



BMJ Open Screening and management of sleep disorders in patients with fibromyalgia syndrome: a French multicentred, prospective, observational study protocol (FIBOBS)

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ABSTRACT

Introduction Sleep disorders are still often underestimated in patient care management even though they are present in the criteria of the American College of Rheumatology for the diagnosis of fibromyalgia syndrome (FMS). The objective of this study will be to assess the current situation of sleep disorders in patients with FMS in France and to estimate its prevalence.

Methods and analysis The FIBOBS study is a multicentred, prospective, observational trial performed by 46 specialised chronic pain structures in France. Patients with FMS visiting for a first consultation or follow-up (if they have already been followed up for less than a year with a pain management service) will be included after giving their informed consent. Data will be collected through the physician questionnaire filled during the inclusion visit. Patient self-questionnaires will be completed from home. The primary outcome of the study will be to estimate the prevalence of sleep disorders classified into three categories: (a) poor sleep quality in general, (b) sleep apnoea syndrome and (c) restless legs syndrome, using self-administered questionnaires.

Ethics and dissemination This protocol is approved by the ethics committee Comité de Protection des Personnes 'Ile de France II' in accordance with French regulations. The results will be disseminated through peer-reviewed journals and conferences.

Trial registration number NCT04775368.

INTRODUCTION

Background and rationale

Fibromyalgia syndrome (FMS) is defined as a diffusing pain which lasts for more than 3 months and not only influences the demise in functional capacities but also reduces them in a variable manner that is dependent on time and the individual affected. The WHO recognised FMS in 1992 and it was initially classified as a rheumatic disease. Since January 2006, it has been accepted as a disease and has been globally recognised as a

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ To our knowledge, FIBOBS is the first large-scale trial that investigates the prevalence of sleep disorders in patients with fibromyalgia syndrome.
- ⇒ The study will be carried out in 46 specialised chronic pain structures in France to ensure good representativeness.
- ⇒ Since the symptoms in chronic pain are generally underestimated by healthcare professionals, our study uses patient's self-questionnaires to evaluate outcomes.
- ⇒ The prevalence of sleep disorders established by scoring of validated questionnaires will not be confirmed by the gold standard measure (polysomnography).

major cause of morbidity with a very negative impact on quality of life (QoL).¹

In France, the prevalence of the pathology of FMS is estimated at 1.6% and mostly affects women (93%).² Its diagnosis has been based on criteria defined by the American College of Rheumatology (ACR) and its first classification was proposed in 1990 and 20 years later, revised to provide better diagnostic sensitivity.^{3 4} To meet the criteria for its diagnosis, a patient must meet the three following conditions: (a) Widespread Pain Index (WPI)≥7 and Symptom Severity Scale (SSS)≥5 or 3≤WPI≤6 and SSS≥9, (b) painful symptoms present at the same intensity for at least 3 months and (c) any other cause of chronic osteoarticular pain that is excluded.

Although present in the ACR criteria, sleep disorders are still often underestimated in patient care. For many years, the bi-directional relationship between sleep disorders and chronic pain has been highlighted in literature where numerous studies have

described the existence of sleep disorders, especially in patients with FMS.^{5 6} This is particularly important since sleep has been linked to a range of outcomes on chronic pain including work interference and productivity.^{7 8} The prevalence of these disorders varies greatly and some studies report that 60%–90% of patients are affected.⁹ A report from the French national health authority indicated that only 20% of patients are affected.¹⁰ Similarly, the prevalence of sleep apnoea syndrome within a population is estimated to be between 45% and 65.9% while it is between 33% and 42% for restless legs syndrome (RLS).¹¹ The global discrepancy on prevalence in literature regarding sleep disorders in FMS sufferers, and the absence of specific measures in French recommendations for the management of this syndrome have prompted us to propose an assessment of sleep disorders in the French population.

OBJECTIVES

In view of existing literature, we believe that screening and management of sleep disorders in patients with FMS are likely to have a positive influence on QoL, pain management and emotional well-being. The FIBOBS study will first assess the prevalence of sleep disorders classified into three categories: (a) poor sleep quality in general, (b) risk of sleep apnoea syndrome and (c) risk of RLS in patients with FMS who consult specialised pain management services in France. Second, the trial will assess the severity of FMS, its impact on patients' QoL, the pain experience and the impact of pain on patients' daily behaviour. Moreover, FIBOBS will evaluate patients' state of anxiety and depression and the percentage of patients that are previously diagnosed and treated for sleep disorders. The tools used by pain centres to assess the main symptoms of FMS (pain, asthenia, sleep disorders and cognitive disorders) as well as the therapeutic measures implemented (both pharmaceutical and non-pharmaceutical) will also be described.

METHODS AND ANALYSIS

Study design

This multicentred, prospective and observational study will be carried out within 46 specialised chronic pain structures in France (in university and non-university hospitals) spread over the French territory. This trial includes the completion of multiple questionnaires following a consultation with a pain physician. Due to the nature of the intervention, only a single group will be studied. The recruitment period is from April 2021 to December 2022 and the follow-up period varies from 1 to 14 days. The study will be completed in January 2023.

Eligibility criteria

For inclusion, participants must meet the following inclusion criteria: (a) be aged 18 years old and over, (b) be able to read, write and understand the French language,

(c) have a diagnosis of FMS according to ACR 2010 criteria (primary and secondary FMSs are eligible), (d) have consulted for the first time or for a follow-up visit if a patient has already been followed up for less than a year, (e) have access to an internet connection, (f) be affiliated to a social security system and (g) have signed an informed consent form.

Exclusion criteria will consist of: (a) patients undergoing anti-cancer treatment or having completed treatment less than 2 years ago, (b) patients under guardianship, deprived of liberty, safeguard of justice, (c) pregnant or breastfeeding women, (d) patient presenting a serious psychiatric pathology that does not allow compliance of the questionnaires and (e) patient who refuses to participate in research.

Interventions

This study is an observational one because its primary objective is to assess the current situation in France and to estimate the prevalence of sleep disorders in patients with FMS. The consultation with a pain physician will be carried out according to the standard guidelines and habits at each centre and for each investigator. During the consultation, the pain physician will collect contact details, global data (date of the visit), patient description (birthdate, gender, inclusion and exclusion criteria, comorbidities and concomitant diseases) and data regarding FMS (online supplemental data). Then, patients will complete self-questionnaires at home within 2 weeks after inclusion visit (figure 1).

The individual results of the diagnostic questionnaires carried out by the patient with personalised advices will be communicated by email to the pain physician. This can eventually lead to a modification in the patient's care, since depending on the results, the patient can be referred by his pain physician to a sleep specialist for a more thorough diagnostic and management of his disorders, according to French recommendations.¹² This study may therefore lead to a change in the course and management of the patient suffering from FMS.

Patient and public involvement

No patient involved on the trial design.

Outcome measures

The primary outcome is to quantify the prevalence of sleep disorders based on the following results from four diagnostic orientation questionnaires: Pittsburgh Sleep Quality Index (PSQI) score, Stop-Bang, the single question for rapid screening of RLS and International RLS (IRLS) criteria.

The PSQI is a validated self-administered questionnaire with a high sensitivity and specificity containing 19 items which can assess sleep disorders. A score lower or equal to 5 indicates 'good sleepers' while a score above 5 shows the 'bad sleepers'.¹³ From the results obtained from the patients in this trial, the prevalence of sleep disorders will be assessed.

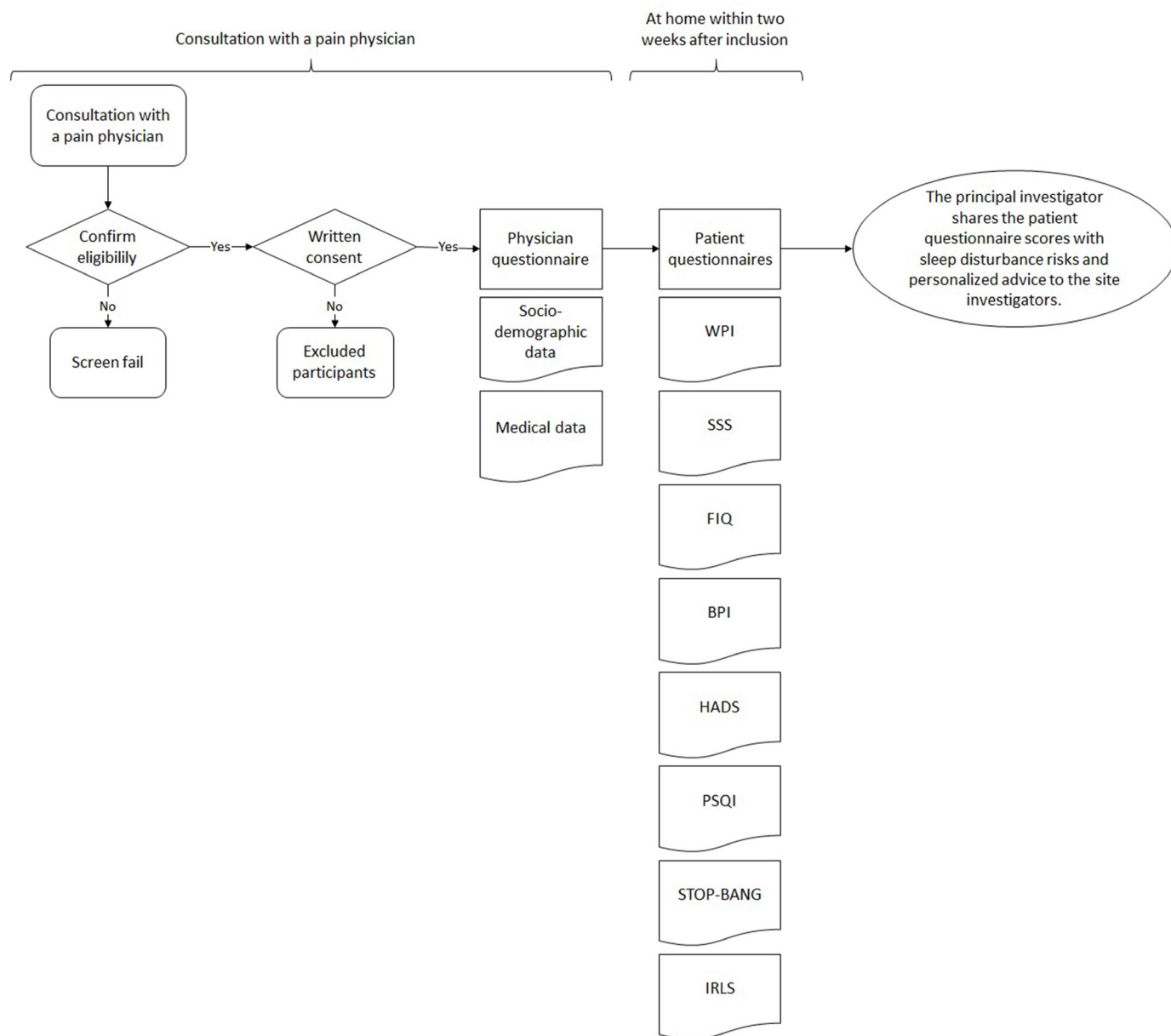


Figure 1 FIBOBS participant pathway. This figure represents the pathway of patients with fibromyalgia syndrome included in the study for the screening and management of sleep disorders. BPI, Brief Pain Inventory; FIQ, Fibromyalgia Impact Questionnaire; HADS, Hospital Anxiety and Depression Scale; IRLS, International Restless Legs Syndrome; PSQI, Pittsburgh Sleep Quality Index; SSS, Symptom Severity Scale; WPI, Widespread Pain Index.

Sleep disorders needing a specific care regimen performed by a sleep specialist (sleep apnoea syndrome and RLS) will be detected via two validated questionnaires:

1. The Stop-Bang questionnaire enables an orientation of the diagnostic towards sleep apnoea syndrome by considering eight factors: snoring, fatigue, observed apnoea, arterial hypertension, body mass index, gender, age and the circumference of the patients' neck. Responses less than or equal to 2 'yes' indicates a low risk of obstructive sleep apnoea while a number of responses greater than or equal to 3 'yes' reflects an intermediate to high risk.^{14 15}
2. The single question for rapid screening of RLS is a detection tool that permits diagnosis of likely RLS.¹⁶

Patients who answer positively will then fill out the IRLS questionnaire which will make it possible to evaluate the severity of RLS. There are four classifications: (a) for a score between 0 and 10, the disorder is of mild severity, (b) between 11 and 20, the disorder is moderate severity, (c) between 21 and 30, the disorder is severe and (d) between 31 and 40, the disorder is very severe.¹⁷

Based on the obtained results, the prevalence regarding the risk of having sleep apnoea or RLS will be assessed.

The secondary outcomes will be assessed with the following measures:

1. Severity of FMS will be assessed by way of two self-administered questionnaires: the WPI and the SSS.



The WPI counts the number of pain areas during the week before the consultation. The score is comprised between 0 and 19, whereas the SSS has a scale between 0 and 12 and focuses on fatigue, sleep disorders, cognitive symptoms and somatic symptoms.¹⁸

2. The impact of FMS on a patient's day-to-day life will be estimated using the Fibromyalgia Impact Questionnaire. This test permits an evaluation of the functional incapacity and the repercussions of the syndrome on a day-to-day basis. It assesses major symptoms such as pain, fatigue, sleep disorders, morning rigidity, anxiety and depression.¹⁹
3. Pain perception and its impact on a patient's day-to-day behaviour will be assessed by way of the Brief Pain Inventory survey. This questionnaire assesses the impact of pain on seven general aspects of the patient's life: activity, mood, capacity to walk, work, relations, sleep and pleasure of life.^{20 21}
4. Anxiety and depression will be evaluated via the Hospital Anxiety and Depression Scale.²² For each component (anxiety and depression), the score obtained will be analysed. A score less than or equal to 7 indicates an absence of symptomatology, a score between 8 and 10 indicates symptomatology, a score greater than or equal to 11 indicates definite symptomatology.
5. The evaluation tools used by the pain physician to assess pain, asthenia, sleep disorders and memory disorders will be included in the physician's questionnaire, even though it may be worth noting that there may be a difference between the patients and physicians' assessment of pain, as shown in Seers *et al* where 78% of studies showed that there was an underestimation of pain estimated by professionals compared with patients reporting.²³
6. The proposed therapeutics for the management of symptoms associated with FMS will be collected.
7. The patient's questionnaire will allow the identification of patients having already been diagnosed and treated for sleep disorders. This questionnaire will also permit a comparison of this prevalence with assessed prevalence on the basis of the three specific questionnaires.

Each patient will autonomously complete the questionnaires at home at an appropriate time and will be given 14 days after the consultation to complete all questionnaires.

Sample size

Since the main objective is to estimate the prevalence of sleep disorders, the calculation of the number of subjects relies primarily on the precision of the percentage estimate and its 95% CI. Assuming that this prevalence will be of the order of 70% and setting a precision of the order of $\pm 4\%$, it will be necessary to include at least 505 patients to reach this precision.

Recruitment

The investigative team in different pain management services in France will be responsible for identifying potential patients. During the first consultation or for a

follow-up visit (if they have already been followed up for less than a year), eligible patients from centres participating in the study will be recruited by the investigator (pain physician).

Data collection

A web-based data collection tool will be used for this study to store data from all participants. This electronic case report form (e-CRF), created and managed by Walisco, will be available at each of the investigating centres.

During the consultation, the pain physician will complete a questionnaire containing sociodemographic and medical data.

Regarding the at home self-administered questionnaires, once the patient file is created in the e-CRF by the investigating team, the patient will receive a link allowing them to connect to the online platform to fill out the various questionnaires. If the questionnaires are not completed, a reminder is provided to the patients by email and/or SMS before 2 weeks deadline. The patients' contact details will never be accessible to the sponsor of the study. A clinical research associate (CRA) of the sponsor will follow-up on the inclusion and the completion of the patient questionnaires in the e-CRF and in case, contact the investigator staff to grant a high exhaustivity of collected data.

Data entry, visualisation or modification will only be possible via the e-CRF pages (data entry masks). A connection will be made by a unique identifier and password specific to each user and will depend on their role and responsibilities in the study. The investigators, CRAs and other members of the investigating centres will only be able to see the 'physician questionnaire' part on the e-CRF, while the patient will only be able to see the 'patient questionnaire' part. The CRA monitor will only have access to the patient consent and the CRA coordinator of the sponsor centre will have access to the patient and physician questionnaires.

The study data will be anonymised before any transmission, including for data analysis (date of birth will be replaced by age, expressed in months). The encrypted data will then be transmitted to the centre responsible for data management and statistical analysis (Direction of Clinical Research and Innovation of Clermont-Ferrand) via a secure internet connection. All documents and data related to the study present in the investigating centres will be archived there under the responsibility of the principal investigator, for at least 15 years after the end of the study.

Data analysis plan

Analysis will be performed with Stata Software (V.15, StataCorp, College Station, Texas, USA).

A descriptive analysis of the data will be carried out which will include the estimates in absolute value and percentages (%) for the qualitative variables as well as the mean and SD, medians, IQRs and ranges for the

quantitative variables. The distribution of continuous variables will be evaluated graphically.

In the analysis of the data, two groups of patients will be studied: those consulting the specialised chronic pain structure for the first time and those already followed for less than a year. The primary outcome analysis will show a prevalence of sleep disorders in patients with FMS. The rate will be converted into a percentage with a 95% CI. Secondary analyses will describe patients according to their sociodemographic and clinical characteristics based on usual statistics, namely frequencies, percentages, means, SD, median and IQR.

The relationships between these characteristics and the presence of sleep disorders will be conducted using the usual testing methods: χ^2 test (or Fisher's exact test if appropriated) for categorical data, and Student's t-test (or Mann and Whitney test if data are non-normal) for continuous data. The normality of the data will be evaluated graphically and using the Shapiro-Wilk test.

A two-sided $p < 0.05$ will be considered as statistically noticeably.

Although we expect few or no missing data, a description of the missing data for each variable (number and %) will be produced. If more than 5% of missing data were to be found, a sensitivity analysis will be performed to characterise their nature and to propose the most appropriate input method.

Data monitoring

Considering the pathology, age and physical condition of included patients, this procedure will not present any additional risk and is considered to have minimal constraints. The quality control procedures for this study will be defined according to the risk-based monitoring guidelines set out in the Swiss Clinical Trial Organisation's Guidelines for Good Operational Practice, V.3.0. A monitoring plan, including all the modalities and provisions specific to this study, will be drawn up. It will define in particular the points monitored and the data verification procedures. For this study, low-risk monitoring with remote quality control is planned. A set-up and a closing visit will be organised for each participating centre. These visits will be performed by videoconference or by telephone call.

Quality control will only start once the first patient is included at the site. The frequency of telephone calls for remote monitoring will be adjusted to the rhythm of inclusion in the centre.

The FIBOBS study will assess the prevalence of sleep disorders in patients with FMS who consult a specialised pain management service in France. No adverse events or serious adverse events are expected given the provisions and vigilance that apply to this type of study.

ETHICS AND DISSEMINATION

Ethics and safety consideration

An ID-RCB registration number has been requested from the *Agence Nationale de Sécurité du Médicament et des Produits de Santé* (ANSM): IDRCB number 2020-A02940-39. The protocol and the informed consent form were approved by the Comité de Protection des Personnes 'Ile de France II' (Ethics committee) on 11 February 2021 (20.10.26.73210 RIPH2 HPS). Notice of information was made to the ANSM on 15 February 2021.

The investigator will explain the study to the patient and will give them an informational form. Even with the low risk involved in this study, informed consent will be obtained from all participants on the day the consultation is performed. Patients willing to participate in the study will also sign a written consent form (online supplemental data).

Confidentiality

All data used in this study will be confidential and patients' identity will be protected by a coded number specific to the study. The contact details will never be accessible to the sponsor of the study. Data processing will be implemented to allow analysis of the results of the research in relation to the objectives of the study. These data processing operations will all comply with the General Data Protection Regulation and with the amended law of 6 January 1978 (*Loi Informatique et liberté*) in France on information technology, files and freedoms. Data will be entered into a secure trial database (health data host). A subcontractor, Walisco based near Lyon, France will manage the data hosting.

Dissemination plan

The final report will be written by the coordinating investigator in collaboration with the sponsor's clinical research unit and the biostatistician in charge of the study. The final version will be sent to the sponsor, to the competent authority and to the Ethic committee within 1 year after the effective end of the research, that is, maximum 2 weeks after the inclusion of the last subject. This time limit will be reduced to 90 days in the case of premature termination of the research.

A report of the overall results of the study will be issued so that each investigator can transmit it to the patients who wish to know these results. The data will only be disclosed after prior joint agreement between the coordinating investigator and the sponsor. The results will be the subject of communication and publication.

One investigator from each centre that has included patients (with analysable data for at least the primary endpoint) may be included in at least one study publication. It is understood that the allocation of author ranks will be done on a case-by-case basis, depending on the actual contributions and participation of the investigators from each centre. If the number of authors authorised by the journal does not allow it, at least the name of the

principal investigator of each centre will appear in the list of collaborators/investigators of the publication.

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Contributors GA is the chief investigator who has the idea of the research. GA and EG conceived and designed the study, led on the protocol development and writing. MLF, CC and CP contributed to conceive the study, as member of the scientific board. PP, MB, VH and EG contributed to the writing of the protocol, the recruitment of site investigators and the completion of regulatory formalities. All authors contributed to drafting the manuscript or revising it critically and approved the final version to be published.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by Comité de Protection des Personnes 'Ile de France II' 20.10.26.73210 RIPH2 HPS. Participants gave informed consent to participate in the study before taking part.

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