Identifying concepts of physical activity which are clinically meaningful to patients and care providers: A systematic review of qualitative studies

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Objective

Project aim

Identify aspects of PA that are meaningful to patients to inform a core set of digital measures of PA

Research questions

1. What concepts of PA are globally meaningful to patients and their health care providers? How is each concept meaningful to patients and their health care providers?
2. What concepts of PA are clinically meaningful and support informed clinical decision making?

Methods

Systematic literature review (SLR)

1. Therapeutic area selection:
   - Parkinson’s Disease (PD), Multiple Sclerosis (MS), Chronic Obstructive Pulmonary Disease (COPD), cancer, Duchenne’s Muscular Dystrophy (DMD), Chronic Heart Failure (CHF), Sickle Cell Disease, osteoarthritis (OA), and sarcopenia.
2. Search strategy and study selection:
   - MeSH, CINAHL, EMBASE, MEDLINE, Physiotherapy Evidence Database, Cochrane Library, WHO Global Health Library.
   - Search terms: physical activity, impairment, meaningful, constraint, SRF, core-set, DHT.
   - Data filtering: abstract, inclusion, exclusion.
3. Data extraction and synthesis:
   - Data was extracted by two reviewers using a predefined data extraction form.
   - Findings included quotes, PA concepts of interest.

Background

- Physical activity (PA) is an essential component of health, with impairments of PA linked to higher risk of falls, reduced quality of life, and increased likelihood of chronic disease and premature death.
- The Food and Drug Administration (FDA) developed patient-focused drug development (PFDD) guidelines to ensure clinical outcomes are underpinned by aspects of health that are meaningful to patients.
- Digital health technology (DHT) derived measures provide opportunities to capture physical activity in meaningful real life contexts, with more granularity to support informed clinical decision making.
- Providing clarity on common core concepts of physical activity will provide a valuable pathway forward for innovative, patient-centered measurement of PA.

Conceptual model for digital measurement of physical activity

The aspects of PA that patients described as most meaningful were related to the way impairments restricted their participation in self-care, domestic, and community & leisure activities. Representative quotes for each meaningful aspect of health (MAH) are provided from the patient perspective for a variety of therapeutic areas, though the provider perspective was also considered.

Results

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Discussion

- Identifying MAHs from patient and provider perspectives in this SLR was the essential first step in developing our conceptual model for the measurement of PA.
- COIs and outcomes were later added as part of a broader evidence generation process, including a modified delphi approach with subject matter experts for selecting our core digital measures of PA:
  - Step count, number of walking bouts at specified bout durations, walking speed, measures of postural sway, and time spent in MVPA.
  - Core measures of PA were selected based on maturity of DHTs on the market, the evidence available for the PA measures captured by those DHTs, and potential clinical research and practice applications.
  - DATAcc by DiMe’s Library of Digital Measurement Products was also developed to catalog verification, analytical validation, and clinical validation (V3) studies7 for technologies measuring PA outcomes.
- Ontologies and stakeholder-specific resources were generated to align the field with key definitions and use cases that are necessary to promote standardization and drive the adoption of digital PA measures.
- The research and resources enable the development and selection of meaningful digital measures of PA in clinical trials and clinical care, moving the industry forward by reducing duplicative efforts and speeding the path to discoveries that will benefit the patients we aim to serve.

References