



**Development and Validation of an Experience Sampling Method
Questionnaire (ESM) for Digital Monitoring of Mental State in
Psychiatric Hospitalization: Convergence of ESM reports,
Standard Clinical Assessments, and Smartwatch Data**

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Abstract

This study presents the development and validation of a unique Digital Experience Sampling Method (ESM) questionnaire specifically adapted for monitoring changes in the mental state of patients during psychiatric hospitalization. The questionnaire was carefully crafted through focus groups involving patients and clinical staff, ensuring its relevance and applicability to the unique characteristics of mental state changes in a hospitalization setting.

To evaluate the validity of the ESM questionnaire, symptom severity trends obtained from the questionnaire will be compared with estimates derived from the Positive and Negative Syndrome Scale (PANSS) assessment. Data will be collected from 100 subjects over a 14-day psychiatric hospitalization period. In addition to the ESM questionnaire, smartwatch sensors will monitor physiological indicators.

Feasibility and patient compliance will be assessed by examining patients' willingness to use the digital ESM questionnaires and the smartwatch sensors. The study will also cross-reference self-reported sleep quality and activity levels captured in the ESM questionnaires with objective physiological indicators and nursing staff reports, providing insights into the reliability of the patient-reported data.

Furthermore, the study will evaluate the impact of the ESM data on clinical decision-making by physicians throughout the 14-day psychiatric hospitalization period. Patient satisfaction and satisfaction among the multidisciplinary team with the monitoring model will also be assessed.

This research underscores the potential of digital technologies to enhance patient-centered care and facilitate informed treatment decisions in psychiatric hospitalization settings.

Introduction

Assessing the mental state of the patient hospitalized in a psychiatric ward is essential for providing optimal treatment during the hospitalization and determining the recommendations for continued treatment after discharge. This evaluation is mainly based on the assessment of the patient's subjective experience in a variety of aspects (such as mood, thoughts, feelings, and emotional pain) and the evaluation of his/her functioning (such as behavior, social functioning, mental functioning, level of daily activity, sleeping mechanisms, eating). Frequent documentation throughout the day of the patient's self-reports on his condition and function monitoring is rare in routine care in psychiatric inpatient wards, even though the patient's subjective perspective on his mental condition is an integral part of the psychiatric evaluation.

The positive and negative syndrome scale (PANSS) for schizophrenia (Kay et al., 1987) is the "gold standard" medical scale for measuring the severity of symptoms in patients with schizophrenia spectrum disorders. It is conducted through a brief interview rather than a self-report. Several valid assessment tools rely on the patient's self-report of his condition and focus on psychiatric symptoms (PROM - Patient-reported outcome measure), such as (SCL-90) The Symptom Checklist 90 (Derogatis et al., 1973), and The Brief Symptom Inventory (BSI) (Derogatis & Melisaratos, 1983). Many tools focus on specific disorders, such as The Beck Depression Inventory (Beck et al., 1996), to assess depression. Other self-report questionnaires focus on the patient's quality of life, which is also essential for evaluating his psychiatric condition, such as MANSA - the Manchester Short Assessment of Quality of Life (Priebe et al., 1999). Despite the extensive use of self-report questionnaires in research and with outpatients, few valid tools focus on self-report of the mental state of the patient during his hospitalization in the psychiatric ward, such as the BASIS: The Behavior and Symptom Identification Scale (Eisen et al., 1986), focuses on both the presence of symptoms and the monitoring of function.

The patient's report from memory about various symptoms and functional characteristics experienced in a period ranging from a week to a month is typical in these standard tools. These measurement tools are widely used for research purposes. Still, there is difficulty in using them in clinical work within the inpatient ward due to their length, difficulty in allocating personnel to deliver the questionnaire, note and analyze the results, and difficulty in using the collected data as a tool available for the work of the staff in the ward. Due to

these difficulties, few studies use PROMS questionnaires among hospitalized psychiatric patients. With the advancement of technology and the prevalence of smartphones, it became possible to use digital questionnaires to monitor mental states. Wong et al. (2022) described the use of digital PROMS questionnaires to characterize the symptoms and the improvement in the mental state throughout psychiatric hospitalization; this follow-up was carried out at the time of admission to the hospital and at the time of discharge when the standard questionnaires demonstrated an improvement in the mental state of the hospitalized patients. These findings indicated the importance of using self-report questionnaires in the treatment routine throughout psychiatric hospitalization to provide more accurate treatment to hospitalized patients.

There are inherent disadvantages to performing a clinical assessment using standardized questionnaires. Using the patient's memory to record symptoms is prone to biases due to a tendency to remember complex events more strongly and difficulty recalling moments when powerful symptoms were not experienced, or there were no symptoms. In addition, there is difficulty in examining slight changes in the patient's condition, which are often below the sensitivity threshold of the standard tools (Shiffman et al., 2008; Csikszentmihalyi & Larson, 2014).

In the field of psychopathology, there is a growing awareness that the models that describe the psychological experience are dynamic, change over time, and their understanding requires multiple samples and sometimes continuous monitoring while paying attention to the microenvironmental factors that surround the person and influence his condition (Myin-Germeys et al., 2009; Myin-Germeys et al., 2018).

Momentary Assessment Strategies

Momentary assessment strategies use repeated real-time sampling of subjects' behaviors and experiences. The sample can be discrete (e.g., by self-reporting about subjective aspects of the experience at a given moment), continuous (e.g., by continuous monitoring of physiological indicators using sensors), or combined (Varese et al., 2019). The strategies often used are the Experience Sampling Method-ESM (Delespaul, 1995; Hektner et al., 2007) and EMA - Ecological Momentary Assessment (Stone & Shiffman, 1994; Shiffman et al., 2008); both methods will be referred to below as ESM. The ESM is a method Structured based on a diary, in which the subjects are asked to report their thoughts, feelings, and symptoms during their daily life, as well as to describe the context in which the report takes

place, for example, location, social situation, and activity. They can also assess their satisfaction with the current situation that was sampled. ESM is a strategy with significant advantages in research in psychiatry and somatic problems and is the basis for studies in optimizing clinical decisions in these fields (Verhagen et al., 2016). With the development of technology and the frequent use of smartphones, the collection of samples, the analysis of their characteristics, and the use of sensors on mobile phones (Ben-Zeev et al., 2016) became simple and more available for conducting ESM studies. It was also found that the patient's response to electronic diary management is significantly better than using paper and pencil for running a diary (Stone et al., 2003). To assess the validity of the ESM questionnaire for psychiatric symptoms, it is customary to compare the results obtained from standard measures such as the PANSS assessment, widely recognized as the gold standard for evaluating psychiatric symptoms, with the observed changes in symptom evaluation using the ESM questionnaires (Harvey et al., 2021).

Use of ESM methodology during psychiatric inpatient stays

Studies using ESM methodology for ambulatory patients used diverse ESM questionnaires (Csikszentmihalyi & Larson, 2014; Hare et al., 2015; Chen et al., 2016a, 2016b; Wilhelm & Schoebi, 2007). However, those questionnaires are not useful in examining patients' experience in the unique situation of psychiatric hospitalization. For example, questions inquire regarding the description of the current situation, such as, "Where are you?" "Who are you with?" (Csikszentmihalyi & Larson, 2014), which is often unsuitable to ask in a hospital. In addition, it is necessary to refer to the fact that hospitalized patients are in an acute phase of their illness, and their condition should be assessed accordingly. The use of ESM models during psychiatric hospitalization has been tested and found to be feasible and valid (Kimhy et al., 2006; So et al., 2013). Studies have examined momentary changes in the mental state of hospitalized psychiatric patients (Houben et al., 2017; Hallensleben et al., 2029;; Lucht et al., 2022; Brüdern et al., 2022). However, we did not find a study examining the use of the ESM model to support the clinical decisions of the treating staff in the psychiatric ward.

Use of wearable sensors and self-report of symptoms among psychiatric patients

In a systematic review of 35 studies that use data collected from the mobile phone and information collected through wearable sensors, Seppälä et al. (2019) found an association between data collected by sensors and symptoms of schizophrenia, bipolar disorders, and

depression. However, the use of such data in clinical settings to support therapeutic interventions is not yet been thoroughly evaluated.

Lahti and his associates (2021) found that there is a possibility to identify an association between data collected by sensors, to the worsening of the mental state of patients diagnosed with schizophrenia. These illustrate the need for further research in the unique population of psychiatric patients and the lack of research information concerning hospitalized psychiatric patients during the acute phase of their illness.

Zarbo and colleagues (2022) assessed adherence to and usability of the Experience Sampling Method (ESM) and actigraph in patients with a schizophrenia spectrum disorder. They found differences in compliance between the patients residing in psychiatric rehabilitation housing in the community and healthy controls. They reported that the presence of a multi-disciplinary team is critical to ensure patients' responsiveness to using wearable sensors and answering ESM questionnaires. A complete psychiatric hospitalization setting constitutes an environment adapted to patients' compliance for monitoring. Zarbo et al. (2022) also pointed out that subjects monitored through ESM questionnaires and actigraphs reported that their involvement in the monitoring process improved their mental well-being through understanding their feelings, attention to daily routines, and rewarding occupation in utilizing their time. Participation in the monitoring procedure affects the patient's experience; this function deserves further research.

Research Objectives

1. General purpose

The present study aims to develop an Experience Sampling Method (ESM) questionnaire tailored specifically for the distinctive context of psychiatric hospitalization; an instrument not currently employed in the clinical field. The study will outline the various stages involved in questionnaire development. The primary objective of this study is to validate the ESM questionnaire by comparing the trends in symptom severity as reported through the ESM questionnaire with the PANSS assessment of symptom severity during a 14-day psychiatric hospitalization period.

2. Specific Aims:

1. Development of an ESM questionnaire specifically tailored to the unique circumstances psychiatric patients face during their hospitalization.

2. Investigation of the feasibility and compliance of patients in participating in the study, including their willingness to complete digital ESM questionnaires three times a day and wear the smartwatch sensor throughout their hospitalization. Additionally, we will explore potential differences in adherence and compliance among subjects with different psychiatric diagnoses regarding their willingness to participate in the study, complete self-report ESM questionnaires, and wear the smartwatch.
3. Examination of the validity of the ESM questionnaire in predicting the trends of change in symptom severity among psychiatric patients during a 14-day psychiatric hospitalization period. This validity will be evaluated by comparing the trends in symptom severity as measured by the ESM questionnaire with the trends observed in four PANSS assessments conducted throughout the hospitalization.
4. The validity of subjects' self-reports on sleep quality and activity level will be assessed by comparing the self-report ESM data with the physiological indicators collected by the smartwatch. Additionally, the ESM indices will be compared to reports from the nursing staff on the ward. Furthermore, we will explore whether these comparisons yield different outcomes among subjects with different psychiatric diagnoses.
5. The effectiveness of the monitoring model will be assessed by examining the impact of exposing the psychiatrists to ESM data, as well as the physiological indicators collected by the smartwatch, on the decision-making process regarding changes in the patient's medication plan during psychiatric hospitalization.
6. Patient satisfaction:
Assessing patient satisfaction with the monitoring model used throughout their 14-day hospitalization. Following the monitoring period, subjects will be asked to provide feedback on their satisfaction levels through questionnaires.
7. The satisfaction of the multi-disciplinary teams (physicians, nursing staff, clinical psychologists, social workers, occupational therapists):
At the end of the study, the teams will report through questionnaires on their satisfaction with using this monitoring model and its influence on the team's clinical decision-making.

Description of the research process

The research will be carried out in two phases:

1. **Development of the monitoring questionnaire - Content validity phase** - This phase has been fully completed, and its results will be presented in the preliminary

results chapter. At this research stage, the core content domains of the monitoring questionnaire will be developed. The research process in this phase includes the following:

1. Examining the content of scales from the Positive and Negative Syndrome Scale (PANSS) for schizophrenia and The Symptom Checklist-90-R (SCL-90-R) questionnaire: At this stage, the psychiatric symptoms, and the main criteria for assessing a mental state as emerged from those questionnaires were examined for discussion in the focus groups.
2. Focus group No. 1: The first focus group included patients hospitalized in the psychiatric ward. The purpose of the focus group is to formulate the ESM core and additional content domains and the questionnaire items and to discuss the optimal measurement frequency according to the hospitalized patients' opinions. The focus group will also examine the wording that best suits how the patients describe their mental state.

Participants

The focus group recruited nine subjects over age 18 (6 women and three men) hospitalized by consent in the psychiatric wards at the Sheba Medical Center, who signed informed consent to participate in the study. The criteria for exclusion from the study were: patients with a low level of compliance to treatment, patients suffering from a significant active physical illness, intellectual disability, or complex organic conditions including dementia conditions, patients who cannot read and write in the Hebrew language, patients who are not qualified to give informed consent. The participants were given a refund of expenses for canceling the time involved in participating in the focus group using shopping vouchers of 100 NIS.

Indices

The subjects' point of view regarding the psychiatric symptoms they suffered from during their hospitalization was examined during a free discussion. Emphasis was placed on the symptoms that change daily throughout the hospitalization and how much they indicate a change in their mental state. We also investigated what information they would like to report to the treatment team about their mental state throughout the hospitalization. After the free discussion, the position of the

subjects was examined regarding the criteria for assessing mental state as they emerged from the monitoring scales of the PROM questionnaires.

After a qualitative analysis of the information collected at this stage, the main themes of the ESM questionnaire were formulated. According to the themes found, suggestions were developed for the questionnaire items while noting how the patient's symptoms were worded. A professional transcriber transcribed the discussion.

3. Focus group No. 2: The second focus group includes a multi-disciplinary team working in the psychiatric inpatient wards. In a free discussion, the multi-disciplinary team members examined the core issues that should appear in the questionnaire for monitoring the mental state of hospitalized patients, then explored and expressed their opinion regarding the issues raised by the patients in the first focus group. The result of this step will be an ESM questionnaire adapted to the needs of the patients and the clinical staff in the inpatient wards.

Participants

At this stage, seven staff members working in the psychiatric hospitalization wards in Sheba Medical Center (3 women and four men), who signed informed consent to participate in the study, participated in the focus group. Inclusion criteria: Staff members work in the inpatient wards and have a valid Israeli license. The group was attended by two physicians in the psychiatry internship stage, two nursing staff members, an occupational therapist, a social worker, and a clinical psychologist.

Indices

In the discussion, the participants floated important themes for monitoring according to their points of view. After a free discussion, the participants were presented with the themes raised by the patients in the previous focus group. They were also presented with the possible questionnaire items formulated after the last stage, and their position was examined regarding the appropriateness of fitting these items to the questionnaire. In addition, the discussion dealt with the optimal sampling frequency, in their opinion.

The initial formulation of the ESM questionnaire items.

The questionnaire items were formulated considering the information collected in the focus groups. An effort was made to use the patients' words to ask about their mental state. In addition, existing and valid self-report items marked as necessary by the patients and staff in the focus groups discussion were selected. Items from these questionnaires were reformulated according to the ESM approach that examines the current state. At the end of this stage, an ESM questionnaire was developed, which consists of 15 items on a five levels Likert scale. In the questionnaire, there was another item of a Visual Analogue Scale type where the subject had to mark his mood on a scale ranging from 1-100.

4. Focus group No.3: The third focus group included hospitalized inpatients for cognitive debriefing - Cognitive debriefing is the process by which a patient questionnaire is actively tested among representatives of the target population and target language group to determine whether respondents understand the questionnaire as the authors intended it to be understood.

Participants

The focus group recruited six subjects over 18 (two women and four men) hospitalized with consent in the psychiatric unit at the Sheba Medical Center, who signed an informed consent to participate in the study. The criteria for exclusion from the study were: patients with a low level of compliance to treatment, patients suffering from a significant active physical illness, developmental, intellectual disability, or complex organic conditions including dementia, patients who cannot read and write in the Hebrew language, patients who are not qualified to give informed consent. The participants were given a refund of expenses for canceling the time involved in participating in the focus group using shopping vouchers of 100 NIS.

Indices

For each item in the developed ESM questionnaire, subjects were asked to describe freely what they thought the item was testing. In addition, to each item, we discussed how appropriate the question was in their opinion to describe their mental state throughout the hospitalization and whether they would change anything in the wording. At the end of this part of the discussion, the subjects were asked how many times a day they would be willing to report their mental

state, how many items they would be ready to answer, and what additional questions they would like to be asked to learn about their condition. In addition, we examined the patients' attitudes regarding their agreement to answer questions via mobile phone and their agreement to continue answering a similar questionnaire after their discharge from the hospital.

Research Process

The focus groups were held at Sheba Medical Center on 5/18/22, 08/9/22, and 11/09/22. The groups were guided by the researcher and another facilitator, who work as senior clinical psychologists in the psychiatric inpatient wards at the Sheba Medical Center. A professional transcriber attended each group and typed the conversation throughout the focus groups. The transcripts of the discussions in the focus groups were qualitatively analyzed. After collecting and processing the data from the focus group, the ESM questionnaire was improved and refined, considering the findings.

2. **Running the monitoring model - Feasibility and Validity phase** - this phase will begin in the middle of 2023 and is expected to continue for 18 months.

Participants

To conduct the monitoring model, we will recruit 100 subjects hospitalized in the inpatient wards. To receive feedback on implementing the monitoring model from the multi-disciplinary care team working in the wards, we will recruit 30 multi-disciplinary team members. The running will be carried out in two stages:

- Pre-Test - 20 patients and feedback from 5 multi-disciplinary – estimated time – 3 months.
- Field Test - 80 additional patients and feedback from 30 multi-disciplinary staff members – estimated 12 months.

The study inclusion criteria for the patients: adults are consenting hospitalized in a psychiatric hospital at the Sheba Medical Center in the open part of the ward who owns a mobile smartphone. Exclusion criteria: patients with a low level of treatment compliance, patients with a developmental or intellectual disability, complex organic conditions including dementia, patients who cannot read and write in the Hebrew language, and patients who are incapable of informed consent.

The study inclusion criteria for the multi-disciplinary team: multi-disciplinary team members who work in the psychiatric inpatient wards at the Sheba Medical Center. The staff members will have a valid Israeli license (from the professions of medicine, nursing, psychology, social work, and occupational therapy).

Indices

Pre-test indices –

1. The process involves selecting ESM questionnaire items based on their distribution indices to ensure optimal item distribution. It also includes refining the wording of items with low variability scores within and between subjects, aiming to enhance their variability.
2. We will evaluate the satisfaction indicators of the clinical staff working in the ward based on the monitoring indicators. If needed, we will enhance the implementation of the monitoring model within the clinical team in the ward.

Field test indices –

3. The validation of the ESM questionnaire will be conducted by comparing the change trends in the questionnaire indices during a 14-day psychiatric hospitalization period to the change trends in four different measurements of psychiatric symptoms assessed by the PANSS diagnostic tool, which is widely recognized as the gold standard in psychiatric symptom assessment. The subject's assessment using PANSS will be conducted at four different time points:
 - a. T1 - at study entry (day 1)
 - b. T2 - during the first week of the study (between days 4-6)
 - c. T3 - during the second week of the study (between days 10-12)
 - d. T4 - at the end of the study (day 14)
4. Feasibility and compliance:
 - a. The responsiveness to participation in the monitoring model - The number of subjects who agreed to participate in the study out of the subjects we offered to participate.
 - b. The extent of responding to the self-report questionnaires over 14 days multiplied by three times a day.
 - c. The degree of responsiveness to wearing and charging the smartwatch for 14 days.

- d. The degree of difference between subjects with different psychiatric diagnoses (psychotic spectrum, depression, mania, and personality disorders) in their adherence and responsiveness to agree to participate in the study, answer the self-report ESM questionnaires and wear and charge the smartwatch.
5. The validity of the subject's ESM self-reports on sleep quality and activity level:
 - a. The validity of the subject's self-reports on sleep quality -The subject's self-reported data about his sleep quality and number of awakenings will be compared to physiological indicators that the smartwatch will collect (number of hours of sleep, number of awakenings) and will be equalized in addition to the medical reports of the nursing staff in the ward.
 - b. The validity of the subject's self-reports on his activity level:
The subject's self-reported data about his energy and activity level will be compared to physiological indicators that the smartwatch will collect (number of steps, accelerations) and will be equalized in addition to the reports of the nursing staff in the ward.
 - c. The degree of difference between subjects with different psychiatric diagnoses (psychotic spectrum, depression, mania, and personality disorders) in correspondence between the self-report and the physiological indices and the reports of the nursing staff.
6. The effect of exposing the psychiatrists to the patient's monitoring indicators on their clinical decisions regarding him will be examined in a short questionnaire that the physician will fill out after each medication change and mark on a Likert scale of 1 5 - how much the exposure to the monitoring indicators influenced the clinical decision.
7. Patient satisfaction: After 14 days of monitoring, the subjects will report their satisfaction with using the monitoring model throughout the hospitalization through questionnaires.
8. The satisfaction of the multi-disciplinary teams: At the end of the study, the teams will report through questionnaires on their satisfaction with using this monitoring model and its influence on the team's clinical decision-making.

Research Process

After recruiting the patient for the study and signing informed consent, the monitoring application (Datos Health) and the wearable smartwatch application (Garmin) will be installed on the patient's smartphone. The patient will receive an extensive explanation from the research team's representative on the self-reporting method and will experience using the application.

From this stage, the hospitalized subject will receive ongoing clinical care, alongside participation in monitoring indicators by self-reporting in the ESM questionnaires using the Datos Health application and physiological indices monitoring by using the Garmin smartwatch. The trial will end after 14 days or until the patient's discharge (whichever comes first). The ESM self-report sampling will be conducted a frequency of 3 times a day in a semi-random manner:

- The first sample will be randomly sampled between 8-10 am.
- A second sample will be randomly sampled between 1-3 pm.
- A third sample will be randomly sampled between 7-10 pm.

In each clinical discussion of the subject's mental state, the ward staff will watch the dashboard of the Datos Health application, which will display the subject's self-report measures and physiological indicators. For each change in the patient's clinical status, determined by the physician (change of medication, vacation, preparation for discharge, discharge), the physician will answer a questionnaire in which he will document how much (between 1-5) the clinical decision was influenced by the monitoring indicators he observed.

The feasibility and compliance, Validity, and changes in the patient's condition over timeline indicators will be collected for 14 days and analyzed at the study's end. The patient satisfaction indicators will be tested after 14 days of monitoring through a questionnaire sent to each subject. The satisfaction indicators of the clinical staff in the ward will be tested through questionnaires sent to the clinical staff at the end of the study.

Place of conducting the research

The research will be carried out at the psychiatric inpatient wards A, B, and C in the psychiatric division at the Sheba Medical Center.

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Ethics

The study was approved by the Helsinki Committee of the Sheba Medical Center.