REPORTING

WORKGROUP #3 – COMPILED RECOMMENDATIONS

These recommendations were compiled as an output of the Advancing the Utility of Digital Sensing Tools for Mental Health Research workshop ("Digital Sensing Workshop") sponsored by the UCLA Depression Grand Challenge, Wellcome Trust and NIMH. Workshop participant roster may be found at: https://ucla.box.com/v/dig-sensing-wkshp-pubroster.

Note: Workgroup 3 produced two reports—one on study design and one on reporting.

Please submit feedback at https://bit.ly/dig-sensing-report-feedback by August 31, 2023.

Reporting

We propose the adoption of the EVIDENCE-MH (EValuating connecteD sENsor teChnologiEs for Mental Health) Checklist

Purpose

The EVIDENCE-MH (EValuatIng connecteD sENsor teChnologiEs for Mental Health) was adapted from the EVIDENCE checklist created by the Digital Medicine Society (DiME). This adaptation was developed by a multidisciplinary group of content experts convened by the Digital Sensing Workshop, representing the clinical sciences, technology development, computer science, and data analytics. The aim of EVIDENCE-MH is to promote high quality reporting in studies where the primary objective is the investigation and evaluation of personal sensing tools using networked sensor technologies to capture, process, and create algorithms to generate measures of behavioral, psychological, and/or physiological function related to mental health. Using EVIDENCE-MH, those preparing, reading, or reviewing personal sensing studies in mental health will be better equipped to distinguish necessary reporting.

Section/Topic	#	Importance	Checklist Item	Page #
TITLE				
Title	1	Preferred	Explicitly identify the study as proof of concept, verification, analytical validation, clinical validation, and/or utility and usability. If limited by journal specified word length, it is recommended to include the evaluation type as key words.	
ABSTRACT				
Structured Summary	2	Required, individual elements as applicable for journal	Provide a structured summary including the following items, as applicable to the study: evaluation type (proof of concept, verification, analytical validation, clinical validation, and/or utility and usability), study objectives, targets and outcomes measures, digital products used, wear location, reference standard, sample size, key results, and conclusions.	
METHODS				
Study setting and dates	5	Required	Describe the setting, locations, and relevant dates, including periods of recruitment and data collection	
Ethics and Informed Consent	6	Required	Include a statement that Institutional Review Board (IRB) approval or Ethics Committee review of the study documentation was completed. Indicate whether a written consent was obtained from the study participants.	

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Protocol and Registration	7	Preferred	Report trial or study registration number.	
Participants	8	Required	Define the recruitment strategy, eligibility criteria (inclusion, and exclusion criteria).	
Adherence promotion processes	9	Required	Report processes used to promote participant adherence to the study protocol, including participant training, adherence monitoring, outreach processes, and participant compensation.	
Public involvement	10	Preferred	Describe processes of engagement of representative people with lived experience in research processes, including formulation of study questions, study design, conduct of study, analysis and interpretation of data, and dissemination of findings.	
Connected Sensor Technology				
Make and Model	11a	Required	State the make and model of the connected sensor technology used. Include version numbers and any changes to technology as relevant.	
Product Availability/ Maturity	11b	Preferred	Describe if the connected sensor technology is a custom prototype or a product that is currently on the market, available for purchase.	
Sensor Characteristics	11c	Required	Describe the sensor modality(ies) and sample level data characteristics (ex. units, sampling rate, etc.) used for data collection in as much detail as possible.	
Form Factor and Wear Location	11d	Required	Describe the form factor (physical shape) and wear location (precise anatomic position of sensor)	
Software				
Algorithm Description	12a	Required	Describe in as much detail as possible the algorithm used for data analysis in the study. If a new algorithm is being created, describe in as much detail as possible the procedure for building the algorithm. Procedures used for validating the algorithm can be included in the statistical analysis section.	
Version Number and Manufacturer	12b	Required	State the version number and manufacturer of any software used for data collection and analysis where possible.	
Wear Time	13	Preferred	Determine the minimum wear time for sufficient data capture and a meaningful data set used in analysis.	
Reference Standard	14	Required	Describe the standard to which the performance of the connected sensor technology is being compared.	

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Assessment	15	Required	Clearly identify targets and outcomes measured. Describe any self-report methods used to label sensor data or features. Describe protocols for prompts, including for frequency, triggers, and reminders.	
Training for Staff and/or Participants	16	Preferred	Describe any training given to study participants and/or staff for how to properly use the connected sensor technology.	
Data Analysis				
Statistical Analysis	17a	Required	Describe all statistical analyses.to perform verification, analytical and/or clinical validation of the solution utilized in research.	
Machine Learning	17b	Required	Describe all machine learning methods and model assumptions.	
Missing Data	17c	Required	Describe methods used for managing missing data.	
Sample Size	17d	Required	Indicate how the sample size was determined. In cases of N-of-1 studies, authors may describe the sample size based on number of measurements rather than the number of participants.	
RESULTS				
Participant Flow	18	Required	A diagram similar to a STROBE or CONSORT flowchart is strongly recommended to show numbers for participant recruitment to study completion.	
Participant Demographics	19	Required	Describe the participant demographics that are minimally necessary for the study. Indicate the number of participants with missing data for each variable of interest.	
Data analysis				
Missing Data	20a	Required	Report missing data for all data types, including self-report, EMA, interview, and sensor data. Report how missing data were managed in data analysis.	
Main Results	20b	Required	Describe the study's findings.	
Robustness Checks	20c	Preferred	Describe robustness checks on data analyses.	
Usability and Technical Problesm	21	Preferred	Describe any technical problems that impacted the study results	
Adverse Events	22	Required	Describe unintended effects of technology causing physical or psychological harms	
Feedback from Participants and Study Staff	23	Preferred	Describe any feedback from participants and study staff and/or findings from satisfaction surveys.	

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DISCUSSION				
Summary of Findings	24	Required	Summarize the main findings and relevance for the patient population and its clinical application.	
Comparison to Existing Literature	25	Required	Compare results to similar studies and describe potential reasons for any major differences observed.	
Limitations	26	Required	Discuss limitations of study methods and/or the connected sensor technology used.	
Conclusions	27	Required	Provide interpretation of findings and any implications for clinical care or future research.	
OTHER				
Funding and Competing Interests	28	Required	Describe sources of funding or other support received for work.	
SUPPLEMENTAL OR METHODS (as appropriate for publication)				
Feature list	29	Required	Provide a list of features included in analyses	
Non-standardized measures and EMA	30	Required	Provide copies of any non-standardized assessment measures or EMA.	