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# Gender bias in the pharmacological management of pain, anxiety, and depression in general practice

**Submission date**
14/04/2025

**Recruitment status**
Recruiting

**Registration date**
22/04/2025

**Overall study status**
Ongoing

**Last Edited**
22/04/2025

**Condition category**
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

## Plain English summary of protocol

Background and study aims
Gender norms influence how patients express symptoms and seek care, while healthcare providers may hold biases that affect treatment decisions. Research shows disparities in care based on the sex of both patients and physicians, often disadvantaging female patients, especially when treated by male doctors. Pain, anxiety, and depression are frequent reasons for consultation and potential markers of gender-based disparities in care. Yet, no study has examined how physician gender affects the prescription of analgesic and psychotropic drugs. This study aims to analyze the relationships between the prescription of analgesics and/or psychotropic drugs (anxiolytics, antidepressants), the sex of the patient, the sex of the physician, and potential gender biases. It will quantitatively examine the association between the reimbursement of these medications and the sex of the patient, the sex of the physician, and their interaction and qualitatively explore how gender-related differences in prescribing practices emerge during general practice consultations.

Who can participate?
People aged 18 and over consulting their GP's for pain and/or anxiety and/or depressive symptoms

What does the study involve?
A convergent mixed-methods approach will be used. The quantitative component will quantify potential prescribing differences using patient data from the ESND (French National Health Data System Sample) linked to physician data. Multivariate analysis models will be implemented. The qualitative component will help explain these differences through consultation observations and post-consultation interviews with patients and general practitioners. An inductive thematic analysis of the observation notes and interview transcripts will be conducted.

What are the principal benefits and risks of participating?
This research may have multiple impacts: 1. By sharing findings in scientific journals, conferences, and medical education, the study can raise awareness among physicians about gender biases, encouraging more reflective and equitable clinical practice; 2. Presenting results

to participating physicians could help them recognize and adjust their own biases; 3. The study could inform public health efforts to address gender bias in healthcare and encourage medical schools and continuing education programs to integrate gender-sensitive training, following examples from Switzerland, Germany, and the Netherlands.

No risk to participating has been identified.

Where is the study run from?
The study takes place in mainland France.

When is the study starting and how long is it expected to run for?
October 2022 to September 2026

Who is funding the study?
GIRCI (Ile de France inter-regional clinical research and innovation grouping), DGOS (Department of Healthcare Organization), Ministry of Health, France.

Who is the main contact?
Nathalie Pelletier-Fleury (MD, PhD), research director, INSERM (National Institute of Health and Medical Research), nathalie.pelletier-fleury@inserm.fr

# Contact information

### Type(s)
Public, Scientific, Principal Investigator

### Contact name
Dr Nathalie Pelletier-Fleury

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
ReSP-IR 2022 023-PP

# Study information

### Scientific Title
Gender bias in the pharmacological management of pain, anxiety, and depression in general practice: a mixed-methods approach

### Acronym
BIGDAD

### Study objectives
Several hypotheses can be formulated:
There are gender biases among healthcare providers depending on the sex of the patients.
The expression of pain, anxiety, and depression from the patient's perspective may differ between men and women.
The physician's sex influences the prescription of analgesics, anxiolytics, and antidepressants differently depending on the patient's sex.
The physician's sex influences the prescription of sick leave differently depending on the patient' s sex.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
Approved 14/01/2025, CEEI/IRB INSERM (101 rue de Tolbiac, Paris, 75013, France; +33144236000; christine.dosquet@inserm.fr), ref: 24-1158

### Study design
Convergent parallel mixed-methods study

### Primary study design
Observational

### Secondary study design
Mixed quantitative and qualitative components

### Study setting(s)
GP practice

### Study type(s)
Other

### Participant information sheet
Not available in web, please use contact details to request a participant information sheet.

### Health condition(s) or problem(s) studied
Pharmacological management of pain, anxiety, and depression in general practice.

### Interventions
This is a convergent mixed-methods approach. The quantitative component will allow for the measurement of potential prescription differentials using patient data from the ESND (National Health Data System Sample), linked with physician data from the Healthcare Professionals Directory. The qualitative component will shed light on the underlying factors behind these differences, through consultation observations and interviews with patients following their observed consultation with their GP.

### Intervention Type
Other

### Primary outcome measure
1. The association between the reimbursement of analgesic, anxiolytic, and/or antidepressant medications and the sex of the patient, the sex of the physician, and their interaction, measured using collected and linked patient and physician data, at one timepoint
2. Gender-related prescription differentials measured using qualitative data collected during GP consultations, at one timepoint

### Secondary outcome measures
1. The association between the reimbursement of daily sick leave benefits among patients who have been prescribed analgesics and/or psychotropic medications, and the sex of the patient, the sex of the physician, and their interaction, measured using collected and linked patient and physician data, at one timepoint
2. Patients' expressions of pain, anxiety, and/or depression that may contribute to gender-based differences in prescribing practices, measured using data collected during GP consultations, at one timepoint
3. Patients’ complaints interpreted, discussed, and received by GPs, measured using data collected during GP consultations, at one timepoint
4. Medication prescribing carried out during the consultation—focusing on how treatment is presented, discussed, negotiated, and the extent to which shared decision-making is involved - using data collected during GP consultations, at one timepoint
5. Patients’ experiences of the consultation about their presenting complaint and the resulting prescription measured using data collected during GP consultations, at one timepoint

### Overall study start date
01/10/2022

### Completion date
30/09/2026

## Eligibility

### Key inclusion criteria
Quantitative component:
The study will include all individuals aged 18 and over in France, using data from the National Health Data System (SNDS).

Qualitative component:
The qualitative analysis will involve general practitioners practicing in private offices or community health centers. It will focus on consultations with patients who either present with complaints of pain, anxiety, or depression, or in which such issues arise during the consultation.

### Participant type(s)
Patient, Health professional, Population

### Age group
Mixed

### Lower age limit
18 Years

### Upper age limit
100 Years

### Sex
Both

### Target number of participants
Around 500,000 individuals in the ESND. 20 volunteer GPs will be recruited for the ethnographic observation of consultations over a period of 2.5 days each. It is expected that between 200 and 250 patient consultations will be observed. 40 patients will be selected for individual interviews following their consultation.

### Key exclusion criteria
Persons under 18 or unable to give consent (for qualitative approach).

### Date of first enrolment
15/01/2025

### Date of final enrolment
31/12/2025

## Locations

### Countries of recruitment
France

### Study participating centre
**Dr F Loez**
547 Avenue De Dunkerque
Lille
France
59160

### Study participating centre
**Dr Raphaelle Delpech**
201 bis avenue du maréchal Foch
Bagneux

France
92220

# Sponsor information

**Organisation**
Inserm

**Sponsor details**
101 rue de Tolbiac
Paris
France
75013

**Sponsor type**
Research organisation

**Website**
https://www.inserm.fr/

**ROR**
https://ror.org/02vjkv261

# Funder(s)

**Funder type**
Government

**Funder Name**
GIRCI Île-de-France (interregional clinical research and innovation grouping)

# Results and Publications

**Publication and dissemination plan**
1. Planned sharing of findings in scientific journals, conferences, and medical education
2. Presenting results to participating physicians

**Intention to publish date**
31/12/2026

**Individual participant data (IPD) sharing plan**

The dataset generated and analysed from the quantitative component will be available upon request from Dr Nathalie Pelletier-Fleury (MD, PhD), nathalie.pelletier-fleury@inserm.fr.

• The type of data that will be shared -> The dataset generated by the project researchers is available upon request.
• Timing for availability -> As soon as the project researchers have completed and published their analyses.
• Whether consent from participants was required and obtained -> These are anonymized data from health insurance reimbursement databases. No participant consent is required.
• Comments on data anonymization -> The French medico-administrative databases (SNDS) does not contain any directly identifying data. The application of all measures to preserve data confidentiality and integrity, defined by the law (loi n˚ 2016–41 of 26/01/2016), is guaranteed by Inserm.
• Any ethical or legal restrictions -> Access to the SNDS database is granted to Inserm research units in accordance with French legislation (loi n° 2019–774 of 24/07/2019 and Décret n° 2021–848 of 29/06/2021). Under this legal framework, studies approved by Inserm using data solely from SNDS do not require separate ethics committee authorisation.

Datasets generated and analysed from the qualitative component of the study are not expected to be made available to ensure confidentiality.

## IPD sharing plan summary

Available on request