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The nationwide SoPsy-Depression cohort: study rationale, design, and baseline patient characteristics

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Additional Declarations:
Tables 1 to 7 are available in the Supplementary Files section.

The nationwide SoPsy-Depression cohort: study rationale, design, and baseline patient characteristics

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Abstract

Depressive disorders are among the most prevalent and disabling psychiatric conditions, affecting up to 20% of the general population. Diagnosis still relies on clinical evaluation, and efforts to identify robust biomarkers are limited by the marked phenotypic heterogeneity of depressive disorders. Sleep and circadian disturbances are highly prevalent in major depressive episode (MDE) and represent promising candidate markers, yet their characterization across depressive subtypes remains incomplete. The SoPsy-Depression cohort is a nationwide, prospective, multicenter study designed to harmonize multimodal assessment of sleep and circadian alterations across depressive disorders in routine care. The cohort aims to enroll more than 1000 participants (adults and children) with a current MDE over 10 years across an expanding network of French psychiatric and sleep centres. A Delphi consensus established a standardized set of clinician-administered and self-report questionnaires assessing psychiatric symptoms, sleep, circadian rhythms and substance use. Subjective measures are complemented by objective assessments including actigraphy, polysomnography and biological circadian markers. This report presents the study rationale, design and first descriptive data after two years of inclusion. As of November 2025, 158 participants were enrolled (82% unipolar, 18% bipolar). Completion rates for adult mandatory questionnaires currently approach 70%. Preliminary data reveal high rates of insomnia, hypersomnia, poor sleep quality and psychiatric comorbidities. Objective sleep measures suggest alterations in sleep continuity and circadian patterns, consistent with previous reports in depression. The SoPsy-Depression cohort demonstrates the feasibility of large-scale harmonized multimodal assessment of sleep and circadian disturbances and provides a framework to identify clinically meaningful profiles across depressive phenotypes.

Keywords: Major depressive episode, Sleep disturbances, Circadian rhythms, Cohort study, Biomarkers, Precision psychiatry

Background

Depressive disorders are among the most prevalent and disabling psychiatric conditions, affecting up to 20% of the general population [1,2]. The World Health Organization projects that depression will become the leading cause of disability worldwide by 2030. This growing public health burden is marked by profound impairments in psychosocial functioning, reduced quality of life, high suicide risk [1,2], and substantial economic costs due to productivity loss and increased healthcare utilization [1,2]. Still, the diagnosis of a major depressive episode (MDE) relies solely on clinical evaluation and standardized diagnostic criteria defined in the DSM-5 TR [3]. Efforts to identify clinically applicable biomarkers have so far yielded few robust and generalizable results [2]. Overcoming the marked heterogeneity of depressive disorders remains a major challenge for precision psychiatry.

Sleep and circadian rhythm disturbances are among the most consistent and biologically plausible candidates for identifying such biomarkers given their high prevalence and burden in depressive populations [4]. More than 90% of individuals with MDEs report sleep abnormalities [5], and longitudinal studies have demonstrated that insomnia and related disturbances are both risk factors and prodromal indicators of depression [6,7]. These alterations frequently persist into remission and are associated with increased symptom severity, relapse risk, impaired functioning and quality of life and substantial healthcare and economic burden [7,8]. Objective sleep and rhythm assessments using polysomnography (PSG) and actigraphy consistently show disrupted sleep architecture, impaired sleep efficiency, and altered circadian regulation in patients and at-risk individuals [9–20].

However, findings across studies remain inconsistent, likely due to the heterogeneity of depressive phenotypes. Even the historically robust reduction in slow-wave sleep (SWS) has shown limited reproducibility across cohorts [12]. Addressing this variability requires the identification of biologically coherent subgroups with significant number of subjects in each subgroup, and the use of multimodal approaches capable of capturing the complexity of sleep and circadian regulation in depression. To date, no large-scale study has systematically combined subjective symptom assessments, objective sleep and circadian measures (including actigraphy, video-PSG, Multiple Sleep Latency Tests - MSLT), and endogenous circadian

biomarkers (24-hour 6-sulfatoxymelatonin and cortisol), within a harmonized real-world clinical framework.

Objectives of the study

To address these challenges, we established a nationwide, multicenter cohort of patients with MDEs, capturing the full spectrum of depressive presentations encountered in routine clinical practice. As a preliminary objective, we aimed to harmonize assessment practices for MDEs by defining a standardized set of clinician-administered and self-report questionnaires, using a Delphi consensus method. Using this predefined set, the primary objective is to characterize sleep disturbances and circadian rhythm alterations across depressive disorder subtypes, including unipolar and bipolar depression, with or without suicidal behavior, seasonal, psychotic, melancholic forms, across age groups with varying sleep-related symptoms and sleep patterns. Secondary objectives are to (1) identify more homogeneous subgroups of patients presenting with sleep and circadian disturbances and (2) identify markers of disease trajectory, treatment response, and depressive relapse.

Methods

General study design:

This is a prospective non-interventional, nationwide multicenter cohort of patients with a MDE in France. This article describes the third version of the study protocol (September 2025). The SoPsy-Depression cohort was launched in April 2023 with a target of 1000 patients enrolled over a 10-year inclusion period across at least 41 centres. Recruitment is continuous and embedded in routine clinical care: each patient is assessed at baseline (inclusion visit) using the pre-defined set of questionnaires validated by Delphi, with additional assessments conducted during standard follow-up consultations (PSG, MSLT, sleep diary, 6-sulfatoxymelatonin dosage, actigraphy) at the physician's discretion (Study timeline in Table 1 & Table S1). This design enables characterization of sleep and psychiatric disorders while ensuring representativeness and real-world clinical practice.

Study population :

- Inclusion and exclusion criteria

Participants are recruited from routine outpatient or inpatient psychiatric and sleep clinics. Eligible individuals must present a current MDE according to DSM-5 TR criteria, regardless

of associated features (e.g., psychotic, melancholic or seasonal subtypes) or comorbidities. Both children (from 2 to 18 years old) and adults covered by the national health insurance system are eligible. Minors are be enrolled under specific procedures involving their legal representatives.

Exclusion criteria include inability to read or understand French, medical conditions preventing reliable questionnaire completion, or inability to provide informed non-opposition (emergency situations, severe cognitive impairment).

- Informed non-opposition

All patients are given a written information note explaining the use of their clinical data for research purposes, as well as a verbal explanation of the study provided by a qualified physician. Only patients who do not express opposition are enrolled in the study. For minors, the study information is provided both to the child and to their two legal representatives, and enrollment requires that none of the three parties expresses opposition.

Procedures

- Recruitment and inclusion visit

All patients presenting with an MDE at participating centres (n = 41) are systematically approached during a clinical consultation or during hospitalization to receive information about the study and their potential participation. Patients interested to participate are informed about the study by trained medical team, non-opposition is recorded, and eligibility is verified. Participants then undergo a thorough, standardized, clinical assessment conducted on site by clinicians, including psychiatric and other medical history, detailed characterization of the current MDE, sleep history, substance use screening, and the administration of Delphi-defined clinician-rated questionnaires. Self-report questionnaires from the Delphi-defined set are completed remotely by participants. After the clinical visit, patients receive by an email with a secure link providing access to the ePRO platform connected to the eCRF database, allowing them to complete the questionnaires from home within one month following the inclusion visit.

This system ensures direct and secure integration of responses into the eCRF database. The estimated completion time is 25-30 minutes for the mandatory questionnaires, and 30–45 minutes when both mandatory and optional sets are administered. In addition to the

mandatory questionnaire set, optional questionnaires may be selected by the investigator at their discretion (Table 2).

Sociodemographic and objective data from routine sleep and/or psychiatric assessments (e.g., PSG, sleep diaries, MSLT, melatonin and cortisol assays, etc.) are recorded in the eCRF (Table 3).

- Follow-up visits

No study-specific follow-up visits are scheduled and most data are collected during the inclusion visit. Routine clinical assessments performed as part of standard care may serve as follow-up evaluations at the investigator's discretion. When appropriate, questionnaires and objective assessments can be re-administered during these visits to capture longitudinal changes.

Data collection

- Choice of measurements

Preliminary outcome: validation of a set of questionnaires for the SoPsy-Depression cohort

The preliminary outcome of the SoPsy-Depression cohort was the validation of a standardized set of clinician-administered and self-report questionnaires assessing sleep, psychiatric and substance use disturbances in MDE including pediatric assessments. This selection was established through a Delphi method [21].

A panel of 34 expert investigators reviewed an initial pool of 94 instruments measures. Consensus for selection was defined as ≥ 80% agreement, while questionnaires with 50-79% agreement were reconsidered in a second evaluation round. This validation procedure followed the French National Health Authority guidelines (HAS) for best-practice recommendations [22] and standard Delphi-based consensus process [23–25] and has been detailed elsewhere [21].

The Delphi process resulted in a core mandatory set and an optional set of questionnaires, forming the basis for subjective measures assessment within the cohort. In total, 24 questionnaires were designated as mandatory (including one clinician-administered instrument for adults, the lifetime Columbia-Suicide Severity Rating Scale – C-SSRS) and 26 as optional (including three clinician-administered instruments for adults: The C-SSRS "last week", the Young Mania Rating Scale - YMRS, the Montgomery-Asberg Depression Rating Scale - MADRS, and the Mini International Neuropsychiatric Interview - MINI). The full list

of instruments is provided in Table 2 and further described in the published validation study [21].

Primary and secondary outcomes:

The primary outcomes focus on the comprehensive phenotypic characterization of MDE and include:

1) Subjective measures of sleep disturbances,

2) Subjective measures of sleep-wake rhythm alterations,

both derived from the Delphi-validated questionnaire set,

3) Phenotypic characterization of depressive disorder subtypes, including unipolar and bipolar depression, suicidal vs. non-suicidal forms, seasonal vs. non-seasonal forms, psychotic and melancholic features, age group (children/adolescents, adults, older adults), and sleep duration patterns (short or long sleepers).

The secondary outcomes include:

1) Identification of data-driven subgroups sharing common sleep and circadian profiles, using subjective measures (questionnaires) and objective measures (PSG, actigraphy, and 24-hour urinary assays of 6-sulfatoxymelatonin and cortisol).

2) Identification of sleep and circadian variables associated with clinical course, including disease progression, treatment response, and depressive relapse, integrating subjective and objective assessments.

- Data collection of demographic and clinical data

Sociodemographic and clinical data, along with all questionnaire-based measures, are systematically entered into the eCRF. Recorded variables include demographics, psychiatric history, depressive subtypes, comorbidities, treatment exposure, and sleep- and circadian-related questionnaire data. When available, objective assessments are also captured, including PSG, MSLT, sleep diaries, actigraphy, and 24-hour urinary assays of 6-sulfatoxymelatonin and cortisol. A detailed overview of collected variables is provided in Table 3.

Data management

The SoPsy-Depression cohort study has a data management plan (DMP) and applies FAIR (Findable, Accessible, Interoperable, Reusable) principles to the data generated in the study. The (re)use of data by internal and external partners to answer more research questions is

encouraged. Data access is governed by a formal procedure. Internal collaborators must submit a written request specifying the objectives and justification for the proposed data extraction, which is reviewed by the Scientific Committee. External researchers may access the data only within the framework of an approved research collaboration with the SoPsy-Depression consortium. All project materials and data are organized and documented to ensure efficient reuse.

Statistical analyses

Statistical analyses will be performed by the Clinical Research Unit (URC PNVSNSO, North-West Sector) at Bichat Claude-Bernard Hospital, AP-HP, Paris.

The sample size calculation was performed to determine the minimum number of participants required to ensure adequate precision for the estimated prevalence of sleep disturbances in MDE [26]. With 1000 patients, an expected prevalence of 90% yields a 95% confidence interval of [86% - 94%] (8% width), meeting the precision required for the study's objectives. This number represents the minimum target sample size. Recruitment will continue over the planned 10-year period and the final cohort size may substantially exceed this threshold.

Descriptive statistics will be computed for all clinical and paraclinical variables. Continuous variables will be summarized as means with standard deviations (SD) or medians with interquartile ranges for non-normally distributed data, while categorical variables will be summarized as counts and percentages. Specific statistical analysis plans will be developed a priori for each study objective, integrating current scientific knowledge, particularly regarding subjective sleep-related measures. Exploratory hierarchical clustering will be performed to identify homogeneous patient subgroups, and the determinants of subjective measures within these subgroups will be examined using appropriate regression models. Missing data on the primary outcome will be handled using multiple imputation by chained equations. Other missing or invalid data will be excluded. Analyses will be performed using R software (version 3.5 or later; R Foundation for Statistical Computing, Vienna, Austria; http://www.R-project.org).

Baseline characteristics of the population

Baseline descriptive characteristics of the participants included so far are presented only to illustrate the structure and implementation of the cohort. These data are descriptive and intended to document the cohort design rather than to report preliminary results or perform inferential analyses.

Cohort status

The SoPsy-Depression cohort was launched in April 2023. The study is ongoing and both inclusions and follow-up (if planned) assessments are still being collected.

As of November 2025, 158 participants were enrolled, including 129 with unipolar (82%) and 29 with bipolar disorder (18%). Four participants were children (2 males, 2 females), with a mean age of 12.2 ± 2.5 years (IQR 11-13). In adults, the mean age was 39.1 ± 13.8 years (IQR 26-49), 67% were female, and the mean adult BMI was 27.0 ± 10.2.

Of the total of 41 centres that had formally joined the study, 25 were open to recruitment, and 11 were actively enrolling participants. The operational status of participating centres is expected to evolve over time.

Clinical characteristics in adults

The mean age at onset of the first MDE was 15.1 ± 10.5 years, and patients had experienced an average of 3.5 ± 3.7 lifetime depressive episodes. Among the 51 patients with available data on (hypo)manic episodes, the mean age at first episode was 17.1 ± 18.3 years, with an average of 0.4 ± 1.6 manic and 1.6 ± 3.6 hypomanic episodes over lifetime. The mean age at first psychotropic medication use was 27.0 ± 11.6 years, while the first psychiatric hospitalization occurred at a mean age of 29.0 ± 14.3 years; participants reported a mean number of 2.1 ± 3.0 lifetime hospitalizations.

Clinical characteristics and psychiatric comorbidities at inclusion are shown in Fig. 1. Sleep disturbances were highly prevalent with 71% reporting insomnia and 24% hypersomnia. Common psychiatric comorbidities included trauma-related disorders (49%), anxiety disorders (38%), substance use disorders (28%), and eating disorders (23%). Suicidal ideation was reported by 64% of participants and 40% had a history of at least one suicide attempt.

Psychiatric, sleep and substance use profiles from baseline questionnaires

Preliminary adult questionnaire data, including completion rates, are shown in Table 4 and Fig. 2. Psychiatric assessments indicated severe depressive symptoms (QIDS-SR16) and moderate anxiety levels (GAD-7), along with high trait anxiety on the STAI-YB and scores consistent with anxious-depressive features on the HADS. A total of 32.9% of respondents reported a positive lifetime suicidal ideation score on the C-SSRS.

Sleep and circadian measures revealed moderate insomnia severity (ISI), mild but non-pathological daytime sleepiness (ESS; 51.4% with score ≥ 10), marked hypersomnia (HSI) and very poor sleep quality (PSQI). Chronotype estimates indicated an overall advanced chronotype on the MCTQ (72% classified as advanced), with 21% of participants exhibiting social jetlag, defined as a difference greater than 2 hours between the midpoint of sleep on workdays and free days. In contrast, optional MEQ scores suggested a more neutral chronotype. More than one-third of participants screened positive for restless legs symptoms and 46% shows subsyndromal seasonal sensitivity on the GSS (SPAQ).

Substance-use questionnaires showed no clinically tobacco dependence (Heaviness of Smoking Index) and no clinically significant alcohol-use disorder (short-AUDIT). Among the eight participants with available CUDIT-R data, mean scores suggested problematic cannabis use (mean score > 13).

Completion rates for the mandatory adult questionnaires were as follows: 1 questionnaire was fully completed by more than 70% of participants (ISI), 12 questionnaires between 50–70% (C-SSRS, QIDS-SR16, HAD, STAI-B, GAD-7, ASRS, AUDIT short, PSQI, MCTQ, ESS, Hypersomnia HSI, Berlin questionnaire), 3 questionnaires between 30-50% (MDQ, ASSIST-Lite, RLS question), 2 questionnaires between 10–30% (Heaviness of Smoking Index and SHQ), and 1 questionnaire by less than 10% of participants (CUDIT-R). Optional questionnaires showed lower and more heterogeneous completion (details in Table 4).

Additional assessments

Objective sleep and circadian data were available only for a subset of patients: 32 underwent PSG (Table 6), 26 had analyzable actigraphy data (Table 7), and no participants completed MSLT, or 24-hour 6-sulfatoxymelatonin assessments. In addition, 19 participants completed sleep diaries (Table 5). At this stage, only descriptive analyses were performed.

Polysomnography results

PSG measures reported here correspond to sleep markers commonly examined in MDE (Table 6). Observed values included prolonged sleep latency (>30 min), reduced total sleep time (TST) relative to the average sleep duration reported in the French population (7 h 32 min [27]), time in bed exceeding TST by more than one hour, increased wake after sleep onset (WASO > 45 min), lower sleep efficiency (<80%), and high fragmentation (sleep fragmentation index >20). Sleep architecture showed higher proportions of N1 and N3 sleep and relatively lower REM sleep, while N2 remained within commonly reported ranges. REM sleep latency fell within typical limits (>150 min). The apnea-hypopnea index (AHI) indicated that 6 of 29 participants had moderate obstructive sleep apnea (15 ≤ AHI < 30 events/h), and 4 had severe obstructive sleep apnea (AHI ≥ 30 events/h). A representative hypnogram illustrating typical sleep patterns in patients with MDE is shown in Figure 3.

Sleep diary measures were consistent with these findings (Table 4), indicating shorter TST (TST<7h), lower sleep efficiency (< 70%), prolonged sleep onset latency (> 60 min), and increased WASO (> 75 min).

Actigraphy results

Actigraphy measures similarly indicated disrupted sleep (Table 7), with moderately fragmented sleep (fragmentation index > 30), reduced sleep efficiency (<80%) and increased WASO (> 80 min). In contrast, sleep onset latency (<30 min) and TST (>7 h) were within normal ranges.

Non-parametric circadian rhythm analysis (NPCRA), which captures rest-activity rhythm organization and is sensitive to disturbances associated with disease and aging showed a relative amplitude (RA) of 0.84 (range 0-1), reflecting a preserved day-night contrast in activity levels. Interdaily stability (IS), an index of the regularity of the sleep-wake rhythm across days (range 0-1), was low (IS = 0.33), indicating poor stability of the rest-activity cycle over the recording period. Intradaily variability (IV), which quantifies rhythm fragmentation within the 24-h cycle (range 0-2), was low-moderate (IV = 0.83).

Circadian phase markers derived from actigraphy indicated the timing of the most active and least active periods. The onset of the 10 most active hours (M10 onset) and the onset of the 5

least active hours (L5 onset) occurred relatively late, suggesting a delayed rest-activity phase. As normative thresholds for actigraphy-derived circadian parameters remain heterogeneous across studies, these metrics are best interpreted descriptively, in relation to the overall organization of the rest-activity rhythm.

Discussion

The SoPsy-Depression cohort is a nationwide initiative designed to characterize sleep and circadian disturbances across the spectrum of depressive disorders in routine clinical settings. This cohort profile presents the study design, the Delphi-based consensus process implemented across a national network, and baseline descriptive characteristics of the participants included to date, presented to document the structure and implementation of the cohort. By combining standardized clinician-administered and self-report instruments with objective sleep and circadian measures, the SoPsy-Depression cohort enables comprehensive psychiatric, sleep and substance-use phenotyping. This approach provides a harmonized framework for capturing the multidimensional expression of MDE.

The current descriptive findings are consistent with existing literature, highlighting the central role of sleep disturbances in depression [5]. High rates of insomnia, hypersomnia, and poor sleep quality were observed in both clinical assessments and self-reported questionnaires, supporting the relevance of sleep and circadian features as potential clinical markers in MDE. In contrast, subjective daytime sleepiness reported on the Epworth scale was not pathological, which differs from previous reports [28–30] and underscores the importance of examining heterogeneity of sleep disorders across depressive subtypes. These sleep profiles were observed in the context of frequent psychiatric comorbidities as consistently reported in the literature, including anxiety [31–33], psychotrauma [34–36] and substance-use [37], reflecting the clinical complexity of depressive disorders in real-world settings. Objective sleep measures obtained from PSG, actigraphy and sleep diaries suggested alterations in sleep continuity, although these data were available only for a subset of participants. Across modalities, preliminary patterns were broadly consistent with prior literature, including reduced TST, prolonged sleep onset latency, decreased sleep efficiency and increased WASO, which are features commonly reported in depressive disorders [15,38,39]. Polysomnography findings were generally concordant with previous studies, although the classical biomarkers of

shortened REM sleep latency [14] was not systematically observed in this baseline sample. This likely reflects the clinical heterogeneity of the cohort and the stage of enrolment rather than the absence of such patterns. Actigraphy showed broadly similar tendencies, but interpretation remains limited by the lack of broadly validated clinical cut-offs and by methodological variability across studies. Importantly, these observations are presented asdescriptive baseline characteristics intended to illustrate the phenotypic diversity captured within the cohort, rather than as inferential analyses. As the cohort expands, larger samples will enable more robust investigations, including age-dependant developmental and trajectory analyses as well as stratification into more homogeneous clinical subgroups. This will be particularly relevant given reported differences in sleep and circadian profiles between unipolar and bipolar depression [40]. Together, these data highlight the value of large-scale, systematic phenotyping to explore variability in sleep–wake regulation across the spectrum of depressive disorders.

A major achievement of this early phase is the harmonization of assessment procedures across a nationwide network of expert centres. The Delphi consensus method led to the definition of a standardized set of mandatory and optional questionnaires [21], providing a shared clinical language and enabling data comparability across the 41 participating centres. As expected in a large multicentre cohort, questionnaire completion rates were heterogeneous across instruments and centres. Most mandatory questionnaires were completed by a majority of participants, whereas optional instruments showed lower completion rates, likely reflecting differences in assessment burden, perceived relevance and local clinical routines. These observations provide an overview of data availability at this stage of the cohort and may guide future data-driven refinement of the assessment battery, including the identification of the most informative questionnaires for routine clinical use.

At the time of this report, only two years after start of inclusion, the SoPsy-Depression cohort remains in an early phase of development, and not all participating centres are fully operational or actively recruiting. Consequently, both sample size and data completeness are expected to improve as recruitment expands and stabilizes. No follow-up visits have yet been recorded in the eCRF. This reflects the study's initial focus on baseline characterization, as well as the fact that follow-up assessments are aligned with routine clinical care rather than fixed

research visits. As a result, the timing and registration of follow-up data may vary across centres and depend on clinical scheduling, investigator availability, and local data-entry practices. Ongoing efforts aim to increase awareness among clinical teams regarding the importance of follow-up data registration. In parallel, the progressive activation of additional centres and recruitment in centres not yet enrolling participants are expected to further enhance longitudinal data capture over time. Within this context, the SoPsy-Depression cohort also presents several key strengths, including strong mobilisation of a nationwide network of centres despite the absence of dedicated funding, broad national representativeness, wide phenotypic diversity reflecting real-word clinical practice. Another major strength is the large sample size, with at least 1000 patients undergoing high-quality phenotyping, including both subjective and objective measures. The study also benefits from the support of a multidisciplinary consensus conference contributing to harmonised study procedures.

Several limitations should be considered when interpreting these early findings. First, participants are included on the basis of a current MDE regardless of episode severity, chronicity, or treatment resistance, and present with a wide range of psychiatric and medical comorbidities. While this increases analytic complexity, it reflects real-world clinical practice and enhances the external validity of the cohort. Second, the number of included children and adolescents remains limited, likely due to complex consent procedure and the smaller number of pediatric centres, additional regulatory requirements for inclusion, and more complex consent procedures. Expanding recruitment in child and adolescent psychiatry centres will be important, particularly given the growing burden of depressive disorders in younger populations [41,42] and the distinct clinical features of MDE in children and adolescents compared with adults, which may have implications for identification and clinical management. The use of age-appropriate questionnaires also raises methodological challenges, as several instruments commonly used in adults are not validated in individuals under 18 years of age. Another limitation relates to the number of questionnaires included in the assessment battery. Although the broad range of instruments was intentionally selected to maximize phenotypic characterization and biomarker discovery, incomplete completion of certain questionnaires limits their immediate analytic utility. This observation will inform future optimization of the assessment strategy, including the identification of the most informative instruments based on usage and data quality.

Finally, the availability of objective sleep and circadian measures currently varies across centres, reflecting differences in local equipment, clinical routines, and resource availability. As additional centres become fully operational, recruitment and the number of physiological recordings (actigraphy, PSG, MSLT, and biological assays) are expected to increase substantially, further strengthening the cohort's capacity to investigate sleep and circadian alterations across depressive disorders.

Conclusions

The SoPsy-depression cohort represents a nationwide effort to harmonize multimodal assessment of sleep and circadian disturbances across the spectrum of depressive subtypes, while integrating additional biological and physiological markers. The study maintains an open policy for external collaboration and already supports ancillary projects, including the ongoing SoSad study investigating REM sleep characteristics in depressive disorders with and without seasonal patterns. As recruitment expands and longitudinal follow-up data accumulate, the cohort will constitute a unique and growing data resource to identify clinically meaningful sleep and circadian signatures across depressive subtypes. Ultimately, this cohort is expected to become a unique resource supporting the development of precision and personalized approaches integrating sleep and circadian medicine into the psychiatric care of depression.

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Supplementary Information

The online version contains supplementary material available at …

Data availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Statements and Declarations

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Competing Interests

The authors have no relevant financial or non-financial interests to disclose.

Author Contributions

Project administration: PAG. Funding acquisition: PAG, JM. Conceptualization: PAG, CS, PB. Methodology: PAG, CS, PB, AMF. Formal analysis: HR, RC. Writing – original draft preparation: HR. Writing – review and editing: all authors. Data curation: HR, RC.

Pierre-Alexis Geoffroy, Julia Maruani, Carmen Schröder and Patrice Bourgin contributed to the study conception and design. Material preparation, data collection and analysis were performed by Héloïse Rach and Renaud Cornic. The first draft of the manuscript was written by Héloïse Rach and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Ethics approval

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation, and with the Helsinki Declaration of 1975, as revised in 2008. All procedures have been approved by a French Institutional Review Board (Comité de Protection des Personnes Sud-Méditerrannée I, national identification number 2021-A03242-39) on 23/03/2022.

The study has been registered into the Clinicaltrials.gov/ct2/home (NCT05866991).

Non-opposition to participate

Non-opposition was obtained from all individual participants included in the study.

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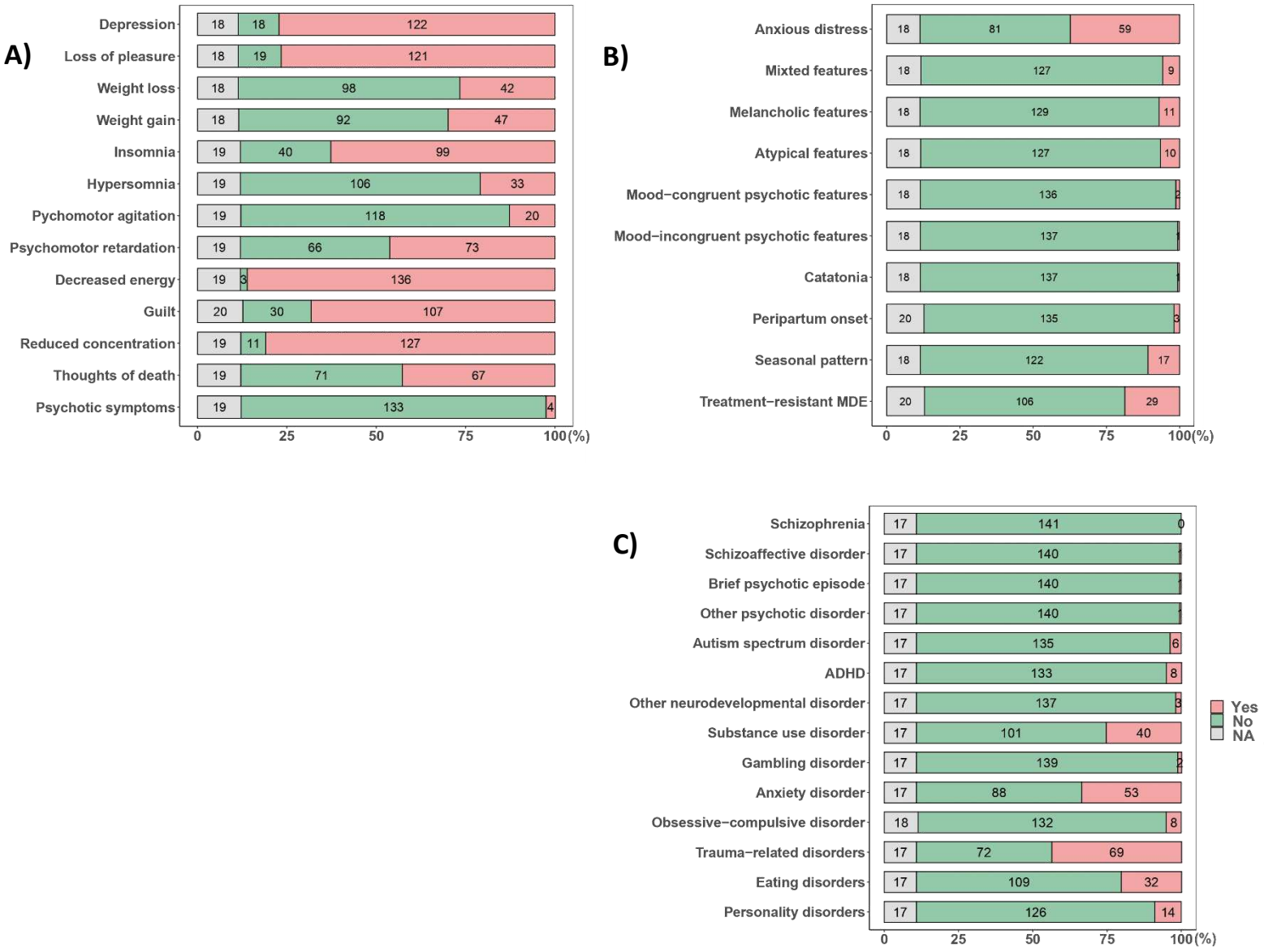


Fig. 1 Patients psychiatric profiles at inclusion. Fig. 1A shows characterization of the MDE at inclusion, Fig. 1B shows associated features, and Fig. 1C shows associated psychiatric comorbidities. For each figure, horizontal bars indicate the number of patients who responded "Yes" (red), "No" (green) or for whom no response was available (NA, grey). The x-axis represents the percentage of the total patients. MDE: Major Depressive Episode; ADHD: Attention Deficit Disorder with/without Hyperactivity; NA: missing data.

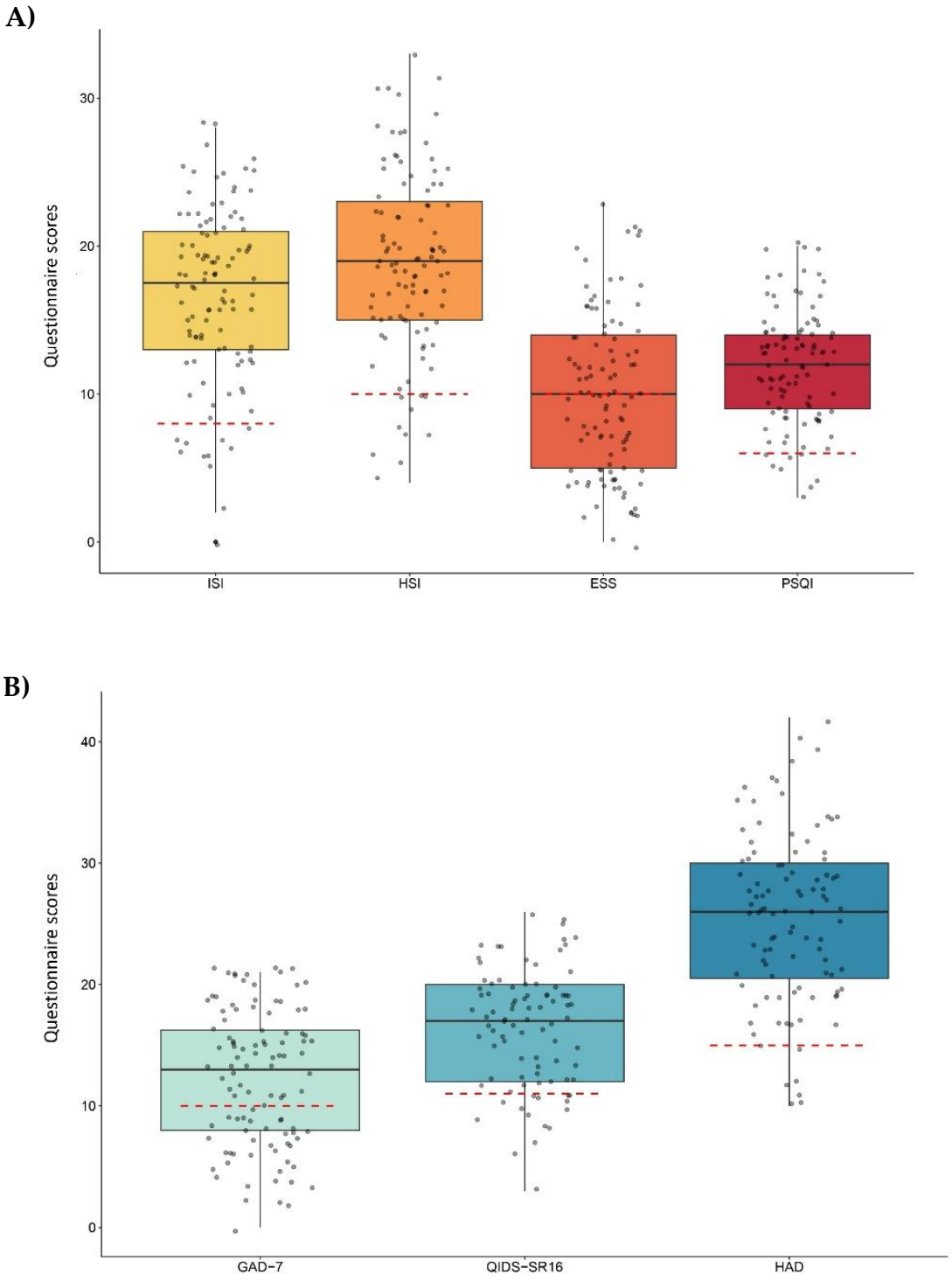


Fig. 2: Boxplots of key sleep and psychiatric questionnaire scores in adults patients. Fig. 2A shows sleep questionnaires, and Fig. 2B shows psychiatric questionnaires. The horizontal red dashed lines indicate pathological cut-offs for each questionnaire. Only questionnaires with a completion rate ≥50% are presented. The medians, mean (cross), minimum, maximum, and outlier values are shown on boxplots. Sample sizes for each questionnaire were as follows : ISI (n = 108), HSI (n = 102), ESS (n = 103), PSQI (n = 100), GAD-7 (n = 104), QIDS-SR 16 (n = 89), HAD (n = 100). ISI: Insomnia Severity Index; Hypersomnia Severity Index; ESS: Epworth Sleepiness Scale; PSQI: Pittsburgh Sleep Quality Index; GAD-7: Generalized Anxiety. Disorder – 7 items; QIDS-SR: Quick Inventory of Depressive Symptomatology - Self Report; HAD: Hospital Anxiety and Depression scale.

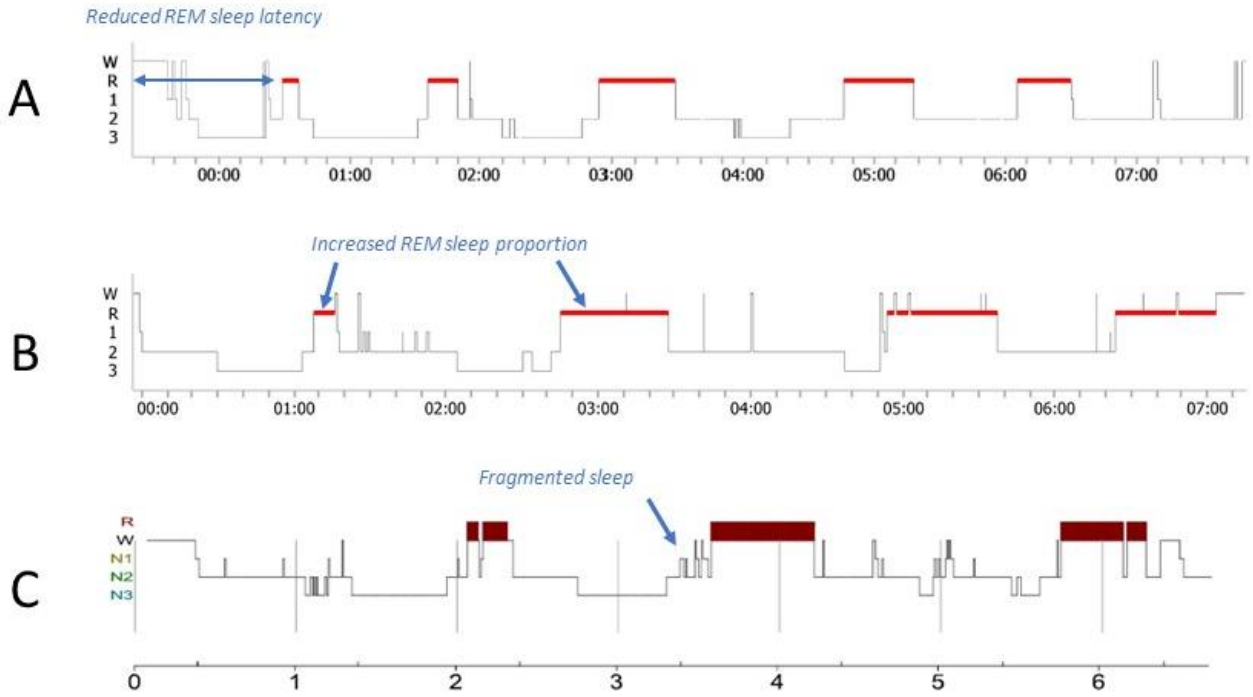


Fig. 3: Representative hypnograms illustrating typical sleep architecture alterations in major depressive episodes. Panels show reduced REM latency (A), increased REM sleep proportion (B), and fragmented sleep with frequent awakenings (C). Sleep stages (Wake - W, N1, N2, N3, Rapid Eye Movement sleep - REM) are plotted across the recording period, with REM periods highlighted in red.

Supplementary Files

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