have chronic pain)
- 91% completed any ecological momentary assessment (not required nor directly incentivized)
- Without excluding participants based on low compliance, we observed high preoperative (Median = 80%) and postoperative (Median = 72%) compliance with EMAs delivered 3x per day
- Weak **positive** association with age

Preprint



Digital assessment is highly feasible



- 77 patients undergoing spine surgery
- 86% compliance with EMA 5x/day for 3 weeks before surgery
- High willingness to complete digital assessment

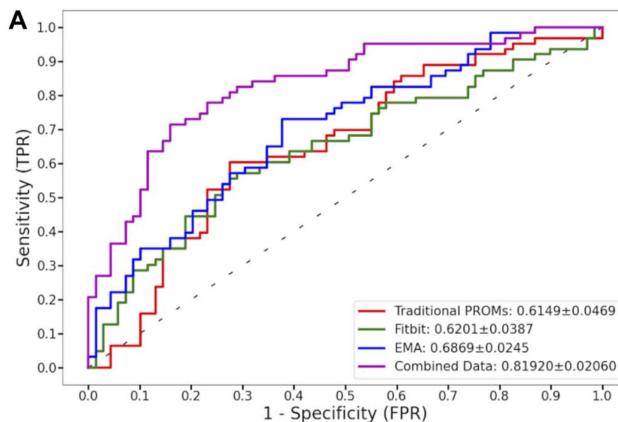
Paper



Digital assessment improves prediction of surgery outcomes



- 133 patients undergoing lumbar surgery for degenerative spine disease
- Features derived from digital health data led to a 34% improvement in predictions of postoperative outcomes

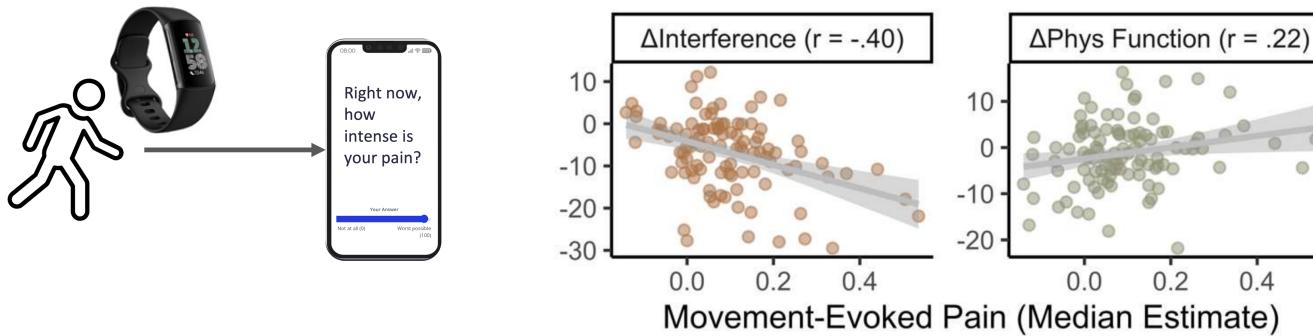


Paper



Digital assessment can facilitate phenotyping of heterogeneous chronic pain conditions

- 133 patients undergoing lumbar surgery for degenerative spine disease
- In-vivo assessment of movement-evoked pain was among the strongest predictors of early postoperative outcomes



Preprint



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