Digital Phenotyping Adherence, Feasibility, And Tolerability In Outpatients With Schizophrenia

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Introduction

- Digital phenotyping (; i.e., using mobile technology to collect data *in situ*) has potential for use in symptom assessment and clinical trials for schizophrenia (SZ).
- Digital phenotyping is typically divided into "active" (e.g., surveys, cognitive tests, videos) and "passive" modalities (e.g., psychophysiology, geolocation, phone use).
- Active modalities show adherence rates between 60-98% (M = 78.7%) for surveys, but this estimate may be biased by the use of adherence cut-offs.
- Adherence for passive modalities has not been examined.
- It is currently unknown how person-related and study-related factors may impact adherence.
- Feasibility and tolerability have also received relatively little attention in SZ.
- **Hypotheses:**
  - **Adherence would be lower in SZ than CN.**
  - **Age, education, cognitive impairment, number of children, current employment, and symptoms would be associated with adherence.**
  - **Active and passive methods would be feasible.**
  - **Active and passive methods would be tolerable.**

Methods

- Participants included 54 SZ and 55 controls (CN). The groups did not differ on age, sex, parental education, or race; however, CN had higher personal education.
- Participants completed the BNSS, PANSS, LOF, MCCB, and a post-study debriefing interview.
- Participants completed six days of digital phenotyping using a phone and smartband provided by the researchers:
  - Active:
    - Signal-contingent (momentary) surveys quasi-randomly 8 times per day. Surveys used skip logic and infrequency items.
    - Event-contingent (morning, event [following planned pleasurable event], and evening) surveys, 1 of each per day on demand.
  - Passive:
    - Phone accelerometry (ACL), geolocation (GPS), and ambulatory acoustics (VOX).
    - Smartband (Band) accelerometry, electrodermal activity, and skin temperature.
- Active and phone passive measures collected using mEMA by Ilumivu, smartband was Empatica Embrace.
- Participants compensated $20 per hour in the lab, $1 per survey, and $80 for returning study equipment.

Digital phenotyping methods can be completed by individuals with SZ with good adherence, feasibility, and tolerability.

Table 1. Recommendations for digital phenotyping studies.

Active

1. **Contact participants 3-4 days into the study period. Longer studies may need more frequent check-ins.**
2. Plan for missing data and pilot carefully to find any technology problems.
3. **Use survey skip logic to reduce participant burden while still measuring items of interest.**
4. Conduct psychometric evaluation and use multiple items per construct.
5. **Infrequency or "catch" items and/or item reaction times may be used to detect invalid responding.**
6. **If using an adherence cut-off, make sure it does not disproportionately impact any given group. Consider excluding *days* with insufficient data rather than *participants*.**
7. Have phone apps provide active data feedback to participants.

Passive

1. **Pair continuous passive data collection with active data to drill down into the contexts that are most relevant in daily life.**
2. **Passive data is a valuable *adjunct* to clinician ratings and diagnostic evaluations.**
3. Have phone apps provide passive data feedback to participants.
4. Consider how specific populations — especially those with cognitive impairments — understand the risks and benefits of passive data collection to obtain informed consent.
5. Passive data requires validation, particularly regarding verification (does the sensor collect what it should?), analytic validation (what information does a sensor provide?), and clinical validation (is a sensor's data clinically useful?).

Results

Adherence

- SZ demonstrated lower adherence (64%, SD = 34%) than CN (75%, SD = 29%) for active but not passive adherence.
- Across both groups, survey adherence was highest for morning (80%, SD = 27%) followed by event (72%, SD = 36%) then momentary (61%, SD = 27%) and evening (65%, SD = 34%) surveys.
- In both groups, passive data adherence was greatest for ACL (88%, SD = 29%) followed by GPS (75%, SD = 39%), VOX (45%, SD = 32%), and Band (24%, SD = 31%) data.
- Adherence to surveys was lower on days 4 and 5 relative to day 1 and on Saturdays.
- Passive data adherence decreased over the days of the study period in both groups and was lower on Saturdays in CN but not SZ.
- Greater survey adherence was associated with higher functioning in SZ; in CN it was associated with lower age and lower mean survey time.
- Greater passive data adherence was associated with lower positive symptoms, lower negative symptoms, lower functioning, and greater education in SZ. No predictors were significant in CN.

Feasibility

- SZ were slower to complete surveys and less variable in response times relative to CN; however, both groups completed a comparable number of items.
- The use of 20% and 30% cut-offs not disproportionately exclude SZ participants while 50% does.
- Infrequency items were endorsed approximately 1% of the time in both groups. Infrequency item endorsement was more likely for longer surveys.
- Both groups encountered similar obstacles; meetings and technology problems were associated with lower adherence.

Tolerability

- Both groups rated the procedures favorably with high positive ratings and low negative ratings.

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