Recommendations for Defining and Reporting Adherence Measured by Biometric Monitoring Technologies

May 12th, 2022 11am ET
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Recommendations for Defining and Reporting Adherence Measured by Biometric Monitoring Technologies

May 12th, 2022 11am ET
Disclosures

• JPB (Signifier Medical Technologies and Philips)
• LB (Novartis)
• RC (Verily Life Sciences)
• AC (Pfizer and Ali Ciger Ventures UG [haftungsbeschränkt])
• KLF (K Health, Trusst Health Inc, InquistHealth, and Social Wellness)
• ESI (Koneksa Health)
• CJM (Astra Zeneca and Abbvie)
• CAN (Pfizer)
• IRRC (ICON plc)
• BV (Byteflies)

All other authors indicated no disclosures
Background

- Biometric monitoring technologies (BioMeTs): Connected digital tools that process data captured by mobile sensors using algorithms to generate measures of behavioral or physiological function

- Suboptimal adherence to data collection procedures or a study intervention is often the cause of a failed clinical trial (Eysenbach, 2005)

- If we build it, will they come?
Objectives

Conduct a systematic literature review of published studies reporting adherence captured by BioMeTs to:

- identify studies that have used these tools to capture adherence to data collection procedures and/or study interventions
- describe the various methods used to measure adherence
- compare the definitions of adherence reported in the literature

... then use this information to identify gaps and compile recommendations for investigators
Number of papers identified: 940

- No human participants: 116
- In-vitro studies: 6
- Did not include a BioMeT: 619
- Did not capture data outside of clinic/lab: 22
- Did not report adherence: 53
- Retrospective or secondary data use: 23
- Written in non-English: 1

Number of papers excluded: 840

Number of papers included: 100
Number of BioMeTs included: 110

Wearables, positive airway pressure devices, smart clothing, blood pressure monitors, smartphones, oral appliances, glucometers, ingestibles, implantables, smart scales, patches, exercise equipment, and more…
Adherence data

<table>
<thead>
<tr>
<th>Category</th>
<th>Definition</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>PASSIVE</td>
<td>Designed to be used continuously</td>
<td>Fitness trackers</td>
</tr>
<tr>
<td>SESSION-BASED</td>
<td>Designed to be used during sessions</td>
<td>Connected exercise equipment</td>
</tr>
<tr>
<td>TASK-BASED</td>
<td>Designed to be used as a one-off task</td>
<td>Connected weight scales</td>
</tr>
</tbody>
</table>
Adherence data

Duration of use
Minutes/day
Hours/night

Number of measurements
Number of tasks completed
Number of days with usage

Categorical variable
% with usage >x hours/day
% who completed >y tasks

Adherence reported as duration of use
Adherence reported as number of measurements
Adherence reported as a categorical variable

Highest resolution data
Lowest resolution data
Adherence data

Heterogeneity of adherence data increased as resolution of adherence data decreased
Gaps and Recommendations
Gap 1: Sensor-based adherence data were not reported in 29.9% of screened manuscripts

- **Recommendation 1:** Develop and/or use BioMeT sensors to capture sensor-based adherence data in addition to their primary purpose

- **Recommendation 2:** Collect and report adherence data that are a direct reflection of actual use, rather than a surrogate
Gap 2: BioMeT manufacturer or model & software information missing for 10% and 68% of tools

- **Recommendation 3**: Provide a clear description of the sensor or sensors capturing adherence data.

- **Recommendation 4**: Describe the algorithm or algorithms that convert sample-level measurements into a measurement of adherence.
Gap 3: Heterogeneity of adherence definitions increased alongside decreasing resolution of adherence data

- **Recommendation 6**: Report primary adherence as a continuous variable of time for passive or session based BioMeTS
- **Recommendation 7**: Report primary adherence as a continuous variable of time for task based BioMeTS
- **Recommendation 8**: Categorical adherence data are reported with continuous adherence data
- **Recommendation 9**: Categorical definitions of adherence should be based on clinical validation data
Key Takeaways

• With **increased consistency and reporting** of adherence and associated data elements, it will become possible to meta-analyze adherence data to identify determinants.

• Understanding determinants of adherence allows for the development and testing of **targeted interventions** to optimize adherence.

• Increased adherence to BioMeTs will ultimately improve the quality and efficiency of clinical trials.

Full paper available at *Journal of Medical Internet Research*: https://www.jmir.org/2022/4/e33537/
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