Conceptual model of digital measures for common mental health disorders

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This was informed by an expert working group and patient advisory committee. These digital measures for common mental health disorders (CMHD) provide objective, longitudinal real world data, augmenting the traditional clinical scales and assessments. For more on the methodology:

Visit webpage

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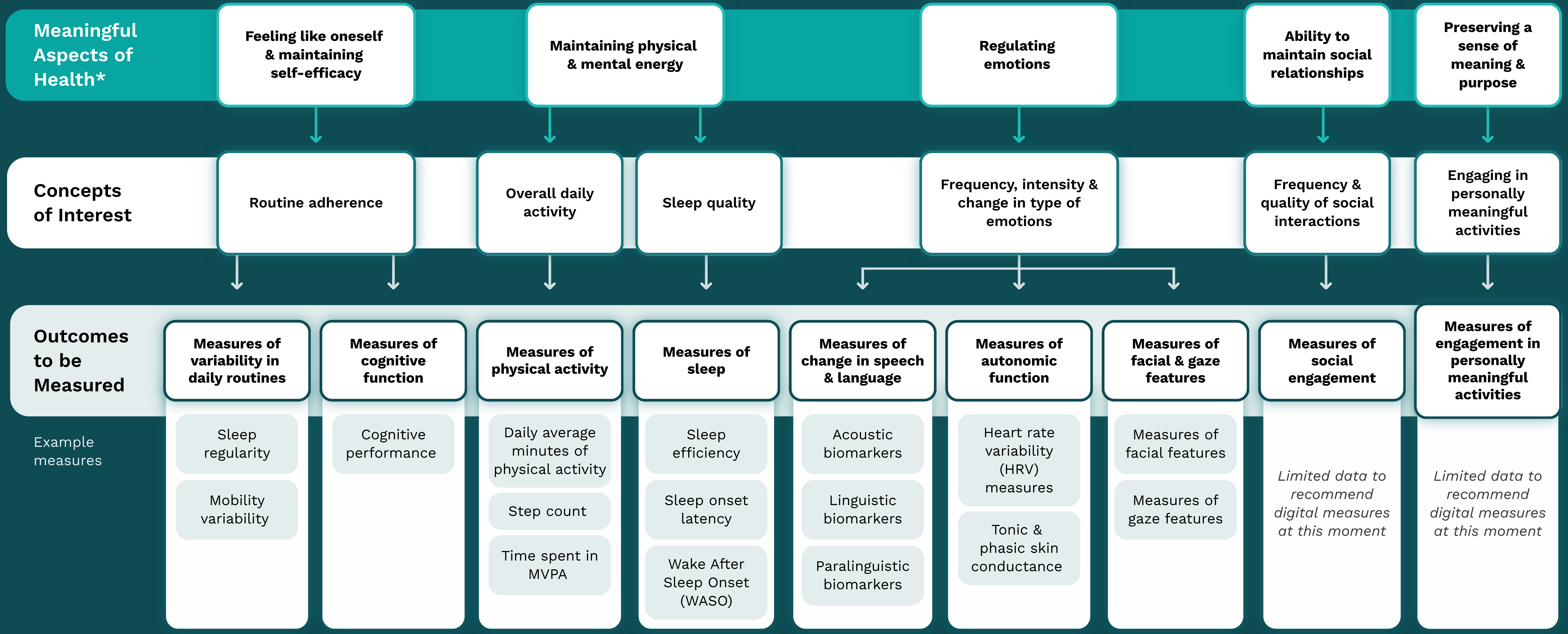

*All 5 meaningful aspects of health are interconnected and may impact one another.

Variability in daily routines

DESCRIPTION

The digital measure of variability in daily routines assesses day-to-day consistency in behavioral patterns in individuals with CMHD. While circadian rhythms regulate primary daily behaviors such as sleep, secondary routines are influenced by environmental, social, and personal choice factors. Disruptions may contribute to or reflect symptom severity, while regularity may be associated with improved clinical status in individuals with CMHD (1, 2)

Sleep Regularity Index (SRI)

Description

Evaluates circadian rhythm regularity in individuals with CMHD by quantifying the probability of being in the same sleep–wake state at any two time points 24 hours apart, producing a score from 0 to 100 where higher values indicate more consistent sleep–wake patterns.

Example endpoint (PMC12404321)

Sleep Regularity Index (SRI), derived from 7-day wrist accelerometer data, assessed at baseline and used to predict incident depression and anxiety over follow-up.

Units: Percentage (%) **Frequency**: daily, weekly average
Modality: sDHT; Smartphone

View the ontology of this measure from the previously released Core Measures of Sleep project.

Mobility variability

Description

Quantifies day-to-day variability in movement patterns over time, capturing fluctuations in mobility timing and behavior derived passively from smartphone and sensor-based digital health technology (sDHT) data. Mobility variability reflects spatial-temporal variability across and within CMHD and may be indicative of affective states or psychomotor activity (3). Given the use of passive location-based data collection, implementation should ensure robust privacy, security, and ongoing, informed consent.

Example endpoint (PMC8449302)

GPS-derived mobility patterns including location variance (variability in GPS location), location entropy (variability in time spent at location clusters) and circadian movement (extent to which sequence of locations followed a 24-hour pattern).

Units: unitless **Frequency:** daily **Modality** sDHT, Smartphone

Cognitive function

DESCRIPTION

The digital measure of cognition function assesses domains such as attention, memory, executive function, processing speed, and working memory through validated tasks validated tasks delivered via smartphone, tablet, or computer (i.e., clinical outcome assessments (COAs), such as patient reported outcomes (PRO) or clinician-reported outcomes (ClinRO)). The input technology can be used to collect passive behavioral signals (e.g., typing dynamics, speech patterns, input interactions) to augment the active PRO/ClinRO assessment, often in real-world contexts. They are intended to complement, not replace, established COAs, adding measurement sensitivity.

Cognitive performance

Description

Evaluate cognitive functioning in an individual with CMHD, focusing on how attention, memory, and executive function vary within and across mental health disorders and relate to everyday functioning.

Example endpoint (NCT04951609)

Cognitive Performance on a neurocognitive battery (eg, cogstate computerized cognitive battery) at baseline and week 6.

Units: standardized score **Frequency**: baseline, 6 week
Modality: Smartphone; Computer/Tablet

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Physical activity

DESCRIPTION

The digital measures of physical activity reflect a person's bodily movement patterns, intensity, and duration. Measures of physical activity encompass all daily movement, including exercise, and are readily captured using widely available smartphones and fitness/wellness products, enabling scalable, low-burden data collection. This is particularly relevant in CMHD, where individuals may not engage in high intensity activities, even with clinical improvement, and changes may instead be observed in overall activity and daily movement.

Step count

Description

Step count represents the total number of steps taken per day and provides a simple, objective measure of overall physical activity and mobility in individuals with CMHD. This measure is widely used in clinical and digital health research due to its ease of collection and scalability and can be personalized to an individual's baseline, allowing changes to be interpreted relative to their typical activity level.

Example endpoint (NCT02669082)

Change from baseline in actigraphy-measured daytime Activity Level, as evaluated by the number of steps, at the end of the treatment period up to 8 weeks.

Units: counts **Frequency:** daily **Modality:** sDHT, smartphone

View the ontology of this measure from the previously released Core Measures of Physical Activity project.

Time spent in moderate to vigorous physical activity (MVPA)

Description

MVPA reflects time spent in higher-intensity physical activity beyond general daily movement. It is defined as the cumulative time spent at or above ≥3 metabolic equivalents (METs), where 1 MET represents resting energy expenditure (sitting quietly). Our patient advisory committee noted that given MVPA captures only higher-intensity activity, it may may not fully represent broader aspects related to maintaining physical energy.

Example endpoint (NCT02781688)

Change in minutes of moderate-to-vigorous physical activity (MVPA) at 3 months following physical activity intervention which includes active counseling, workout facility access, and a FitBit for self-monitoring

Units: time (e.g., minutes) **Frequency:** daily **Modality:** sDHT, smartphone

View the ontology of this measure from the previously released Core Measures of Physical Activity project.

Daily average minutes of physical activity

Description

Daily average minutes of physical activity captures the time spent in day-to-day functional movement, which is considered behaviorally relevant in CMHD, with reduced engagement in physical activities often indicating a worsening of symptoms in CMHD.

Example endpoint (NCT05505578)

Change in average minutes of daily physical activity from baseline to 12 weeks.

Units: time/duration (e.g., minutes/day) **Frequency:** daily **Modality:** sDHT, smartphone

DIGITAL CLINICAL MEASURES

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Sleep

DESCRIPTION

The digital measure of sleep quality reflects how well a person has slept. Sleep is closely linked to mental health, with bidirectional relationships observed between sleep disruption and symptom burden across CMHD (4,5). The example endpoints rely solely on actigraphy, but note that the accuracy of sleep assessments generally improves when multimodal data is used.

Sleep efficiency

Description

Defined as the proportion of time spent sleeping when the individual intends to sleep calculated as [(Total sleep time/total time in bed) * 100]. Reduced sleep efficiency is commonly observed in CMHD and is associated with fragmented sleep, insomnia symptoms, and impaired next-day functioning.

Example endpoint (NCT02669082)

Change from baseline in actigraphy-measured sleep efficiency (%) at the end of treatment period (8 weeks)

Units: Percentage (%) **Frequency:** weekly **Modality:** sDHT

View the ontology of this measure from the previously released Core Measures of Sleep project.

Sleep onset latency

Description

Captures the duration of time an individual takes to first achieve sleep after intending to sleep (SOL = $t_{sleep\ onset} - t_{bedtime}$ where $t_{bedtime}$). It has been has been associated with greater subsequent CMHD symptom burden across affective and behavioural domains.

Example endpoint (NCT04478305)

Sleep onset latency assessed by actigraphy at 4, 8, 12, & 16 weeks after the start of study participation.

Units: time (e.g., minutes) **Frequency:** every 4 weeks **Modality:** sDHT

View the ontology of this measure from the previously released Core Measures of Sleep project.

Wake After Sleep Onset (WASO)

Description

WASO is the sum of the length of all wake events in the primary sleep period. It is reliably associated with reduced sleep quality, increased nocturnal disruption, and higher symptom burden across many CMHDs.

Example endpoint (NCT04478305)

Change in WASO measured by actigraphy at baseline, week 13 and week 39.

Units: time (e.g., minutes) **Frequency:** daily **Modality:** sDHT

View the ontology of this measure from the previously released Core Measures of Sleep project.

DIGITAL CLINICAL MEASURES

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Change in speech & language

DESCRIPTION

The measures of speech and language assess shifts in how a person sounds, how they speak, and what words they use compared to their typical baseline. Reflecting clinical practice where speech is routinely used to evaluate how a person is feeling, these measures were supported by 86% of experts in a Delphi panel as digital measures for CMHD. However, speech is a complex and highly variable measure influenced by methodological factors such as elicitation tasks, recording conditions, and analysis approaches, highlighting the need for continued work on standardization and protocol definition to ensure reproducibility and clinical utility (6).

Acoustic Biomarkers

Description

Assess measurable acoustic features of speech production including harmonic-to-noise ratio, cepstral peak prominence (CPP) speech rate, and vocal intensity that may serve as indicators of disease progression, severity, or treatment efficacy across CMHD (7). Based on decades of research, speech samples can be reliably collected remotely, with acoustic features consistent with laboratory-based recordings across time and frequency domains.

Example endpoints (NCT04420793)

- Mean change in speaking rate from baseline to week 8 **Units**: words per minute **Frequency**: Daily or 2–3x per week Modality: smartphone, computer/tablet; headset
- Reduction in the standard deviation of speaking rate **Units**: words per minute **Frequency**: Daily or 2–3x per week Modality: smartphone, computer/tablet; headset
- Change from baseline in Harmonic to Noise Ratio **Units:** syllables per second **Frequency**: Daily or 2–3x per week Modality: smartphone, computer/tablet; headset
- Mean change in CPP value from baseline over time **Units**: decibels (dB) **Frequency**: Daily or 2–3x per week **Modality**: smartphone, computer/tablet; headset

Linguistic biomarkers

Description

Refers to the content of speech, lexical access, the words an individual chooses in a sentence, and how they pair words together to form sentences, including syntax, grammar, semantics, and vocabulary concepts. Linguistic features are dependent on language, dialect, and cultural context, requiring careful development and validation to ensure cross-population generalizability.

Example endpoint (NCT04420793)

- Change in mean syntactic complexity score from baseline to week 4 **Units**: unitless (composite score) **Frequency**: 2-3x per week **Modality**: smartphone, computer/tablet
- Change in lexical density ratio from baseline to week 4 **Units**: ratio (0-1) **Frequency**: 2-3x per week **Modality**: smartphone, computer/tablet
- Change in average sentiment polarity score from baseline to week 4 **Units**: continuous scale (-1 to +1); probability score **Frequency**: 2-3x per week **Modality**: 2-3x per week
- Percent of first-person singular pronouns relative to total word count at baseline and week 4 **Units**: percentage (%) **Frequency**: daily **Modality**: smartphone, computer/tablet

Paralinguistic Biomarkers

Description

Paralinguistic elements include non-verbal communication such as emotion, cultural cues, and dialects. These features reflect how speech is delivered and may index underlying affective and communicative processes in CMHD populations. For example intonation patterns or emotional states may reflect affective modulation in ASD (8).

Example endpoint (NCT06045897)

- Change in intonation or pitch variability from baseline to week 4 **Units**: Hertz (Hz); SD of pitch **Frequency**: daily, 2-3x per week **Modality**: smartphone, computer/tablet
- Change in pause rate from baseline to week 4 **Units**: pause per minute; pause duration (seconds); % time pausing **Frequency**: daily **Modality**: smartphone, computer/tablet
- Change in emotional recognition from baseline to week 4 **Units**: Probability (0–1); valence scale (-1 to +1) **Frequency**: daily **Modality:** smartphone, computer/tablet

DIGITAL CLINICAL MEASURES

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Autonomic function

DESCRIPTION
The digital measures of autonomic function capture objective physiological indicators used to define and measure how the body responds to emotional and psychological states. CMHD experts supported their use alongside other digital measures, as they provide indirect physiological information that can enhance sensitivity and interpretation of other digital CMHD measures.

Heart Rate Variability (HRV) measures

Description
Quantify HRV to assess autonomic nervous system regulation. HRV is influenced by individual factors such as age, sex, and BMI, contributing to variability across populations. The increased availability of sDHTs enables broader collection of HRV. However, differences in acquisition and reporting across studies highlight the need for clearer standardisation to support comparability and interpretation across CMHD

Example endpoints (NCT06390267)
Change in HRV in milliseconds (ms) across groups from baseline, during the stressor, and post-stressor (up to 3 hours)

Units: Milliseconds **Frequency:** 4 Hz
Modality: sDHT

Tonic & phasic skin conductance

Description
Captures skin conductance, including tonic (baseline arousal) and phasic (event-related responses), reflecting sympathetic nervous system activity associated with stress and emotional reactivity. Skin conductance can be collected continuously and non-invasively using sDHTs. Expert deliberation from the Delphi process highlighted that direct association to specific emotional states requires further validation.

Example endpoints (NCT04426448)
Change in physiological arousal as measured with sensors to assess skin conductance at baseline, week 1, week 2, and week 3.

Units: microsiemens **Frequency:** weekly
Modality: sDHT

Facial & gaze features

DESCRIPTION
The digital measures of facial and gaze features consist of observable features in facial muscle activity and eye movements, including expression, attention, and visual engagement. Facial features are observable movements of facial muscles, quantified through Action Units (AUs) or other facial landmarks. Gaze features quantify eye movement and attention, including direction, fixations, saccades, and duration. These measures provide objective data of emotional expression and attentional processes relevant to CMHD and can be captured using widely available technologies such as smartphone and tablets.

Measures of facial features

Description
Measures of facial features provide objective data for nonverbal behavioral parameters associated with emotional expression, social engagement, and behavioral response. Evidence indicates that these behaviors vary with symptoms severity and over time and be quantified using automated facial analysis.

Example endpoints (10.1101/2024.10.21.24315850)
Spontaneous eyeblink rates in patients with schizophrenia compared to healthy controls.

Units: rate (count/time) **Frequency:** per session **Modality:** smartphone; computer/tablet

Measures of gaze features

Description
Capture gaze features to index social attention and attentional orienting to others' eye direction. Spatial visual attention is reliably cued by eye gaze, but variability in task design and feature extraction across studies highlights the need for clearer standardization to support additional evidence generation in CMHD research.

Example endpoints (PMC12532700)
Differences in eye-movement performance during facial emotion processing across autism-spectrum disorder subtypes and typical development

Units: Unitless (z-score) **Frequency:** per session **Modality:** smartphone; computer/tablet

More outcomes to be measured

This section includes outcomes that did not achieve the level of consensus required to be included in the digital measures set. While supported by a growing evidence base, these emerging measures are either too condition-specific or may require further research and technological maturation.

Concepts of Interest	**Routine adherence**	**Overall daily activity**	**Sleep quality**	**Frequency, intensity, & change in type of emotions**	**Frequency & quality of social interactions**	**Engaging in personally meaningful activities**
More Outcomes to be Measured	Medication adherence Attendance at work or school	Time sedentary Time spent standing Postural stability on standing	Active/restless in sleep window Time spent sleeping Sleep staging	Features from EEG (e.g., theta-beta power ratio, alpha rhythm)	Frequency/duration of social interactions Content and amount of speech and language Duration/frequency of calls or text Physical proximity to others	Time spent at home Duration or frequency of activities Duration or frequency of user interaction with App or sDHT Dietary behaviors

A note on methodology for measure inclusion

If ≥ 75% of Delphi experts recommended inclusion, the measure is considered a digital measure

If ≤ 25% of Delphi experts recommended inclusion, the measure was rejected as a digital measure

If < 75% and > 25% of Delphi experts recommended inclusion, the measure was reviewed further:

It is considered a digital measure if the technology is mature, even if the clinical evidence base is not yet broadly supported across all CMHD

It is considered an emergent measure if the technology is not yet considered mature OR if the measure is too specific to specific disorders

In all other cases, the measure was rejected (technology immature and measure too specific)

See the full results of the Delphi expert process.

Conceptual model of digital measures for common mental health disorders

To learn more about this conceptual model, the measures, and the dataset:

Visit webpage

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