Pontifícia Universidade Católica do Rio de Janeiro

Abel González Mondéjar

On the identification of Digital Phenotyping for Enhanced Bipolar Disorder Monitoring

Tese de Doutorado

Thesis presented to the Programa de Pós–graduação em Informática of PUC-Rio in partial fulfillment of the requirements for the degree of Doutor em Informática.

Advisor : Prof. Alberto Barbosa Raposo
Co-advisor: Profª. Greis Francy Mireya Silva Calpa

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He majored in Informatics Engineering at the University of Matanzas, Cuba (2015), where he had the opportunity to participate in the ACM-ICPC Contest due to graduation and worked as a professor once he graduated. He has a Master's in Informatics from PUC-Rio, Brazil (2019) and presents partial dissertation results in SeGAH19 in Kyoto, Japan (2019) and final results in CBMS20 in Rochester, USA (2020). Due to his Ph.D., he conducts his research at the UFRJ Institute of Psychiatry, working with medical personnel, seniors, and junior researchers, publishing partial results of this thesis in SeGAH24 in Madeira, Portugal (2024), working with IPUB psychologist and psychiatrist in ongoing articles publications and identifying opportunities for next research.
In addition, he has more than ten years of industry experience working as a software developer. He worked as a developer, project manager, and professor in Cuba. Later, in Brazil, he interned at the Tecgraf Institute PUC-Rio and is currently a System Analyst at the same institution. In recent years, he has focused on real-time monitoring of medical systems, project management, UI/UX, and data analysis in interdisciplinary projects with Petrobras company.

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For those who had to say goodbye to their home country
and create a new one away from their relatives.

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Abstract

González Mondéjar, Abel; Raposo, Alberto Barbosa (Advisor); Silva Calpa, Greis Francy Mireya (Co-Advisor). **On the identification of Digital Phenotyping for Enhanced Bipolar Disorder Monitoring**. Rio de Janeiro, 2024. 160p. Tese de Doutorado – Departamento de Informática, Pontifícia Universidade Católica do Rio de Janeiro.

Bipolar disorder is a condition marked by changes between mania and depression, with the highest suicide rate in mental health diseases. To follow up patient behavior, digital technologies, such as mobile health (mHealth) applications, propose a continuous data collection of those patients using active data (patient input information such as daily mood) or passive data (collecting data from smartphone sensors). The information collected is the digital phenotype, but it often fails because the patient does not adhere to these solutions. In addition, capturing contextual information, such as the weather conditions of a patient's localization, is not considered. This thesis aims to develop a comprehensive digital phenotype framework that integrates active, passive, contextual, and clinical data (APCC), leveraging mHealth solutions to enhance the real-time monitoring, early detection, and personalized management of bipolar disorder. First, since there is no consensus on the relevant characteristics of mHealth, we conducted a systematic review of the literature that highlighted open gaps and opportunities. Then we developed a mHealth called BraPolar2 and collected active and passive data from 22 patients at the Institute of Psychiatry (IPUB) of the Federal University of Rio de Janeiro (UFRJ) for 6 months resulting in an adherence of 68.6%. Patients reported an improvement in their condition to manage their bipolarity in a semi-structured interview. Then, as contextual information is not considered in digital phenotype analysis, we validated the relevant variables with IPUB specialists in a semi-structured interview. Finally, we propose a unified dataset to contribute to the study of the digital phenotype in people with bipolar disorder with specialists. This thesis contributes by implementing strategies that improve adherence in mHealth, focusing on the potential benefits and challenges of using APCC data in clinical practice. The results underscore the importance of a multidisciplinary approach, including psychiatrists, to ensure that the system meets clinical needs and supports effective patient care.

Keywords

m-Health; bipolar disorder; data collection; digital phenotype; active data; passive data; contextual data; telemedicine; patient adherence.

Resumo

González Mondéjar, Abel; Raposo, Alberto Barbosa; Silva Calpa, Greis Francy Mireya. **Identificando a fenotipagem digital para um monitoramento aprimorado do transtorno bipolar**. Rio de Janeiro, 2024. 160p. Tese de Doutorado – Departamento de Informática, Pontifícia Universidade Católica do Rio de Janeiro.

O transtorno bipolar é uma condição marcada por mudanças entre mania e depressão, com a maior taxa de suicídio em doenças de saúde mental. Para acompanhar o comportamento do paciente, tecnologias digitais, como aplicativos de saúde móvel (mHealth), propõem uma coleta contínua de dados desses pacientes usando dados ativos ou dados passivos. As informações coletadas são conhecidas como fenótipo digital, mas muitas vezes falham porque o paciente não adere a essas soluções. Além disso, a captura de informações contextuais, como as condições climáticas da localização de um paciente, não é considerada. Esta tese visa desenvolver uma estrutura abrangente de fenótipo digital que integre dados ativos, passivos, contextuais e clínicos (APCC), alavancando soluções de mHealth para aprimorar o monitoramento em tempo real, a detecção precoce e o gerenciamento personalizado do transtorno bipolar. Primeiro, como não há consenso sobre as características relevantes do mHealth, conduzimos uma revisão sistemática da literatura que destacou lacunas e oportunidades abertas. Em seguida, desenvolvemos um mHealth chamado BraPolar2 e coletamos dados ativos e passivos de 22 pacientes do Instituto de Psiquiatria (IPUB) da Universidade Federal do Rio de Janeiro (UFRJ) por 6 meses resultando em uma adesão de 68,6%. Os pacientes relataram uma melhora em sua condição para gerenciar sua bipolaridade em uma entrevista semiestruturada. Então, como as informações contextuais não são consideradas na análise do fenótipo digital, validamos as variáveis relevantes com especialistas do IPUB em uma entrevista semiestruturada. Finalmente, propomos um dataset unificado para contribuir com o estudo do fenótipo digital em pessoas com transtorno bipolar com especialistas. Esta tese contribui implementando estratégias que melhoram a adesão em mHealth, com foco nos potenciais benefícios e desafios do uso de dados do APCC na prática clínica. Os resultados ressaltam a importância de uma abordagem multidisciplinar, incluindo psiquiatras, para garantir que o sistema atenda às necessidades clínicas e apoie o atendimento aprimorado ao paciente.

Palavras-chave

m-Health; transtorno bipolar; coleta de dados; fenótipo digital; dados ativos; dados passivos; dados contextuais; telemedicina; adesão do paciente.

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List of Abreviations

APK – Android Application Package

BD – Bipolar Disorder

CAAE – Certificate of Presentation of Ethical or *Certificado de Apresentação de Apreciação Ética*

CGI-BP – Global Clinical Impression for Bipolar Disorder

DFH – Distance from Home

DSM-5-TR – Diagnostic and Statistical Manual of Mental Disorders

DP – Digital phenotyping

EDA – Electrodermal activity

EMA – Ecological Momentary Assessment

EWS – Early Warning Signals

ICF – Informed Consent Forms

IPUB/UFRJ – Institute of Psychiatry of UFRJ or *Instituto de Psiquiatria da UFRJ*

ISAD-BR – Morbidity Awareness Test

LGPD – General Personal Data Protection Law or *Lei Geral de Proteção de Dados Pessoais*

MAUQ – Mhealth Usability Questionnaire

mHealth – Mobile health applications

PANSS – Positive and Negative Syndrome Scale

REC – Research Ethics Committee

SMS – Short Message Service

SUS – Unified Health System or *Sistema Único de Saúde*

UFRJ – Federal University of Rio de Janeiro or *Universidade Federal do Rio de Janeiro*

YMRS – Young Mania Rating Scale

Alis Grave Nil

Nothing is heavy to those who have wings, *PUC-Rio.*

1
Introduction

Bipolar disorder (BD) is a mental condition marked by changes between mania and depression (MARTINO; MAGIONCALDA, 2022) within the spectrum of schizoaffective disorder according to the Diagnostic and Statistical Manual of Mental Disorders (DSM-5-TR) (APA, 2022), making it a complex and demanding mental health diagnosis, which requires the clinical experience of psychologists and psychiatrists (BAUER; S., 2022). Usually, these specialists investigate patients with BD by assessing the severity of manic depression and severity of symptoms as perceived morbidity using a set of tests, such as the Young Mania Rating Scale (YMRS) (T; Z; STEFAN, 2023), the Hamilton Depression Rating Scale (HDRS) (BUSK et al., 2020), the Morbidity Awareness Test (ISAD-BR) (FONSECA; MOGRABI; LANDEIRA-FERNANDEZ, 2018), the Global Clinical Impression for Bipolar Disorder (CGI-BP) (KOZICKY et al., 2022) and the Positive and Negative Syndrome Scale (PANSS) (ANDERSON et al., 2017). Through them, it is possible to adjust the dosage of medications and follow-up with patients over time.

In addition to those tests, different studies have emerged that involve mobile health applications (mHealth) to track mood fluctuations in BD (FROST et al., 2013; FAURHOLT-JEPSEN et al., 2019; SEPPäLä et al., 2019; MONDEJAR et al., 2019a; DAUS et al., 2020a; FAURHOLT-JEPSEN; KESSING, 2022; GARCíA-ESTELA et al., 2022). Those studies focus on identifying patient behaviors that can indicate the beginning of manic or depressive episodes (FELLENDORF et al., 2021; LIN; CHIOU, 2022; BOS et al., 2022a). This contributes to the early detection and prediction of changes in patients with BD (PUIATTI et al., 2011), reducing the risk of significant functional impacts. For that, specialists can use the collected data from mHealth applications to offer personalized monitoring by tracking sleep patterns, activity levels, social interactions, and mood fluctuations. This information, over time, provides valuable information for early detection and monitoring of treatment outcomes (MONDEJAR et al., 2019a; EBNER-PRIEMER et al., 2020a; PANDEY; AZLAN; GILLETT, 2022; MAATOUG et al., 2022). This continuous follow-up is known as the *digital phenotype*, which refers to the use of digital technologies, such as smartphones and wearable devices, to collect and analyze data on individuals' behaviors, activities, and physiological responses to gain insight into their mental health conditions (ORSOLINI; FIORANI; VOLPE, 2020).

As the digital phenotype requires data collection over time, we categorized them into active and passive data. While active data consists of information users input consciously and voluntarily into the mHealth application, such as their mood or energy, passive data are automatically collected by smartphone sensors in the background, capturing information such as acoustic characteristics or the duration of phone calls (MONDEJAR et al., 2019a). As the data collected are widely used in mHealth solutions (FAURHOLT-JEPSEN et al., 2019; MONDEJAR et al., 2019a; MONDEJAR et al., 2020; GHOSH; DEY, 2021; GARCíA-ESTELA et al., 2022) (FAURHOLT-JEPSEN; KESSING, 2022), in a previous study, we developed a mHealth named BraPolar (MONDEJAR et al., 2019a; MONDEJAR et al., 2020) to capture active and passive data in bipolar people. In that study, we identified that the data collection process can be compromised if users do not use the application or the application does not have all the necessary strategies to collect data from users.

In addition to active and passive data used in mHealth applications, contextual data such as temperature, sunlight, atmospheric pressure and relative humidity, directly and indirectly, influence patients with bipolar disorders, being able to modulate their moods in general or intensify bipolar episodes (MONTES; SERRANO; PASCUAL-SANCHEZ, 2021). This information can provide relevant information that could help specialists analyze variables such as weather, temperature, and holidays, which can influence clinical evaluation (HIRAKAWA; TERAO, 2022). Thus, this study used this combination of active, passive, and contextual data collection, which we denominated as APCC data (active, passive, and contextual). Although this approach could be promising, active data require patient adherence and lack of them can compromise research quality (JAKOB et al., 2022); concerning passive data, inadequate sensor definition can imply battery drain (CONSTANTINIDES et al., 2018); insufficient data analysis from collected data presented to specialists can compromise consultation quality (SIEGEL-RAMSAY et al., 2023) and contextual data are ignored.

Observing traditional follow-up in people with bipolar disorder and the lack of adherence to mHealth applications, we developed a set of strategies to improve adherence and, consequently, digital phenotype analysis by specialists. As this may be challenging, a strategy considering APCC data may help specialists improve patient follow-up. So, **we argue that the use of APCC strategy it may improve the analysis of specialists in the follow-up of bipolar patients**.

To test our argument, we first evaluate trends and relevant characteristics in studies related to mHealth, particularly active and passive data collection strategies. Then, based on the experience of our previous studies (MONDEJAR et al., 2019a; MONDEJAR et al., 2020), we developed an mHealth called BraPolar2, supported by specialists from the Institute of Psychiatry (IPUB) of the Federal University of Rio de Janeiro (UFRJ), and tested initially with 22 bipolar people for six months. Then, we evaluated the influence of contextual data in clinical assessment. Finally, we summarized the APCC data and the results of the psychological scale to evaluate the data collected with specialists, encapsulating all sets of steps in decision support data. The proposed decision support data intends to be able to provide a non-intrusive mHealth to monitor people with bipolar disorder, reducing user interaction and improving adherence and study quality. In addition, the mHealth application developed as part of this work can help specialists have a decision support system to follow up with patients with bipolar disorder.

1.1 Research problem statement

Although the potential of the analysis of the digital phenotype is promising, the evidence base for their use in terms of data collection strategies, adherence to mHealth, and non-consideration of contextual data is still limited. Furthermore, the first problem is that there is no agreement on how and what mHealth features (sensors and final-user interaction) are necessary to collect active and passive data in mHealth applications. Second, people's non-adherence to mHealth could lead to suboptimal quality studies and make data difficult for specialists to interpret. Finally, context-sensitive data analysis is not addressed and could enhance specialist analysis. In summary, these are the key problems addressed in this thesis.

- **Problem 1**: Lack of definition in collecting active and passive data features in mHealth applications.
- **Problem 2**: Insufficient adherence of patients with bipolar disorder to mHealth applications.
- **Problem 3**: Missed contextual data in digital phenotype analysis.
- **Problem 4**: Insufficient datasets with the integration of APCC data.

Finally, the main scope of the investigation is aligned to evaluate a strategy that considers data collection strategies, ensuring scalability, and improved digital phenotype analysis. As a consequence, a decision support dataset was obtained that considers data analysis to improve digital phenotype analysis; furthermore, the experience of more than six years in a similar project

(MONDEJAR et al., 2019a; MONDEJAR et al., 2020; MONDEJAR et al., 2024) allows the use of a strategy to collect contextual data in people with bipolar disorder.

1.2 Goal and research questions

Develop a comprehensive digital phenotype framework that integrates active, passive, contextual, and clinical data, leveraging mHealth solutions to enhance the real-time monitoring, early detection, and personalized management of bipolar disorder. Therefore, in this thesis, we expect to answer the following research questions:

- **RQ1**: What are the relevant features for collecting active and passive data in mHealth applications?
- **RQ2**: What factors influence adherence to mHealth applications? How can it be improved in patients with bipolar disorder?
- **RQ3**: How contextual data can improve digital phenotype analysis by specialists?
- **RQ4**: How to integrate active, passive, contextual, clinical and demographical data?

1.3 Research method

To address the research questions raised, we conducted the following steps. First, through a Systematic Literature Review (SLR), we investigated the trends and relevant features to collect active and passive data. Then, considering the SLR findings that adherence to mHealth can compromise study quality due to the lack of collected data, we brainstormed with IPUB specialists to define the necessary features of a mHealth (BraPolar2) considering the minimum interaction with the patient application to improve adhesion, as excessive information requests impact user adhesion to mHealth. Later, we conducted a longitudinal study, initially with 22 patients with bipolar disorder at the IPUB Institute and verified adherence to BraPolar2 (MONDEJAR et al., 2024). Then we highlight the relevance of contextual data in clinical assessment and propose conducting a semi-structured interview with IPUB specialists. Finally, we propose a strategy to improve the analysis of the digital phenotype with specialists through data set support that considers APCC data collected over time of bipolar people as a encapsulated use case.

As a result, we identified a set of relevant features to evaluate the digital phenotype in mHealth applications. Regarding adherence, we observed that the BraPolar2 application is easy to use and has a positive effect on patients with bipolar disorder, demonstrating adherence of 68.64% to the developed mHealth. In addition, we obtain feedback by specialists about the relevance of contextual data. Finally, we generate a dataset to be evaluated in further studies.

1.4 Main contributions

This thesis' contributions are detailed and linked with brief descriptions and citations of our published articles in recent years, which have made contributions to research and the field of health information by developing mHealth to follow bipolar people (MONDEJAR et al., 2019a) supported by the cell dependency test and the usability evaluation (MONDEJAR et al., 2020) with specialists. Even if they do not directly align with the objectives of this work, their influence and experience obtained over the years helped to create the support system proposed in this work. The main contributions of this thesis are listed below, sorted by research question (RQ).

RQ1 - What are the relevant features for collecting active and passive data in mHealth applications? :

– **Literature gap**: Data Collection in mHealth: no clear features and method to collect data (KAPPELER-SETZ et al., 2013; COELHO; BASTOS-FILHO, 2016).
  Our contribution: Identify trend keys for active (user input, mood tracking, medication adherence) and passive features (sensor data like screen time, GPS, sleep patterns) for bipolar disorder monitoring. These features help build better data-driven models for digital health, optimizing data acquisition in mHealth applications.

– **Literature gap**: Many patients with bipolar disorder may not be familiar with mobile apps designed for disease management and monitoring (HOLMES et al., 2016; ZULUETA et al., 2018; EBNER-PRIEMER et al., 2020a).
  Our contribution: Insights on how user-friendly interfaces can improve the efficiency of active data collection, making data input easier and more intuitive for users, particularly in the mental health domain.

RQ2 - What factors influence adherence to mHealth applications? How can it be improved in patients with bipolar disorder?:

- **Literature gap**: Lack of compliance to LGPD (MONDEJAR et al., 2019a; MONDEJAR et al., 2020).
  Our contribution: Certificate of presentation of Ethics Review number 60585422.3.0000.5263 (CAEE in Portuguese) and Informed consent form for patients and specialists.

- **Literature gap**: Personalized solution for public mental health institutions (MONDEJAR et al., 2024).
  Our contribution: A registered mHealth (BraPolar2) to capture active and passive data from cellphones in people with bipolar disorder shows the feasibility of the proposed solution in Brazilian public health.

- **Literature gap**: Low adherence/engagement to mHealth applications (YILDIRIM; CORREIA, 2015; JAKOB et al., 2022; MONDEJAR et al., 2024).
  Our contribution: An adaptation of the mHealth usability questionnaire to conduct a qualitative interview in mHealths. Adhesion of 68.6%, above the average of 56.6% for mHealths.

- **Literature gap**: Exhaustive cellphone dependency test (MONDEJAR et al., 2024).
  Our contribution: Dependency ratio formula, considering screen interaction over time (DEPr = (TOi/DCd)/100), from collected passive data.

RQ3 - How contextual data can improve digital phenotype analysis by specialists?:

- **Literature gap**: Digital phenotype analysis does not consider contextual variables (DORNELES et al., 2023; MONDEJAR et al., 2024).
  Our contribution: By incorporating contextual data (for example, weather and social events), the thesis demonstrates how external factors influence mental health and how they can be integrated into AI models for phenotype analysis. The inclusion of contextual data to improve the analysis of digital phenotype who contributes to more precise predictive

analytics in mental health monitoring.

- **Literature gap**: No clear statement on how contextual data could be incorporated into Clinical Decision Support Systems (CDSS) (CHAPMAN et al., 2017; BARBOSA et al., 2021; HIRAKAWA; TERAO, 2022; AL-SAEDI et al., 2022).
  Our contribution: Specialists can use the enhanced digital phenotype data for more accurate clinical decision-making, improving telemedicine diagnostics by considering a fuller picture of the patient's environment and behavior.

RQ4 - How to integrate active, passive, contextual, clinical and demographical data?:

- **Literature gap**: Heterogeneous data sources (LAZAR; FENG; HOCHHEISER, 2017).
  Our contribution: Research provides a framework for integrating heterogeneous data sources, creating a unified data set that improves the accuracy of general data and the insight of the patient. This improves data interoperability in digital health knowledge.

- **Literature gap**: No clear consensus for the architecture of the scalable mHealth systems (DELWICHE; SLAUGHTER, 2019). **Our contribution**: The integration framework contributes to the design of a scalable system architecture that handles various data types and sources in real time, supports telemedicine applications, and improves patient monitoring.

- **Literature gap**: Not enough datasets related with mental disorder (MONDEJAR et al., 2019a; MONDEJAR et al., 2020; WILKERSON; LANOUETTE; SHAREFF, 2021; MONDEJAR et al., 2024).
  Our contribution: A dataset containing active, passive and contextual data from patients with bipolar disorder in Brazil.

1.5 Thesis structure

This thesis is structured as follows: In **Chapter 2**, we present background information to support the understanding of this research. In **Chapter 3**, we discuss related work to contextualize this thesis concerning the literature. In **Chapter 4**, we present the approach proposed in this investigation, where we present the SLR results with the relevant features to collect active and passive data in mHealth. In addition, we mention the BraPolar2 redesign process and two adherence studies evaluating this characteristic in bipolar patients. Later, we conducted a semi-structured evaluation with 11 specialists to obtain their perception of the relevance of contextual data. Also, we present the data preparation process to be analyzed in the subsequent studies by specialists. Moreover, **Chapter 5** presents the publications obtained over the years of research, limitations and the following steps that will be carried out in future work. Finally, **Chapter 6** and **Chapter 7** present bibliography and annexes, respectively, containing the supporting material for this thesis.

2
Background

This chapter presents the theoretical basis of this research. First, we describe the main concepts of bipolar disorder, how patients are treated at IPUB Institute, and how specialists analyze demographic and clinical information. Then, we mention contextual data concepts and digital phenotype as the use and influence of mobile technologies to monitor and treat bipolar people through active and passive data.

2.1
Bipolar disorder

Bipolar disorder is a recurrent, chronic, and severe disease that significantly affects the quality of life of the patient and burdens the family and society, making it the second most challenging mental illness to treat (BAUER; S., 2022). Individuals with bipolar disorder experience fluctuating mood states, including manic, depressive, and sometimes mixed states, with depressive episodes being the most common cause of morbidity and suicide (BAUER, 2022).

According to the Diagnostic and Statistical Manual of Mental Disorders (DSM-5-TR) (APA, 2022), bipolar disorder is classified into two types: type I and type II. Although type I consists of one or more manic episodes or mixed episodes, in type II there are one or more major depressive episodes accompanied by at least one hypomanic episode (APA, 2022). In both types of bipolar disorder, there exists a lack of self-awareness (SILVA et al., 2014) that compromises adhesion to treatment.

2.2
Support patients with BD in IPUB Institute

Patients with bipolar disorder typically engage with healthcare specialists (psychologists and psychiatrists) considering the following circumstances: by their own decision (voluntarily), by the recommendation of their specialists, or by suggestions from a family member or companion. These services are accessible through the private medical center or the Unified Health System (SUS in Portuguese). These services, conducted through the Psychosocial Care Network (RAPS in Portuguese), provide support at various points of care for people with mental disorders or problems arising from the use of crack, alcohol and other drugs. In this direction, a reference Institute in Rio de Janeiro is the Institute of Psychiatry of the UFRJ (IPUB) (Figure 2.1).

Figure 2.1: Institute of Psychiatry at the Federal University of Rio de Janeiro (IPUB)

The IPUB is a multiservice center: educational institution, university hospital with an outpatient clinic, inpatient wards, emergency on-call, and day services, among others. This center constitutes a psychiatric institution and maintains clinical research in psychoanalysis. To develop the work of researchers, they have the voluntary participation of patients and, above all, the participation of almost all researchers in the care provided at the institution, providing direct care or supervision to patients with mental illnesses treated at the IPUB (FIGUEIREDO; TENÓRIO, 2002). One of the areas of particular relevance is the consultation and monitoring of people with mental disorders and bipolar disorder.

The IPUB has a multidisciplinary team of psychologists and psychiatrists who treat people with bipolar disorder and provide free weekly consultations. In addition, it has collaborated with the Department of Psychology at PUC-Rio in research related to bipolar disorder (SILVA et al., 2013; De Assis Da Silva et al., 2014).

2.3 Demographic and clinical data

On average, follow-up in patients with bipolar disorder in IPUB is once a month but can be more or less frequent depending on the severity. In the first consultation, specialists record demographic data from the patient, for example, name, age, first bipolar episode, previous clinical data, number of admissions, predominant polarity, polarity of the first episode, and number of suicide attempts. At various times, but not continuously, clinical assessment scales are applied, primarily related to symptoms of mania and depression, which are also registered. Storing this prior patient information is essential, as specialists take the history and evolution of the disease over time as a reference when evaluating the patient's current status.

One of the several tests used by specialists for patient evaluation is the Young Mania Rating Scale (YMRS) providing a comprehensive evaluation of manic symptoms (ALTMAN; ØSTERGAARD, 2019), the Hamilton Rating Scale for Depression (HRSD) for depression evaluation (FENTON; MCLOUGHLIN, 2021), the Clinical Global Impression-Bipolar (CGI-BP), providing clinicians with a comprehensive understanding of symptom severity and treatment response (SAMARA; LEVINE; LEUCHT, 2023) and the Positive and Negative Syndrome Scale (PANSS) is commonly used to assess negative symptoms in bipolar disorder patients, revealing a two-dimensional structure consisting of diminished expression and apathy, akin to non-affective psychotic disorders (IHLER et al., 2023). With the results of those scales, specialists can administer or adjust drug treatment as soon as the patient needs it, the most common being lithium carbonate (Avelar Ferreira et al., 2014), and non-pharmacological methods used as a complement can positively influence patient improvement. However, the lack of self-awareness in patients of their disease makes it challenging to define a diagnosis, influence patient adherence to treatment (SILVA et al., 2014), and impact the course of the disease.

2.4 Contextual data

Despite the mentioned factors that can influence patient adherence to a continuous follow-up of their disease, factors such as temperature, sunlight, atmospheric pressure, and relative humidity directly and indirectly affects patients with bipolar disorders, allowing them to modulate their moods in general or intensify bipolar episodes (MONTES; SERRANO; PASCUAL-SANCHEZ, 2021). The rise in temperature and extra sunshine for more than four months can make a person vulnerable to more manic episodes and relapses, and hence hospital admissions. Weather can influence mood changes seasonally, with a daily maximum temperature significantly predicting the onset of the transition to manic mood states (HIRAKAWA; TERAO, 2022). The associations between vulnerability to climate conditions and lifetime suicide attempts that have appeared in patients with bipolar disorder constitute an important factor to be taken into account when treating bipolar disorder and remain a challenge to be abroad in digital solutions.

2.5 Active and passive data

Several mHealths are studied for their potential application in the treatment of bipolar disorder. By continuously monitoring illness activity, monitoring mood, psychoeducation, and medication tracking (BARDRAM; MATIC, 2020). Research shows that smartphone monitoring can identify emerging changes in bipolar disorder symptoms and offer early interventions (FAURHOLT-JEPSEN; BAUER; KESSING, 2018). These results are comparable to the few studies that used smartphone sensor data (for example, location and application use) to detect self-reported symptoms of depressive episodes and manic episodes (ANTOSIK-WóJCIńSKA et al., 2020). More research is needed to confirm these results and to create functional instruments to monitor and predict phase changes in bipolar disorder (DUNSTER; SWENDSEN; MERIKANGAS, 2021). As a result, mobile applications can help diagnose and manage bipolar disorder but require more research and standard regulation.

Active data

A study by CARVALHO et al. (2019) highlights that the digital phenotype and technology can help traditional psychiatry because the collection of smartphone data in patients allows the discovery of behavioral data, such as erratic or exaggerated sending and response patterns. Messages/calls, risk-taking behavior could be corrected if tracked by GPS, and even impulsivity based on physiological data, such as heart rate or excessive screen use. In addition, the author (CARVALHO; PIANOWSKI, 2019) emphasizes that the main advantage has a reference over time to assess these people's data retrospectively, but that no solution effectively captures these possible behavioural markers that can be improved using active and passive data.

Passive data

As mHealth applications can capture multiple human behavior and activity dimensions data, those allow evaluations in naturalistic settings (BARDRAM; MATIC, 2020). They can collect passive data on behavioral aspects such as mobility, physical activity, phone call statistics, and voice characteristics, which may be markers for monitoring disease activity (SEDANO-

CAPDEVILA et al., 2021). When active data are combined with passive data, the accuracy of monitoring and predicting mood states can be increased (HEYDARIAN; SHAKIBA; KALHORI, 2023). However, there are limitations to consider. Some applications do not protect privacy and evidence-based content (FAURHOLT-JEPSEN; BAUER; KESSING, 2018). The heterogeneity of the symptoms of bipolar disorder and the lack of reproducibility pose challenges for the development of apps (ANTOSIK-WóJCIńSKA et al., 2020) (DUNSTER; SWENDSEN; MERIKANGAS, 2021). Furthermore, the validity of self-monitored smartphone-based symptoms compared to clinically assessed symptoms is still being investigated. Despite these limitations, mHealth has the potential to play a significant role in supporting patients with bipolar disorder by providing tools to monitor, predict, and manage their condition.

2.6 Digital phenotype in mental health monitoring

The rise of mobile technologies has improved the treatment of mental health conditions, helping patients and specialists to closely detect and follow fluctuations in Early Warning Signals (EWS) of bipolar disorder. This section describes how digital technologies are used in this scope.

First, it is important to note that a phenotype refers to the observable characteristics or traits of an organism produced by the interaction between its genetic constitution and the environment (MONTANUCCI et al., 2023). This principle is fundamental in study areas, including genetics (MONTANUCCI et al., 2023), ecology (RöCKEL et al., 2022), and also used in the area of mental health (MONDEJAR et al., 2019b; EBNER-PRIEMER et al., 2020b; ORSOLINI; FIORANI; VOLPE, 2020). As patients with mental illness use digital technologies, some studies focus on identifying EWS: patient behaviors that can indicate the beginning of manic or depressive episodes (BOS et al., 2022a). This concept is widely recognized in the literature (FELLENDORF et al., 2021; LIN; CHIOU, 2022), and the main EWS usually includes the frequency and intensity of physical movement, social interaction, psychological stress, and mood changes.

EWS data can improve early detection and prediction of changes in patients with bipolar disorder (PUIATTI et al., 2011), reducing the risk of significant functional impacts. Continuous evaluation of EWS enables personalized monitoring by specialists, including tracking sleep patterns, activity levels, social interaction, and mood fluctuations, which provides valuable information for early detection and monitoring of treatment outcomes (MONDEJAR et al., 2019a; EBNER-PRIEMER et al., 2020a; PANDEY; AZLAN; GILLETT, 2022; MAATOUG et al., 2022). In the literature, this continuous monitoring is known as **digital phenotype**, which refers to the use of digital technologies, such as smartphones and wearable devices, to collect and analyze data on individuals' behaviors, activities, and physiological responses to gain insight into their mental health conditions (ORSOLINI; FIORANI; VOLPE, 2020).

2.7 Challenges collecting data in mHealth

Considering mHealth has helped patients with mental illness follow their mood and energy fluctuations, these solutions (GARCíA-ESTELA et al., 2022; FAURHOLT-JEPSEN; KESSING, 2022) require users to interact with mHealth when collecting active data actively. One factor to consider is encouraging patients' adherence to mobile applications; in this sense, MURNANE ET AL. (2015) conducted a study to analyze the reasons for adopting, adhering, and abandoning mHealth. The study showed that users could quickly uninstall the app on their mobile devices if it bothers them with too many notifications, causes battery drain, or does not notify them of any activity.

Recent studies (GROSSMAN et al., 2020; PATOZ et al., 2021; LEIZ et al., 2022; ORTIZ et al., 2023a; PAHWA et al., 2024) highlight the difficulty in patient adhesion to mHealth, and we consider this factor relevant when dealing with patients with bipolar disorder. Therefore, researchers must look for less intrusive alternatives that do not interfere with patient's daily life and provide more reliable information. Also, in conjunction with an awareness of the application's use during the disease, active data collection (requires the user to interact with the application) and passive data (data collected without user intervention) are relevant to be addressed.

A study by BOURLA ET AL. (BOURLA et al., 2018) recommends using background data on mobile assets managed by mHealth. The author considers that automatically generated (passive) data reduces biases and limits the sense of invasion that questionnaires can cause; however, specialists mentioned (MONDEJAR, 2019) that mHealth should be used as a complement in clinical evaluation. Baldram (BARDRAM; FROST; MARCU, 2011) showed that patients preferred the app over the old paper questionnaire system and observed that patients with bipolar disorder interacted more through their electronic devices than in the real world, opening a new field: digital phenotype analysis. In the chapter, we mention some mHealth solutions to follow up with people with bipolar disorder.

3
Related Work

This chapter presents work related to this research, mainly on studies involving mHealth applications to collect data from individuals with bipolar disorder. Additionally, we highlight the open opportunities that our research aims to address.

Considering the relevance and complexity of the follow-up of patients with bipolar disorder, we found a set of Systematic Literature Review (SLR) performed over the last five years in which we identified that psychiatric patients have an increased risk of suicide. As follow-up patients is crucial, SEDANO ET AL. (2021) investigated the effects of mHealth applied to ecological momentary assessment (EMA). EMA is a method of evaluation that consists of asking patients questions in real-time and in the patient's usual environment. BADRAM ET AL. (2020) focused on a one-decade analysis. The authors examined a set of SLRs in a historical context and evaluated them based on the specific mental disorders, the technology that those works have used, and the nature and scale of the clinical investigations in which they have been used. A work by DUNSTER ET AL. (2021) emphasizes using active and passive data collected in real-time in a systematic review, highlighting the relevance of circadian cycles, sleep patterns, and motor activity in people with bipolar disorder. Finally, ANTOSIK ET AL. (2020) investigated the most common data analysis, machine learning algorithms, and predictive modeling in mHealth data with patients with bipolar disorder, addressing the current literature and considerations of methodology.

3.1
mHealth solutions in the literature

In this section, we present mHealth solutions to follow up with people with bipolar disorder and recent related work. We also discuss the benefits and limitations of mobile apps in supporting patients with bipolar disorder.

As smartphones have become ubiquitous, it opens opportunities to passively, actively, and continuously measure people's mood, cognition, and behavior, especially during the COVID-19 pandemic (TOROUS; BRADY, 2020). In this context, several mHealth solutions have been developed over time to monitor people with bipolar disorder (FAURHOLT-JEPSEN et al., 2019; MONDEJAR et al., 2019a; MONDEJAR et al., 2020; GHOSH; DEY, 2021; GARCíA-ESTELA et al., 2022; FAURHOLT-JEPSEN; KESSING, 2022). Research using mHealth and treatment (TOROUS; BRADY, 2020; GHOSH; DEY, 2021) has already demonstrated positive results in improving mental health care for patients with bipolar disorder (FAURHOLT-JEPSEN; KESSING, 2022). Below, we describe some examples of solutions and projects in this area.

- MONARCA I and II (FAURHOLT-JEPSEN et al., 2019; FAURHOLT-JEPSEN; KESSING, 2022) is a project with two versions that help users monitor and visualize their behavior. For example, it indicates users' physical state, reminding them to perform specific tasks. It provides feedback on their behaviors and recommends healthier actions. Although trials did not show a reduction in readmissions, the author suggests improvements in quality of life and reduced perceived stress.
- SIMPLe (GARCíA-ESTELA et al., 2022) is a smartphone app for bipolar disorder that uses technology and evidence-based interventions to provide access to psychoeducational content. Through projects, a web-based questionnaire on clinical data and treatment history at the beginning and after six months, subjective data from continuous app use, and usage patterns recorded by the app server.
- BraPolar (MONDEJAR et al., 2019a; MONDEJAR et al., 2020) is a mHealth application developed to assist specialists in monitoring persons diagnosed with bipolar disorder. The application gathers data on cellphone addiction and uses it to identify changes in patient behavior, aiming to identify variations in mood and behavior, offering early signs of mood shifts before they lead to severe functional outcomes. As both studies were conducted with non-bipolar people, it is necessary to consider specific variables for those populations regarding adherence, considering this is a frequent limitation in both studies.

Although these solutions provide different approaches to monitoring people with bipolar disorder, the MONARCA I, MONARCA II, SIMPLe, and our previous mHealth solution BraPolar (MONDEJAR et al., 2019a; MONDEJAR et al., 2020) exhibit several limitations. On the one hand, MONARCA I (FAURHOLT-JEPSEN et al., 2019) may not be as effective as active data in recognizing early signs of depression and mania; on the other hand, the MONARCA II (FAURHOLT-JEPSEN; KESSING, 2022) experiment seeks to overcome this constraint using a smartphone system that combines subjective and objective indicators of illness activity in both. They did not consider observation strategies to improve adherence to the study, leading to data collection issues. Finally, SIMPLe (GARCíA-ESTELA et al.,

2022) shows difficulties with the effectiveness and evidence-based support of the app for user adherence, along with biases and costs.

Despite the constraints that underscore the difficulties in creating and executing mHealth solutions, which involve concerns about effectiveness (FAURHOLT-JEPSEN et al., 2019), user-friendliness (FAURHOLT-JEPSEN; KESSING, 2022), costs (GARCíA-ESTELA et al., 2022), data collection process (SEDANO-CAPDEVILA et al., 2021) (HEYDARIAN; SHAKIBA; KALHORI, 2023) and lack of clear definition of sample size 2020 and adherence to mHealth were frequent limitations in the analyzed studies and are summarized in Section 3.3.

3.2
BraPolar mHealth application previous version

Considering the potential to follow people with bipolar disorder, in this section, we mention the development process of the first version of BraPolar (patient and specialist versions) (MONDEJAR, 2019) as the main results of the evaluations carried out.

Development and tests with BraPolar (patient version)

In the first version of BraPolar (MONDEJAR et al., 2019a), we developed a pilot version to collect active and passive data involving six non-bipolar disorder users (3 men and 3 women), with an age range of 26 to 54 years, intending to identify usability problems according to different ages and different levels of dependence of user cell phones, to evaluate the application with bipolar disorder users later.

First, we brainstormed with five specialists and identified a set of key parameters that could indicate EWS and serve as a basis for the longitudinal study, and were summarized in active (mood, specialized assistance, medication, sleep patterns, overview of status) and passive data (social interaction, physical and psychomotor activity, and acoustic characteristics) (MONDEJAR, 2019).

Second, we intended to carry out the tests involving patients with bipolar disorder. However, we needed the prior approval of the IPUB Research Ethics Committee and the submission of the project to "*Plataforma Brasil*" to carry out experiments with human beings. Considering that this last process can take time, we decided to carry out this pilot study with six non-bipolar volunteers. Then, we conducted a cell phone dependency test (YILDIRIM; CORREIA, 2015) with those volunteers (Table 3.2) and performed a set of activities. As a result, we identified, for example, that some participants with greater cell dependence did not feel comfortable viewing stored information, a factor that we believe to be harmful in further studies of patients with bipolar disorder.

Table 3.1: Cellphone dependency test results

Participant	Sex	Age	Punctuation	Nomophobia
P1	M	53	80	Medium
P2	F	26	35	Low
P3	F	54	106	Critical
P4	F	35	68	Medium
P5	M	51	41	Low
P6	M	47	92	Medium

Taking into account the feedback of participants and specialists' requirements, we designed and developed the BraPolar application and installed the application on volunteers' cell phones in an exploratory way for one month to collect the digital phenotype, and a cell phone dependency test (YILDIRIM; CORREIA, 2015) was conducted to evaluate the degree of cell phone of each participant. Figure 3.1 shows a sample of mood functionality (left) where the volunteer defines their mood by sliding an indicator and the dashboard (right) where the volunteer could view all collected data.

Figure 3.1: Examples of Mood (left) and Dashboard (right) interface in previous version of BraPolar

At the end of the test period, we apply a usability test. First, we use the Think Aloud technique (BONNER et al., 2021) to better identify the interaction experience of the participant with the application, focusing on the user's reaction, the user interface, the terminology, and the information of the application, the learning and use, the data collected and the capacity of the system, applying the User Interaction Satisfaction Questionnaire (QUIS) (GAO; BOEHM-DAVIS, 2023) where was evaluated how users interact with the app, terminology and information presented, learning and using the application, response time of the app, etc. (MONDEJAR, 2019). As a result, participants showed that the application was easy to use, the terminology was clear, and the user interface was appropriate and similar to other applications. Their reaction was observed before and after the interaction. Although the response time to the application was satisfactory, participants in the elderly group had difficulty installing the application, asking for more detailed information at the beginning of the test.

Once we developed the patient version, we developed the necessary functionalities for specialists to use the BraPolar version.

Development and tests with BraPolar (specialist version)

While the BraPolar version developed for patients collected data for three months with volunteers described in the previous subsection 3.2, we developed a BraPolar version for specialists (MONDEJAR et al., 2020). This BraPolar variation aiming follow up patients in next studies. Once the development process was completed, we tested the application with five experts (two psychiatrists and three psychologists). These specialists, aided by the results of the cell dependency test, performed the evaluation using BraPolar. While volunteers used the application (Figure 3.2-left), specialists could follow up (Figure 3.2 right) mood fluctuations of each patient, for example. As a result, they confirmed the relevance of previous knowledge in cell dependency testing and the digital phenotype in remote monitoring in real-time with BraPolar. In addition, using information presented as status and trait markers of non-invasive therapeutic intervention in further studies with patients with bipolar disorder. They also proposed recommendations and reaffirmed the relevance of continuing the project for future evaluations.

Figure 3.2: BraPolar versions: patient (left) and specialist (right)

Finally, a QUIS (GAO; BOEHM-DAVIS, 2023) was applied with five specialists who mentioned the relevance of BraPolar in future clinical evaluations, as they could identify variations in mood and behavior, providing early signs of mood changes before they lead to severe functional outcomes. All extended feedback was summarized in the Master's dissertation (MONDEJAR, 2019) of this author, highlighting the low resource consumption of BraPolar and open opportunities abroad in Section 3.2 of this doctoral thesis.

3.3 Open opportunities and gaps

In the previous section, we mentioned some of the solutions to follow up with people with bipolar disorder. However, after more than six years of research, we identified some common points that must be addressed.

Lack of clarity about relevant features of mHealth to collect active and passive data

mHealth solutions are widely applied in the treatment of mental illness (GHOSH; DEY, 2021) supported by a wide range of sensor-based data streams from location, accelerometer, and social information. These streams provided information on behaviors such as sleep patterns, physical activity, and social interactions (JACOBSON; SUMMERS; WILHELM, 2020; MELCHER; HAYS; TOROUS, 2020), improving the analysis of the digital phenotype. However, there is no clear consensus on all the requirements of

mHealth to support follow-up in patients with bipolar disorder. In addition, it is necessary to optimize strategies to reduce battery drain (ONNELA, 2020). At the same time, data collection is performed on patient smartphones to avoid rejecting the use of mHealth on patient smartphones. These aspects led to the definition of the first research question of this thesis:
RQ1: What are the relevant features of mHealth that can be used to collect active and passive data?

Lack of adherence in mHealth applications
The lack of adherence of participants to mHealth is a common problem (RYAN et al., 2020; DOMINIAK et al., 2022; ORTIZ et al., 2023b). This implies missing data and greater uncertainty compared to clinical data acquisition (SIEGEL-RAMSAY et al., 2023) that affects the quality of the study; also, poor recruitment and inadequate resource allocation are common challenges that can hamper the assessment of mHealth interventions with the clinical trial methodology (JAKOB et al., 2022). In previous work (MONDEJAR et al., 2019a; MONDEJAR et al., 2020), we mention the relevance of the longitudinal study proposed by IPUB specialists. From that, we defined the second research question of this work:
RQ2: What factors influence adherence to mHealth applications? How can it be improved in patients with bipolar disorder?

Contextual data in digital phenotype
Digital phenotype refers to the diversity and complexity of an individual's digital behaviors and characteristics, particularly regarding active and passive data. Considering that AD and PD collected over time can help specialists improve their analysis (MONDEJAR et al., 2020), contextual data such as weather conditions and traffic, for example, were ignored. Those variables could indicate ambient situations that can subjectively influence user decisions, such as stress, depression, or happiness collected by AD and PD. Finally, since the researched studies do not consider contextual data in digital phenotype analysis, we address this thesis's third research question:
RQ3: How can contextual data improve digital phenotype analysis?

Data merge and preparation for next statistical analysis
Integration and statistical analysis of various types of data (BIN et al., 2020) (active, passive, contextual, clinical, and demographic) collected through mHealth solutions and the psychological test are the key to understanding patient behavior, symptom patterns, and potential triggers in the treatment

of bipolar disorder. However, at the end of this work, we had five different datasets. It remains necessary to structure them to improve the data analysis process in statistical software such as SPSS. Therefore, we propose the following research question.
RQ4: How can we integrate several sources of active, passive, contextual, clinical, and demographic data to provide a comprehensible data set for specialist analysis?

3.4 Conclusions

In this chapter, we explored various aspects of Bipolar Disorder and the potential of the digital phenotype to improve the treatment and management of this complex condition. We discussed the role of mobile technologies and the digital phenotype in bridging this gap. Using smartphones to collect active and passive data presents a promising approach to monitoring mood, cognition, and behavior in patients with bipolar disorder. The next chapter details the methodology for satisfying each open gap mentioned above.

4
Proposed Approach

This thesis aims to contribute to the enhancement of digital phenotype analysis in m-health applications for individuals with bipolar disorder using active, passive, contextual, clinical and demographic data. To achieve this objective, we structure our proposal into four main research questions. First, our objective was to identify the relevant features in m-Health to collect active and passive data (RQ1). To respond to that topic, we conducted a Systematic Literature Review (SLR) involving questions about features and data collection methods used in m-health applications, described in Section 4.1. Later, we aimed to know the factors that influence adherence to m-health applications and how to improve it (RQ2). For that, we research those factors both in the literature and with specialists in Bipolar Disorder. That research allowed us to redesign the previous BraPolar application (MONDEJAR et al., 2019a; MONDEJAR et al., 2020) into a new one with features to improve adherence and was initially tested with 22 IPUB bipolar patients (MONDEJAR et al., 2024). The development process was described in Section 4.2. Then, we hypothesize and investigate how contextual data can improve clinical assessments (RQ3), described in Section 4.3. To address this question, we evaluated past and consultation-day contextual data to support the final stage of this proposal. Finally, we present a set of steps to conform a dataset merging active, passive, contextual, clinical, and demographic data (RQ4), described in Section 4.4. These steps are summarized in Figure 4.1.

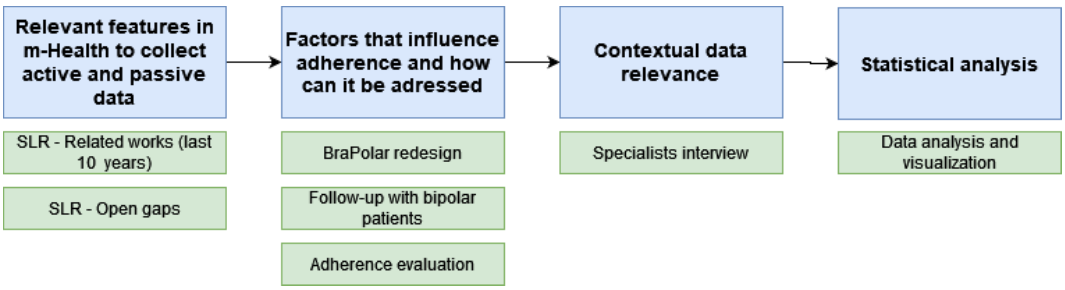


Figure 4.1: Proposed Approach flow

4.1
RQ1- Relevant features in mHealth to collect active and passive data

This section describes an SLR process, following the review steps described by Kitchenham (KITCHENHAM et al., 2009) to conduct systematic reviews of software engineering research, which involves careful planning (Subsection 4.1.1), revision process (Subsection 4.1.3), and creation of a review report for detailed evaluation and analysis of studies (Subsection 4.1.4).

4.1.1 Review Planning

Our review focuses on the requirements and optimization of mHealth applications to support patients with bipolar disorder. Given the purpose of the review, the following research questions and inclusion criteria have been established.

SLR Research Questions:
- SLR-RQ1: What features and data types are typically captured in mHealth applications?
- SLR-RQ2: What data collection methods are usually used with mHealth sensors?
- SLR-RQ3: What are the main battery consumption sensors?

4.1.2 Inclusion and exclusion criteria

We included studies published in the last 10 years (June 2013 - June 2023) related to mobile applications' use to monitor bipolar disorder. We included original research published in journals or conference proceedings, full papers, and studies available with full access study cases. We excluded duplicate studies, surveys, and systematic reviews. Also, we do not consider mHealths that lack transparency in the data analysis methodologies used or medical/psychiatric literature that claims to work with bipolar patients but does not conduct research with mHealth. We also removed papers unrelated to mHealth, such as mechanics, socio-cultural, etc., studies based exclusively on qualitative assessments, epidemiological studies and books, short papers, and technical reports.

4.1.3 Revision Process

We selected five electronic databases for the review: ACM digital library, IEEE Xplore, Science Direct, Springer-Link, and PubMed, as they encompass the primary research repositories in computer science and psychology/psychiatry. As Science-Direct only allows for a maximum of 8 operators, we selected the most crucial ones to prioritize the essential ones.

After performing the search queries (Table 4.1.3), three researchers reviewed the selected publications and divided the task. Subsequently, each researcher examined their respective subset, and the other two researchers evaluated the subsets to arrive at a definitive judgment on inclusion. An additional researcher was appointed as the referee in a disagreement. When choosing articles, we considered the following quality attributes: the purpose of the study, which features and data types are usually captured in mHealth, data collection methods are generally used with mHealth sensors, how to avoid data outliers in a real-time data stream, and the results obtained.

Table 4.1: Search queries and results

Electronic Database	Query	Retrieved Studies
Springer Link	'("cell phone" OR "mobile phone" OR "m-health" OR "mobile health") AND ("bipolar disorder" OR "manic depressive" OR "mood swing" OR "mood fluctuation" OR "mood variation") AND ("self-management" OR "follow-up" OR "monitoring" OR "self-tracker") AND (contextual OR "active data" OR "passive data" OR "digital phenotype" OR sensor OR capture OR collect OR feature)'	551
Science Direct	("cell phone" OR "mobile phone" OR "m-health" OR "mobile health") AND ("bipolar disorder") AND ("monitoring") AND ("digital phenotype" OR "data" OR "sensor")	265
IEEE Xplore	("Full Text Only":"cell* phone" OR "Full Text Only":"mobile phone" OR "Full Text Only":"m-health" OR "Full Text Only":"mobile health") AND ("Full Text Only":"bipolar disorder" OR "Full Text Only":"manic depressive" OR "Full Text Only":"mood swing" OR "Full Text Only":"mood fluctuation" OR "Full Text Only":"mood variation") AND ("Full Text Only":"self-management" OR "Full Text Only":"follow-up" OR "Full Text Only":"monitoring" OR "Full Text Only":"self-tracker") AND ("Full Text Only":contextual OR "Full Text Only":"active data" OR "Full Text Only":"passive data" OR "Full Text Only":data OR "Full Text Only":"digital phenotype" OR "Full Text Only": sensor OR "Full Text Only":capture OR "Full Text Only":collect OR "Full Text Only":feature)	108
ACM Digital Library	"query": ("cell* phone" OR "mobile phone" OR "m-health" OR "mobile health") AND ("bipolar disorder" OR "manic depressive" OR "mood swing" OR "mood fluctuation" OR "mood variation") AND ("self-management" OR "follow-up" OR "monitoring" OR "self-tracker") AND (contextual OR "active data" OR "passive data" OR "digital phenotype" OR sensor OR capture OR collect OR feature) "filter": Article Type: Research Article, E-Publication Date: (06/01/2013 TO 06/30/2023)	101
Pubmed	(cell* phone OR mobile phone OR m-health OR mobile health) AND (bipolar disorder OR manic depressive OR mood swing OR mood fluctuation OR mood variation) AND (self-management OR follow-up OR monitoring OR self-tracker) AND (contextual OR active data OR passive data OR digital phenotype OR sensor OR capture OR collect OR feature)	94
Total		1119

A total of 1119 articles were obtained from the search. These articles were divided into three subsets, consisting of 400, 400, and 319 studies, respectively. Each researcher assessed the articles and conducted a peer review with the other two. We found a total of 32 duplicated studies. After the pre-selection process based on title and abstract, the number of articles remaining was 1087. We divided these articles into three subgroups, each containing 375, 375, and

337. Each subset was assigned to one of the three researchers who thoroughly read the full text and applied the inclusion/exclusion criteria.

The two remaining authors reviewed each article from their subsets. In cases of uncertainty, a fourth researcher was consulted for additional input. Of the extensive selection process, 54 articles were chosen for our review, as illustrated in Figure 4.2.

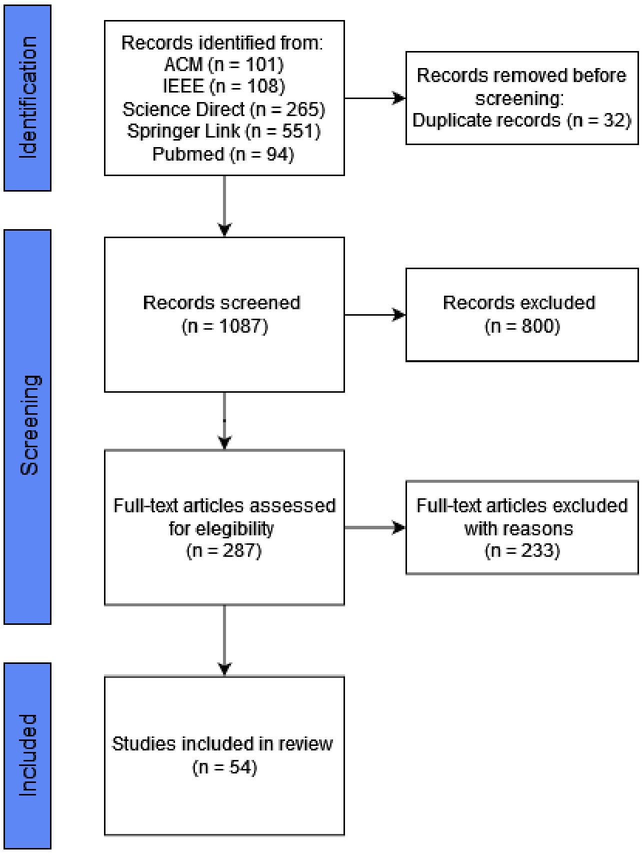


Figure 4.2: Research selection procedure

Next, we presents an analysis of the selected research studies reviewed on mHealth technologies in the monitoring and management of bipolar disorders. It searched 11 databases for studies published between January 2013 and June 2023 with the aim of understanding the role of mHealth applications in mental health care.

4.1.4 Findings

The 54 chosen research studies were published in journals and conferences between 2013 and June 2023 in online databases (IEEE, ACM, Springer, Sci Direct, and PubMed) in conferences and journals. On the one hand, they were gathered from IEEE and ACM conferences 4 and 6 articles, respectively. On the other hand, we consider from Springer, Sci Direct, and PubMed a total of 10, 13, and 21 articles. Detailed paper information on databases and conferences is in Annex 7.13. Regarding the years of publication, we present the total of articles chronologically in Annex 7.14. In Figure 4.3, we synthesize the number of articles per database, type and year.

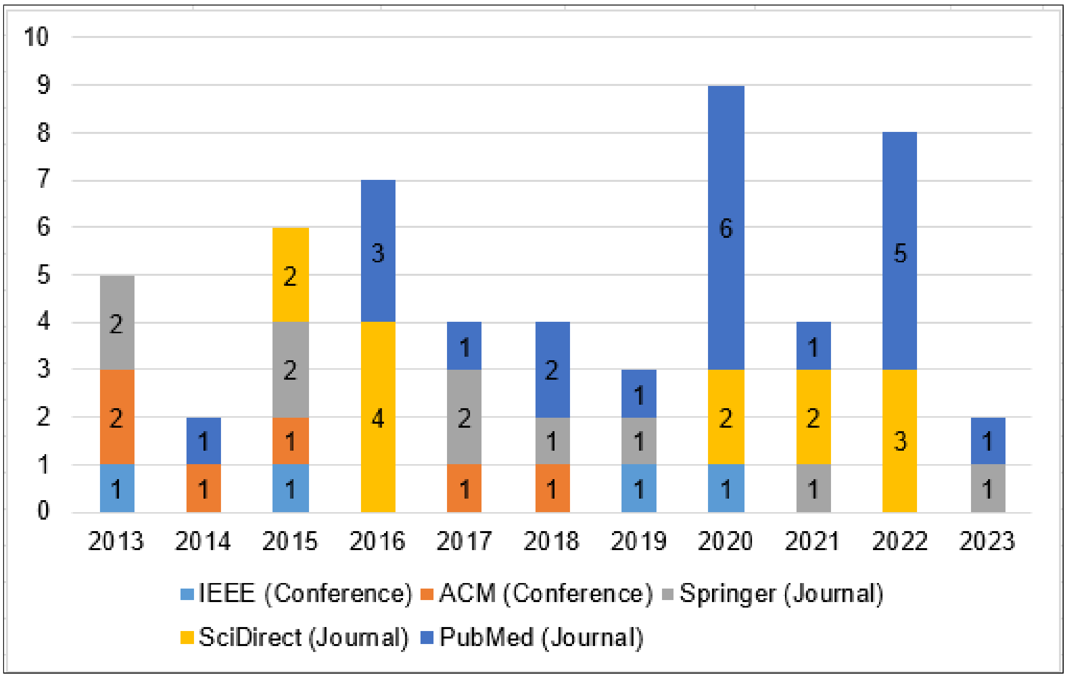


Figure 4.3: Total of selected articles by Database, Type, and Year

Based on our analysis of these studies and in line with our research objectives, we have identified typical characteristics and data types commonly recorded in mHealth. Furthermore, we have observed that data collection methods often involve mHealth sensors. We have also examined strategies used to prevent data outliers in real-time data streams and the advantages and limitations of these approaches. Furthermore, we have investigated the key characteristics that influence the results of these studies. These findings are detailed below.

SLR-RQ1: What features and data types are commonly captured in mHealth?
Several studies supported by mHealth include the collection of data using mobile sensors from installed smartphone applications (MONDEJAR et al., 2019b; FAURHOLT-JEPSEN et al., 2021; TSENG et al., 2022a). Collecting this information at a time could identify patterns in patient behavior. In this sense, several characteristics, such as mood, sleep patterns, and patient movement patterns, could be identified and supported by sensor data (HIDALGO-MAZZEI et al., 2016; MONDEJAR et al., 2019b; FAURHOLT-JEPSEN et al., 2023). Furthermore, these features are classified into active

and passive data (MONDEJAR et al., 2019b). While active data are directly dependent on the interaction of patients with their mobile phones, passive data are collected in the background without the intervention of patients. Below, we describe the main sensors that the authors utilize, and we present the main features associated with these sensors as data types applied in these studies.

Mobile sensors and cellphone capabilities (passive data)
The mobile sensors used in the smartphone to monitor patients with bipolar disorder include GPS (Global Positioning System), gyroscopes, accelerometers, and sound sensors (OSMANI et al., 2013; GRUNERBL et al., 2015; CHAPMAN et al., 2017). These sensors provide opportunities to collect rich empirical data on free-living activity patterns, monitor Early Warning Signs of relapse, discern mood changes, and measure physical health factors such as total activity and sedentary periods (MAYORA et al., 2013). The MONARCA system incorporates a wrist-worn activity monitor and a mobile electrodermal activity (EDA) sensor for continuous physiological monitoring (ALVAREZ-LOZANO et al., 2014). Smartphone usage patterns and sensor data can be used as an objective measurement device to help with psychiatric care and provide additional information to healthcare professionals.

Several studies support the use of cell phone microphones (MOHIUDDIN et al., 2013; ABDULLAH et al., 2016; MONDEJAR et al., 2019b), and sound sensors (MOHIUDDIN et al., 2013; GOULDING et al., 2022) are widely used to verify the amount of time that a person uses his mobile phone as ambient noise. In addition, augmented call logs / duration (MOHIUDDIN et al., 2013; DORYAB et al., 2015; FAURHOLT-JEPSEN et al., 2016; CONSTANTINIDES et al., 2018; RYAN et al., 2020; EBNER-PRIEMER et al., 2020b; GOULDING et al., 2022; DOMINIAK et al., 2022) and text messages (DORYAB et al., 2015; RYAN et al., 2020; CHOKSI et al., 2020; EBNER-PRIEMER et al., 2020b; GOULDING et al., 2022; DOMINIAK et al., 2022) indicate that the patient could enter a mania phase.

As in the mania phase the patient tends to be more agitated, the mobile accelerometer (FROST et al., 2013; OSMANI et al., 2013; DORYAB et al., 2015; COELHO; BASTOS-FILHO, 2016; ABDULLAH et al., 2016; CHAPMAN et al., 2017; CAO et al., 2017; PALMIUS et al., 2017a; ZULUETA et al., 2018; MONDEJAR et al., 2019b; FAURHOLT-JEPSEN et al., 2019; ORSOLINI; FIORANI; VOLPE, 2020; DAUS et al., 2020b; CHOKSI et al., 2020; GOULDING et al., 2022; ORTIZ et al., 2023b) is used by the authors to track physical activity and movement. Following this approach, phone usage

(MOHIUDDIN et al., 2013; FAURHOLT-JEPSEN et al., 2014; ABDULLAH et al., 2016; FAURHOLT-JEPSEN et al., 2017; MüHLBAUER et al., 2018; CONSTANTINIDES et al., 2018; MONDEJAR et al., 2019b; DAUS et al., 2020b; GOULDING et al., 2022) are mentioned as an alternative, but depend on the commitment of the user with their smartphones (MONDEJAR et al., 2019b).

Other studies (KAPPELER-SETZ et al., 2013; MAYORA et al., 2013) suggest external devices such as the use of electrodermal activity (EDA) to support the diagnosis and treatment of patients with bipolar disorder as an indicator of the emotional state and level of stress of a person who incorporates a sensor system into the shoe or socks.

In some selected studies, it was impossible to determine which mobile sensor was applied. On the one hand, a set of studies did not specify which sensor uses their mHealth (KAPPELER-SETZ et al., 2013; ALVAREZ-LOZANO et al., 2014; HIDALGO-MAZZEI et al., 2015; GRUNERBL et al., 2015; FAURHOLT-JEPSEN et al., 2015; HIDALGO-MAZZEI et al., 2016; FAURHOLT-JEPSEN et al., 2017; ARRIBAS et al., 2018; BEN-ZEEV et al., 2019; GARCíA-ESTELA et al., 2022; AUDIBERT et al., 2022; STANISLAUS et al., 2022; DOMINIAK et al., 2022; BOS et al., 2022b; FAURHOLT-JEPSEN et al., 2023) claim that the mobile sensor is used; however, it is not clear how.

Figure 4.4 presents the number of research articles studies that use each type of sensor/capability of mobile phones.

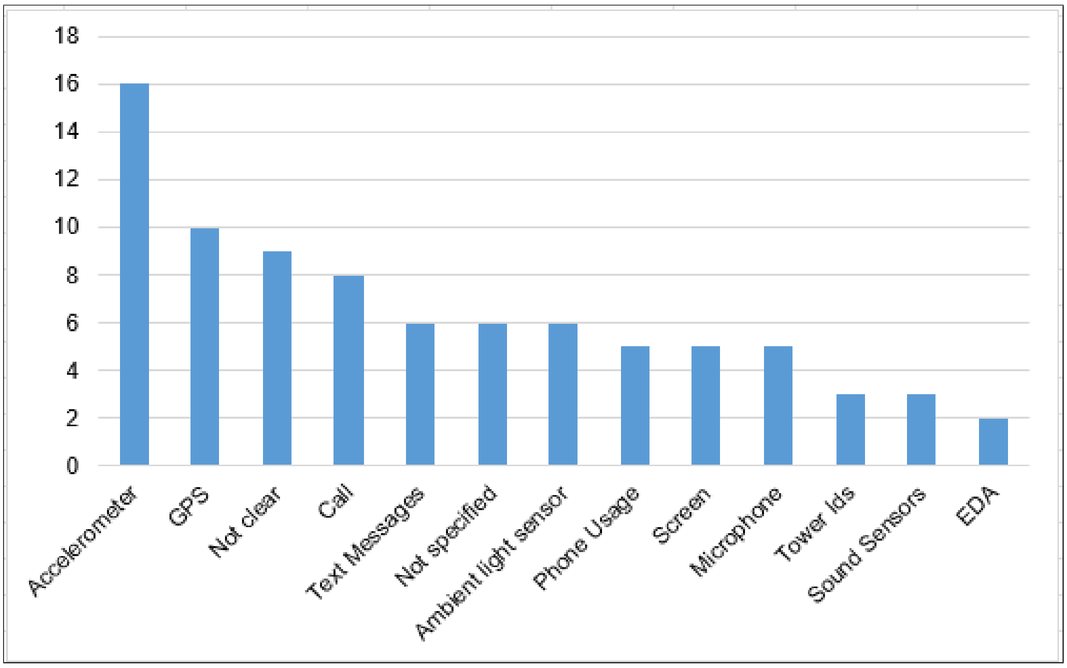


Figure 4.4: Mobile sensors and cellphones capabilities commonly used

Features (active data)

As several sensors are used in mHealth applications to capture information in the background when users use their mobile phones, mHealths can also provide enhanced analysis by capturing active patient data when they enter consciously and voluntarily information into mHealth and complement passive data. With this information, we can evaluate features relevant to the medical area, such as mood, energy levels, sleep patterns, and physical and social interaction. Some work in the area can use walking patterns, physical activity, and screen use (HIDALGO-MAZZEI et al., 2016) or use accelerometers to monitor activity bursts and discern mood changes (FROST et al., 2013). Moreover, the collected data on sleep patterns were inferred by analyzing light sensor data and detecting interactions with the phone to infer bed and wake-up times (FAURHOLT-JEPSEN et al., 2023). In fact, the system tracked screen usage as a measure of phone activity (CHAPMAN et al., 2017), and the physical and social activity collected by smartphones was found to correlate with clinical ratings of depression and mania.

This set of features that mix active and passive data was used to predict and forecast disease symptoms, such as mood, in patients with bipolar disorder (CONSTANTINIDES et al., 2018) and provides information on symptoms of mental illness and supports remote monitoring and interaction between patients and clinicians. In the following, we describe the common features found in our SLR:

– **Mood**: the analyzed articles provide study mood in various ways: ZULUETA ET AL. (2018) uses passively collected mobile phone keyboard activity to build deep digital phenotypes of depression and mania in subjects with bipolar disorder. Another study estimates mood scores using a set of algorithms trained on data from the current day, comparing the calculated values with self-reported scores to identify a mood range (DORYAB et al., 2015). A different study (KAMARSU et al., 2020) investigates associations in real time and in time between affect, mood, and social interactions in people with bipolar disorder, using automated surveys to assess these variables twice a day for 11 weeks. Additionally, a study (DOMINIAK et al., 2022) uses phone-based assessment to determine changes in mood state since previous contact with the patient, classifying mood into different phases based on rating scale scores. Finally, research efforts have developed information technology platforms for continuous electronic self-monitoring of illness activity in bipolar disorder, including collecting objective smartphone data on behavioral activities that reflect the level of illness activity (FAURHOLT-JEPSEN et al., 2016).

- **Sleep patterns**: through him, it is possible to investigate various symptoms of mental disorders and establish behavioral indices related to mental health and sleep/wake patterns (CHOKSI et al., 2020). Sleep patterns are believed to be strongly associated with symptoms of mental disorders and are used to distinguish between disturbed, regular, and restful sleep (CONSTANTINIDES et al., 2018). Furthermore, studies compare sleep measurements between different study groups and find that patients with newly diagnosed bipolar disorder have more irregular sleep patterns, reduced sleep quality, delayed sleep patterns, and more variability in daily sleep patterns compared to healthy controls (STANISLAUS et al., 2020). Sleep patterns were collected through surveys randomly sent to participants over several weeks, focusing on morning responses (KAUFMANN et al., 2016). Additionally, sleep patterns are used in decision rules to identify potential relapses in bipolar disorder, where certain sleep-related behaviors trigger an alert (MOHIUDDIN et al., 2013).

- **Keyboard**: it can sense emotions or moods through keyboarding features. Research suggests that typing speed plays a major role in identifying user emotion with the help of keystroke dynamics. In a study, a Bayesian Network classifier studied user typing speed on X (Twitter) and achieved an overall classification accuracy of 67.52%. In another, users typed their emotional state regularly, and keyboard activity was recorded in all applications (ZULUETA et al., 2018). With a Random Forest model, authors achieved a mean classification accuracy of 84%, where typing speed seemed to be the most important dynamic typing feature. These results show that this keyboard features, in particular, how a user types and indicates a user's emotion or mood.

- **Physical Activity**: it plays a valuable function in assessing and monitoring a person's health and well-being in that it can objectively measure an individual's physical activity level. This trait can be judged on many aspects like calls, SMS, inbound, outbound, and many more (FROST et al., 2013). Moreover, the physical activity feature could be applied to interventions and behavior change programs to promote and monitor changes in physical activity behavior. Text messaging and other features of mobile phone technology are feasible and acceptable tools for promoting physical activity among adolescents (KHOUBAEVA et al., 2022). Embedding this physical activity element in these interventions can function as a way of facilitating self-monitoring and reminders for physical activity. Overall, the physical activity feature may provide additional insights into a person's activity levels and improve efforts to encourage and sustain a physically active way of life.

– **Social Activity**: it can tell how much the patient socially engages with others by looking at calls and text messages (FROST et al., 2013). This feature allows for understanding people's social interactions or relationships, which can be useful in mental health or behavior change interventions (KHOUBAEVA et al., 2022). Although the social activity feature cannot directly measure social activities, it can indirectly show social activities by mobility behaviors, such as where people go, which could give some hints regarding social behaviors and networks of individuals (CONSTANTINIDES et al., 2018). The intervention content was adjusted to fit within the social activity feature so that mobile phone platforms could be used to send reminders, self-monitoring, and adherence to the intervention (KAMARSU et al., 2020). In conclusion, the social activity feature can be beneficial in understanding individuals' social behavior and relationships and could be used to improve behavioral and mental health interventions.

– **Energy levels**: are designed to depict an individual's continuity and habits patterns, especially concerning the person's moves and the distance from her home. It considers energy in the sum of latitude and longitude, which can hide some subtle things in the data. So if you had somebody traveling in different directions but had a routine, for example, that means there is possibly low power in latitude or longitude. However, there is an exact regularity in the routine. The daily movement on the distance from home (DFH) feature can be estimated using the Euclidean distance as pointed Palminus (PALMIUS et al., 2017a).

– **Speech/Voice**: speech or voice features can help detect fluctuations in mood MUAREMI ET AL. (2022) found that acoustic features, such as speaking length, phone call length, harmonics-to-noise ratio, and number of short turns/utterances, can predict mood states in individuals with bipolar disorder. MCINNIS ET AL. (2020b) found the predictability of each mood state in bipolar disorder subjects by analyzing speech segmentation, including silences, captured by smartphone models preloaded with the 'PRIORI' app. KARAM ET AL. (2016) described a methodology to collect unstructured speech continuously and unobtrusively through the recording of day-to-day phone conversations, which allowed for the differentiation of hypomanic and depressive episodes from a euthymic phase. Also, GIDEON ET AL. (2022a) recruited subjects with rapid-cycling bipolar disorder and found that speech-based classifiers could significantly differentiate different mood states. Therefore, speech or voice features can provide insights into mood fluctuations (FAURHOLT-JEPSEN et al., 2016; DAUS et al., 2020b; DOMINIAK et al., 2022; TSENG et al., 2022a).

– **Medication**: this feature can be helpful in bipolar disorder by providing a means of managing symptoms and reducing the risk of episode recurrence. The main treatment for bipolar disorder is pharmacotherapy, which can stabilize the mood and lower the frequency of manic and depressive episodes (MATTHEWS et al., 2015). Nevertheless, despite medication, high recurrence rates of episodes and inter-episode symptom levels can persist. So, by adding the medication feature to the treatment plan, people with bipolar can take their medications on time and have a good log of their medication usage (CHAPMAN et al., 2017). It may also offer reminders for medication dosage, check for the medication's side effects, and help patients communicate with their providers about medication changes or concerns (CHOKSI et al., 2020). Therefore, by integrating the medication feature into the overall treatment plan, individuals with bipolar disorder can optimize the benefits of medication therapy and improve their overall well-being.

Figure 4.5 shows the number of research articles that use each feature type.

Data type

The data types evaluated in the provided papers include active, passive, and contextual data. In (MONDEJAR et al., 2019b), we defined two main groups of data to collect: active data and passive data. Active data includes mood state and acoustic characteristics, while passive data includes data collected from the participants' phones. In addition, contextual data (MOHIUDDIN et al., 2013) refer to a set of sensors to collect information on ambient light levels, sound levels, movement information, and aspects of television usage focused only indoors. In summary, we found 44 research studies on active data, 37 of

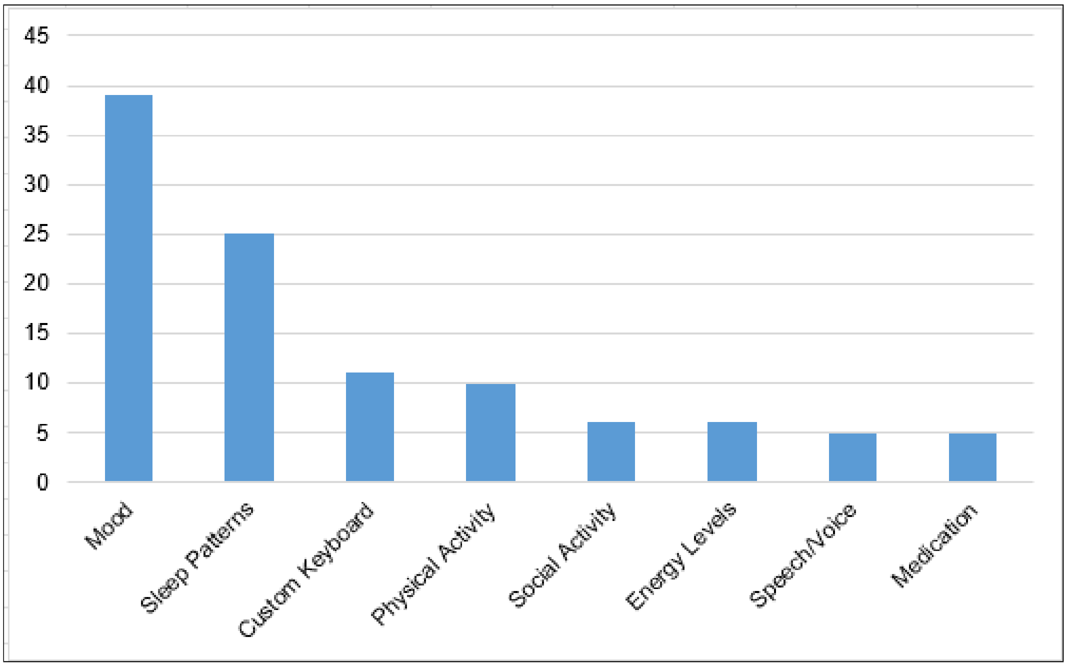


Figure 4.5: Common mobile features in mHealth

which were collected from passive data, and only one mentioned contextual data. In Annex 7.16, we tabulate these three categories and show the studies mentioned related to each.

SLR-RQ2: What data collection methods are generally used with mHealth sensors? Data collection in mHealth involves collecting various data types from mobile health applications (KARTHAN et al., 2022). This process includes gathering sensor data, including battery, light, location, screen, proximity, communication logs, and step count. That is, sensor readings from these devices are used to sense what an individual does, where an individual is, and with whom an individual is interacting, and those data are recorded for analysis and further studies (CONSTANTINIDES et al., 2018).

Common data collection methods used with mHealth sensors are self-reporting (active data) and passive objective data collected through smartphone sensors (passive data) (OSMANI et al., 2013; ALVAREZ-LOZANO et al., 2014; GRUNERBL et al., 2015; MONDEJAR et al., 2019b). Patients fill in questions about their symptoms and behaviors in active data using daily questions or an app. By overlaying an external context such as location and social interaction data, whereby one of the most important assets in identifying patterns can be a feedback existence that delivers focused interventions, performances can be created products that make sense and can detect patterns of behavior (CONSTANTINIDES et al., 2018). Passive data can be collected in background ways like sensor data (e.g., battery, light, location, screen, proximity, communication logs, step count) automatically recorded by the phone with no patient interaction. These techniques have resulted in the acquisition of constant information about the mental conditions of patients and the daily routine that gives a picture of how a person fluctuates.

Collection strategies

Regarding collection methods, apps typically log data passively in the background (GRUNERBL et al., 2015), background sound using the microphone (ABDULLAH et al., 2016), or periodic location data from GPS (FAURHOLT-JEPSEN et al., 2021). However, there is no consensus on frequency.

Researchers have suggested that validated daily questions for self-assessment and a diary of the mental state of patients are used in this type of study. Daily self-evaluation questions that capture mood, activities, and relationships are an example (COELHO; BASTOS-FILHO, 2016), as are end-of-day diary entries that record sleep patterns and medication use (EBNER-PRIEMER et al., 2020b). Examples of applications that make users check specific symptoms throughout the day are mood and energy levels (FAURHOLT-JEPSEN et al., 2023) or mania and depression (RYAN et al., 2020). These include daily or weekly assessments for mood, energy, time to sleep, and medication adherence (GARCíA-ESTELA et al., 2022).

Some studies use adaptive reminders and surveys to improve data collection for reporting time. This practice complements continuous and periodic self-reporting. Participants receive reminders to complete surveys; if they fail, then a reminder is sent at rounds of intervals (KAUFMANN et al., 2016). To ensure that data collection at any point varies throughout the day, some mHealth randomly select times within defined windows within which it proposes a survey to users (FAURHOLT-JEPSEN et al., 2021). Furthermore, apps running and usage patterns are recorded in the background by the systems, and sleep-related data, such as bedtime and rise time, are measured daily, typically with an option for retrospective data entry (STANISLAUS et al., 2020). Together, the methods provide a wealth of longitudinal, real-time, and archival data needed for comprehensive monitoring and management of mental health disorders.

Data outliers

Outliers are data or points that stray from other data in a dataset. These outliers affect measurement errors, data errors, stakes, and rare events. Outliers are data points or observations that fall far outside of the typical patterns or trends found in the data and can overly affect the measured properties

(PALMIUS et al., 2017a).

One method of avoiding outliers in the collected data is to compute statistics across portions rather than the entire data set. This is useful because it may capture variations in behavior at different times (for example, weekdays vs. weekends). A related approach is to identify and eliminate outlier days that differ considerably from the typical behavior of individuals, such as days where they travel a considerable amount (MATTHEWS et al., 2015). These procedures allow researchers to avoid the pitfalls of outliers and obtain better and more generalizable data for analysis, but it is not widely studied.

SLR-RQ3: Which are the main consumption battery sensors? The consumption of battery sensors refers to the amount of power sensors used in a device. Battery logs can be used to determine which sensors drain the battery too quickly and correct these problems to mitigate battery life degradation. This applies especially to clinical trials, where devices must work for many hours without depleting the batteries of the patients, allowing these devices to be used in the study (CONSTANTINIDES et al., 2018).

The primary consumption battery sensors mentioned by FROST ET AL. (2013) were the log of cell tower connections, screen on/off events, running applications, and installed/uninstalled applications. The authors also mention that using the accelerometer and GPS sensor can consume a considerable amount of battery; in this line, they propose reducing the need for power-consuming sensors like GPS and using WiFi for indoor positioning when available (MAYORA et al., 2013). In addition, the Monsenso smartphone app used in the MONARCA II trial also collects sensor data, including battery, light, location, screen, proximity, communication logs and step count (CONSTANTINIDES et al., 2018), highlighting the need to optimize and reduce battery drain. Finally, another work mentions the use of the smartphone accelerometer for activity detection and the Android location service for location estimation, which combines GPS, Wi-Fi, and cell data (ABDULLAH et al., 2016). However, battery drain was a relevant issue that needed to be addressed.

4.1.5 Limitations and future research directions

Requirements and optimization to support the follow-up of people with bipolar disorder is a large area with many tools and challenges. Although we have tried to choose keywords and search strings that cover all target studies in computer science-indexed sources, this search process may miss some studies.

Open gaps

This review points out some research directions:

- The recruitment and retention of participants for patient interviews is challenging, as many patients with bipolar disorder may not be familiar with mobile apps designed for disease management and monitoring.
- There is no clear description of how active and passive data are collected in mHealth.
- Quality issues with sensor data (data gaps, noisy readings, lack of precision) may compromise data collection.
- Restrictive policies by smartphone manufacturers that limit sensor access.
- Variation in mobile data collection, including different devices and platforms.
- Lack of information on sex and ethnic/racial differences.
- Failure to control for medication use.
- Data sharing is limited due to sensitive and private information.
- Lack of randomized controlled trials investigating the effects of smartphone-based treatment interventions.
- Individual studies with methodological and clinical challenges and risk of bias.

The results of this section highlight the opportunity in mHealth to improve knowledge of the behavioral and clinical patterns of patients with bipolar disorder. However, challenges include issues regarding data quality, the requirement of uniform data gathering methodologies, and technical limitations such as battery usage and sensor availability that must be solved to benefit from mHealth. We also point out some gaps in the literature, including the need for more randomized controlled trials and better approaches to dealing with data privacy and sensitivity. Therefore, in the future, overcoming these challenges and optimizing data integration strategies will play an essential role in the further development of mHealth applications in mental health care and patient outcomes.

4.1.6 Conclusions

Once we have concluded this SLR, detailed in Section 4.1.4, we answer this thesis's first research question (RQ1). Considering each study's heterogeneous features and needs, it is crucial to personalize the characteristics when developing mHealth. Implementing research-grade mHealth to collect active/-passive data presents challenges. First, there is no consensus about active and passive features (active and passive data) controlling battery drain without compromising study quality. In addition, the complexity of the analysis of raw passive data is noteworthy, and the adhesion lask can compromise the quality of the study (KAPPELER-SETZ et al., 2013; COELHO; BASTOS-FILHO, 2016; HOLMES et al., 2016; ZULUETA et al., 2018; EBNER-PRIEMER et al., 2020b). As the issue of missing data is a crucial aspect to consider in the analysis of digital phenotypes based on smartphones (ONNELA, 2020), we hypothesized that contextual data could improve the study of digital phenotypes. Moreover, this SLR pointed out several strategies to be addressed with specialists, mentioned in section 4.2.3; we could identify two request questions:

- RQ2: What factors influence adherence to mHealth? How can it be improved in patients with bipolar disorder?
- RQ3: How can contextual data improve digital phenotype analysis?

Once the main characteristics and trends of the mHealth development were investigated concerning active and passive data, we continued to develop a tool to start the data collection process.

4.2 RQ2- Factors that influence adherence to mHealth and how to improve it

This section describes the proposed redesign process of the BraPolar2 mHealth application, including the main features, justification, and strategies implemented to improve user adherence. To achieve those goals, we describe the previous versions of our app, explain the new set of features requested by specialists, and discuss strategies to reduce abandonment in the collection process. Finally, we present the results of two evaluations verifying adherence with BraPolar2 and validating the tool in this direction.

4.2.1
Project continuation

In previous studies (MONDEJAR et al., 2019a; MONDEJAR et al., 2020), we developed a follow-up Android application for people with bipolar disorder called BraPolar, intending to follow fluctuations in mood and behavior, providing early indications of mood changes before they reach extreme functional consequences. This application has two modules: one for patients (MONDEJAR et al., 2019a) and the other for specialists (MONDEJAR et al., 2020). Although we capture sensor information and save it in a Firebase database, specialists highlighted the importance of the features developed for the follow-up of bipolar disorder, and participants (MONDEJAR et al., 2019a) reported that the app was easy to use, there were no clear criteria on how to capture data, structure them, frequency, and strategies to minimize patient battery drains and adherence, and this could be a problem in a long-term study (MONDEJAR, 2019). Also, considering that those BraPolar versions were a pilot solution tested with a control group of five persons with a non-bipolar disorder, improvements were necessary to optimize or simplify the data collection method and the involved sensors.

4.2.2
Ethical considerations

Since IPUB and PUC-Rio were interested in continuing research, the project continued, and the approval of the Research Ethics Committee (REC) was mandatory for conducting experiments with bipolar patients; we primarily addressed the ethical considerations involved in this project.

As this point was a limitation in a previous study (MONDEJAR, 2019) and in Brazil, to conduct research with humans, it is necessary to obtain the approval of REC, we proceed to submit the project, following the next order:

1. Create the project proposal, including declarations of consent of involved parts of PUC-Rio and IPUB (Annexes 7.1, 7.2, 7.3).
2. Submit to the Brazil Platform [1] and attend the complementary information when requested.
3. Once approved, under the Certificate of Presentation of Ethics Review number 60585422.3.0000.5263 (CAEE in Portuguese), it was possible to conduct experiments in the IPUB Institution.

[1] https://plataformabrasil.saude.gov.br/

Since ethics and privacy issues are critical in mHealth (GELINAS; MORRELL; BIERER, 2023), we developed two informed consent forms (ICF) for patients and specialists. In both versions of ICF, we remark on the Brazilian legal base, particularly with the General Personal Data Protection Law (LGPD in Portuguese), data protection laws, rights over users' data, anonymity, and security process of their collected information, project goals, leading activities to be developed along the research, and the responsible researchers involved with the project as the free decision to abandon research at any time.

4.2.3
Development of BraPolar2 mHealth

Once REC approves and the coordination meetings between PUC-Rio and IPUB are completed, we intend to understand the IPUB workflow to minimize participants' discomfort. In this way, first-time appointments at the IPUB outpatient clinic are scheduled only through SUS, so those interested should look for the Family Clinic or Health Center closest to their territory (place of residence or work) and request an appointment. Later, patients go to IPUB and undergo an initial screening by a psychiatrist to evaluate each case, then mark the next consultation with another psychiatrist who will follow up. As each case differs, some patients return to the IPUB ambulatory (Figure 4.6) every 15 days, once per month, or at another frequency defined by their psychiatrist.

Figure 4.6: Bipolar disorder outpatient waiting room at IPUB Institute

As we intend to minimize patient discomfort, IPUB provided ambulatory medical care, a psychologist, and a psychiatrist to support us. In this and similar space (Figure 4.7), we interview the patients described in Section 4.2.4.

Figure 4.7: Interview rooms at the bipolar disorder outpatient clinic at IPUB.

IPUB process (from the arrival patient to the consult)

Once we know the workflow in the IPUB institution and have defined the local tests with patients, we meet virtually and on-site with IPUB professionals in a new brainstorming session and update them on the latest approaches over those years. Given the characteristics of the usual population of IPUB patients, the new BraPolar2 version should be simplified to minimize patients' interaction with the application. Furthermore, considering the lack of information between sessions, there is no IPUB solution to follow up on these patients or a dataset with this information. As a result, following, we mentioned the main features of bipolar disorder, EWS signals, and feedback mentioned by specialists:

- There are unusual mood, energy, and activity changes.
- Periods of mania with elation and more energetic behavior. Periods of depression marked by low self-esteem and reduced activity.
- Reduced awareness of the disorder and its impact on cognitive and social functioning.
- Changes in physical movement, with less movement during depression and more during mania.
- Altered patterns of social interaction, with reduced desire and capacity during depression and increased during mania.

Specialists have participated in all stages of the Software Development Life Cycle (SDLC) (AGARWAL et al., 2023) and have defined the main features or requirements for the new BraPolar2 app during the impossibility of accessing patients at that moment. For this research, we present the characteristics and trends of previous studies (MONDEJAR et al., 2019a; MONDEJAR et al., 2020) characteristics and trends in the mHealth area described in the SLR (Section 4.1). Later, we transcribe a specialist request as a feature (MCMULLIN, 2023); for example, "the app should be able to capture mood inserted daily as sleep time." In this context, we transform the mood and sleep characteristics. Furthermore, we point out that the commonly collected sensor-based data streams can also be used (JACOBSON; SUMMERS; WILHELM, 2020; MELCHER; HAYS; TOROUS, 2020).

The main features defined for the redesign of our application and the consensus between our development team and specialists are described below.

New features request

This subsection mentions our proposed approach, which uses active and passive data collection from patient's smartphone interaction. As the data collected over time was relevant to specialists (MONDEJAR et al., 2020), we theoretically justified each characteristic and the interfaces involved in the active data process. Later, we will discuss the passive data selection process and data collection strategies.

Despite the features obtained in the SLR (Section 4.1), the specialists mention that the app should be able to help patients insert the following information (active data) once a day, preferred at the end of the day, in agreement with other studies (EBNER-PRIEMER et al., 2020b) briefly described as follows:

- **Mood and mood intensity**: those characteristics may vary throughout the day in bipolar disorder people. Diurnal variation in mood changes has been observed. Patients are more likely to switch from depression to mania or hypomania during the day and from mania/hypomania to depression overnight (VALENZA et al., 2016).
- **Energy level**: energy levels in bipolar patients fluctuate throughout the day, and this fluctuation can affect their mood states; also, low energy levels are closely related to negative mood states in individuals with bipolar disorder (JOHNSON; GERSHON; STAROV, 2015) and on average, energy changes tend to be more informative than mood changes during the manic phases of BD (CHENIAUX et al., 2023).

– **Sleep and quality of sleep**: Sleep and quality sleep play a crucial role in the pathogenesis and clinic of mood disorders. Some bipolar patients have had a sleep disorder for long days, and tracking sleep time, rest time, and quality is critical (KUNOROZVA et al., 2023).
– **Medication**: the lack of medication adherence in bipolar patients can have significant clinical and economic consequences. Non-adherence is associated with poorer long-term clinical outcomes, including decreased likelihood of achieving impacting remission and recovery, increased risk of relapse, recurrence, hospitalization, and suicide attempts (ICICK et al., 2022).
– **Menstruation**: menstruation affects bipolar patients by potentially exacerbating depressive, hypomanic, and manic episodes. Research suggests that a subgroup of women with bipolar disorder may experience menstrual cycle effects on mood symptoms, particularly in the premenstrual phase (KARADAG et al., 2004).

Given the previous brainstorming with specialists and comparing it with the literature, we observe and discuss that although some studies suggest follow-up bipolar disorder at several moments per day (day and night, for example), it may be relevant. However, it could be exhausting for patients; therefore, specialists suggest capturing this information only at night, preferentially after the last medication.

At this point, we suggest a set of sensors and strategies to enhance the data collected. In previous studies (MONDEJAR et al., 2019a; MONDEJAR et al., 2020), we use several sensors and characteristics of cellphones; however, recent studies (CARVALHO; PIANOWSKI, 2019) show the benefits of collecting less passive data to avoid battery drain. Regarding these studies and the clinical experience of specialists, we conclude that using only screen time, considering that excessive use of cellphones or screen time is associated with fluctuation in mood in patients with bipolar disorder (LI et al., 2022). Another study by WANG ET AL.(2022b) showed that sedentary behavior based on screen time was associated with an increased risk of depression, and people who reported more screen time had a significantly higher risk of depression. Furthermore, screen time can be a helpful indicator of understanding user behavior in different situations (MONDEJAR et al., 2019a). Once the primary sensor is defined, we continue the development process. We remark on the implementation considerations for granting adequate data capture.

Adapting requirements into active data

Several studies have tried to engage users to fill in active data information (FAURHOLT-JEPSEN et al., 2019; GARCíA-ESTELA et al., 2022; FAURHOLT-JEPSEN; KESSING, 2022); however, this is challenging. Consequently, we decided to simplify this process to improve adherence to the study. First, we designed a set of prototypes to get specialists' feedback, presenting those designs on a cell phone to simulate patient interaction. In this way, specialists mention that the application should be the most simplified possible given the complexity of follow-up people with bipolar disorder. Consequently, after an iterative development process (AGARWAL et al., 2023), we define a model layout composed of components of a set of simplified interfaces.

– A progress bar on top informing the current progress.
– The current date.
– A label to identify which item we are evaluating with a specific color.
– Brief explanation of what we want to explore.
– A set of options for user interaction.
– Only two buttons: Return and Continue.

It is valid to mention that we do not define any default parameter to avoid confirmation values in patient responses, except those components that are necessary to specify at least a value (sliders, for example); in those cases, it is recommended (KOłAKOWSKA; SZWOCH; SZWOCH, 2020) is defined in 50%. In addition, the user must select or specify a valid value to continue through the app screens.

BraPolar2 user interfaces

As requirements were defined, we designed the application layout and transition supported by the Figma[2], carrying the specialist's recommendations and the minimum possible interaction, presented in Figures 4.8 and 4.9 prototypes.

[2]https://www.figma.com/

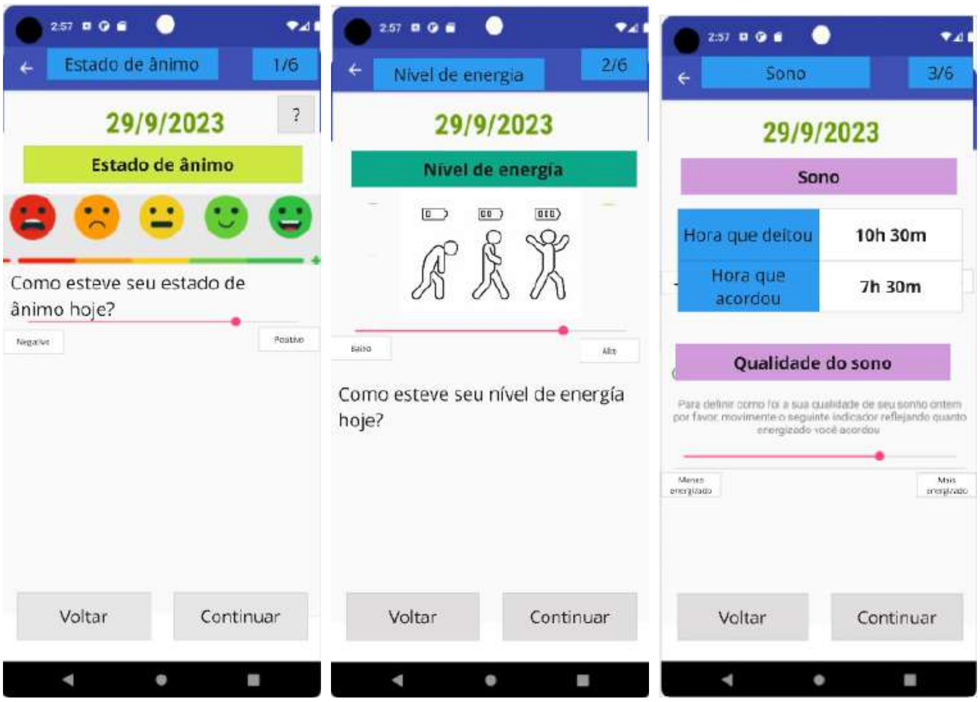


Figure 4.8: BraPolar2 interface prototype: Mood (left), Energy Level (center) and Sleep (right)

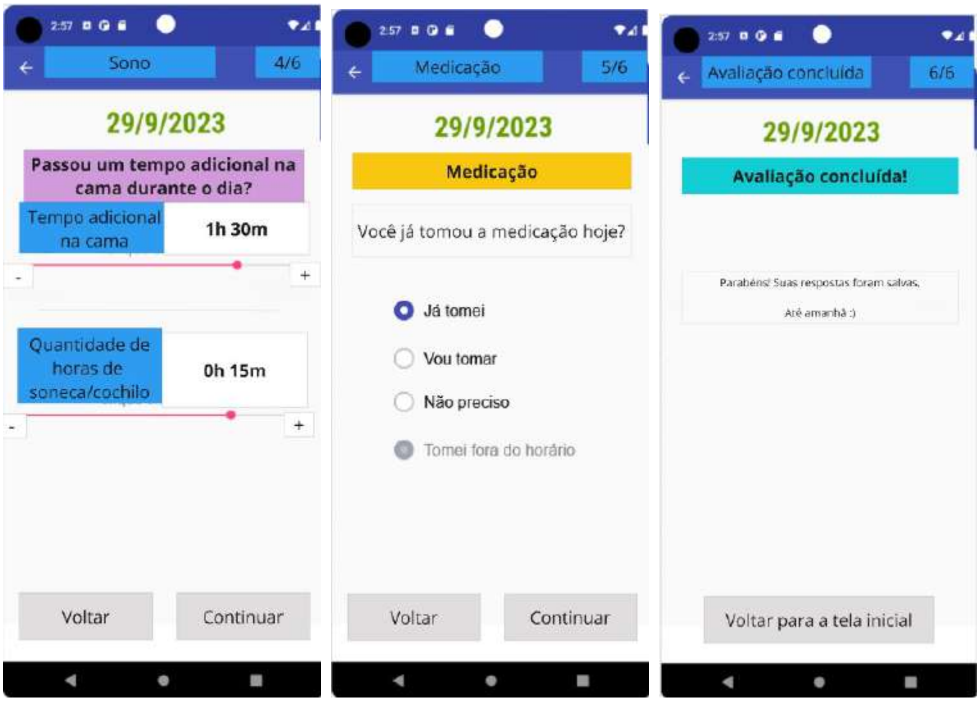


Figure 4.9: BraPolar2 interface prototype: Additional rest time (left), Medication (center) and End Screen (right)

Once the prototype phase was complete, we proceeded to present it to all specialists. However, they recommended removing any visual representation (figures) that makes the patient lose focus, as well as removing the additional rest time (Figure 4.9 left) screen and the last select box in the Medication feature (Figure 4.9 center). As a result, we present the BraPolar2 application user interface and how it was improved concerning the specialists' recommendations for use in bipolar people.

– Home screen (previous fill-up of the form): the application only allows fill the information between 19:00 and 23:59 following the specialist's recommendation. If the patient tries to open the app outside those hour intervals, filling up the forms is not allowed (Figure 4.10).

Figure 4.10: BraPolar2 interface: Home screen (before filling up the form)

– Mood: as a bipolar patient can vary their mood throughout the day, we developed a checkbox approach to select one or several options, as represented (Figure 4.11-left).

– Mood intensity: in the same interface as Mood, we capture mood intensity through a slider from too low to extreme (Figure 4.11-left down).

– Energy level: considering that bipolar patients could vary their energy levels, the specialists propose to leave a slider to give more freedom to them (Figure 4.11-right) in a zero to extremely high level.

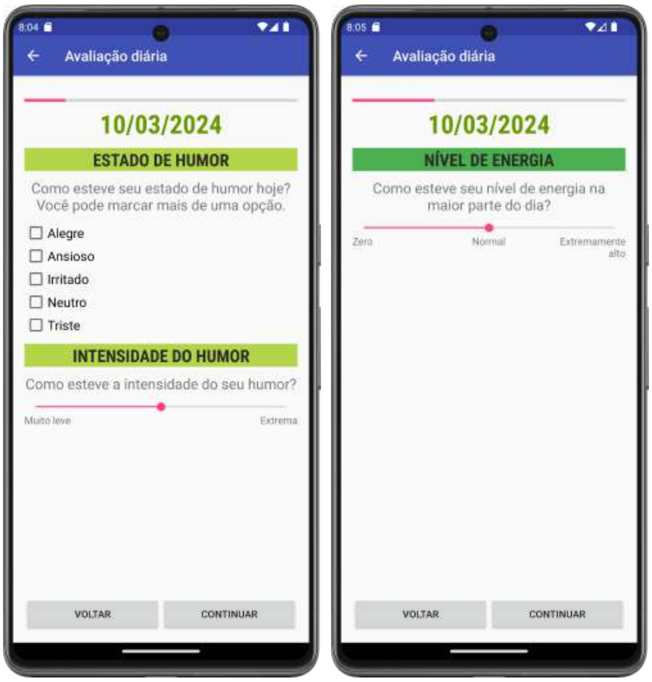


Figure 4.11: BraPolar2 interface: Mood and Mood Intensity and Energy level

- Sleep: as bipolar patients can sleep (or not), we implement this feature to allow users to decide whether to sleep. If they were asleep, it is possible to insert sleep, awake time, and how long they were awakened per hours or minutes (Figure 4.12-left). However, if they were not getting sleep, the mentioned features were disabled when patients selected they had not slept.
- Sleep quality: related to the Sleep feature, we prefer not to overload the Sleep interface and lift this one into another to capture how many times they awake and how restful it was (Figure 4.12-right).
- Medication: as patients in extreme cases of mania or depression tend to avoid taking medication, we developed only three alternatives to be selected to motivate medication adherence when asking them if they had taken their night pill (Figure 4.13-left).

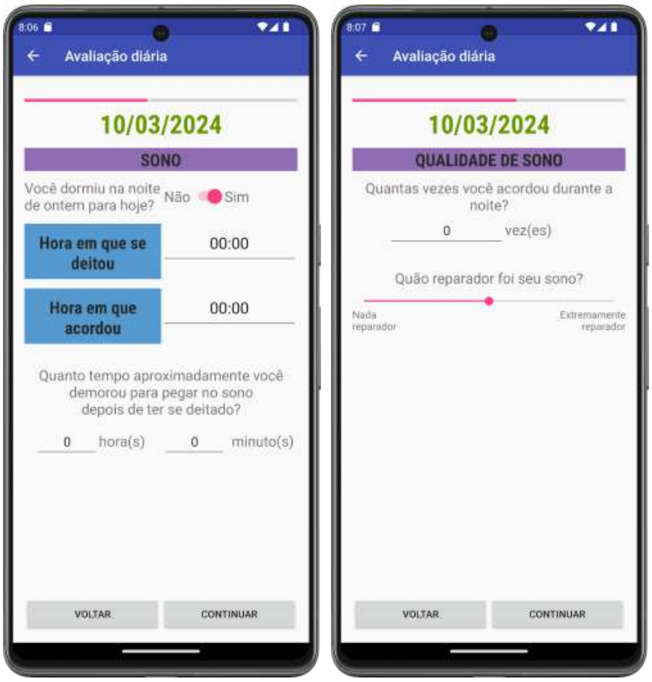


Figure 4.12: BraPolar2 interface: Sleep and Sleep quality screens

– Menstrual cycle: as an additional case to study, we aim to track menstruation self-relate, if applicable, for each patient (Figure 4.13-right). Also, we include a Finish button to indicate the last screen to be filled out.

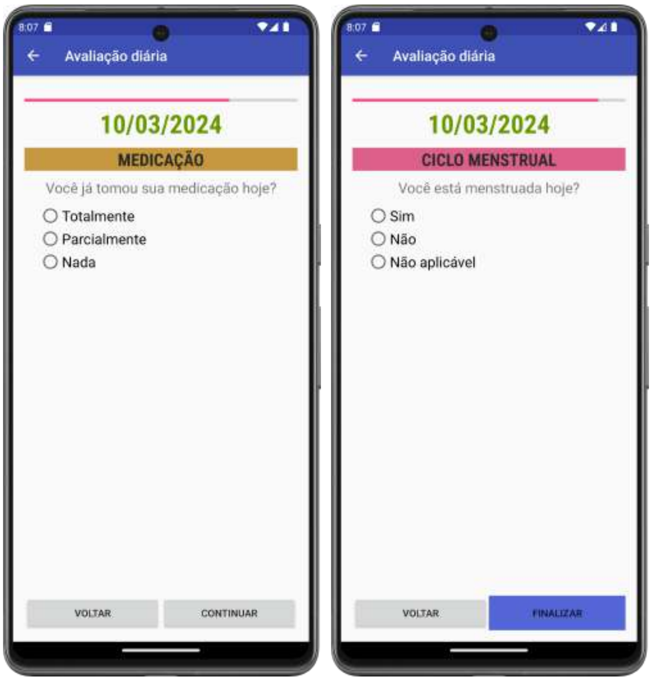


Figure 4.13: BraPolar2 interface: Medication and Menstrual cycle screen.

– Completed screen: we inform the patients that the collection process was finished and show a motivational message to encouraging them to fill out the form the next day (Figure 4.14-left).

– Home screen (after fill-up the form): once the patient concludes their daily evaluation, the main screen in the app informs that the daily information was concluded and he is welcome to fill in the next day (Figure 4.14-right).

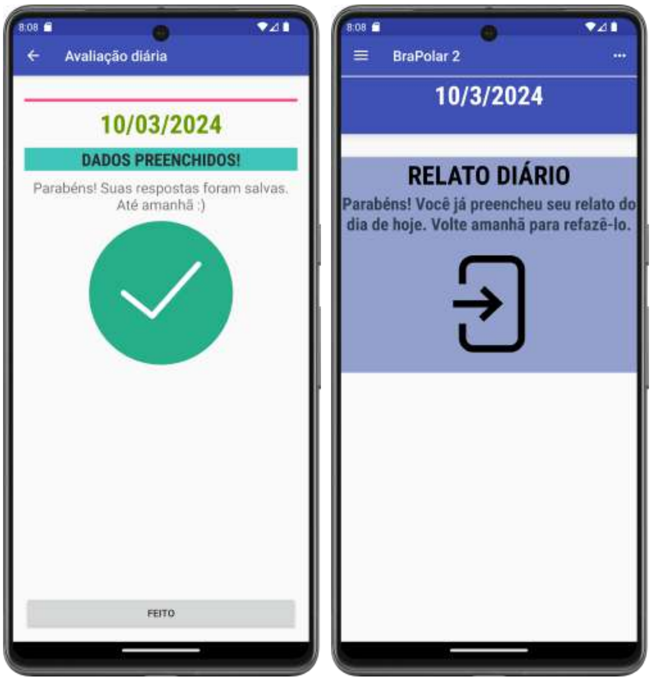


Figure 4.14: BraPolar2 interface: Completed task and Home (after filling up the form) screens

In Table 4.2.3 we summarize the features to be collected in the active data, specifying the graphical control and the valid and default values for each.

Although users can (or cannot) insert daily information voluntarily, we argue that the proposed application could collect additional information. Several studies (MONDEJAR et al., 2019a; FAURHOLT-JEPSEN et al., 2019; MONDEJAR et al., 2020; GHOSH; DEY, 2021; GARCíA-ESTELA et al., 2022; FAURHOLT-JEPSEN; KESSING, 2022) pointed out that the lack of commitment of users to complete daily tasks in mHealth applications limits the quality of the evaluation process. In this line, we propose including other features described in the following sections to enrich data collection for future analysis collected in the background (passive data) to improve the digital phenotype.

Adapting requirements into passive data

While active data depends on the user's interaction with the app, passive data collect subjective information on user cellphone patterns and insights into behavioral patterns and communication activities (MONDEJAR et al., 2019a;

Table 4.2: Graphical controls and rules

Feature	**Graphical control**	**Rule or valid values**	**Default value**
Mood	Checkbox	At least one must be selected	All disabled
Mood intensity	Slider	[0-100]	50
Energy level	Slider	[0-100]	50
Sleep (has sleep)	Switch	Yes/No	Yes
Sleep (sleep and awake time)	Date	[00:00-23:59] for both	00:00 for both
Sleep difficulty (hours and minutes)	Number	[0-24], [0-59]	0 for both
Sleep quality (awake times)	Number	[0-100]	0
Sleep quality (restful)	Slider	[0-100]	50
Medication	SelectBox	At least one must be selected	All disabled
Menstrual cycle	SelectBox	At least one must be selected	All disabled

MONDEJAR et al., 2020); passive data can be collected through smartphones and wearable devices, capturing information in the background such as physical activity, GPS location, interpersonal proximity, and audio recordings (YOUNG et al., 2022). In addition, complementing passive data to the digital phenotype can help traditional psychiatry because collecting smartphone data on patients could allow the discovery of behavioral data, such as erratic or exaggerated sending and response patterns.

Although passive data are valuable for observing patient behavior and device interaction, we do not use other passive data than screen interaction. In (MONDEJAR et al., 2019a; MONDEJAR et al., 2020) we had more freedom to access smartphone sensors of the participants. However, from Android 11 launched in 2020, the policies were more strict and Google only developed the appropriate framework to recognize Health Apps and apply the appropriate policies in April 2024[3]; we were limited to publishing BraPolar2 on the Play Store, as we use mobile phone resources from participants. Despite these challenges, we publish BraPolar2 in the Play Store[4] with the implementation to collect passive data, but we decide to keep only screen interaction, considering

[3]https://support.google.com/googleplay/android-developer/answer/14738291
[4]https://play.google.com/store/apps/details?id=br.abelgodev.brapolar

that the research was ongoing.

Despite the previous point, incorporating more passive data (location tracking, ambient noise levels, or how much the user moves) creates several complexities. The downsides are battery drain, the possibility of violating people's privacy, and the risk of patient abandonment, as occurred with one patient we offered the research at IPUB. Consequently, we decided to collect minimal background data from users (and prevent security issues with Android and Google), focusing on collecting user interaction on the screen, particularly when the smartphone is locked or unlocked. With this information, it will be possible to know smartphone use patterns at different moments of study and can be used as an alternative to the cell phone dependency test proposed by YILDRIM ET AL. (2015).

Database and programming technologies

We prefer to keep the architecture proposed in the previous works (MONDEJAR et al., 2019a; MONDEJAR et al., 2020) using Mobile Backend As Service (BaaS) and Google's Realtime Firebase as a database because they are used in mobile applications for various reasons. On the one hand, BaaS simplifies the development and management of services such as data storage and user authentication (VAZ et al., 2023). On the other hand, Firebase is a cloud-based BaaS platform that provides a back-end infrastructure for mobile apps (ATHANASOPOULOS; LIU, 2022). Although Firebase is well suited for handling unstructured data, such as videos, images, and audio, as a non-relational database (NoSQL), this can be useful in specific scenarios (ATHANASOPOULOS; LIU, 2022; VAZ et al., 2023) for applications that require real-time data updates and handle a large amount of coordinate data from cellphone sensors. Moreover, it supports multiservice recovery for applications that use multiple data stores, ensuring the integrity of the mobile application and minimizing unavailability issues (HU et al., 2017; INUPAKUTIKA et al., 2022). Consequently, for BraPolar2, we keep Firebase to avoid data missing while collecting patient information.

As part of the programming language selection process, we decided to keep Java. This is widely used in mHealth applications as a programming language and easily integrates Firebase as a back-end platform (MONDEJAR et al., 2020; TOROUS; BRADY, 2020; RUSSEL et al., 2023). The combination of Java, and Firebase offers the potential to develop an infrastructure adapted for an agile development process and a data collection and management process in mHealth.

Next, we present the BraPolar2 data collection process to monitor patients with bipolar disorder, intending to capture active and passive data and an adherence test through a semi-structured interview, detailed below.

4.2.4 Collecting data in IPUB Institute

Once the application was developed and tested with specialists, we launched it at the IPUB Institute for patients with bipolar disorder. First, we create 30 users and passwords, this one using a Bitwarden password generator [5] with 15 chars, including upper and lower cases, giving the security in the created password. It is valid to mention that we intend to publish the BraPolar2 application in the Google Play Store[6] in December 2023, but restricted policies regarding data collection do not allow us to proceed as mentioned in the previous subsection of this thesis. Consequently, the compiled version of the app was saved as the Android Application Package (APK) in a secure cloud folder.

Participants

We meet with specialists to define criteria to recruit patients with bipolar disorder at the IPUB Institute. As a result, we include people diagnosed with bipolar people, type 1 or type 2, between 18 and 60 years of age. These patients have confirmed bipolar disorder after IPUB specialists screening and have a compatible Android phone. We did not consider patients who were pregnant, who have a lack of knowledge of the Portuguese language, who cannot learn the technical details of using a smartphone, or who are seriously ill or are also diagnosed with schizophrenia, schizoaffective disorder or delusional. Once those criteria are met, we recruit patients every Tuesday from December 2023 to April 2024.

Regarding specialists, it should be psychologists or psychiatrists with experience applying a set of authorized psychological scales (in Portuguese) by the Ministry of Health of Brazil: Young Mania Rating Scale (Annex 7.8), Hamilton Depression Rating Scale (Annex 7.9), Morbidity Awareness Test (Annex 7.10), Global Clinical Impression for Bipolar Disorder (Annex 7.11), and Positive and Negative Syndrome Scale (Annex 7.12). In addition, specialists should agree to participate in the research and sign the ICF.

Dynamic in IPUB Institute

The follow-up in IPUB with BraPolar2 application started by researchers and

[5]https://bitwarden.com/password-generator/
[6]https://play.google.com/

specialists in patients with bipolar disorder. As bipolar ambulatory services are offered all Tuesdays from 13:00-16:00 hours, about ten or twenty patients (new or returning) arrive every week. Usually, regular IPUB patients. Eight of them were familiar with other investigations developed at IPUB. In this way, we present the study of eligible patients in a private room (Figure 4.7) with a psychologist or psychiatrist who previously signed the ICF. Then, we show a video demo with a sample of our application, highlighting the relevance of following up on their state for days. For those patients who agree to participate in the study, we apply the following set of steps, described in Table 4.2.4.

As the patients' priority is their medical consultation, we intend not to occupy too much time with them to avoid patients tend to lose interest quickly if we interrupt them. In addition, we start the recruitment process with those patients who arrive early to avoid discomfort in that space. Although about 15 patients are present in IPUB weekly, after applying the inclusion criteria, we could only offer the research for a mean of 6 patients per week, and generally only half agreed to participate.

Table 4.3: Workflow test process

Step	**Task**	**Executed by**
1	Explain and sign the Informed Consent Forms.	Researcher
2	Apply a Socio-Demographical form.	Psychologist or Psychiatrist
3	Install the developed application on participant smartphones and log in with individual usernames and passwords.	Researcher
4	Training about the application characteristics and functions.	Researcher
5	Set an alarm to remember to fill in their daily report.	Researcher
6	Apply the YMRS, HDRS, ISAD-BR, CGI-BP, and PANSS scale.	Psychologist or Psychiatrist
7	Ask the patient if they have any doubts about the research.	Researcher
8	Comment with him about their return to study in 30 days to reapply the scales.	Psychologist or Psychiatrist
9	Check in the Firebase database if we were collecting data.	Researcher

Data collection and analysis procedures

Once all procedures, documentation and specialists have been cleared, the first data collection process begins in December 2023 with three patients. All patients were numbered P1... Pn to protect the privacy of participants. We confirm that they should return to IPUB at least three times every 30 days from their admission for next six months. Table 4.2.4 summarizes the process scheduled for current patients until August 2024, totaling 22, with an average age of 40 years, 15 females and 7 males; bipolar disorder was classified as bipolar disorder I (BD1) and bipolar disorder II (BD2), totalling 12 and 10, respectively. Additional personal data was limited to specialists and cannot be shown by LGPD. For those participants who decided not to continue with the research or had finished the data collection, we explained the research results, thanked them for their participation, and assessed to uninstall the BraPolar2 application to avoid continuing to capture data and proceed to block their users the Firebase database.

Table 4.4: Initial patients involved in study

Patient ID	**Admission**	**Genre**	**Age**	**Bipolar type**
P1	19/12/2023	F	57	BD2
P2	19/12/2023	F	48	BD1
P3	19/12/2023	F	42	BD1
P4	30/01/2024	M	40	BD1
P5	09/01/2024	F	49	BD1
P6	09/01/2024	F	51	BD2
P7	07/02/2024	F	40	BD2
P8	09/01/2024	F	29	BD2
P9	06/02/2024	F	45	BD1
P10	20/02/2024	M	28	BD1
P11	20/02/2024	F	24	BD1
P12	20/02/2024	F	35	BD2
P13	20/02/2024	M	50	BD1
P14	20/02/2024	F	37	BD1
P15	05/03/2024	M	26	BD2
P16	05/03/2024	F	48	BD2
P17	12/03/2024	M	28	BD2
P18	12/03/2024	F	26	BD1
P19	19/09/2024	M	32	BD2
P20	26/03/2024	F	36	BD2
P21	26/03/2024	M	52	BD1
P22	02/04/2024	F	48	BD2

Once all the evaluations have been applied by the specialists (Annexes 7.6, 7.7, 7.8, 7.9) and summarized in form (Annex 7.10), we save them in an Excel document as shown in sample Table 4.2.4.

Table 4.5: Scales results structure

Scale	**C1..Cn**
Young1	[0-4]
...	...
Young11	[0-4]
Hamilton1	[0-4]
...	...
Hamilton17	[0-4]
ISAD1	[0,1,3,5]
...	[0,1,3,5]
ISAD17	[0,1,3,5]
CGIBPMania	[1-7]
CGIBPDep	[1-7]
CGIBPGer	[1-7]
CGIBPDisc	[0-7]
PANSS1	[1-7]
...	[1-7]
PANSS7	[1-7]
Medication	Medication1 Dosage1 Mg1 Distribuition1.1 - Distribution1.2 - Distribution1.3 / Medication(n) Dosage(n) Mg(n) Distribuition(n).1 - Distribution(n).2 - Distribution(n).3

First, we create an Excel document that numbers the P1...Pn sheets referring to each patient. Later, we sort in columns the scales (Annexes 7.6, 7.7, 7.8, 7.9) including an additional cell called Medication to save the pills oriented by patient psychiatrists on that consultation day, example: Lithium 300 mg 0-0-4 / Risperidone 3 mg 0-0-1 / Quetiapine 100 mg 0-0-1 / Clonazepam 2.5 mgml 0-0-15 drops. Then, in columns, we provide the Consultation number. Finally, the intersection of column and line (cell) provides the result of a specific scale in a consultation.

Our initial intention was to collect a minimum of three months of follow-up, based on the specialist's recommendation and related work (PALMIUS et al., 2017b; STANISLAUS et al., 2020; GOLDSTEIN et al., 2020; BONNíN et al., 2021); however, some participants felt comfortable continuing for more time, so we decided to continue the research. This flexibility was foreseen in a submitted project to *Plataforma Brasil*.

Despite the willingness and collaborative intention of the participants and the intention to return every 30 days for the specialists to reapply the scales and compare them with previous consultations, only 14 decided to continue the study despite the number of patients initially recruited, as reflected in Table 4.2.4. Those persons returned at least three continuous consultations in the IPUB (not necessarily each 30 days), specialists applied the scales commented in subsection 4.2.5.

Table 4.6: Initial patients involved in study

Patient ID	**Admission**	**Genre**	**Age**	**Bipolar type**
P2	19/12/2023	F	48	BD1
P3	19/12/2023	F	42	BD1
P4	30/01/2024	M	40	BD1
P5	09/01/2024	F	49	BD1
P8	09/01/2024	F	29	BD2
P11	20/02/2024	F	24	BD1
P12	20/02/2024	F	35	BD2
P13	20/02/2024	M	50	BD1
P14	20/02/2024	F	37	BD1
P15	05/03/2024	M	26	BD2
P16	05/03/2024	F	48	BD2
P18	12/03/2024	F	26	BD1
P19	19/09/2024	M	32	BD2
P21	26/03/2024	M	52	BD1

At this point, we could consider the diverse circumstances of a lack of acceptance of the research described in the next subsection.

4.2.5 Adherence evaluation from collected data

Non-adherence to mHealth applications to monitor people with bipolar disorder can lead to incorrect diagnoses by specialists (JAKOB et al., 2022; SIEGEL-RAMSAY et al., 2023). As the goal of the proposed application is to be less intrusive in the day-to-day collection of active user data, following this background approach of collecting subjective information, we could get valuable information that users could forget about on a specific day when asked in consults or feel uncomfortable (SIEGEL-RAMSAY et al., 2023). In this line, since each user has an individual behavior with the app, they could spend different amounts of time between the application screens. Consequently, we would extract subjective information that is not available in a clinical context when comparing how quickly they are proficient in app management.

First, we point out two main reasons people abandon the ongoing research: personal (un)interest and lack of commitment, described in the discussion Section 4.2.7. As research participation is voluntary and personal interest can vary, we were interested in gaining information about those participants who decided to continue with research and their experience with the BraPolar2 application. Consequently, we found two strategies:

1. Qualitative evaluation through an adaptation interview to the mHealth usability questionnaire.

2. Quantitative evaluation of collected active and passive data, supported by Firebase reports.

mHealth Usability Questionnaire adaptation

To identify the aspects that cause patients with bipolar disorder not to fill in the data in a mHealth application and the factors that motivate them to use the application as a habit, we conducted qualitative research on the use of mHealth BraPolar2 supported by an adaptation of the mHealth Usability Questionnaire (MAUQ) (MURO-CULEBRAS et al., 2021). These questionnaires aim to measure different aspects of the usability, satisfaction, and acceptance of mHealth apps among users and healthcare professionals. In addition, it is widely used in the field of study by other authors (MANZANO-MONFORT et al., 2023; MUSTAFA et al., 2021; HAJESMAEEL-GOHARI et al., 2022) who adapt to their native language. Although MAUQ is designed primarily as a self-administered questionnaire, it can also be adapted for interviews to gather more in-depth qualitative insights into user interactions with mHealth applications, avoiding potentially leading to respondent fatigue, affecting the quality of the collected data (GLISE; WIEGNER; JONSDOTTIR, 2020). Consequently, we adapt MAUQ for our population and follow the next steps.

1. Research about strategies to evaluate adherence in mHealths.

2. Translation to Portuguese MAUQ questionnaire.

3. Validate with six specialists the translated questionnaire.

4. Adapt him to conduct a semi-structured interview.

Once we have concluded that phase, we intend to know the next with our interview regarding the BraPolar2 application:

1. Ease of Use.
2. Frequency of use.
3. Motivation.
4. Interface and Satisfaction.
5. Utility.
6. Feelings towards collected passive data.
7. General User Opinion.

As conducting an interview can be challenging, we obtain a questionnaire to assess adherence in a semi-structured interview (Annex 7.11), avoiding closed questions and intending to be an open-ended question that promotes discussion and leads to a conversational partnership (GRANDE et al., 2019; GRAU-CORRAL et al., 2020; LAZAR; FENG; HOCHHEISER, 2017). As part of the preparation, we applied a pilot interview test with six specialists (two psychologists and four psychiatrists) to refine the questions for the patients.

We intend to reach those participants who decided to abandon the research (P1, P6, P7, P9, P10, P14, P17, P19, P20, P22) too; however, it was not possible due to their free decision to stop the research. Furthermore, we focus on 12 people with bipolar disorder who participated in the study and used BraPolar2 for at least two months from the beginning of our research. In Table 4.2.5, we show the patient's ID (column ID), the consultation number (C1...C6), and the date of follow-up by specialists and the interview date highlighted.

Table 4.7: Interviewed bipolar disorder people involved in study

ID	**C1**	**C2**	**C3**	**C4**	**C5**	**C6**
P2	19/12/23	23/01/24	05/03/24	09/04/24	30/04/24	04/06/24
P3	19/12/23	23/01/24	05/03/24	02/04/24	30/04/24	04/06/24
P5	09/01/24	30/01/24	12/03/24	16/04/24	21/05/24	18/06/24
P8	09/01/24	06/02/24	12/03/24	21/05/24	18/06/24	16/07/24
P11	20/02/24	19/03/24	09/04/24	07/05/24	28/05/24	16/07/24
P15	05/03/24	19/03/24	30/04/24	28/05/24	02/07/24	-
P16	05/03/24	26/03/24	14/05/24	18/06/24	16/07/24	-
P18	26/03/24	07/05/24	04/06/24	02/07/24	-	-
P21	26/03/24	16/04/24	21/05/24	18/06/24	16/07/24	-

To be as less intrusive as possible, the interview occurred during one of their normal consultations while waiting for their medical appointment. First, we invited them to participate in the research and proceeded to sign the term of voice record; neither one refused to participate or record their voice and was invited to a consultation room where the questionnaires were applied, recorded, taking written notes (LAZAR; FENG; HOCHHEISER, 2017) and analyzed later.

Firebase global adherence session time

As Firebase can show the global adherence session time for each patient, we could investigate how users interact with the proposed application as an alternative to conducting a user interaction satisfaction questionnaire (QUIS) (SIEGEL-RAMSAY et al., 2023) mentioned in previous studies (MONDEJAR et al., 2019a; MONDEJAR et al., 2020). The following subsection presents the main user adherence results using adapted MAUQ interviews and Firebase reports.

4.2.6 Patients interview results

In this subsection, we describe the main results of the investigation regarding the user's adhesion to the proposed solution and the main findings.

Qualitative evaluation through an adaptation of MAUQ

The interviews with the modified version of MAUQ were conducted at different times for each participant, as explained in Table 4.2.5. In addition, we include their current state on the day of the interview (manic, hypomanic, euthymic, or depressed) defined by their therapists, considering that patients with bipolar disorder can exhibit varying levels of understanding and insight into research participation based on their current mental state (MISRA et al., 2008) and the total interview time, summarized in Table 4.2.6 and is commented on in detail in the discussion subsection (4.2.7).

Quantitative evaluation of collected active and passive data

Data collection started on 19/12/2023 until 02/08/2024. During those months (Figure 4.15), we observed a progressive increase in user over time until we closed the recruitment of new patients on 02/04/2024. Consequently, since new patient recruitment occurs every Tuesday, a peak in the graph is expected, corresponding to the new active users. It is valid to mention that the lack of new users in the graph (flattened) corresponds to the holidays of December

Table 4.8: Patient state in interview day

ID	**Interview date**	**Mental State**	**Total interview time (mm:ss)**
P2	04/06/24	Manic	10:38
P3	04/06/24	Hypomania	16:36
P5	21/05/24	Depressed	14:15
P8	21/05/24	Euthimia	21:49
P11	07/05/24	Depression	18:24
P15	28/05/24	Depression	14:53
P16	14/05/24	Euthimia	11:58
P18	04/06/24	Euthimia	08:58
P21	21/05/24	Euthimia	21:44
Avg time	-	-	**15:28**

and Carnival in Brazil or the inaccessibility of new patients, which fits our inclusion criteria.

As new patient recruitment was completed in April, those who decide to continue with the research keep an active use of BraPolar2, as observed from April to August 2024 and detailed as follows.

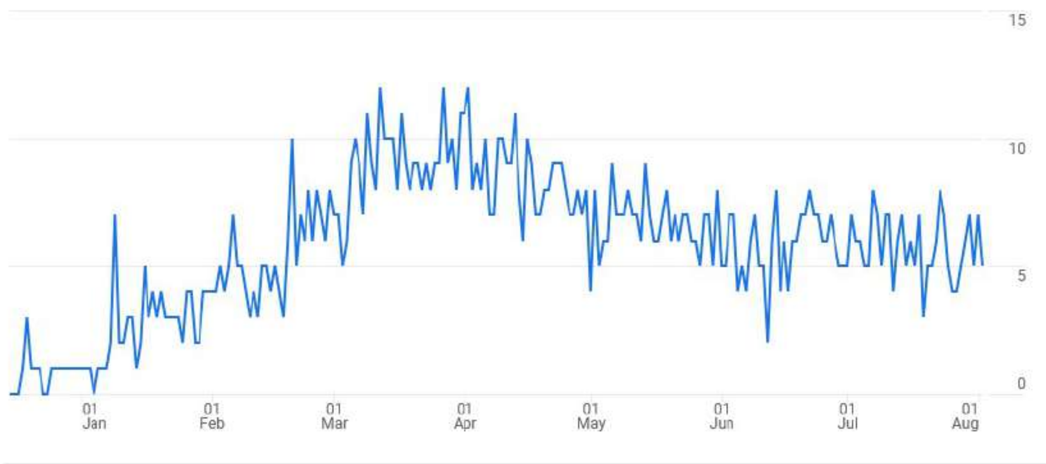


Figure 4.15: Active users over time

– **Active data collection results**

Regarding active data engagement, which requires user intervention with the user interface of the application, we observed an average application use of 2 minutes and 23 seconds (133.73 seconds), and an engagement rate of 68.64% for users who used the BraPolar2 application (start and finish to complete the daily questionnaire) from their first day with the application until the previous day of the interview application to avoid bias. Example: P2 started using BraPolar2 on 19/02/2023 until 02/08/2024. We considered the collected data until 01/08/2024 because the daily form (02/08/2024) can only be submitted at the end of the day.

In Table 4.2.6, we present the list of active users (those currently in research), the device model of their smartphones, the initial and final date of data collection, the number of days of research since the recruitment day (NDR), when BraPolar2 was installed on the mobile phones of participants.

Table 4.9: Patient device models and days of data collection

ID	**Device model**	**Initial date**	**Final date**	**NDR**
P2	Moto E32	19/12/24	04/06/24	168
P3	G780G, SM-A115M	19/12/23	04/06/24	104*
P4	SM-M135M	30/01/24	16/07/24	168
P5	Moto G10	09/01/24	23/07/24	196
P8	X695, SM-A055F	09/01/24	16/07/24	187*
P11	SM-A236M	20/02/24	16/07/24	147
P12	SM-G9500	20/02/24	02/08/24	163
P15	SM-G991B	05/03/24	02/08/24	149
P16	SM-S901E	05/03/24	02/08/24	149
P18	Moto G20	12/03/24	02/08/24	142
P21	2212ARNC4L	26/03/24	02/08/24	128
Total	-	-	-	**1701**

* It is valid to mention although P3 and P8 had participated a total of 168 and 189 days in the research, we calculated NDR 104 and 187 for those cases:

- P3 had their smartphone stolen and informed us two months later that the event totalled 64 days without any data (01/01/2024 - 05/03/2024). BraPolar2 was reinstalled in Consultation #3 on 05/03/2024.
- P8 changed to another one and was absent for two days without any data capture until reinstalling BraPolar2. The user installed BraPolar2 on his new smartphone.

The previous statements justify why P3 and P8 used two smartphone models.

Once NDR is calculated, we present in Table 4.2.6 the list of active users (those currently in research), daily participation (DP) and the average use of the application in seconds (AUA) fetched via Firebase. In addition, we show the percentage of sessions engaged (DP * 100 / NDR) as the adhesion rate (%).

Table 4.10: Patient BraPolar2 adherence

ID	**NDR**	**DP**	**AUA (secs)**	**Adhesion rate (%)**
P2	168	133	29	79.16
P3	104	49	78	47.11
P4	168	164	46	97.62
P5	196	139	52	70.92
P8	187	181	28	96.79
P11	147	124	33	84.35
P12	163	134	36	82.21
P15	149	55	103	36.91
P16	149	74	45	49.66
P18	142	90	88	63.38
P21	128	60	97	46.88
Total	**1701**	**1203**	**58.6 s**	**68.64%**

– **Passive data collection results**

Regarding passive data, which involves this new data collection approach through sensors, we stored 38232 registries from participants' Screens, structured in a Firebase real-time database, detailed in Table 4.2.6.

In a previous study (MONDEJAR et al., 2019a), we used the cellphone dependency test (YILDIRIM; CORREIA, 2015), and we intend to apply it to bipolar patients. However, when we applied it with P1, P2, and P3, it took an average of 40 minutes per person and was extenuating for the patients. Therefore, we decided not to continue to apply him and developed our personalized formula: dependency ratio, based on user-screen interaction. The dependency ratio (DEPr) is calculated by dividing the total interaction (TOi) by the number of days since the start of data collection (DCd) by 100. The result is evaluated on a scale from 0 to 1, where the nearest value to 1 indicates more cellphone dependency.

$$DEPr = (TOi/DCd)/100$$

In Table 4.2.6, we calculate and show this ratio for each participant from the beginning of data collection until 02/08/2024 when we close this thesis data reception.

Table 4.11: Patients passive data collected: event screen

ID	Cell lock	Cell un-lock	Screen On	Screen off	Total in-teractions
P2	1848	407	1240	1016	4511
P3	376	135	309	203	1023
P4	46	11	33	24	114
P5	1551	2973	2974	1521	9019
P8	4120	1479	3283	2316	11198
P11	285	151	256	180	872
P12	218	240	289	169	916
P15	47	10	32	25	114
P16	333	189	314	206	1042
P18	210	130	206	134	680
P21	3650	721	2469	1903	8743

Table 4.12: Participants cellphone dependency ratio

ID	NDR	Total inter-actions	Dependency ratio
P2	168	4511	0.269
P3	104	1023	0.098
P4	168	114	0.006
P5	196	9019	0.460
P8	187	11198	0.599
P11	147	872	0.059
P12	163	916	0.056
P15	149	114	0.008
P16	149	1042	0.070
P18	142	680	0.048
P21	128	8743	0.683

Each participant has a unique dependency on the cellphone (as part of the digital phenotype); we visually present in Figure 4.16 the most and least dependent on the cellphone during research time.

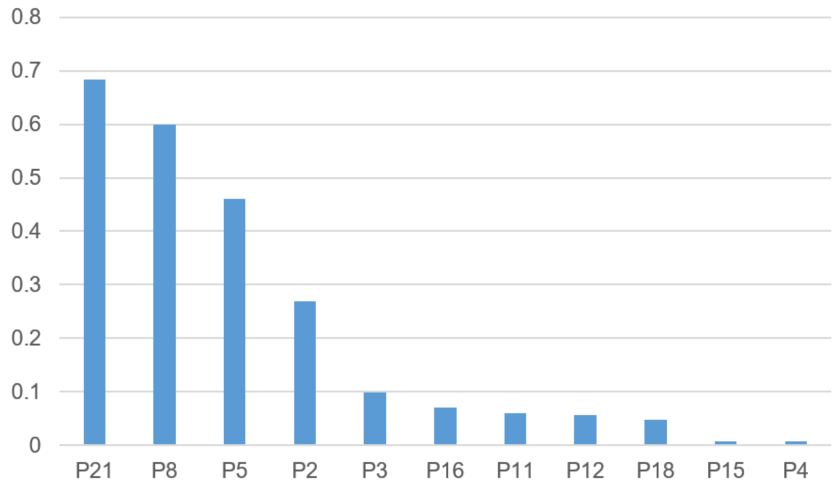


Figure 4.16: Cellphone dependency ratio by patients

Although we have continuous follow-up and patient recruitment, some participants decided not to continue (P1, P6, P7, P9, P10, P13, P14, P17, P19, P20 and P22); we observed that they were not interested and left to complete the daily questionnaire or did not return to IPUB on the scheduled date and summarized the reason for abandonment of the study in Table 4.2.6.

4.2.7 Discussion

First, we want to highlight the complexity of conducting research in patients with psychiatric disorders. In addition, in Brazil, it is forbidden by law to pay participants for clinical studies to prevent volunteers from thinking of their participation as just a way to earn money or work, detracting from the project's main objective; however, transportation reimbursement is allowed as established in the ICF. In this way, we refund R$25.00 for each participant to cover transportation expenses from the second consultation, as established in the ICF signed at the beginning of the research.

Another point, although not commonly mentioned, is about the patients in IPUB who did not agree to participate in the investigation when we offered it. The main justifications were the depression or hypomanic state observed by researchers and specialists, not compromising to return to IPUB from 30 in 30 days, having too many applications on cellphones, not having time to fill up daily information, or concern about privacy. From December 2023 until April 2024, we proposed the research to 47 patients who could participate (fit

Table 4.13: Reasons for patient study abandonment

ID	**Start consultation**	**Last contact**	**Reasons for abandon**	**Adherence rate (%)**
P1	19/12/23	19/12/23	Withdrew after completing the first consultation before installing BraPolar.	0%
P6	09/01/24	06/02/24	Skipped the scales in Consultation 1, started the research on 06/02/2024, and did not return more to IPUB.	0%
P7	06/02/24	05/03/24	Switched to iPhone on 06/03/2024	14.29%
P9	16/01/24	05/04/24	Announced on 09/04 that she cannot go to IPUB or fill out the application claiming a lot of work.	91.25%
P10	06/02/24	02/04/24	Uninstalled the app on 05/04/2024 claiming it was crashing.	62%
P13	20/02/24	02/04/24	Ran away in Consultation 2, returned on 02/04/24, and considering their mental state, we decided to stop the investigation.	0%
P14	20/02/24	20/03/24	Did not return more to IPUB.	56.67%
P17	12/03/24	12/03/24	Withdrew after completing the first consultation before installing BraPolar.	0%
P19	19/03/24	21/04/24	He started doing private consultations.	51.52%
P20	26/03/24	16/04/24	She started doing private consultations.	61.90%
P22	02/04/24	02/04/24	Was not able to apply scales and did not return more to IPUB.	0%

the inclusion criteria), 22 accepted participants, and only 11 concluded the research.

Next, we discuss in detail our observations from the semi-structured interview. Then, we dive into the active/passive data collection process.

– **Interview discussion**

Analyzing interviews may be challenging (LAZAR; FENG; HOCHHEISER, 2017; BARBOSA et al., 2021). Taking into account the notes and prescription of the audios mentioned in Subsection 4.2.5, we analyze each prescription, split into categories (LAZAR; FENG; HOCHHEISER, 2017) and highlight the consideration of the patients for each categorized item:

Ease of Use

The participants generally considered the application practical and easy to use, with some initial challenges overcome with practice. P2 described the application as practical and easy to use, overcoming initial difficulties quickly. P5 found the application very easy to use, highlighting the smooth navigation between screens and the ability to enter the necessary information without problems. P8 found it difficult to view the history of his entries, which negatively impacted his motivation for continued use and the lack of reminders. P11 mentioned that the restricted time to enter the data was a significant problem, resulting in the loss of records. Furthermore, navigation, although generally consistent, presented some glitches. P15 found using the application intuitive, with clear questions and objective markings and did not face significant difficulties in navigation. P16 considered the application easy to use, mentioning that alarms and reminders were not uncomfortable, although he occasionally forgot to respond due to routine. P18 also found the application easy and intuitive but noticed that the answers were reset when returning to a previous page, which was an issue solved later.

Frequency of use

Participants showed variations in the frequency of using the application, influenced by different factors. P2 used the application daily, feeling satisfied and with a sense of mission accomplished after filling in the daily data. P5 highlighted that the lack of availability at certain times affected their frequency of use, emphasizing the importance of having more flexible schedules to facilitate continuous use. P8 mentioned that the absence of reminders negatively affected her frequency of use, indicating that she would have used the application more regularly if she had been notified at specific times. P11 used the application daily, except when he forgot or missed the time allowed for data entry, considering this restriction a significant impediment to continued use. P15 used the app almost daily but occasionally forgot, especially when he was away from home or feeling ill, feeling frustrated when he could not fill in the data after midnight due to the impossibility of retroactive entry. P16 used the application daily but sometimes forgot to fill in the data, especially at night, feeling bad when he could not complete the entries for several days. P18 used the application daily, except on some days when she forgot, usually due to her menstrual routine, feeling frustrated when she failed to fill in the data.

Motivation

The participants presented different motivations for using the application, often related to their daily routines and personal needs. P2 preferred to fill out the information at night, as this coincided with when she took her medication, helping her to remember this important task. P5 felt that the app helped record her mental state, providing self-awareness of her mood and sleep. The absence of a visual history impacted P8's motivation as she would like to see her progress over time, especially concerning personal aspects such as menstruation. P11 did not directly discuss her motivation, but her regular use suggests that she was committed to the process despite the app's limitations. P15 preferred to use the application at night, after completing his daily activities and taking medication, considering filling in the data as a diary that provided a positive feeling of control over his data. P16 also preferred to fill in the data at night but suggested that answering in the morning could be more accurate, especially for questions about sleep and medication. P18 preferred to complete the data in the evening, close to the cut-off time, to ensure that all changes in mood throughout the day were captured.

Satisfaction of Use

The participants presented different opinions on the application interface, highlighting positive aspects and suggesting improvements. P2 liked the interface of the application, thought the information was well organized, and felt comfortable using it in social environments, considering the time spent using it as appropriate and expressing general satisfaction with the application, stating that he would use it again. P5 described the interface as organized and easy to use, as well as feeling comfortable in social settings, and considering that the usage time is adequate, it generally takes around five minutes to complete the entries. P8 found the interface neutral and mentioned that the information was well organized, but felt a lack of adequate notifications and feedback on information entered, feeling comfortable using the application in social environments, but not satisfied with the current version, highlighting the need for improvements to increase usefulness. P11 described the interface as basic and normal, with well-organized and intuitive information, feeling comfortable using the application in social environments, but preferring to use it before bed. P15 considered the application interface simple, but suggested improvements to align with more modern designs, including accessible graphics and results for users. P16 considered the application interface to be simple and well organized, comfortable using the application in social settings, and found the time spent adequate. P18 liked the interface of the app, found the information well organized, felt comfortable using the app in social settings, and found the time spent appropriate.

Utility

Participants expressed different perceptions about the app's usefulness for their health and well-being. P2 found the app useful for remembering to take her medication and managing her bipolar disorder, believing that the app had all the necessary features. P5 considered the application useful for understanding and managing his mental state, but suggested improvements such as greater flexibility in schedules. However, P8, did not find the application useful due to the lack of access to recorded information and the lack of feedback on his daily entries, which diminished his perception of usefulness. P11 also did not find the app particularly useful for monitoring her mood, citing the lack of transparency about where her data go and the lack of practical use in everyday life, highlighting the need for more transparency and features in future versions. P15 believed in the usefulness of the app for mental health, especially if used in conjunction with a psychiatrist or psychologist, suggesting the presentation of graphical results to help users better understand their mood fluctuations. P16 found the application useful, especially for remembering medications, suggesting the inclusion of a field for personal observations to better contextualize the data collected. P18 also found the app useful for keeping track of her mental state, but would like access to visual feedback, such as graphs, to better understand her mood trends.

Feelings towards collected passive data

The participants presented various perceptions about passive data collection in the application, predominating neutral or positive feelings. P2 did not feel uncomfortable with passive data collection and realized that he used his phone differently depending on his mood, preferring to be "off" on days when he did not want to appear on social media. P5 did not mention negative feelings about passive data collection, indicating comfort with the transparency of the application. P8 did not make his feelings about passive data collection explicit. However, his general dissatisfaction with the lack of feedback suggests that greater transparency and feedback on collected data would be beneficial. P15 was initially a little concerned about passive data collection, but felt comfortable after understanding that the process was non-invasive and would help monitor his behavior. P16 was not concerned with passive data collection and noticed variations in phone use depending on his mood. P18 also noticed differences in phone use depending on his mood and thought that the application was light and did not affect the cell phone's performance.

General User Opinion

The participants presented valuable suggestions to improve the usability and effectiveness of the application, with an emphasis on flexibility and data presentation. P2 highlighted the importance of the application in improving your day and positively incorporating it into your daily life. P5 suggested a greater flexibility in the times to fill in the information to facilitate the continuous use of the application. P8 recommended leaving the field of emotions open, without limiting it to predefined options, and eliminating the time limit to fill out the information, which would increase the flexibility and usefulness of the application. P11 did not directly mention feelings about passive data collection. Still, it highlighted the need for greater transparency, suggesting that clearer communication about collecting and using these data could improve their satisfaction. P15 emphasized the need for improvements to the interface and presentation of the results, suggesting that these changes would increase the satisfaction and effectiveness of the application. Both P16 and P18 suggested the inclusion of graphs and analyzes of the collected data, which would help better understand trends and variations in mood over time. P18 also mentioned that allowing correction of the answers without losing previous data would improve usability and overall satisfaction with the application.

– **Active/passive data collection discussion**

Regarding the patient's behavior of abandoning the clinic or disappearing for a while, we asked specialists, and they mentioned that those behaviors are common in psychiatric patients, behavior that we also observed: P13 and P14 spent more than two months, and when they came back, their psychiatric condition did not allow us to continue with them. We also observed that some patients show discomfort with the temperature and traffic conditions that coincide with the heat wave in Brazil during 2023 and the first half of 2024 [7], and this may be another reason why patients do not return to IPUB. Therefore, passive data captured with mHealth may be potentially relevant in these cases, considering follow-ups can indicate insight that needs to be studied despite the existing literature (MONTES; SERRANO; PASCUAL-SANCHEZ, 2021; HIRAKAWA; TERAO, 2022).

We observed that collaboration and adherence could differ between men and women and not between ages. As the men above tended to avoid participating in the study, the women were more collaborative in participating and filling out daily assessments with BraPolar2. However, we tried to include more men to provide a heterogeneous population sample; women were more collaborative, coincident with JAMES ET AL. (JAMES; KANG; MCQUEEN, 2023). Regarding age, we did not observe statistical relevance in adherence to BraPolar2 between younger (26-39) or older (40-52) participants. However, we expected that the adhesion of younger ones would be more significant.

Concerning the cell phone dependency test applied in previous studies with non-bipolar disorder (MONDEJAR et al., 2019a; MONDEJAR et al., 2020), we cannot use it. We applied it to the first three patients (P1-P3), which took about 40 minutes. Later, more 35 minutes to apply the psychological scales (ANDERSON et al., 2017; BUSK et al., 2020; KOZICKY et al., 2022; T; Z; STEFAN, 2023; GUEDES et al., 2023). In the end, the participants showed exhaustion while their main goal in visiting IPUB was to see a specialist, which could compromise the future inclusion of patients. This insight shows that the cell phone dependency test must be applied at another time to avoid user fatigue. Consequently, we suspend this scale's application for the next participants. To address this issue, we developed a Dependency Ratio formula to measure how much patients use mobile phones, and further research will be addressed as an alternative to complex questionnaires.

Usually, mHealth research provides participants with a new cell phone. However, we prefer to use the patient's smartphone to prevent discomfort, avoid carrying another device, and look at adhesion to the research from a realistic scenario. Consequently, the proposed application is compatible with Android versions 9, 11-14, given the heterogeneous model of the participants' smartphones shown in Table 4.2.6, and the adherence was above 80% for P4, P8, P11 and P12. Compared to similar studies (JAKOB et al., 2022), it is

[7]https://www.dw.com/en/brazil-heat-wave-hits-record-temperatures-rio-at-62c/g-68621375

considerably above the mean of 56.6% for mental health, indicating that the design elements of BraPolar2 have contributed to high adherence, such as a simple user interface, reminders, personalized feedback, and ease of use.

Limitations and future work

One of the main limitations is related to the refusal of user background access to BraPolar2, executed by the patient or due to recent Android updates. This particular behavior affected the passive data collected, resulting in data gaps, and should be addressed in the next studies, considering that since April 2024, Google has recognized health apps[8] considering the emerging market of digital mental health.

Another limitation of this study was related to the recruitment process, which affected the sample size in this work. First, as mental health is a sensitive topic and we have restricted inclusion criteria, this significantly impacts the sample size. Second, a set of participants to whom we offered the research and refused to participate commented on privacy, working with incompatible phones (iPhones), or being in a manic/depressive phase. However, we continue the recruitment process every week to identify new insights.

Concerning participants who decided not to continue, we observed that they were not interested and left to fill out the daily prompt or not return to IPUB on the scheduled date. Another set of participants to whom we offered the research and refused to participate commented concerning privacy, working with incompatible phones (iPhones), or being in a manic/depressive phase. Although some users do not when filling out the daily form, by collecting subjective information and comparing it with the specific day they filled out the form, we could infer the mood and energy level by considering the historical data.

In subsequent studies, we continue to follow up with patients with bipolar disorder in IPUB and evaluate individual correlations of symptoms of bipolar disorder and digital phenotype from active and passive data to improve patient monthly consultations. Although we intend to explore how user feedback and user-centered design principles can improve new BraPolar2 versions, we should also investigate strategies to optimize battery drain in mHealth, reducing the risk of low adherence to this issue.

[8]https://support.google.com/googleplay/android-developer/answer/14738291

4.2.8 Conclusions

In conclusion, it is essential to note that smartphone technology provides opportunities to be analyzed, given the population of bipolar disorders, and considering applied strategies to follow-up patients with bipolar disorders opens new opportunities for future research in this field. We evaluated the adhesion to the application with 11 patients with bipolar disorder (Section 4.2.6, indicating an adhesion of 68.64%, reducing the lack of mHealth for this problem. Taking into account the observation made in Section 4.2.7 that weather conditions can influence patient adherence to treatment, in the next sections of this work, we address the last research question of this thesis on how contextual data can improve the analysis of digital phenotype using contextual variables.

Once developed BraPolar2, we detail in Section 4.2.4 how we deploy the application in people with bipolar disorder at the Institute of Psychiatry of the Federal University of Rio de Janeiro (IPUB).

4.3 RQ3- Contextual data to improve digital phenotype analysis

In previous sections, we defined active and passive data concepts and how they are used to follow 11 people with bipolar disorder with BraPolar2. In this section, we present the theoretical background of contextual data and how we use it to improve the analysis of digital phenotype analysis in medical evaluation, completing the decision support system proposed in this thesis for better monitoring of bipolar disorders.

4.3.1 Contextual data definition

Context-awareness consists of the ability of applications to detect changes in their environment and adapt their behaviour (SCHILIT; THEIMER, 1994). Those systems are designed to improve the functionality and intelligence of applications by integrating contextual information, such as location, time, and user preferences (HUANG et al., 2023) to improve decision making and user experience. In this line, pervasive computing is discussed in research contexts provided by several authors (MAYORA et al., 2013; OSMANI et al., 2013; FROST et al., 2013; COELHO; BASTOS-FILHO, 2016; CHAPMAN et al., 2017; MOURA et al., 2020), referring to the integration of technology into various aspects of daily life, particularly in the monitoring and treatment of mental disorders such as bipolar disorder. In this context, it indicates ambient situations that can influence subjective user decisions (REINERTSEN; CLIFFORD, 2018; DORNELES et al., 2023), such as stress, depression, or happiness, or changes throughout life at different time points. Indeed, human behavior is notably influenced by context and environment; however, integrating environmental sensors and contextual information with behaviour monitoring remains unexplored (AL-SAEDI et al., 2022).

In this thesis, we define contextual data as a set of environmental conditions that can influence or affect a person's well-being, such as weather, temperature, weekdays, and near-noise. Although these factors can influence clinical evaluation (HIRAKAWA; TERAO, 2022), we observe that this field remains insufficient data in mHealth and that they can provide relevant information that could help specialists analyze variables in digital phenotype analysis.

As contextual data may include a set of factors that can influence the well-being of individuals (MAYORA et al., 2013; OSMANI et al., 2013; FROST et al., 2013; COELHO; BASTOS-FILHO, 2016; CHAPMAN et al., 2017; MONTES; SERRANO; PASCUAL-SANCHEZ, 2021; HIRAKAWA; TERAO, 2022; DORNELES et al., 2023), we categorize them into three variables: environmental, temporal and social-cultural, summarized in Table 4.3.1 and explained next.

– Environmental variables encompass data that can influence mood and behavior (HIRAKAWA; TERAO, 2022) such as temperature average (high, low, thermal sensation), average humidity levels, precipitation (measured in millimeters), wind speed (both average and maximum) and atmospheric pressure (measured in hectopascals).
– Temporal variables are classified according to time of day (morning, afternoon, evening, and night), day of the week (weekdays versus weekends), and season (spring, summer, autumn, winter) (HILL; CHTOUROU, 2020). We intend to follow the impact of day of week and season patterns of mental health behavior.
– Social and cultural factors impact social interaction, stress levels, and general emotional state (DORNELES et al., 2023). Consequently, we map public holidays, festivals (national, state, or municipal), and local activities like cultural festivals or concerts.

Table 4.14: Initial contextual variables

Contextual Variable	**Details**
Environmental Variables	**Weather Conditions:** Temperature: Recorded as daily high, low, and current temperatures. Humidity: Measured as daily average humidity levels. Wind speed: Measured in km/h. Atmospheric pressure: Measured in hectopascal.
Temporal Variables	**Day of the Week:** Humidity: Measured as daily average humidity levels. Weekdays vs. weekends.
	Season: Spring, summer, autumn, winter.
Social and Cultural Variables	**Public Holidays and commemorative dates** National and local holidays.
	Local Events and Festivals: Cultural festivals or concerts.

The variables mentioned above can be collected from various sources, such as weather APIs from weather services[9], and event listing websites (for local events)[10].

Considering the available literature, we intend to interview specialists to establish baseline knowledge, expectations, and initial perceptions about integrating contextual data in their clinical practice, described in the next subsection.

4.3.2 Semi-structured interview

In this section, we detail the interview to be applied with IPUB specialists to establish baseline knowledge, expectations, and initial perceptions of psychiatrists about the integration of contextual data in the analysis of the digital phenotype.

In a semi-structured interview, the interviewer flexibly asks questions, using open questions and going deeper into some topics (BARBOSA et al., 2021). This kind of interview should contain an introduction, in which the interviewer introduces and explains the purpose of the interview; a warm-up period, in which easy-to-answer questions are asked, such as demographic

[9]http://api.openweathermap.org/data/2.5/onecall
[10]https://calendarific.com/api/v2/holidays

data; the main part of the interview, in which the script is explored; a cool-down period, to defuse any tension that has arisen; and the conclusion, in which the interviewer thanks the interviewee for their time, turns off the recorder, and puts away their notes, indicating that the interview is over (PREECE; SHARP; ROGERS, 2015). Following these recommendations, we interviewed 8 IPUB Institute specialists (5 psychiatrists and 3 psychologists) to understand the relevance of contextual data in the analysis of the digital phenotype in clinical practice.

Topics and questions to abroad

To conduct the interview, first, we had the intention of limiting ourselves to the relevance of contextual data in clinical analysis; however, considering that a meeting with specialists at the IPUB institute can be limited in time, we explore beyond and investigate the following topics and the objective of each.

1. **Basic information**: to understand specialists' expertise and evolving approaches in treating Bipolar Disorder, particularly exploring their experience with digital tools or mHealth applications in clinical practice.

2. **Regular practice**: to explore the current practices of specialists in monitoring and managing mood fluctuations in patients with Bipolar Disorder, focusing on their preferred methods, tools, and data sources.

3. **Professional experience and perception with mHealths**: to delve into specialists' professional expertise and perceptions regarding mental health technologies and digital monitoring in treating mental disorders.

4. **Relevance of contextual data**: focusing on the relevance and integration of contextual data in clinical practice for mental health management and understanding the practical value and challenges of using contextual data to enhance mental health care.

5. **Challenges and opportunities**: to capture the barriers and potential advancements in using contextual data to enhance mental health care in Bipolar Disorder patients.

6. **Suggestions and recommendations**: to capture practical recommendations and ideas for future research managing Bipolar Disorder with mHealths.

Taking into account the experience of semi-structured interviews with patients mentioned in Section 4.2 of this thesis, we created a list of the main topics (mentioned above) so that the conversation becomes more "natural", in line with related research (COSTA; LUCCIO, 2009; PREECE; SHARP; ROGERS, 2015; BARBOSA et al., 2021). The interview script conducted is presented in the Annex 7.17.

4.3.3 Method

The interviews with specialists were conducted face-to-face at the IPUB Institute on Tuesdays in July 2024. As data privacy is a sensible point, the specialists signed the voice authorization form, and the conversation was recorded for later analysis. In Table 4.3.3, we summarize the characterization of the specialists interviewed, numbered from S1 to S8, their specialization (psychiatry or psychologists), years of experience in the treatment of patients with bipolar disorder (YeXP), and the total interview time.

Table 4.15: Interviewed specialists characterization

ID	**Interview date**	**Specialization**	**YeXP**	**Total interview time (mm:ss)**
S1	09/07/24	Psychologist	12	12:02
S2	09/07/24	Psychiatrist	4	22:26
S3	09/07/24	Psychiatrist	9	31:09
S4	09/07/24	Psychologist	6	19:33
S5	16/07/24	Psychologist	17	39:20
S6	23/07/24	Psychiatrist	35	58:31
S7	23/07/24	Psychiatrist	2	19:36
S8	23/07/24	Psychiatrist	8	23:07
Avg	-	-	**11.6**	**28:13**

When conducting the interview, we only consult the script and level the freedom to formulate the question related to each topic in a way that is more appropriate to the interviewee's profile, seeking to maintain the tone of the conversation during the conversation. It is valid to mention that only E6 participated in all stages of the Software Development Life Cycle (AGARWAL et al., 2023) and collaborated to define the main features and requirements of BraPolar2, detailed in Section 4.2.3. Their clinical experience can provide valuable information on the relevance of contextual data found in the literature.

Interview analysis

To analyze the interviews, BARBOSA ET. AL. 2021 recommended the empirical analysis of interviews be based on a combination of interparticipant and intraparticipant approaches (COSTA; LUCCIO, 2009). Through this methodological framework, we conducted a detailed examination of the responses. We identified common themes that cut across individual participants and areas where respondents' responses conflicted or were inconsistent. Description of steps for the analysis process

1. Data Preparation: we transcribed all interviews so that we could ensure the appropriate nuances of how participants conveyed information. We also took note of nonverbal cues, like pauses or emphasis, if applicable. We read the transcripts three times to familiarize ourselves with the data. The themes were identified and key comments were highlighted.

2. Coding: all interviews were open-coded line-by-line for key concepts/-words/reoccurrences. This process occurred by parsing the text into segments and assigning word-based codes that encompass its contents (for example, 'use of mHealth' or 'challenges with patient adherence') in transcription text.

3. Intraparticipant analysis: an intraparticipant analysis was performed within each interview. The goal was to take advantage of the same approach when exploring each participant's responses, looking at their responses both within and across all questions.

4. Interparticipant analysis: this analysis used the question-by-question approach to identify trends and patterns that emerged among all participants. This involved collating answers from all specialists for each question to delineate themes and central tendencies.

5. Identification of conflicts and inconsistencies: At this stage, the analysis aimed at identifying potential conflicts of opinion, apparent inconsistency between answers or any contradiction in answers given to be conflicting by respondents. This even included an expert who theoretically supported digital tools, but acknowledged little or no practical use.

Next, we describe the process and main results of a semi-structured interview to identify contextual data that play a relevant role in analyzing the digital phenotype in bipolar patients.

4.3.4 Qualitative interview with specialists results

We used both interparticipant and intraparticipant analysis to review the responses systematically, synthesizing common themes, recurring challenges, and individual insights. Taking this dual approach, it was possible to gain an understanding of the perspectives of the respondents (exploration), as well as identify the core trends and areas where opinions diverged or contradicted each other amongst the views (insight mapping) and are presented in Table 4.3.4.

Despite the insights collected in the analysis of the interparticipant and intraparticipant, we also identified conflicts and inconsistencies during the interview analysis, grouped into three main points:

- *Familiarity with mHealth Technologies vs. Use in Practice*: specialists recognize the importance of digital technologies, but few use them effectively due to lack of knowledge or confidence.
- *Importance of Contextual Data vs. Integration in Practice*: while all recognize the relevance of contextual data, few can systematically integrate it into their treatment plans.
- *Need for Personalization vs. Practical Reality*: there is a desire to personalize treatment for each patient, but practical barriers such as limited time and resources hinder the implementation of more individualized approaches.

4.3.5 Discussion

Specialists involved in interviews have agreed on the need for contextual data samples that explain the understandable dynamics of Bipolar Disorder. Recognizing the contextual data in which environmental, temporal and social factors influence patient mood, behavior, and health can enrich their analysis. Specifically, specialists agreed that these contextual variables add a layer of rich and important information that cannot be captured in traditional clinical measures. The contextual variables presented in Table 4.3.1 were adapted and included sports events and religious data, remaining to the next, represented in Table 4.3.5.

Table 4.16: Analysis of inter/intra-participant interviews

Topic	Interparticipant Analysis	Intraparticipant Analysis
Pt1: Basic Information	Specialists are specialized in psychiatry (S2, S3, S6-S8) or clinical psychology (S1, S4, S5), with experience ranging from 2 to 35 years in treating Bipolar Disorder (BD).	Specialists like S4 reported that their practice evolved by incorporating new research and clinical supervision. Most do not use mHealth technologies, indicating unfamiliarity with these tools.
Pt2: Current Practice	Mood monitoring and management are primarily conducted through clinical scales (e.g., Hamilton, Young, CGI-BP), patient self-reports, and regular consultations. Integration of these data is done via medical records and consultation notes.	Some interviewees, such as S2 and S6, use complementary tools like affectivogram logs but report that patient adherence is a persistent challenge.
Pt3: Professional Experience and Perception	All specialists have little or no experience with mHealth apps, recognizing potential benefits but also challenges like patient adherence and difficulty maintaining consistent use.	S7 highlighted that although familiar with apps like 'Estabiliza', practical adoption is limited due to patients' lack of proper instruction on usage.
Pt4: Relevance of Contextual Data	Interviewees agree that contextual data, such as weather, social events, and support networks, significantly impact patients' mental health.	S1 and S4 emphasized that integrating contextual data is valuable but mentioned challenges in systematically incorporating this information into clinical practice.
Pt5: Challenges and Opportunities	The main challenges include difficulties in collecting and integrating contextual data and low patient adherence to digital technologies (S2, S6). There is a consensus on the need for more intuitive tools tailored to clinical needs.	S6 suggested improving the design of apps to ensure accessibility and usability, while S8 highlighted the importance of personalization to enhance adherence.
Pt6: Suggestions and Recommendations	Specialists S1 and S3 recommended the development of mHealth apps that provide immediate feedback and are user-friendly. They suggested advancing research to integrate contextual data more effectively into digital phenotyping.	S3 pointed out that technology should evolve to offer clear and accessible reports that facilitate visualization of the patient's history and assist in clinical decision-making.

Table 4.17: Contextual variables defined by specialists after interview

Contextual Variable	**Details**
Environmental Variables	**Weather Conditions:** Temperature: Recorded as daily high, low, and current temperatures. Humidity: Measured as daily average humidity levels. Light exposition: Measured as UV exposition. Clouds: Defined as how cloudy the day is.
Temporal Variables	**Day of the Week:** Weekdays vs. weekends.
	Season: Spring, summer, autumn, winter.
Social and Cultural Variables	**Public Holidays and commemorative dates** National, local holidays and commemorative dates
	Local Events and Festivals: Cultural festivals, concerts, or sports events.
	Religious events: Ramadan, Yom Kippur, Elegua.

4.3.6 Conclusions

In conclusion, specialists validated the contextual presented in Table 4.3.5 as points that can provide deeper insight into the environmental and social factors influencing BD, mentioning that these new predictors - especially light exposure, weekday versus weekend fluctuations and area events - can help anticipate and address changes in patient status, as indicated by other researchers (MAYORA et al., 2013; OSMANI et al., 2013; FROST et al., 2013; COELHO; BASTOS-FILHO, 2016; CHAPMAN et al., 2017; MONTES; SERRANO; PASCUAL-SANCHEZ, 2021; HIRAKAWA; TERAO, 2022; DORNELES et al., 2023). The results (Section 4.3.4), validated by 9 IPUB Institute specialists, highlighted that the contextual presented in Table 4.3.5 can provide a holistic view and offer more information on the environmental and social factors that influence patients with BD. Meanwhile, we observe that collected data start to throw a curious fact: some patients lie about their sleep time despite their behavior with their cellphones. To investigate these and other phenomena, we better consolidate the collected data to identify the digital phenotype in patients with BD.

As such, this enhanced understanding supports the development of more targeted and adaptive treatment strategies in patients with bipolar disorder. In the next section, we establish a correlation between all available data collected during the research.

4.4 RQ4- Integration of active, passive, contextual, clinical, and demographic data

This section explores integrating active, passive, contextual, demographic, and clinical data collected from December 2023 to August 2024 into a dataset. As data preparation is a critical step that ensures the precision and reliability of the results (WILKERSON; LANOUETTE; SHAREFF, 2021), the original data collected from the studies applications should be processed before any statistical analysis (LAZAR; FENG; HOCHHEISER, 2017).

Since no statistical analysis was performed in this work, preparing data for the next steps was challenging to address in this section. In this line, the original and raw data may contain errors, missing values, or inconsistent format, contaminating the entire dataset. In addition, the specific analysis method or software may require data to be organized into a predefined layout or a layout that can be processed (DELWICHE; SLAUGHTER, 2019). In this section, we explore, clean, coding, and organizing the data mentioned by LAZAR ET. AL. (2017).

4.4.1 Avaliable data

Once we have finished the data collection phase, we extract the collected data from BraPolar2 (active and passive data) from Firebase. First, we exported the entire database (70.61 Mb) in a JSON file containing 2713711 lines. Then, we implement a Python script to extract all data collected by BraPolar2 during the research months, unifying all active/passive raw data fetched by BraPolar2 into Excel file, one sheet by feature as presented in Figure 4.17.

	A	B	C
1	date	idPatie	value
17	2024-01-07 22:33:07	P2	77
18	2024-01-08 22:50:37	P2	36
19	2024-01-09 22:40:09	P2	50
20	2024-01-10 23:56:03	P8	50
21	2024-01-11 19:06:45	P5	50
22	2024-01-11 22:38:56	P8	50
23	2024-01-12 19:06:28	P5	50
24	2024-01-12 22:34:33	P2	50
25	2024-01-12 23:21:18	P8	0
26	2024-01-13 19:09:50	P5	61
27	2024-01-13 23:46:54	P2	68
28	2024-01-13 23:58:33	P8	50
29	2024-01-14 23:49:32	P8	100
30	2024-01-15 19:53:56	P5	50
31	2024-01-15 22:15:34	P8	78

Mood | MoodIntensity | Energy

	A	B	C	D
1	date	idPatie	screenOn	isLock
669	2024-01-12 01:15:06	P5	Sim	Não
670	2024-01-12 01:15:25	P5	Não	Sim
671	2024-01-12 01:41:18	P8	Não	Sim
672	2024-01-12 01:48:37	P5	Sim	Não
673	2024-01-12 01:48:38	P5	Sim	Não
674	2024-01-12 01:50:11	P5	Não	Sim
675	2024-01-12 01:52:08	P8	Sim	Sim
676	2024-01-12 01:52:13	P8	Sim	Não
677	2024-01-12 02:00:46	P5	Sim	Não
678	2024-01-12 02:00:47	P5	Sim	Não
679	2024-01-12 02:02:01	P5	Não	Sim
680	2024-01-12 02:06:09	P5	Sim	Não
681	2024-01-12 02:07:22	P5	Não	Sim
682	2024-01-12 06:28:46	P5	Sim	Não

Screen

Figure 4.17: Active (left) and passive (right) data raw sample

For contextual data, we fetched daily data (15/12/2023 to 02/09/2024) from weather services[11], and event listing websites (for local events)[12], and sports[13], storing in a second dataset. Although the research ended on 02/08/2024, some participants (P8 and P21) were interested in continuing to fill in the information in BraPolar2 voluntarily and, considering avoiding discomfort; we left the app installed for these two participants. Figure 4.18 presents a subset of data fetched from the OpenWeather platform for Rio de Janeiro city.

B	C	D	E	F	G	H	I	J
dt_iso	timezone	city_name	lat	lon	temp	visibility	dew_point	feels_like
2023-11-15 00:00:00	-10800	Rio de Jan	-22.9068	-43.1729	26.91	10000	22.75	29.37
2023-11-15 01:00:00	-10800	Rio de Jan	-22.9068	-43.1729	26.91	10000	23.78	29.81
2023-11-15 02:00:00	-10800	Rio de Jan	-22.9068	-43.1729	25.8	4500	23.85	26.76
2023-11-15 02:00:00	-10800	Rio de Jan	-22.9068	-43.1729	25.8	4500	23.85	26.76
2023-11-15 03:00:00	-10800	Rio de Jan	-22.9068	-43.1729	24.03	4500	22.65	24.89
2023-11-15 03:00:00	-10800	Rio de Jan	-22.9068	-43.1729	24.03	4500	22.65	24.89
2023-11-15 04:00:00	-10800	Rio de Jan	-22.9068	-43.1729	24.91	6000	23.88	25.91
2023-11-15 05:00:00	-10800	Rio de Jan	-22.9068	-43.1729	24.91	6000	23.88	25.91
2023-11-15 06:00:00	-10800	Rio de Jan	-22.9068	-43.1729	24.91	8000	23.88	25.91
2023-11-15 07:00:00	-10800	Rio de Jan	-22.9068	-43.1729	24.91	7000	23.52	25.86
2023-11-15 08:00:00	-10800	Rio de Jan	-22.9068	-43.1729	24.91	7000	23.52	25.86
2023-11-15 09:00:00	-10800	Rio de Jan	-22.9068	-43.1729	25.03	8000	22.71	25.86
2023-11-15 10:00:00	-10800	Rio de Jan	-22.9068	-43.1729	25.91	8000	23.58	26.83
2023-11-15 11:00:00	-10800	Rio de Jan	-22.9068	-43.1729	27.05	8000	23.71	30.05

Figure 4.18: Contextual data raw sample

As mentioned in Section 4.2.4, each scale applied (Figure 4.19) was used

[11]http://api.openweathermap.org/data/2.5/onecall
[12]https://calendarific.com/api/v2/holidays
[13]https://ge.globo.com/rj/futebol/noticia/2023/10/31/calendario-do-futebol-brasileiro-em-2024-veja-as-datas.ghtml

by a specialist to each patient consultation clinical data set and recorded in an Excel data set.

Escalas	Consulta 1	Consulta 2	Consulta 3	Consulta 4	Consulta 5	Consulta 6
young1	0	0	2	1	2	0
young2	1	0	0	0	0	0
young3	0	0	1	0	0	0
young4	1	1	0	0	2	0
young5	0	0	2	0	4	2
young6	4	0	0	2	2	0
young7	0	0	0	1	2	0
young8	2	0	0	2	0	0
young9	0	0	0	0	0	0
young10	0	0	0	0	0	0
young11	2	2	1	0	1	0
ham1	1	1	1	1	1	2
ham2	1	0	1	3	2	2
ham3	0	0	0	0	0	0

Figure 4.19: Clinical data sample for each consult (P8)

Finally, when we applied the first scale, we saved the demographic data of all participants in a different dataset, as shown in Figure 4.20.

idPatient	admissionDate	gen	birthdate	maritalSta
P1	19/12/2023	F	04/06/1967	Solteiro
P2	19/12/2023	F	14/10/1976	Solteiro
P3	19/12/2023	F	29/12/1982	Solteiro
P4	30/01/2024	M	03/09/1984	Solteiro
P5	09/01/2024	F	10/04/1975	Solteiro
P6	09/01/2024	F	01/10/1973	Solteiro
P7	06/02/2024	F	01/06/1984	Divorciado
P8	09/01/2024	F	13/02/1995	Solteiro
P9	16/01/2024	F	28/11/1979	Divorciado
P10	06/02/2024	M	03/02/1996	Solteiro

Figure 4.20: Demographic collected data

Once raw data were fetched, we have four datasets: 'RawActivePassiveData_BraPolar.xlsx', 'RawContextualData.xlsx', 'RawParticipantsScalesResults.xlsx' and 'RawParticipantsDemographic.xlsx'. Next, we conduct an exploratory analysis of the data mentioned above.

4.4.2 Data preprocessing and cleaning: removing outliers

Once we have all the data sets, we analyze the data for possible errors. As we work with several information sources, it is particularly important for the data that were entered manually ('RawParticipantsScalesResults.xlsx' and 'RawParticipantsDemographic.xlsx' datasets) to contain fidelity to the data defined by the specialists (Figure 7.18). Although not all errors can be identified (NORMAN, 2002), we intend to minimize them by reviewing them three times to reduce the negative impact of errors. Next, we summarize the data cleaning for each feature and attribute, including the detected error and restored and removed registry.

Active data

Despite the data input restrictions mentioned in Table 4.2.3 to avoid user error input, when analyzing the 'RawActivePassiveData_BraPolar.xlsx' dataset, we observed incorrect format values inserted into the slept and wake-up attributes for P8 and removed those 44 registries. We suggest that this issue may be caused by an incompatibility with the hour format in the specific cellphone models that should be addressed. Also, we found that the Medication feature contains duplicated records (2244 instead of 1122), so we proceeded to remove it. This bug corresponds to duplicated data stored in the Firebase database because the SaveMedication method was called twice.

Passive and contextual data

On the one hand, we found no observable issue when analyzing the passive data (screen interaction) obtained by the BraPolar2 application. On the other hand, the fetched dataset from OpenWeather did not present data issue for the fetched period (15/12/2023 to 02/09/2024). However, in both passive and contextual data, we considered providing more information (or systematizing them) to extract relevant features, described in the subsection organizing data (4.4.4) of this sub-chapter.

Clinical data

As specialists applied the scales in each patient consultation (Table 4.4.2) Young Mania Rating Scale (Annex 7.8), Hamilton Depression Rating Scale (Annex 7.9), Morbidity Awareness Test (Annex 7.10), Global Clinical Impression for Bipolar Disorder (Annex 7.11), and Positive and Negative Syndrome Scale (Annex 7.9), proceed to clean the collected data. A sample of the set of applied scales is shown in Figure 4.19. As this scale application was face-to-face, we identified several issues through the research: lack of data, typos, and incomplete forms; however, we addressed these issues during the research by asking specialists about those blurred results and missing data. In addition, when we transcribed the paper-based scales to an Excel dataset, three researchers (ICF signed) checked the veracity of the data. We only do not have the scale results from the fifth consultation of P5 because she decided to go out that day after applying the interview described in Section 4.2.7 of this thesis.

Table 4.18: Application of available data scales by consult and patient

ID	**C1**	**C2**	**C3**	**C4**	**C5**	**C6**
P2	19/12/23	23/01/24	05/03/24	09/04/24	30/04/24	04/06/24
P3	19/12/23	23/01/24	05/03/24	02/04/24	30/04/24	04/06/24
P4	30/01/24	27/02/24	27/03/24	02/04/24	07/05/24	16/07/24
P5	09/01/24	30/01/24	12/03/24	16/04/24	21/05/24	18/06/24
P8	09/01/24	06/02/24	12/03/24	21/05/24	18/06/24	16/07/24
P11	20/02/24	19/03/24	09/04/24	07/05/24	28/05/24	16/07/24
P12	20/02/24	16/04/24	23/07/24	-	-	-
P15	05/03/24	19/03/24	30/04/24	28/05/24	02/07/24	-
P16	05/03/24	26/03/24	14/05/24	18/06/24	16/07/24	-
P18	26/03/24	07/05/24	04/06/24	02/07/24	-	-
P21	26/03/24	16/04/24	21/05/24	18/06/24	16/07/24	-

Demographic data

As mentioned in Section 4.2.4, at first consultation specialists applied the sociodemographic form (Annex 7.4). During the analysis, we observed missing values, primarily due to incomplete or unclear responses from patients. To address these issues, we performed follow-up checks with specialists to clarify missing or ambiguous information. Figure 4.20 illustrates a sample of the demographic dataset used in this study.

In summary, in this subsection, we examined the coding process for the active, passive, contextual, clinical, and demographic data used in the study, generating a new version of data sets. We also provided an overview of the variables and their measurement scales to facilitate the next step of data preparation.

4.4.3
Data preprocessing and cleaning: coding data

Before starting a statistical analysis, some authors recommend coding the data to ensure the precision, reliability, and interpretability of the results (LAZAR; FENG; HOCHHEISER, 2017; VALLEY et al., 2021). However, when using SPSS, this step can be automated (STEINLEY, 2006; YANG et al., 2022), and data sets can be incorporated into different statistical analyses with SPSS. Despite those recommendations, we check all datasets and classify each feature's attribute, as described next.

Active data

In Table 4.4.3 we summarize features related to patient active data, detailing their attributes, sample data values, data types, and measurement categories. Mood captures emotional states such as "Alegre" (Happy), "Ansioso" (Anxious), "Irritado" (Angry), "Neutro" (Neutral) and "Triste" (Sad), classified as categorical and nominal, reflecting distinct mood categories without inherent order. Mood Intensity and Energy are measured on numerical interval scales, indicating varying levels of intensity (e.g., 0, 15, 70, 100). Sleep includes multiple attributes: sleptDataTime and wakeUpDataTime, both ordinal and capturing the date and time of sleep and waking; minutesToRest, which measures the time taken to fall asleep as a numerical ratio; and totalSleepTime, a ratio variable that quantifies the total hours of sleep. Sleep Quality is also an interval variable, assessing perceived sleep quality with scores like 0, 15, 70, and 100. Medication intake is tracked as categorical nominal data with options such as "Nada" (None), "Parcialmente" (Partially), and "Totalmente" (Completely). Lastly, Menstruation records menstrual status with responses "Sim" (Yes), "Não" (No), and "Não aplicável" (Not applicable), classified as nominal data. In addition, each feature also contains the date (DD/MM/AAAA) and idPatient (P1...P22), which are categorical/ordinal.

Table 4.19: Data features and attributes - active data

Feature	**Attribute**	**Data Sample**	**Data Type**	**Category**
Mood	moodExperienced	Alegre, Ansioso, Irritado, Neutro, Triste	Categorical	Nominal
Mood Intensity	moodIntensityVal	0, 15, 70, 100	Numerical	Interval
Energy	energyLevelValue	0, 15, 70, 100	Numerical	Interval
Sleep	sleptDataTime wakeUpDataTime minutesToRest totalSleepTime	05/02/2024 21:23 06/02/2024 06:17 20 8.90	Categorical Categorical Numerical Numerical	Ordinal Ordinal Ratio Ratio
Sleep Quality	sleepQualityValue	0, 15, 70, 100	Numerical	Interval
Medication	medicationIntake	Nada, Parcialmente, Totalmente	Categorical	Nominal
Menstruation	isMenstruated	Sim, Não, Não aplicável	Categorical	Nominal

Passive data

We present in Table 4.4.3 the original structure of passive data and attributes, data samples, data types, and categories. The ‘date‘ attribute captures the timestamp of the screen event (e.g., "19/12/2023 17:40:17", reflecting a specific moment without indicating order or measurement. The ‘idPatient‘ attribute identifies the patient involved in the screen event, such as "P2," representing unique identifiers without quantitative value. The ‘screenOn‘ attribute records whether the screen was turned on, with possible values "Sim" (Yes) or "Não" (No), representing distinct states without implying a hierarchy. Similarly, the ‘isLocked‘ attribute captures whether the screen was locked, with responses "Sim" (Yes) or "Não" (No), distinguishing screen states without any measurement scale. All features were treated as categorical nominal data.

Table 4.20: Data features and attributes - passive data

Feature	**Attribute**	**Data Sample**	**Data Type**	**Category**
Screen	date	19/12/2023 17:40:17	Categorical	Ordinal
	idPatient	P2	Categorical	Nominal
	screenOn	Sim, Não	Categorical	Nominal
	isLocked	Sim, Não	Categorical	Nominal

Contextual data

In Table 4.4.3 we show the attributes related to contextual data as temperatureAvg (average temperature) and feelsLikeMax (maximum perceived temperature) are represented with numerical values, with temperatureAvg, tempMin (minimum temperature), tempMax (maximum temperature), humidity (e.g., 70.54%), and cloudsAll (level of cloudiness). These measurements provide precise and quantifiable information on environmental conditions. Categorical nominal attributes include weekDay (e.g., "Domingo", Sunday), season (e.g., "Outono", Fall), holiday (e.g., "Tiradentes"), and localEvent (e.g., "Botafogo 5 x 1 Juventude"), each describing temporal, seasonal, or social contexts without inherent ordering.

Clinical data

Finally, in Table 4.4.3, we represent clinical features used to assess patient conditions, detailing their attributes, data samples, data types, and categories. Attributes such as ‘idPatient‘ (e.g., "P8"), ‘idTherapist‘ (e.g., "T3"), and ‘consultNumber‘ (e.g., "C6") are categorical nominal data that uniquely identify the patient, therapist, and consultation session, respectively. The ‘date‘ attribute captures the exact day of the consultation (e.g., "16/06/2024") and is used for chronological tracking of clinical interactions. The ‘currentAffectiveState‘

Table 4.21: Data features and attributes - contextual data

Feature	Attribute	Data Sample	Data Type	Category
Context	date	21/04/2024	Categorical	Ordinal
	temperatureAvg	22.96	Numerical	Ratio
	feelsLikeMax	23.26	Numerical	Ratio
	tempMin	17.9	Numerical	Ratio
	tempMax	29.9	Numerical	Ratio
	humidity	70.54	Numerical	Ratio
	cloudsAll	5	Numerical	Ratio
	weekDay	Domingo	Categorical	Nominal
	season	Outono	Categorical	Nominal
	holiday	Tiradentes	Categorical	Nominal
	localEvent	Botafogo 5 x 1 Juventude	Categorical	Nominal

attribute, classified as categorical and nominal, describes the patient's mood state, such as "Depressão" (Depression). Numerical ratio attributes like 'totalYoung', 'totalHamilton', and 'totalISAD-BR' provide quantitative measures of symptom severity across various scales applied by the therapists, including mania ('bpMania') and depression ('cgiBPDepress'), contributing to a comprehensive understanding of the patient's mental health status. Scores such as 'cgiBPGeral' (overall bipolar severity) and 'totalPANSS' (general psychiatric symptoms) helps the clinical profile, while 'cgiBPDiscriminac' captures specific clinical judgments, like a shift towards depression. Finally, the 'medication' attribute documents detailed treatment regimens, including medications like lithium and risperidone, which are crucial for understanding the pharmacological management of the patient's condition.

Demographic data

Finally, in Table 4.4.3 we outlined the demographic attributes collected for each patient during the first consultation, detailing their data type and category. The idPatient attribute uniquely identifies each patient, categorized as categorical nominal data, as it serves as an identifier without numerical or ordinal significance. admissionDate records the date of admission in our study, treated as nominal data to label specific events without intrinsic order. Attributes such as gender, maritalStatus, isWorking, ethnicity, bipolarDisorderType, and typeOfBipolarPhase are also classified as categorical nominal, representing distinct categories without an inherent hierarchy. The birthdate is ordinal because it captures a sequential position in time. Educational level (education) is classified as ordinal, reflecting an ordered set of educational achievements. Numerical ratio attributes such as beginningDiseaseAge, durationOfDiseaseMonths,

Table 4.22: Data features and attributes - clinical data

Feature	Attribute	Data Sample	Data Type	Category
Clinical	idPatient	P8	Categorical	Nominal
	idTherapist	T3	Categorical	Nominal
	consultNumber	C6	Categorical	Nominal
	date	16/06/2024	Categorical	Ordinal
	currentAffectState	Depressão	Categorical	Nominal
	totalYoung	2	Numerical	Ratio
	totalHamilton	8	Numerical	Ratio
	totalISAD-BR	17	Numerical	Ratio
	bpMania	3	Numerical	Ratio
	cgiBPDepress	3	Numerical	Ratio
	cgiBPGeral	3	Numerical	Ratio
	cgiBPDiscriminac	Virada para depressão	Categorical	Nominal
	totalPANSS	8	Numerical	Ratio
	medication	Litio 300 mg 0-0-5 / Risperidona 3 mg 0-0-1 / Topiramato 100 mg 0-0-1 / Topiramato 50 mg 1-0-0	Categorical	Nominal

suicideAttempt, and psychiatricHospitalization provide quantitative measures with a valid zero point, allowing mathematical comparisons and calculations. These attributes support the analysis of how personal and clinical background factors can influence mental health and treatment outcomes.

4.4.4 Data preprocessing and cleaning: organizing data

Combining several datasets into an SPSS file can be challenging, mainly when dealing with datasets that do not match and were gathered from different sources (AHFOCK; PYNE; MCLACHLAN, 2021). In this line, as our goal was to establish analysis with the collected data, we proceed to organize data as functions of two key variables: 'idPatient' and 'date'. Next, we describe the modifications for each dataset.

Active data

- Mood: we converted the single categorical variable moodValue, which captured different moods (e.g., Alegre, Ansioso), into multiple binary columns (moodHappy, moodSad, moodAnxious, moodNeutral). Each new column indicates whether the patient experienced a specific mood on a given day, using

Table 4.23: Data features and attributes - demographical data

Feature	**Attribute**	**Data Sample**	**Data Type**	**Category**
Demog	idPatient	P18	Categorical	Nominal
	admissionDate	12/03/2024	Categorical	Nominal
	gender	F	Categorical	Nominal
	birthdate	15/07/1998	Categorical	Ordinal
	maritalStatus	Solteiro	Categorical	Nominal
	education	Ensino superior incompleto	Categorical	Ordinal
	isWorking	Ativo	Categorical	Nominal
	ethnicity	Branca	Categorical	Nominal
	bpDisorderType	T1	Categorical	Nominal
	beginDiseaseAge	19	Numerical	Ratio
	typeOfBipPhase	Depressão	Categorical	Nominal
	durOfDisMonths	3	Numerical	Ratio
	suicideAttempt	2	Numerical	Ratio
	psyHospitaliz	0	Numerical	Ratio

"Sim" (Yes) or "Não" (No). This restructuring allows for a more studied analysis of mood patterns, as each mood can be analyzed independently.
- Sleep: we also insert the variable 'totalSleepTime', which represents the total hours of sleep based on the difference between the slept and wakeup times, factoring in any delays in falling asleep, captured by 'minutesToRest'. For example, if a patient went to bed at 22:30 and woke up at 00:00, the total time in bed is 1.5 hours. If it took the patient 10 minutes to fall asleep, this delay is incorporated into the total sleep time, resulting in the final totalSleepTime figure, such as 1.50 hours.

The other features from active data remain without changes.

Passive data

From the original dataset (which records individual events such as whether a phone screen is on or off and if unlocked or not) at precise time instances, we created an different version of this passive data. We represent how many times the phone was unlocked in different time intervals (e.g., unlockCount00To06) and also indicate the cumulative screen on-time in hours per period (e.g. screenTime00To06). This transition from the detailed, event-by-event data to daily aggregates provides and has led to better insights into more overarching phone usage patterns over different times during a single day as well as of how typical a specific behavior is, for example, on the total screen-off time over an entire day.

The other data sets (contextual, clinical, and demographic) remain unchanged.

4.4.5
Loading data into SPSS

We merged all the datasets and grouped them by idPatient and date. Then we import them into SPSS, totalling 46 variables and 1320 records, as presented in Figure 4.21.

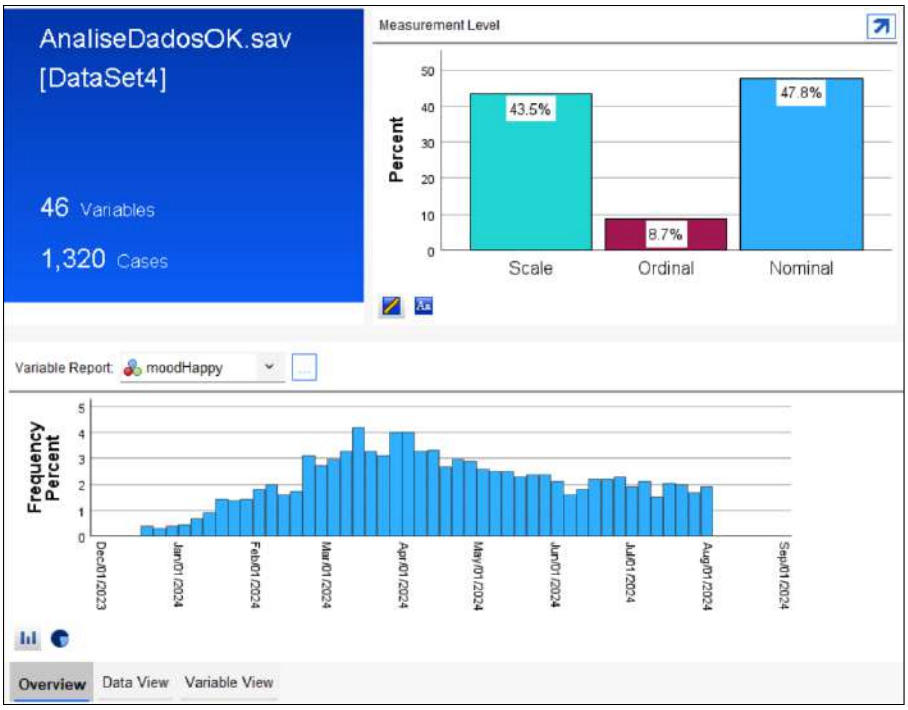
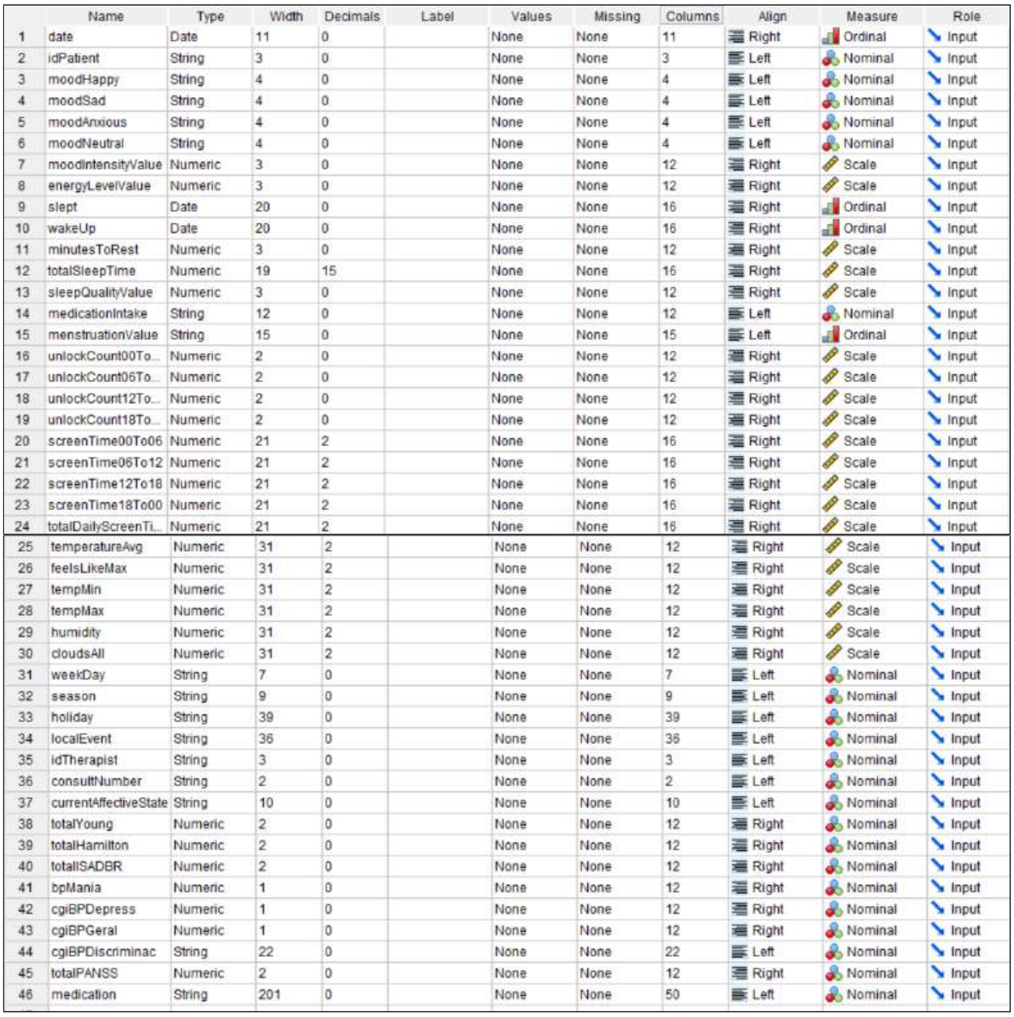


Figure 4.21: Overview screen in SPSS with loaded dataset

Finally, we adjust the imported Measure column in SPSS and label the imported data set, resulting in a sorted one with the characteristics presented in Figure 4.22.



	Name	Type	Width	Decimals	Label	Values	Missing	Columns	Align	Measure	Role
1	date	Date	11	0		None	None	11	Right	Ordinal	Input
2	idPatient	String	3	0		None	None	3	Left	Nominal	Input
3	moodHappy	String	4	0		None	None	4	Left	Nominal	Input
4	moodSad	String	4	0		None	None	4	Left	Nominal	Input
5	moodAnxious	String	4	0		None	None	4	Left	Nominal	Input
6	moodNeutral	String	4	0		None	None	4	Left	Nominal	Input
7	moodIntensityValue	Numeric	3	0		None	None	12	Right	Scale	Input
8	energyLevelValue	Numeric	3	0		None	None	12	Right	Scale	Input
9	slept	Date	20	0		None	None	16	Right	Ordinal	Input
10	wakeUp	Date	20	0		None	None	16	Right	Ordinal	Input
11	minutesToRest	Numeric	3	0		None	None	12	Right	Scale	Input
12	totalSleepTime	Numeric	19	15		None	None	16	Right	Scale	Input
13	sleepQualityValue	Numeric	3	0		None	None	12	Right	Scale	Input
14	medicationIntake	String	12	0		None	None	12	Left	Nominal	Input
15	menstruationValue	String	15	0		None	None	15	Left	Ordinal	Input
16	unlockCount00To...	Numeric	2	0		None	None	12	Right	Scale	Input
17	unlockCount06To...	Numeric	2	0		None	None	12	Right	Scale	Input
18	unlockCount12To...	Numeric	2	0		None	None	12	Right	Scale	Input
19	unlockCount18To...	Numeric	2	0		None	None	12	Right	Scale	Input
20	screenTime00To06	Numeric	21	2		None	None	16	Right	Scale	Input
21	screenTime06To12	Numeric	21	2		None	None	16	Right	Scale	Input
22	screenTime12To18	Numeric	21	2		None	None	16	Right	Scale	Input
23	screenTime18To00	Numeric	21	2		None	None	16	Right	Scale	Input
24	totalDailyScreenTi...	Numeric	21	2		None	None	16	Right	Scale	Input
25	temperatureAvg	Numeric	31	2		None	None	12	Right	Scale	Input
26	feelsLikeMax	Numeric	31	2		None	None	12	Right	Scale	Input
27	tempMin	Numeric	31	2		None	None	12	Right	Scale	Input
28	tempMax	Numeric	31	2		None	None	12	Right	Scale	Input
29	humidity	Numeric	31	2		None	None	12	Right	Scale	Input
30	cloudsAll	Numeric	31	2		None	None	12	Right	Scale	Input
31	weekDay	String	7	0		None	None	7	Left	Nominal	Input
32	season	String	9	0		None	None	9	Left	Nominal	Input
33	holiday	String	39	0		None	None	39	Left	Nominal	Input
34	localEvent	String	36	0		None	None	36	Left	Nominal	Input
35	idTherapist	String	3	0		None	None	3	Left	Nominal	Input
36	consultNumber	String	2	0		None	None	2	Left	Nominal	Input
37	currentAffectiveState	String	10	0		None	None	10	Left	Nominal	Input
38	totalYoung	Numeric	2	0		None	None	12	Right	Nominal	Input
39	totalHamilton	Numeric	2	0		None	None	12	Right	Nominal	Input
40	totalSADBR	Numeric	2	0		None	None	12	Right	Nominal	Input
41	bpMania	Numeric	1	0		None	None	12	Right	Nominal	Input
42	cgiBPDepress	Numeric	1	0		None	None	12	Right	Nominal	Input
43	cgiBPGeral	Numeric	1	0		None	None	12	Right	Nominal	Input
44	cgiBPDiscriminac	String	22	0		None	None	22	Left	Nominal	Input
45	totalPANSS	Numeric	2	0		None	None	12	Right	Nominal	Input
46	medication	String	201	0		None	None	50	Left	Nominal	Input

Figure 4.22: Variable view of data in SPSS

4.4.6 Conclusions

In this section, we integrated data from active, passive, contextual, clinical and demographic sources into a combined dataset for later analysis. We cleaned and pre-processed each dataset, dealing with errors such as duplicated records, poorly formatted times etc. As a result, four datasets were built based on: (i) active/passive data; (ii) contextual data; (iii) clinical scales; and (iv) demographic data. These datasets were formatted into different ones for convenient exploration and further statistical analysis. The data were then binned as binary classes for moods and grouped over timescales to improve the interpretability and analytical capacity of the dataset specialists. After integrating the data sets using patient ID and date as primary keys, we provide an SPSS file and a ready data set for statistical analysis in preparation for hypothesis testing and insight from specialists in next studies.

5
Final Remarks And Future Works

This thesis studied how APCC data can be integrated and used for digital phenotyping to improve the treatment of patients with bipolar disorder. We developed a mobile health (mHealth) application to increase patient adherence and precision in behavioral monitoring, focusing on mood fluctuations. The development and deployment of BraPolar2 enabled us to show the potential of mHealth solutions in managing the mental health of 22 patients with bipolar disorder. Our results show that contextual data with active and passive data, together, rather than individually, contribute to a better overall overview of patient status, which can make a difference in clinical assessment and further intervention strategies. Furthermore, the user retention rate was evaluated at 68.64%, and 11 specialists highlighted the potential of contextual data in clinical evaluation. However, further research must be done, which will be discussed in the next section.

5.1
Limitations

Next, we present the main limitations and propose how to address them in future works.

Theoretical limitations include threats to the theoretical aspects that affect the study and possible deficiencies in our literature review on BD approaches and related topics.

- BraPolar2 were developed through interdisciplinary work between the Departments of Informatics and Psychology at PUC-Rio and IPUB Institute. Using some terms for both areas was a challenge that the team had to overcome. In addition, a factor to consider is that each patient may have different levels of engagement with their mobile phones and may influence the result. Finally, monitoring by one of the patient's family members could help to obtain more reliable results.

- A limited set of participants: we start with 22 patients with bipolar disorder, but we only conclude the study with 11. We consider that a larger sample would likely increase the reliability of the investigation, which may have affected the generality of our conclusions. The sample of participants in both studies (patients and specialists) may not be sufficient to reach conclusive results, as this sample size did not allow us to achieve statistically significant results beyond a general approach to the proposed solution.

Limitations with BraPolar2 These limitations include threats to the assessments performed in the Section 4.2.3 that affect the study.

- During the development of the work, one of the main limitations of the study was the long periods suggested by specialists to evaluate the application with people with BD, which implies a longer time to obtain reliable results. However, we consider it sufficient for a pilot study with bipolar people for 6 months. In a further study, we also believe that a significant amount of time is needed to assess whether patients' quality of life will improve after using the application and how this will help specialists in the remote monitoring process.

- The current version of BraPolar2 is only compatible with Android 9.0 (Android Pie) and later versions. We considered using older versions to increase the range of compatible devices, but we would lose compatibility with Firebase.

The use of external components such as a smartwatch, smart ring, or other devices could have improved the accuracy of the data collected by possible distortions in cellphone sensors in the subsequent studies. We concluded that it could be an inconvenience to use them in older people or people who are not used to using them when they are in a manic or depressive state. Both psychologists and psychiatrists agreed to waive the use of these devices for this research.

5.2 Publications

1. A. González Mondéjar, G. F. M. Silva-Calpa, A. B. Raposo and D. C. Mograbi, "BraPolar: an mHealth Application for Remote Monitoring of People with Bipolar Disorder," 2019 IEEE 7th International Conference on Serious Games and Applications for Health (SeGAH), Kyoto, Japan, 2019, pp. 1-8, doi: 10.1109/SeGAH.2019.8882469.

2. A. González Mondéjar, G. F. M. Silva-Calpa, A. Barbosa Raposo and D. C. Mograbi, "An mHealth Application for Remote Monitoring of People with Bipolar Disorder through Digital phenotype and Smartphone Dependency," 2020 IEEE 33rd International Symposium on Computer-Based Medical Systems (CBMS), Rochester, MN, USA, 2020, pp. 388-391, doi: 10.1109/CBMS49503.2020.00080.

3. A. González Mondéjar, G. F. M. Silva-Calpa, A. Barbosa Raposo and D. C. Mograbi, "Redesign of an mHealth Application for Individuals with Bipolar Disorder: A Strategy for User Adherence and Effective Data Collection" 2024 IEEE 12th International Conference on Serious Games

and Applications for Health (SeGAH), Madeira, Portugal, 2024, pp.1-9, 2024, doi: 10.1109/SeGAH61285.2024.10639601 (Annex 7.19).

5.3 Future Work

Despite the findings observed in the development of the thesis, some points may be addressed. First, while BraPolar2 reports improved adhesion and data collection with patients with bipolar disorder, further refinements are needed to optimize its usability and minimize user burden considering the patient feedback, described in Section 4.2.7. Also, considering the developed framework in terms of data collection, future versions could incorporate machine learning models to predict mood changes and personalize intervention strategies based on individual behavioral patterns and information visualization strategies to present the collected data to patients and specialists. In addition, more studies are necessary to explore the long-term impacts of continuous monitoring on patient outcomes and the efficacy of clinical interventions based on APC data.

Furthermore, collaborations with other mental health professionals and institutions would provide opportunities to validate the proposed mHealth system in broader clinical settings.

5.4 Conclusions

This thesis presents a comprehensive digital phenotype framework development process that integrates active, passive, contextual, and clinical data, leveraging mHealth solutions to enhance the real-time monitoring, early detection, and personalized management of bipolar disorder. The findings reflect the relevance of mobile health technologies (mHealth) to monitoring bipolar disorder through the BraPolar2 application. This work highlights the potential of integrating active, passive, contextual, clinical, and demographic data to build a holistic view of the digital phenotype, contributing to the possibility of improving the identification of the digital phenotype in follow-up bipolar disorder.

6
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7 Appendices

7.1 Annex A - Declaration of consent to conduct research and authorization to consult medical records in the Bipolar Disorder research laboratory UFRJ

Instituto de Psiquiatria
Universidade Federal do Rio de Janeiro

Declaração de Anuência para Realização de Pesquisa e Autorização para Consulta a Prontuário no Laboratório de Pesquisa em Transtorno Bipolar

Declaro que tenho conhecimento do protocolo de pesquisa intitulado "BraPolar: Um aplicativo m-Health para monitoramento remoto de pessoas com Transtorno Bipolar" cujo pesquisador principal é o Dr. Daniel Mograbi.

Autorizo a consulta dos prontuários de pacientes atendidos no ambulatório desse serviço para os fins a que se destina o projeto de pesquisa, como sempre de acordo com as disposições de manutenção de sigilo dos dados e dos nomes dos pacientes. Além disto, tenho conhecimento e autorizo que a pesquisa se desenvolva no Laboratório de Pesquisa em Transtorno Bipolar, tão logo o CEP-IPUB assim autorize.

Rio de Janeiro, 12 de fevereiro de 2020.

Elie Cheniaux

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7.2 Annex B - Declaration of authorization for data collection at the UFRJ Psychiatry Institute

Declaração de Autorização para Coleta de dados no Instituto de Psiquiatria da UFRJ

Declaro que autorizo a realização da pesquisa intitulada "BraPolar: Um aplicativo m-health para monitoramento remoto de pessoas com Transtorno Bipolar" cujo pesquisador principal é o Prof. Daniel Mograbi. Além disto, autorizo a consulta dos prontuários de pacientes atendidos no ambulatório desse serviço para os fins a que se destina o projeto de pesquisa, como sempre de acordo com as disposições de manutenção de sigilo dos dados e dos nomes dos pacientes. A autorização da realização da pesquisa é condicionada à aprovação da mesma pelo Comitê de Ética em Pesquisa do IPUB.

Rio de Janeiro, 08 de junho de 2022,

Jorge Adelino Rodrigues da Silva

Prof. Jorge Adelino Rodrigues da Silva
Diretor do IPUB/UFRJ
PE: 037035-8 - CREMERJ: 52.14273.4

7.3
Annex C - Institutional consent letter (PUC-Rio)

PONTIFÍCIA UNIVERSIDADE CATÓLICA DO RIO DE JANEIRO

CARTA DE ANUÊNCIA INSTUTUCIONAL

Declaro, para os devidos fins, que o Programa de Pós-Graduação em Psicologia (Psicologia Clínica) do Departamento de Psicologia da Pontifícia Universidade Católica do Rio de Janeiro (PUC-Rio) concorda com a execução do projeto de pesquisa de Pós-Doutorado intitulado "BraPolar: um aplicativo m-health para monitoramento remoto de pessoas com Transtorno Bipolar", a ser desenvolvido na linha de pesquisa Clínica e Neurociências por Rafael Assis da Silva, sob orientação do Prof. Daniel Mograbi.

Rio de Janeiro, 20 de junho de 2022.

Profa. Luciana Fontes Pessoa
Diretor do Departamento de Psicologia

Profª Luciana Fontes Pessôa
Diretora
Deptº Psicologia - PUC - Rio

Departamento de Psicologia
PUC-Rio
Prof. Luciana Fontes Pessoa
Diretora do Departamento de Psicologia
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Rio de Janeiro - RJ - Tel. (021) 35271185 / 35271186 / Fax 3527.1187
E-mail: psidir@puc-rio.br

7.4
Annex D - Sociodemographic data of patients

Identificação	Iniciais	TCL	Data

DADOS SOCIODEMOGRÁFICOS

Nome completo:

Gênero:

0. Feminino
1. Masculino

Data de nascimento:

Idade:

Situação conjugal:

0. Casado
1. Divorciado
2. Solteiro
3. Viúvo

Escolaridade (anos):

0. Sem educação formal
1. Ensino fundamental incompleto
2. Ensino fundamental completo
3. Ensino médio incompleto
4. Ensino médio completo
5. Ensino superior incompleto
6. Ensino superior completo
7. Pós-graduação (mestrado ou doutorado)

Anos de escolaridade:

Status ocupacional:

0. Inativo
1. Ativo

Cor/raça

0. Branca
1. Parda
2. Negra
3. Outros

HISTÓRICO DA DOENÇA
Transtorno Bipolar: 0. Tipo 1 1. Tipo 2
Idade de início da doença (primeiro episódio): Tipo: Duração da doença:
Tentativa de suicídio (com verdadeira intenção de morrer): 0 Não 1 Sim (quantas vezes):
Internação psiquiátrica: 0 Não 1 Sim (quantas vezes):

7.5 Annex E - Young Mania Rating Scale (YMRS)

(E2) ESCALA DE AVALIAÇÃO DE MANIA DE YOUNG

01 - HUMOR E AFETO ELEVADOS

Este item compreende uma sensação difusa e prolongada, subjetivamente experimentada e relatada pelo indivíduo, caracterizada por sensação de bem-estar, alegria, otimismo, confiança e ânimo. Pode haver um afeto expansivo, ou seja, uma expressão dos sentimentos exagerada ou sem limites, associada à intensa relação com sentimentos de grandeza (euforia). O humor pode ou não ser congruente ao conteúdo do pensamento.

(0) Ausência de elevação do humor ou afeto
(1) Humor ou afeto discreta ou possivelmente aumentados, quando questionado.
(2) Relato subjetivo de elevação clara do humor; mostra-se otimista, autoconfiante, alegre; afeto apropriado ao conteúdo do pensamento.
(3) Afeto elevado ou inapropriado ao conteúdo do pensamento; jocoso.
(4) Eufórico; risos inadequados, cantando.

(X) Não avaliado

02 - ATIVIDADE MOTORA - ENERGIA AUMENTADA

Este item compreende a psicomotricidade - e expressão corporal - apresentada pelo paciente, incluindo a sua capacidade em controlá-la, variando desde um grau de normalidade, até um estado de agitação, com atividade motora sem finalidade, não influenciada por estímulos externos. O item compreende ainda o relato subjetivo do paciente, quanto à sensação de energia, ou seja, capacidade de produzir e agir.

(0) Ausente
(1) Relato subjetivo de aumento da energia ou atividade motora
(2) Apresenta-se animado ou com gestos aumentados
(3) Energia excessiva; às vezes hiperativo; inquieto (mas pode ser acalmado).
(4) Excitação motora; hiperatividade contínua (não pode ser acalmado).

(X) Não avaliado

03 - INTERESSE SEXUAL

Este item compreende ideias e/ou impulsos persistentes relacionados a questões sexuais, incluindo a capacidade do paciente em controlá-los. O interesse sexual pode restringir-se a pensamentos e desejos não concretizados, em geral verbalizados apenas após solicitação, podendo chegar até a um comportamento sexual frenético e desenfreado, sem qualquer controle ou crítica quanto a riscos e normas morais.

(0) Normal; sem aumento.
(1) Discreta ou possivelmente aumentado
(2) Descreve aumento subjetivo, quando questionado.
(3) Conteúdo sexual espontâneo; discurso centrado em questões sexuais; autorrelato de hipersexualidade.
(4) Relato confirmado ou observação direta de comportamento explicitamente sexualizado, pelo entrevistador ou outras pessoas.

(X) Não avaliado

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04 – SONO

Este item inclui a redução ou falta da capacidade de dormir, e/ou a redução ou falta de necessidade de dormir, para sentir-se bem-disposto e ativo.

(0) Não relata diminuição do sono
(1) Dorme menos que a quantidade normal, cerca de 1 hora a menos do que o seu habitual
(2) Dorme menos que a quantidade normal, mais que 1 hora a menos do que o seu habitual
(3) Relata diminuição da necessidade de sono
(4) Nega necessidade de sono

(X) Não avaliado

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05 – IRRITABILIDADE

Este item revela a predisposição afetiva para sentimentos/emoções como raiva ou mau-humor apresentados pelo paciente frente a estímulos externos. Inclui baixo-limiar à frustração, com reações de ira exagerada, podendo chegar a um estado constante de comportamento desafiador, querelante e hostil.

(0) Ausente
(2) Subjetivamente aumentada
(4) Irritável em alguns momentos durante a entrevista; episódios recentes (nas últimas 24 horas) de ira ou irritação na enfermaria
(6) Irritável durante a maior parte da entrevista; ríspido e lacônico o tempo todo.
(8) Hostil; não cooperativo; entrevista impossível.

(X) Não avaliado

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06 – FALA (velocidade e quantidade)

Este item compreende a velocidade e quantidade do discurso verbal apresentado pelo paciente. Inclui sua capacidade de percebê-lo e controlá-lo, por exemplo, frente a solicitações para que permaneça em silêncio ou permita que o entrevistador fale.

(0) Sem aumento
(2) Percebe-se mais falante do que o seu habitual
(4) Aumento da velocidade ou quantidade da fala em alguns momentos; verborréico, às vezes (com solicitação, consegue-se interromper a fala).
(6) Quantidade e velocidade constantemente aumentadas; dificuldade para ser interrompido (não atende a solicitações; fala junto com o entrevistador).
(8) Fala pressionada, ininterruptível, contínua (ignora a solicitação do entrevistador).
(X) Não avaliado

07 – LINGUAGEM – DISTÚRBIO DO PENSAMENTO

Este item refere-se a alterações da forma do pensamento, avaliado pelas construções verbais emitidas pelo paciente. O pensamento pode estar mais ou menos desorganizado, de acordo com a gravidade das alterações formais do pensamento, descritas a seguir:

Circunstancialidade: fala indireta que demora para atingir o ponto desejado, mas eventualmente vai desde o ponto de origem até o objetivo final, a despeito da super inclusão de detalhes;

Tangencialidade: incapacidade para manter associações do pensamento dirigidas ao objetivo - o paciente nunca chega do ponto inicial ao objetivo final desejado;

Fuga de idéias: verbalizações rápidas e contínuas, ou jogos de palavras que produzem uma constante mudança de uma idéia para outra; as idéias tendem a estar conectadas e, mesmo em formas menos graves, podem ser difíceis de ser acompanhadas pelo ouvinte;

Ecolalia consonante: repetição automática de palavras ou frases, com entonação e forma que produzem efeito sonoro de rima;

Incoerência: fala ou pensamento essencialmente incompreensíveis aos outros, porque as palavras ou frases são reunidas sem uma conexão com lógica e significado.

(0) Sem alterações
(1) Circunstancial; pensamentos rápidos.
(2) Perde objetivos do pensamento; muda de assuntos frequentemente; pensamentos muito acelerados
(3) Fuga de ideias; tangencialidade; dificuldade para acompanhar o pensamento; ecolalia consonante
(4) Incoerência; comunicação impossível.
(X) Não avaliado

08 – CONTEÚDO

Este item compreende ideias e crenças apresentadas pelo paciente, variando, de acordo com a intensidade, de ideias novas e/ou incomuns ao paciente, ideação supervalorizada (ou seja, crença falsa, intensamente arraigada, porém susceptível à argumentação racional), a delírios (crenças falsas, baseadas em inferências incorretas sobre a realidade, inconsistentes com a inteligência e antecedentes culturais do paciente, e que não podem ser corrigidas pela argumentação). Conteúdos comumente encontrados no paciente maníaco, incluem:
Ideias místicas: de conteúdo religioso;
Ideias paranóides: crença de estar sendo molestado ou perseguido;
Ideias de grandeza: concepção exagerada da própria importância, poder ou identidade, incluindo posses materiais, qualidades incomuns e relacionamentos especiais com personalidades famosas ou entidades místicas;
Ideias de referência: crença de que o comportamento dos outros tem relação consigo próprio ou de que eventos, objetos ou outras pessoas possuem um significado particular e incomum para si.

(0) Normal
(2) Novos interesses e planos compatíveis com a condição sociocultural do paciente, mas questionáveis.
(4) Projetos especiais totalmente incompatíveis com a condição socioeconómica do paciente; hiper-religioso.
(6) Ideias supervalorizadas
(8) Delírios

(X) Não avaliado

09 – COMPORTAMENTO DISRUPTIVO AGRESSIVO

Este item compreende a atitude e as respostas do paciente ao entrevistador e à situação da entrevista. O paciente pode apresentar-se desconfiado ou irônico e sarcástico, mas ainda assim respondendo aos questionamentos, ou então não cooperativo e francamente agressivo, inviabilizando a entrevista.

(0) Ausente, cooperativo.
(2) Sarcástico; barulhento, às vezes, desconfiado.
(4) Ameaça o entrevistador; gritando; entrevista dificultada.
(6) Agressivo; destrutivo; entrevista impossível.

(X) Não avaliado

10 – APARÊNCIA - OBSERVAÇÃO

Este item compreende a apresentação física do paciente, incluindo aspectos de higiene, asseio e modo de vestir-se.

(0) Arrumado e vestido apropriadamente
(1) Descuidado minimamente; adornos ou roupas minimamente inadequados ou exagerados.
(2) Precariamente asseado; despenteado moderadamente; vestido com exagero.
(3) Desgrenhado; vestido parcialmente; maquiagem extravagante.

(4) Completamente descuidado; com muitos adornos e adereços; roupas bizarras.

(X) Não avaliado

11 – INSIGHT (discernimento)

Este item refere-se ao grau de consciência e compreensão do paciente quanto ao fato de estar doente. Varia de um entendimento adequado (afetivo e intelectual) quanto à presença da doença, passando por concordância apenas frente à argumentação, chegando a uma negação total de sua enfermidade, referindo estar em seu comportamento normal e não necessitando de qualquer tratamento.

(0) *Insight* presente: espontaneamente refere estar doente e concorda com a necessidade de tratamento

(1) *Insight* duvidoso: com argumentação, admite possível doença e necessidade de tratamento.

(2) *Insight* prejudicado: espontaneamente admite alteração comportamental, mas não a relaciona com a doença, ou discorda da necessidade de tratamento.

(3) *Insight* ausente: com argumentação, admite de forma vaga alteração comportamental, mas não a relaciona com a doença e discorda da necessidade de tratamento.

(4) *Insight* ausente: nega a doença, qualquer alteração comportamental e necessidade de tratamento.

(X) Não avaliado

7.6 Annex F - Hamilton Depression Rating Scale (HDRS-17)

(E1) ESCALA HAMILTON PARA AVALIAÇÃO DA DEPRESSÃO (HAM-D 17 itens)

Assinale o item que melhor caracteriza o paciente na semana anterior e anote o número no local apropriado

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1-HUMOR DEPRIMIDO (tristeza, desesperança, desamparo, inutilidade)

0. Ausente
1. Sentimentos relatados apenas ao ser inquirido.
2. Sentimentos relatados espontaneamente, com palavras.
3. Comunica os sentimentos não com palavras, isto é, com a expressão facial, a postura a voz e a tendência ao choro.
4. Sentimentos deduzidos de comunicação verbal e não verbal do paciente.

2- SENTIMENTO DE CULPA

0. Ausente
1. Autorrecriminação: sente que decepcionou os outros.
2. Ideias de culpa ou ruminação sobre erros passados ou más ações.
3. A doença atual é um castigo. Delírio de culpa.
4. Ouve vozes de acusação ou denúncia e/ou tem alucinações visuais ameaçadoras.

.

3- SUICÍDIO

0. Ausente
1. Sente que a vida não vale a pena.
2. Desejaria estar morto ou pensa na possibilidade da própria morte.
3. Ideias ou gestos suicidas.
4. Tentativa de suicídio (qualquer tentativa séria marcar 4).

4-INSÔNIA INICIAL

0. Sem dificuldade para conciliar o sono.
1. Queixa-se de dificuldade ocasional para conciliar o sono, isto é, mais de meia hora.
2. Queixa-se de dificuldade para conciliar o sono todas as noites.

5-INSÔNIA INTERMEDIÁRIA

0. Sem dificuldade.
1. O paciente se queixa de inquietude e perturbação durante a noite.
2. Acorda a noite – qualquer saída da cama, marcar 2 (exceto para urinar).

6-INSÔNIA TARDIA

0. Sem dificuldade.
1. Acorda de madrugada, mas volta a dormir.
2. Incapaz de voltar a conciliar o sono ao deixar a cama.

7-TRABALHO E ATIVIDADE

0. Sem dificuldade.
1. Pensamentos e sentimentos incapacidade, fadiga ou fraqueza relacionada a atividades: trabalho ou passatempos
2. Perda de interesse por atividades (passatempos ou trabalho - quer diretamente relatada pelo paciente, quer indiretamente, por desatenção, indecisão ou vacilo). Sente que precisa esforçar-se para o trabalho ou atividade.
3. Diminuição do tempo gasto em atividades ou queda de produtividade. No hospital, marcar 3 se o paciente não passar ao menos três horas por dia em atividades externas (trabalho hospitalar ou passatempo).
4. Parou de trabalhar devido à doença atual. No hospital, marcar 4 se o paciente não se ocupar de outras atividades além de pequenas tarefas do leito, ou for incapaz de realizá-las sem ajuda.

8-RETARDO - OBSERVAÇÃO

(lentidão de ideias e fala; dificuldade de concentração; atividade motora diminuída)

0. Pensamento e fala normais
1. Lentificação discreta à entrevista
2. Lentificação óbvia durante à entrevista
3. Entrevista difícil
4. Estupor completo

9-AGITAÇÃO - OBSERVAÇÃO

0. Nenhuma
1. Inquietação
2. Mexe as mãos, cabelos, etc.
3. Movimenta-se bastante, não consegue permanecer sentado durante a entrevista
4. Retorce as mãos, rói as unhas, puxa os cabelos, morde os lábios

10- ANSIEDADE PSÍQUICA

0. Sem ansiedade
1. Tensão e irritabilidade subjetivas
2. Preocupação com trivialidades
3. Atitude apreensiva aparente no rosto ou na fala

4. Medo expresso sem serem inquiridos

11-ANSIEDADE SOMÁTICA

Concomitantes fisiológicos da ansiedade tais como: gastrointestinais (boca seca, flatulência, indigestão, diarreia, cólicas, eructações), cardiovasculares (palpitações, cefaleias), respiratórias (hiperventilação, suspiros), frequência urinária, sudorese.

0. Ausente
1. Duvidoso ou trivial: sintomas menores, relatados quando questionados
2. Leve: paciente descreve espontaneamente os sintomas, que não são acentuados ou incapacitantes
3. Moderado: mais do que 2 sintomas e com maior frequência. São acompanhados de estresse subjetivo e prejudicam o funcionamento normal
4. Grave: numerosos sintomas, persistentes e incapacitantes na maior parte do tempo, ou ataques de pânico quase diariamente

12-SINTOMAS SOMÁTICOS GASTROINTESTINAIS

0. Nenhum
1. Perda de apetite, mas alimentando-se voluntariamente. Sensação de peso no abdômen.
2. Dificuldade de comer se não insistirem. Solicita ou exige laxativos, ou medicações para os intestinos, ou para sintomas digestivos.

13- SINTOMAS SOMÁTICOS EM GERAL

0. Nenhum
1. Peso nos membros, nas costas ou na cabeça. Dores nas costas, cefaleia, mialgias. Perda de energia e cansaço.
2. Qualquer sintoma bem caracterizado e nítido, marcar 2.

14- SINTOMAS GENITAIS

Sintomas como: perda de libido, distúrbios menstruais.

0. Ausentes
1. Leves
2. Intensos

15- HIPOCONDRIA

0. Ausente
1. Auto-observação aumentada (com relação ao corpo)
2. Preocupação com a saúde
3. Queixas frequentes, pedidos de ajuda etc.
4. Ideias delirantes hipocondríacas

16-PERDA DE PESO

0. Sem perda de peso ou perda de peso NÃO causada pela doença atual
1. Perda de peso provavelmente causada pela doença atual. Perda de menos de meio quilo
2. Perda de peso definitivamente causada pela doença atual. Perda de meio quilo ou mais

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17- CONSCIÊNCIA DA DOENÇA

0. Reconhecer que está deprimido e doente
1. Reconhece a doença, mas atribui-lhe a causa à má alimentação, ao clima, ao excesso de trabalho, à vírus, à necessidade de repouso etc.
2. Nega estar doente

7.7 Annex G - Morbidity Awareness Test (ISAD-BR)

(E5) ESCALA DE CONSCIÊNCIA DE MORBIDADE PARA TRANSTORNOS AFETIVOS (DO HUMOR)
(ISAD-BR)

Indique o escore apropriado com um X:
1=consciência OU não pode ser avaliado ou item não relevante; 3=consciência moderada; 5=sem consciência.

1. Consciência de sofrer de um transtorno afetivo (do humor).

   (1) Não pode ser avaliado ou item não relevante

   (1) consciência (3) consciência moderada (5) sem consciência

2. Consciência da eficácia do tratamento para os sintomas atuais ou para prevenir recidivas.

   (1) Não pode ser avaliado ou item não relevante

   (1) consciência (3) consciência moderada (5) sem consciência

3. Consciência das consequências da doença sobre o trabalho, família e vida social.

   (1) Não pode ser avaliado ou item não relevante

   (1) consciência (3) consciência moderada (5) sem consciência

4. Consciência de apresentar humor deprimido/expansivo ou irritável (conforme apropriado).

   (1) Não pode ser avaliado ou item não relevante

   (1) consciência (3) consciência moderada (5) sem consciência

5. Consciência de apresentar acentuado(a) aumento/redução de atividades prazerosas (conforme apropriado).

   (1) Não pode ser avaliado ou item não relevante

   (1) consciência (3) consciência moderada (5) sem consciência

6. Consciência de apresentar ganho/perda significativo(a) de peso (conforme apropriado).

   (1) Não pode ser avaliado ou item não relevante

   (1) consciência (3) consciência moderada (5) sem consciência

7. Consciência de apresentar insônia ou hipersonia (conforme apropriado).

   (1) Não pode ser avaliado ou item não relevante

   (1) consciência (3) consciência moderada (5) sem consciência

8. Consciência de apresentar alentecimento ou agitação psicomotor(a) (conforme apropriado).

   (1) Não pode ser avaliado ou item não relevante

   (1) consciência (3) consciência moderada (5) sem consciência

9. Consciência de apresentar fadiga ou excesso de energia.

(1) Não pode ser avaliado ou item não relevante

(1) consciência (3) consciência moderada (5) sem consciência

10. Consciência de apresentar sentimentos de inutilidade ou culpa, ou autoestima aumentada ou grandiosidade.

(1) Não pode ser avaliado ou item não relevante

(1) consciência (3) consciência moderada (5) sem consciência

11. Consciência de apresentar lentidão da fala ou verborragia/tagarelice (conforme apropriado).

(1) Não pode ser avaliado ou item não relevante

(1) consciência (3) consciência moderada (5) sem consciência

12. Consciência de apresentar bradipsiquismo/fuga de ideias (conforme apropriado).

(1) Não pode ser avaliado ou item não relevante

(1) consciência (3) consciência moderada (5) sem consciência

13. Consciência de apresentar baixo nível de atenção/distração.

(1) Não pode ser avaliado ou item não relevante

(1) consciência (3) consciência moderada (5) sem consciência

14. Consciência de apresentar aparência desleixada.

(1) Não pode ser avaliado ou item não relevante

(1) consciência (3) consciência moderada (5) sem consciência

15. Consciência de apresentar sintomas de confusão-desorientação.

(1) Não pode ser avaliado ou item não relevante

(1) consciência (3) consciência moderada (5) sem consciência

16. Consciência de ter relações sociais pobres.

(1) Não pode ser avaliado ou item não relevante

(1) consciência (3) consciência moderada (5) sem consciência

17. Consciência de apresentar delírios e alucinações (conforme apropriado)

(1) Não pode ser avaliado ou item não relevante

(1) consciência (3) consciência moderada (5) sem consciência

7.8
Annex H - Clinical Global Impression for Bipolar Disorder (CGI-BP)

(E3) ESCALA DE IMPRESSÃO CLÍNICA GLOBAL – VERSÃO BIPOLAR (CGI- BP)

Item I – Gravidade da doença

Considerando sua experiência clínica total com pacientes bipolares, quão gravemente doente tem estado o paciente durante a última semana?

MANIA:

DEPRESSÃO:

TR. BIPOLAR GLOBAL:

Em caso de tanto mania como depressão terem escore igual ou superior a 3, discriminar:

( ) *estado misto* ( ) *virada para mania* ( ) *virada para depressão*

ESCORES:

1. **Normal, não doente** (sem sintomas)
2. **Minimamente doente** (sintomas mínimos, manteve funcionamento eficiente)
3. **Levemente doente** (baixo nível de sintomas, sofrimento subjetivo, pouco ou nenhum prejuízo funcional)
4. **Moderadamente doente** (alguns sintomas proeminentes, prejuízo funcional moderado)
5. **Acentuadamente doente** (sintomas significativos, prejuízo funcional muito substancial)
6. **Gravemente doente** (sintomas muito evidentes, incapaz de funcionar na maioria das áreas)
7. **Muito gravemente doente** (sintomas extremos, completamente incapacitado, requerendo cuidados extra

7.9 Annex I - Positive and Negative Syndrome Scale (PANSS)

(E4) PANSS – POSITIVE SCALE

P1 – DELÍRIOS: Crenças que são infundadas, irrealistas e idiossincráticas.

Base para avaliar: conteúdo do pensamento expresso na entrevista e sua influência nas relações sociais e no comportamento.

1 – Ausente – A definição não se aplica.
2 – Mínimo – Patologia questionável: pode estar no extremo superior dos limites normais.
3 – Leve – Presença de um ou dois delírios que são vagos, não cristalizados e não tenazmente mantidos. Os delírios não interferem com o pensamento, relações sociais ou comportamento.
4 – Moderado – Presença de uma série de delírios instáveis, pobremente formados, ou de alguns delírios bem formados que ocasionalmente interferem com o pensamento, relações sociais ou comportamento.
5 - Moderado grave – Presença de numerosos delírios bem formados que são tenazmente mantidos e ocasionalmente interferem com o pensamento, relações sociais ou comportamento.
6 – Grave – Presença de um conjunto estável de delírios que são cristalizados, possivelmente sistematizados, tenazmente mantidos, e claramente interferem com o pensamento, relações sociais ou comportamento.
7 – Extremo - Presença de um conjunto estável de delírios que são altamente sistematizados ou muito numerosos e que dominam a maior parte das áreas da vida do paciente. Isso frequentemente resulta em ação inapropriada ou irresponsável, a qual pode até mesmo ameaçar a segurança do paciente ou de outros.

P2 – DESORGANIZAÇÃO CONCEITUAL: Processo desorganizado de pensamento caracterizado pela ruptura do sequenciamento direcionado a um objetivo (por ex., circunstancialidade, tangencialidade, afrouxamento das associações, ilogicidade grosseira, ou bloqueio do pensamento).

Base para avaliar: processo cognitivo-verbal observado durante o curso da entrevista.

1 – Ausente – A definição não se aplica.
2 – Mínimo – Patologia questionável: pode estar no extremo superior dos limites normais.
3 – Leve – O pensamento é circunstancial, tangencial ou paralógico. Há alguma dificuldade em direcionar os pensamentos para um objetivo, e algum afrouxamento das associações pode ser evidenciado sob pressão.
4 – Moderado – Capaz de focar os pensamentos quando as comunicações são breves e estruturadas, mas se torna frouxo ou irrelevante quando lida com comunicações mais complexas ou quando está sob mínima pressão.
5 - Moderado grave – Geralmente tem dificuldade em organizar os pensamentos, como evidenciado por frequentes irrelevâncias, perda da conectividade, ou afrouxamento das associações quando não está sob pressão.
6 – Grave – O pensamento está seriamente descarrilado e internamente inconsistente, resultando em irrelevâncias grosseiras e ruptura dos processos de pensamento, o que ocorre quase constantemente.
7 – Extremo – Os pensamentos apresentam tal ruptura que o paciente está incoerente. Há um acentuado afrouxamento das associações, o que resulta em total fracasso da comunicação (por ex. "salada de palavras") ou mutismo.

(E3) ESCALA DE IMPRESSÃO CLÍNICA GLOBAL – VERSÃO BIPOLAR (CGI- BP)

Item I – Gravidade da doença

Considerando sua experiência clínica total com pacientes bipolares, quão gravemente doente tem estado o paciente durante a última semana?

MANIA:

DEPRESSÃO:

TR. BIPOLAR GLOBAL:

Em caso de tanto mania como depressão terem escore igual ou superior a 3, discriminar:

( ) *estado misto* ( ) *virada para mania* ( ) *virada para depressão*

ESCORES:

1. **Normal, não doente** (sem sintomas)
2. **Minimamente doente** (sintomas mínimos, manteve funcionamento eficiente)
3. **Levemente doente** (baixo nível de sintomas, sofrimento subjetivo, pouco ou nenhum prejuízo funcional)
4. **Moderadamente doente** (alguns sintomas proeminentes, prejuízo funcional moderado)
5. **Acentuadamente doente** (sintomas significativos, prejuízo funcional muito substancial)
6. **Gravemente doente** (sintomas muito evidentes, incapaz de funcionar na maioria das áreas)
7. **Muito gravemente doente** (sintomas extremos, completamente incapacitado, requerendo cuidados extra

P3 – COMPORTAMENTO ALUCINATÓRIO: Relato verbal ou comportamento indicando percepções que não são geradas por estímulos externos. Isso pode ocorrer nas modalidades auditiva, visual, olfativa ou somática.

Base para avaliar: relato verbal e manifestações físicas durante o curso da entrevista, assim como relatos de comportamento por parte de trabalhadores de cuidados primários ou familiares.

1 – Ausente – A definição não se aplica.
2 – Mínimo – Patologia questionável: pode estar no extremo superior dos limites normais.
3 – Leve – Uma ou duas alucinações claramente formadas, porém raras, ou então um número de percepções anormais vagas que não resultam em distorções do pensamento ou do comportamento.
4 – Moderado – Alucinações ocorrem frequente, mas não continuamente, e o pensamento e o comportamento do paciente são afetados apenas em pequena monta.
5 - Moderado grave – Alucinações são frequentes, podem envolver mais de uma modalidade sensorial e tendem a distorcer o pensamento e/ou levam a uma ruptura no comportamento. O paciente pode ter uma interpretação delirante dessas experiências e responder a elas emocionalmente e, às vezes, responder a elas verbalmente também.
6 – Grave – Alucinações estão presentes quase continuamente, causando uma grande ruptura no pensamento e no comportamento. O paciente as trata como percepções reais, o funcionamento é impedido pelas frequentes respostas emocionais e verbais a elas.
7 – Extremo – O paciente está quase totalmente preocupado com alucinações, as quais virtualmente dominam o pensamento e o comportamento. As alucinações levam a uma rígida interpretação delirante e provocam respostas verbais e comportamentais, incluindo obediência a alucinações imperativas.

P4 – EXCITAÇÃO: Hiperatividade como refletida em comportamento motor acelerado, resposta exacerbada a estímulos, hipervigilância, ou excessiva labilidade afetiva.

Base para avaliar: manifestações comportamentais durante o curso da entrevista, assim como relatos de comportamento por parte de trabalhadores de cuidados primários ou familiares.

1 – Ausente – A definição não se aplica.
2 – Mínimo – Patologia questionável: pode estar no extremo superior dos limites normais.
3 – Leve – Tende a ficar levemente agitado ou hipervigilante durante a entrevista, mas sem episódios de excitação ou acentuada labilidade de humor. Pode haver uma leve pressão para a fala.
4 – Moderado – Agitação ou hipervigilância é claramente evidente durante a entrevista, afetando a fala e a mobilidade geral, ou episódios de "explosão" ocorrem esporadicamente.
5 - Moderado grave – Hiperatividade significativa ou frequentes "explosões" de atividade motora são observadas, tornando difícil para o paciente permanecer sentado por mais do que alguns minutos num dado período.
6 – Grave – Excitação acentuada domina a entrevista, restringe a atenção, e afeta até certo ponto funções pessoais tais como alimentar-se e dormir.
7 – Extremo - Excitação acentuada interfere seriamente com a alimentação e o sono e faz as interações interpessoais virtualmente impossíveis. A aceleração da fala e da atividade motora podem resultar em incoerência e exaustão.

P5 – GRANDIOSIDADE: Auto opinião exagerada e convicções não realistas de superioridade, incluindo delírios de habilidades extraordinárias, riqueza, conhecimento, fama, poder e correção moral.

Base para avaliar: o conteúdo do pensamento expresso na entrevista e sua influência no comportamento.

1 – Ausente – A definição não se aplica.
2 – Mínimo – Patologia questionável: pode estar no extremo superior dos limites normais.
3 – Leve – Alguma expansividade ou presunção é evidente, mas sem delírios de grandeza bem delineados.
4 – Moderado – Sente-se distinta e irrealisticamente superior aos outros. Alguns delírios pobremente formados sobre status ou habilidades especiais podem estar presentes, mas não produzem nenhum efeito.
5 - Moderado grave – Delírios bem delineados relativos a habilidades notáveis, status, ou poder são expressos e influenciam a atitude, mas não o comportamento.
6 – Grave – Delírios bem delineados de notável superioridade envolvendo mais de um parâmetro (riqueza, conhecimento, fama, etc.) são expressos, influenciam notavelmente as interações, e podem afetar o comportamento.
7 – Extremo – O pensamento, as interações e o comportamento são dominados por múltiplos delírios de assombrosa habilidade, riqueza, conhecimento, fama, poder, e/ou estatura moral, que podem ser bizarros.

P6 – SUSPICÁCIA / PERSEGUIÇÃO: Ideias de perseguição não realistas ou exageradas, como refletidas em precaução, uma atitude de desconfiança, hipervigilância suspicaz, ou delírios francos de que outros pretendem prejudicá-lo.

Base para avaliar: o conteúdo do pensamento expresso na entrevista e sua influência no comportamento.

1 – Ausente – A definição não se aplica.
2 – Mínimo – Patologia questionável: pode estar no extremo superior dos limites normais.
3 – Leve – Apresenta uma atitude "defensiva" ou de franca desconfiança, mas pensamentos interações e comportamento são minimamente afetados.
4 – Moderado – A desconfiança é claramente evidente e se impõe na entrevista e/ou no comportamento, mas não há evidência de delírios persecutórios, e não parece afetar a atitude ou as relações interpessoais do paciente.
5 - Moderado grave – O paciente mostra acentuada desconfiança, levando a uma extensa ruptura das relações interpessoais, ou então há delírios persecutórios bem delineados que têm um impacto limitado nas relações interpessoais e no comportamento.
6 – Grave – Delírios de perseguição penetrantes e bem delineados que podem ser sistematizados e que interferem significativamente nas relações interpessoais.
7 – Extremo – Uma rede de delírios persecutórios sistematizados domina o pensamento, as relações sociais e o comportamento do paciente.

P7 – HOSTILIDADE: Expressões verbais e não verbais de raiva e ressentimento, incluindo sarcasmo, comportamento passivo-agressivo, insulto verbal e agressão.

Base para avaliar: comportamento interpessoal observado durante a entrevista e relatos por parte de trabalhadores de cuidados primários ou familiares.

1 – Ausente – A definição não se aplica.
2 – Mínimo – Patologia questionável: pode estar no extremo superior dos limites normais.
3 – Leve – Comunicação indireta ou disfarçada de raiva, tal como sarcasmo, desrespeito, expressões de hostilidade, e irritabilidade ocasional.
4 – Moderado – O paciente apresenta uma atitude excessivamente hostil, exibindo irritabilidade frequente e expressão direta de raiva ou ressentimento.
5 - Moderado grave – O paciente está altamente irritável e, em certas ocasiões, está verbalmente insultuoso ou ameaçador.
6 – Grave – Ausência de cooperação e insultos ou ameaças verbais notavelmente influenciam e seriamente afetam as relações sociais. O paciente pode estar violento e destrutivo, mas não está fisicamente agressivo em relação aos outros.
7 – Extremo – Acentuada raiva resulta em extrema falta de cooperação, tornando impossível outras interações, ou episódio (s) de agressão física em relação aos outros.

7.10
Annex J - Scales results

RESULTADO DE ESCALAS

Identificação: **Nome do paciente:**
Gênero: **Idade:** **Avaliação #:**
Data: **Examinador:**
Estado afetivo atual:
( ) Depressão ( ) Eutímico ( ) Misto ( ) Hipomania ( ) Mania

ESCALA YOUNG DE AVALIAÇÃO DA MANIA

1-	2-	3-	4-	5-	6-
7-	8-	9-	10-	11-	

TOTAL (YOUNG): _____

ESCALA DE HAMILTON PARA DEPRESSÃO

1-	2-	3-	4-	5-	6-
7-	8-	9-	10-	11-	12-
13-	14-	15-	16-	17-	

TOTAL (HAMILTON): _____

CONSCIÊNCIA DE MORBIDADE (ISAD-BR)

1-	2-	3-	4-	5-	6-
7-	8-	9-	10-	11-	12-
13-	14-	15-	16-	17-	

TOTAL (ISAD-BR): _____

CGI-BP

Mania: ____ Depressão: ____ Tr Bipolar (global): ____

Em caso de tanto mania como depressão terem escore igual ou superior a 3, discriminar:
( ) estado misto ( ) virada para mania ( ) virada para depressão

PANSS – POSITIVE SCALE

1-	2-	3-	4-	5-	6-
7-					

TOTAL (PANSS): _____

Medicamentos atuais (e respectivas doses):

7.11
Annex K - MAUQ adaptation in a semi-structured interview

Apresentação da pesquisa

Facilidade de Uso (BraPolar-Interv_F):

F1- Como você descreveria a facilidade de uso do aplicativo?

F2- Houve alguma parte do aplicativo que você achou difícil de entender ou utilizar?

F3- A navegação foi consistente ao mover-se entre as telas?

F4- A interface do aplicativo permitiu que você utilizasse todas as funções, como inserir informações, responder a lembretes e visualizar informações?

F5- Qual parte do aplicativo é mais difícil de utilizar e por quê?

F6- Quando cometeu um erro ao usar o aplicativo, conseguiu se recuperar rapidamente?

F7- Houve algum momento que o aplicativo atrapalhou algo que você estava fazendo no seu celular? Como foi essa experiência?

F8- O que você acha do sistema de avisos do aplicativo (alarme/lembrete de preenchimento diário?

F9- Estes lembretes, foram desconfortáveis em algum momento? Descreva as circunstâncias no qual isto foi um inconveniente.

Frequência de uso (BraPolar-Interv_FU):

FU1- Você utiliza o aplicativo BraPolar todos os dias?

FU2- Caso não tenha conseguido preencher diariamente, por qual motivo você deixou de utilizar o aplicativo em alguns dias?

FU3- Como você se sente quando deixa de preencher os dados no aplicativo?

FU4- Como você se sente depois de preencher os dados no aplicativo?

FU5- Como você se sente quando deixa de utilizar o aplicativo por vários dias?

Motivação (BraPolar-Interv_M):

M1- Momento Preferido de Uso:

M2- Existe um momento específico durante o dia que você prefere preencher as informações no aplicativo?

M3- Por quê você prefere usar o aplicativo nessa hora?

M4- Você costuma abrir o aplicativo mais de uma vez por dia? Por quê?

M5- Em termos de utilidade para manter um registro do seu estado mental, o quão útil você acha o aplicativo para este fim?

1

Interface e Satisfação (BraPolar-Interv_I):

I1- Você gosta da interface do aplicativo BraPolar?

I2- As informações no aplicativo estavam bem organizadas para que você pudesse encontrar facilmente o que precisava?

I3- O aplicativo reconheceu e forneceu informações adequadas para te orientar sobre o andamento das suas ações?

I4- Sente-se confortável ao usar o aplicativo BraPolar em ambientes sociais?

I5- O tempo gasto no uso deste aplicativo foi adequado para você?

I6- Você usaria novamente o aplicativo BraPolar?

I7- No geral, está satisfeito com o aplicativo BraPolar?

Utilidade (BraPolar-Interv_U):

U1- O aplicativo BraPolar foi útil para sua saúde e bem-estar?

U3- O aplicativo BraPolar lhe ajudou a gerenciar a bipolaridade de maneira eficaz?

U4- Este aplicativo possui todos os recursos e capacidades que você esperava?

U5- Você poderia usar o aplicativo mesmo quando a conexão com a Internet fosse ruim ou indisponível?

Sentimentos em relação aos dados passivos coletados (BraPolar-Interv_S):

S1- Como você se sente em relação a coleta de dados por trás do aplicativo,

como por exemplo o tempo em que a tela ficou ligada?

S2- Você acha que utiliza o telefone de maneira diferente dependendo do seu humor?

S3- Qual a sua opinião sobre o desempenho do seu celular após começar a utilizar o aplicativo BraPolar?

S4- Tem notado alguma diferença que gostaria de descrever?

Opinião Geral do Usuário (BraPolar-Interv_O):

O1- Como você acha que o aplicativo poderia melhorar para atender melhor às suas necessidades?

O2- Você mudaria alguma funcionalidade do aplicativo? Que funcionalidade seria esta?

O3- Você percebeu alguma mudança no seu dia a dia desde que começou a usar o aplicativo? Quais mudanças seriam essas?

Encerramento

2

7.12
Annex L - Total of papers by Database and Type

Database	Articles	Total
IEEE - Conference	(CHOKSI et al., 2020; MAYORA et al., 2013; MONDEJAR et al., 2019b; GRUNERBL et al., 2015)	4
ACM - Conference	(FROST et al., 2013; CAO et al., 2017; CONSTANTINIDES et al., 2018; ALVAREZ-LOZANO et al., 2014; MATTHEWS et al., 2015; OSMANI et al., 2013)	6
Springer - Journal	(FAURHOLT-JEPSEN et al., 2019; MOHIUDDIN et al., 2013; MüHLBAUER et al., 2018; FAURHOLT-JEPSEN et al., 2021; DORYAB et al., 2015; ORTIZ et al., 2023b; HIDALGO-MAZZEI et al., 2015; FAURHOLT-JEPSEN et al., 2017; KAPPELER-SETZ et al., 2013; CHAPMAN et al., 2017)	10
Sci Direct - Journal	(COELHO; BASTOS-FILHO, 2016; GOLDSTEIN et al., 2020; DEPP et al., 2015; SCHWARTZ et al., 2016; KAUFMANN et al., 2016; AUDIBERT et al., 2022; BONNíN et al., 2021; TSENG et al., 2022a; KAMARSU et al., 2020; KHOUBAEVA et al., 2022; FLETCHER; MURRAY, 2021; FAURHOLT-JEPSEN et al., 2015; HIDALGO-MAZZEI et al., 2016)	13
PubMed - Journal	(GARCíA-ESTELA et al., 2022; ORSOLINI; FIORANI; VOLPE, 2020; TIL; McInnis; COCHRAN, 2020; ARRIBAS et al., 2018; RYAN et al., 2020; GOULDING et al., 2022; BOS et al., 2022b; STANISLAUS et al., 2022; ABDULLAH et al., 2016; FAURHOLT-JEPSEN et al., 2021; PALMIUS et al., 2017a; DAUS et al., 2020b; FAURHOLT-JEPSEN et al., 2014; HOLMES et al., 2016; FAURHOLT-JEPSEN et al., 2016; DOMINIAK et al., 2022; STANISLAUS et al., 2020; EBNER-PRIEMER et al., 2020b; ZULUETA et al., 2018; FAURHOLT-JEPSEN et al., 2023; BEN-ZEEV et al., 2019)	21
Total	-	**54**

7.13
Annex M - Total of articles by Year

Year	Articles	Total
2013	(MOHIUDDIN et al., 2013; KAPPELER-SETZ et al., 2013; MAYORA et al., 2013; OSMANI et al., 2013; FROST et al., 2013)	5
2014	(FAURHOLT-JEPSEN et al., 2014; ALVAREZ-LOZANO et al., 2014)	2
2015	(DEPP et al., 2015; DORYAB et al., 2015; HIDALGO-MAZZEI et al., 2015; GRUNERBL et al., 2015; MATTHEWS et al., 2015; FAURHOLT-JEPSEN et al., 2015)	6
2016	(COELHO; BASTOS-FILHO, 2016; ABDULLAH et al., 2016; SCHWARTZ et al., 2016; KAUFMANN et al., 2016; HOLMES et al., 2016; FAURHOLT-JEPSEN et al., 2016; HIDALGO-MAZZEI et al., 2016)	7
2017	(PALMIUS et al., 2017a; CAO et al., 2017; FAURHOLT-JEPSEN et al., 2017; CHAPMAN et al., 2017)	4
2018	(ARRIBAS et al., 2018; MüHLBAUER et al., 2018; CONSTANTINIDES et al., 2018; ZULUETA et al., 2018)	4
2019	(FAURHOLT-JEPSEN et al., 2019; BEN-ZEEV et al., 2019; MONDEJAR et al., 2019b)	3
2020	(GOLDSTEIN et al., 2020; TIL; McInnis; COCHRAN, 2020; RYAN et al., 2020; DAUS et al., 2020b; ORSOLINI; FIORANI; VOLPE, 2020; STANISLAUS et al., 2020; KAMARSU et al., 2020; EBNER-PRIEMER et al., 2020b; CHOKSI et al., 2020)	9
2021	(FAURHOLT-JEPSEN et al., 2021; BONNíN et al., 2021; FAURHOLT-JEPSEN et al., 2021; FLETCHER; MURRAY, 2021)	4
2022	(GOULDING et al., 2022; BOS et al., 2022b; STANISLAUS et al., 2022; AUDIBERT et al., 2022; TSENG et al., 2022a; DOMINIAK et al., 2022; KHOUBAEVA et al., 2022; GARCíA-ESTELA et al., 2022)	8
2023	(ORTIZ et al., 2023b; FAURHOLT-JEPSEN et al., 2023)	2
Total	-	**54**

7.14
Annex N - Mobile sensors and cellphones capabilities commonly used

Sensor or smartphone capability	Used by	Total
Accelerometer	(COELHO; BASTOS-FILHO, 2016; OSMANI et al., 2013; FAURHOLT-JEPSEN et al., 2019; GOULDING et al., 2022; FROST et al., 2013; CHAPMAN et al., 2017; ZULUETA et al., 2018; MONDEJAR et al., 2019b; CHOKSI et al., 2020; ABDULLAH et al., 2016; DORYAB et al., 2015; ORTIZ et al., 2023b; PALMIUS et al., 2017a; DAUS et al., 2020b; ORSOLINI; FIORANI; VOLPE, 2020; CAO et al., 2017)	16
GPS	(GOULDING et al., 2022; CHOKSI et al., 2020; MAYORA et al., 2013; FAURHOLT-JEPSEN et al., 2021; DORYAB et al., 2015; MONDEJAR et al., 2019b; PALMIUS et al., 2017a; ORSOLINI; FIORANI; VOLPE, 2020; MüHLBAUER et al., 2018; TSENG et al., 2022a)	10
Not clear	(GRUNERBL et al., 2015; ARRIBAS et al., 2018; FAURHOLT-JEPSEN et al., 2015; FAURHOLT-JEPSEN et al., 2023; GARCíA-ESTELA et al., 2022; STANISLAUS et al., 2022; HIDALGO-MAZZEI et al., 2015; ALVAREZ-LOZANO et al., 2014; DOMINIAK et al., 2022)	9
Call	(MOHIUDDIN et al., 2013; GOULDING et al., 2022; RYAN et al., 2020; EBNER-PRIEMER et al., 2020b; DORYAB et al., 2015; CONSTANTINIDES et al., 2018; FAURHOLT-JEPSEN et al., 2016; DOMINIAK et al., 2022)	8
Text Messages	(GOULDING et al., 2022; RYAN et al., 2020; CHOKSI et al., 2020; EBNER-PRIEMER et al., 2020b; DORYAB et al., 2015; DOMINIAK et al., 2022)	6
Not specified	(HIDALGO-MAZZEI et al., 2016; BEN-ZEEV et al., 2019; BOS et al., 2022b; FAURHOLT-JEPSEN et al., 2017; KAPPELER-SETZ et al., 2013; AUDIBERT et al., 2022)	6
Ambient light sensor	(MOHIUDDIN et al., 2013; GOULDING et al., 2022; MONDEJAR et al., 2019b; ABDULLAH et al., 2016; CONSTANTINIDES et al., 2018)	5
Screen	(CONSTANTINIDES et al., 2018; FROST et al., 2013; FAURHOLT-JEPSEN et al., 2016; MATTHEWS et al., 2015)	5
Microphone	(MOHIUDDIN et al., 2013; ABDULLAH et al., 2016; MONDEJAR et al., 2019b)	3
Cellphone antenna	(FROST et al., 2013; FAURHOLT-JEPSEN et al., 2021; FAURHOLT-JEPSEN et al., 2016)	3
Sound Sensors	(MOHIUDDIN et al., 2013; GOULDING et al., 2022)	2
EDA	(KAPPELER-SETZ et al., 2013; MAYORA et al., 2013)	2

7.15
Annex O - Common mobile features in mHealth

Feature	Used by	Total
Mood	(GOULDING et al., 2022; HIDALGO-MAZZEI et al., 2016; GOLDSTEIN et al., 2020; TIL; McInnis; COCHRAN, 2020; COELHO; BASTOS-FILHO, 2016; MOHIUDDIN et al., 2013; FAURHOLT-JEPSEN et al., 2015; BEN-ZEEV et al., 2019; FAURHOLT-JEPSEN et al., 2019; RYAN et al., 2020; FROST et al., 2013; FAURHOLT-JEPSEN et al., 2023; KHOUBAEVA et al., 2022; GARCíA-ESTELA et al., 2022; FLETCHER; MURRAY, 2021; ZULUETA et al., 2018; MONDEJAR et al., 2019b; MATTHEWS et al., 2015; FAURHOLT-JEPSEN et al., 2017; STANISLAUS et al., 2022; DEPP et al., 2015; FAURHOLT-JEPSEN et al., 2021; DORYAB et al., 2015; ORTIZ et al., 2023b; HIDALGO-MAZZEI et al., 2015; CONSTANTINIDES et al., 2018; ALVAREZ-LOZANO et al., 2014; KAMARSU et al., 2020; SCHWARTZ et al., 2016; KAUFMANN et al., 2016; AUDIBERT et al., 2022; ORSOLINI; FIORANI; VOLPE, 2020; BONNíN et al., 2021; FAURHOLT-JEPSEN et al., 2021; HOLMES et al., 2016; TSENG et al., 2022a; FAURHOLT-JEPSEN et al., 2016; DOMINIAK et al., 2022; CAO et al., 2017)	39
Sleep patterns	(COELHO; BASTOS-FILHO, 2016; TIL; McInnis; COCHRAN, 2020; MOHIUDDIN et al., 2013; FAURHOLT-JEPSEN et al., 2015; BEN-ZEEV et al., 2019; GOULDING et al., 2022; FROST et al., 2013; KHOUBAEVA et al., 2022; GARCíA-ESTELA et al., 2022; FAURHOLT-JEPSEN et al., 2017; CHOKSI et al., 2020; STANISLAUS et al., 2022; EBNER-PRIEMER et al., 2020b; DORYAB et al., 2015; HIDALGO-MAZZEI et al., 2015; CONSTANTINIDES et al., 2018; MONDEJAR et al., 2019b; ALVAREZ-LOZANO et al., 2014; KAUFMANN et al., 2016; DAUS et al., 2020b; AUDIBERT et al., 2022; TSENG et al., 2022a; FAURHOLT-JEPSEN et al., 2016; DOMINIAK et al., 2022; STANISLAUS et al., 2020)	25

Feature	Used by	Total
Physical activity	(COELHO; BASTOS-FILHO, 2016; TIL; McInnis; COCHRAN, 2020; OSMANI et al., 2013; KHOUBAEVA et al., 2022; CHAPMAN et al., 2017; FAURHOLT-JEPSEN et al., 2017; KAPPELER-SETZ et al., 2013; DORYAB et al., 2015; CONSTANTINIDES et al., 2018; AUDIBERT et al., 2022; FAURHOLT-JEPSEN et al., 2014)	11
Medication	(HIDALGO-MAZZEI et al., 2016; GOLDSTEIN et al., 2020; FAURHOLT-JEPSEN et al., 2015; BEN-ZEEV et al., 2019; MONDEJAR et al., 2019b; GOULDING et al., 2022; GARCíA-ESTELA et al., 2022; MATTHEWS et al., 2015; AUDIBERT et al., 2022; FAURHOLT-JEPSEN et al., 2014; FAURHOLT-JEPSEN et al., 2019)	11
Energy levels	(HIDALGO-MAZZEI et al., 2016; TIL; McInnis; COCHRAN, 2020; MOHIUDDIN et al., 2013; ARRIBAS et al., 2018; RYAN et al., 2020; FAURHOLT-JEPSEN et al., 2023; GARCíA-ESTELA et al., 2022; ORTIZ et al., 2023b; HIDALGO-MAZZEI et al., 2015; SCHWARTZ et al., 2016)	10
Social Activity	(FAURHOLT-JEPSEN et al., 2015) (FAURHOLT-JEPSEN et al., 2017) (DORYAB et al., 2015) (ALVAREZ-LOZANO et al., 2014) (AUDIBERT et al., 2022) (FAURHOLT-JEPSEN et al., 2016)	6
Speech/Voice	(FAURHOLT-JEPSEN et al., 2017; KAMARSU et al., 2020; ORSOLINI; FIORANI; VOLPE, 2020; FAURHOLT-JEPSEN et al., 2014)	4
Keyboard	(ZULUETA et al., 2018; MONDEJAR et al., 2019b; CAO et al., 2017)	3
Speech/voice	(TIL; McInnis; COCHRAN, 2020; ORSOLINI; FIORANI; VOLPE, 2020; FAURHOLT-JEPSEN et al., 2017)	3

7.16 Annex P - Categories of data types

Data type	Articles	Total
Active	(GOULDING et al., 2022; HIDALGO-MAZZEI et al., 2016; COELHO; BASTOS-FILHO, 2016; TIL; McInnis; COCHRAN, 2020; MOHIUDDIN et al., 2013; ARRIBAS et al., 2018; FAURHOLT-JEPSEN et al., 2015; BEN-ZEEV et al., 2019; FAURHOLT-JEPSEN et al., 2019; RYAN et al., 2020; FROST et al., 2013; FAURHOLT-JEPSEN et al., 2023; KHOUBAEVA et al., 2022; GARCíA-ESTELA et al., 2022; FLETCHER; MURRAY, 2021; CHAPMAN et al., 2017; FAURHOLT-JEPSEN et al., 2017; STANISLAUS et al., 2022; DEPP et al., 2015; ABDULLAH et al., 2016; FAURHOLT-JEPSEN et al., 2021; EBNER-PRIEMER et al., 2020b; DORYAB et al., 2015; ORTIZ et al., 2023b; HIDALGO-MAZZEI et al., 2015; CONSTANTINIDES et al., 2018; MONDEJAR et al., 2019b; ALVAREZ-LOZANO et al., 2014; KAMARSU et al., 2020; SCHWARTZ et al., 2016; KAUFMANN et al., 2016; PALMIUS et al., 2017a; DAUS et al., 2020b; AUDIBERT et al., 2022; ORSOLINI; FIORANI; VOLPE, 2020; BONNíN et al., 2021; MüHLBAUER et al., 2018; FAURHOLT-JEPSEN et al., 2021; FAURHOLT-JEPSEN et al., 2014; HOLMES et al., 2016; TSENG et al., 2022a; FAURHOLT-JEPSEN et al., 2016; DOMINIAK et al., 2022; STANISLAUS et al., 2020)	44
Passive	(GRUNERBL et al., 2015; MONDEJAR et al., 2019b; GOLDSTEIN et al., 2020; TIL; McInnis; COCHRAN, 2020; OSMANI et al., 2013; MOHIUDDIN et al., 2013; BEN-ZEEV et al., 2019; FAURHOLT-JEPSEN et al., 2019; GOULDING et al., 2022; RYAN et al., 2020; FROST et al., 2013; FAURHOLT-JEPSEN et al., 2023; ZULUETA et al., 2018; MATTHEWS et al., 2015; BOS et al., 2022b; FAURHOLT-JEPSEN et al., 2017; KAPPELERSETZ et al., 2013; CHOKSI et al., 2020; MAYORA et al., 2013; ABDULLAH et al., 2016; FAURHOLT-JEPSEN et al., 2021; EBNER-PRIEMER et al., 2020b; DORYAB et al., 2015; ORTIZ et al., 2023b; HIDALGO-MAZZEI et al., 2015; CONSTANTINIDES et al., 2018; ALVAREZ-LOZANO et al., 2014; PALMIUS et al., 2017a; DAUS et al., 2020b; ORSOLINI; FIORANI; VOLPE, 2020; MüHLBAUER et al., 2018; FAURHOLT-JEPSEN et al., 2014; TSENG et al., 2022a; FAURHOLT-JEPSEN et al., 2016; DOMINIAK et al., 2022; STANISLAUS et al., 2020; CAO et al., 2017)	37
Contextual	(MOHIUDDIN et al., 2013)	1

7.17 Annex Q - Interview with specialists: contextual data relevance

Procedimento para Condução de Entrevistas semi-estruturada com Especialistas – Dados Contextuais

1. Preparação

Objetivo: entender a relevância dos dados contextuais na análise da fenotipagem digital para melhorar o aplicativo BraPolar2.

Documentação: Levar cópias do consentimento informado, roteiro de entrevista, e materiais de apoio, como a proposta de tese de doutorado e informações sobre o BraPolar2.

Ambiente: Escolher um ambiente tranquilo e confortável para a entrevista em caso que seja presencial, garantindo privacidade. Na hipótese que a entrevista seja online, vai depender da disponibilidade e ambiente do entrevistado.

Probing: Usar técnicas de probing para aprofundar nas respostas. Exemplo: "Você pode explicar mais sobre isso?" ou "Pode dar um exemplo específico?"

2. Introdução

Boas-vindas: Agradecer pela participação e apresentar-se.

Explicação do Propósito: Esta entrevista visa coletar informações sobre como fatores contextuais, como clima e eventos sociais, podem influenciar o comportamento e o humor de pacientes com transtorno bipolar, ajudando a melhorar o monitoramento e o tratamento por meio de aplicativos de saúde móvel.

Consentimento Informado: Explicar o consentimento informado, assegurando a confidencialidade e o uso dos dados para fins acadêmicos.

Contextualização: Fornecer uma breve explicação sobre fenotipagem digital e dados contextuais:

- Fenotipagem Digital: Fenotipagem digital refere-se à coleta e análise de dados sobre o comportamento e estado de saúde de uma pessoa por meio de tecnologias digitais, como smartphones e wearables.
- Dados Contextuais: Dados contextuais incluem informações sobre o ambiente e circunstâncias ao redor de uma pessoa, como condições climáticas, eventos sociais, e hora do dia, que podem influenciar seu humor e comportamento.
- Aplicativo BraPolar2.

3. Estrutura da Entrevista

Parte 1: Informações Básicas

- Nome:

Qual é a sua especialização e quantos anos de experiência você tem no tratamento do Transtorno Bipolar (TB)?

Como sua abordagem ao tratamento do TB evoluiu ao longo dos anos?

Você já usou ferramentas digitais ou aplicativos de mHealth em sua prática clínica antes? Se sim, por favor especifique.

Você pode descrever sua experiência com essas ferramentas? Quais foram as vantagens e limitações?

Parte 2: Prática Corrente

- Monitoramento e Gestão:

Como você monitora e gerencia atualmente as flutuações de humor em seus pacientes com TB?

Quais métodos ou ferramentas específicas você considera mais eficazes?

- Fontes de Dados:

Em quais tipos de dados (por exemplo, autorrelatos de pacientes, escalas clínicas) você se baseia principalmente para tomar decisões?

Como você integra essas fontes de dados em seus planos de tratamento?

Parte 3: Experiência e Percepção Profissional

- Experiência com Tecnologias de Saúde Mental:

Pode descrever sua experiência com tecnologias de saúde mental, como aplicativos de mHealth?

Quais são os principais benefícios e desafios que você encontrou ao utilizar essas tecnologias?

- Percepção sobre Fenotipagem Digital e Dados Contextuais:

Antes desta entrevista, você já estava familiarizado com os termos fenotipagem digital e dados contextuais?

Qual é a sua percepção sobre a utilização de tecnologias digitais para monitorar e tratar transtornos mentais?

Parte 4: Relevância dos Dados Contextuais

- Importância dos Dados Contextuais:

Quais tipos de dados contextuais (por exemplo, condições climáticas, eventos sociais) você considera mais relevantes para a análise da saúde mental dos pacientes?

Pode fornecer exemplos específicos de como dados contextuais ajudaram no diagnóstico ou tratamento de um paciente?

- Integração na Prática Clínica:

Como você integra atualmente dados contextuais na sua prática clínica? Que ferramentas ou métodos você utiliza?

Quais são os principais desafios que você enfrenta ao integrar esses dados?

Parte 5: Desafios e Oportunidades

- Desafios na Utilização de Dados Contextuais:

Quais são os principais desafios que você enfrenta ao integrar dados contextuais na prática clínica?

Como você acredita que esses desafios podem ser superados?

- Oportunidades de Melhoria:

Que oportunidades você vê no futuro para melhorar a coleta e utilização de dados contextuais?

Que funcionalidades você gostaria de ver em um aplicativo como o BraPolar2 para melhor atender às necessidades dos pacientes?

Parte 6: Sugestões e Recomendações

Sugestões para a Pesquisa:

Quais melhorias você sugeriria para a coleta de dados contextuais em aplicativos de mHealth?

Como você acha que a pesquisa pode avançar para melhor integrar dados contextuais na fenotipagem digital?

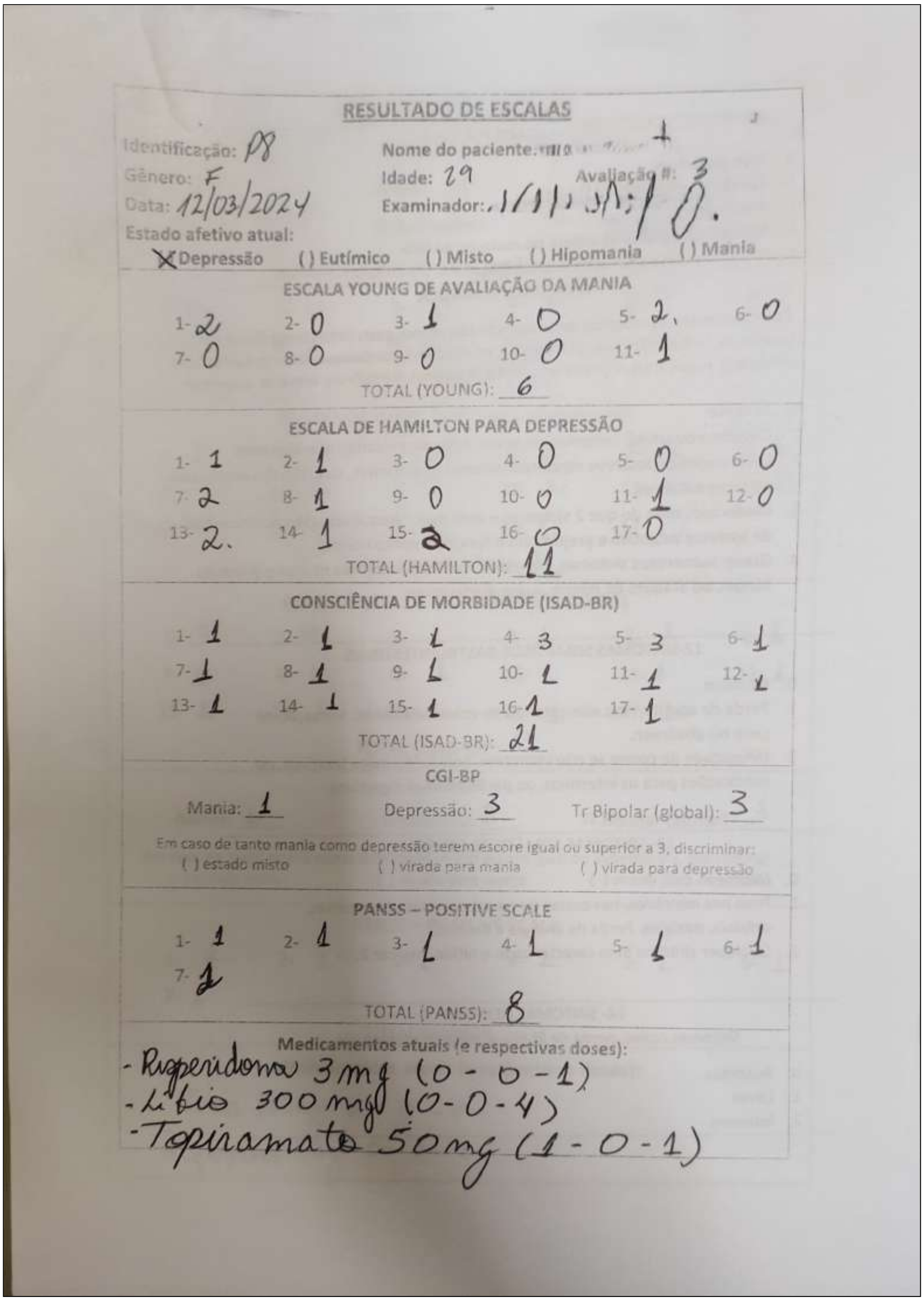
Como você imagina o papel da evolução da tecnologia no gerenciamento do TB nos próximos 5 a 10 anos?

Que avanços você gostaria de ver nas ferramentas digitais de saúde?

Feedback Geral:

Há mais algum comentário ou sugestão que você gostaria de adicionar sobre a integração de dados contextuais em soluções digitais para o tratamento de transtorno bipolar?

7.18
Annex R - Scales result applied to P8 in third consult



RESULTADO DE ESCALAS

Identificação: P8 — Nome do paciente: [illegible]
Gênero: F — Idade: 29 — Avaliação #: 3
Data: 12/03/2024 — Examinador: [illegible]
Estado afetivo atual:
(X) Depressão ( ) Eutímico ( ) Misto ( ) Hipomania ( ) Mania

ESCALA YOUNG DE AVALIAÇÃO DA MANIA

1- 2 2- 0 3- 1 4- 0 5- 2 6- 0
7- 0 8- 0 9- 0 10- 0 11- 1

TOTAL (YOUNG): 6

ESCALA DE HAMILTON PARA DEPRESSÃO

1- 1 2- 1 3- 0 4- 0 5- 0 6- 0
7- 2 8- 1 9- 0 10- 0 11- 1 12- 0
13- 2 14- 1 15- 2 16- 0 17- 0

TOTAL (HAMILTON): 11

CONSCIÊNCIA DE MORBIDADE (ISAD-BR)

1- 1 2- 1 3- 1 4- 3 5- 3 6- 1
7- 1 8- 1 9- 1 10- 1 11- 1 12- 1
13- 1 14- 1 15- 1 16- 1 17- 1

TOTAL (ISAD-BR): 21

CGI-BP

Mania: 1 Depressão: 3 Tr Bipolar (global): 3

Em caso de tanto mania como depressão terem escore igual ou superior a 3, discriminar:
( ) estado misto ( ) virada para mania ( ) virada para depressão

PANSS – POSITIVE SCALE

1- 1 2- 1 3- 1 4- 1 5- 1 6- 1
7- 1

TOTAL (PANSS): 8

Medicamentos atuais (e respectivas doses):

- Risperidona 3mg (0 - 0 - 1)
- Lítio 300 mg (0 - 0 - 4)
- Topiramato 50mg (1 - 0 - 1)

7.19 Annex S - Certificate of attendee in IEEE International Conference SeGAH24


12TH INTERNATIONAL CONFERENCE ON SERIOUS GAMES AND APPLICATIONS FOR HEALTH, MADEIRA

SeGAH' 24

ATTENDEE CERTIFICATE

Abel Gonzalez Mondejar

This certify that **Abel Gonzalez Mondejar** attended the IEEE 12th International Conference on Serious Games and Applications for Health, held in Madeira from August 7th to August 9th, 2024.

Nuno Rodrigues
General Chair

Sergi Bermúdez I Badia
General Chair

IEEE PORTUGAL SECTION