ISRCTN25187077 https://doi.org/10.1186/ISRCTN25187077

How health centers organize to offer better, more accessible care

Submission date	Recruitment status	[_] Prospectively registered
06/08/2025	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/09/2025	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
08/08/2025	Other	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
In recent years, the way doctors and other healthcare professionals work together in France has been changing. Instead of working alone, many now work as teams in health centers. These teams include general practitioners (GPs), nurses, medical assistants, and even social workers. The goal is to offer patients more complete care that is easier to access and better organized. However, it's not yet clear which ways of organizing these teams work best, especially for patients who are more vulnerable because of age, poverty, or social situations. This study, called EPIDAURE-2, aims to understand how different health centers organize care, how patients and professionals experience it, and whether this improves access and quality of care.
The study is especially focused on the role of the primary care doctor (known in France as the médecin traitant), who is meant to coordinate each patient's care, and how this role fits into increasingly team-based care models.

Who can participate?
Patients of all ages (adults and accompanied children) who have named a GP at one of the participating health centers, and all professionals working in the selected health centers during the study period, including doctors, nurses, administrative staff, and others.

What does the study involve?
This is an observational study, which means no treatment or care will be changed. Instead, the study will collect information through:
- Questionnaires filled out by patients about their experience and satisfaction with care.
- Questionnaires filled out by healthcare professionals about how their teams are organized and how they feel about their work.
- Social and demographic data, including a measure of patient vulnerability using the EPICES score (a tool used in France to assess social disadvantage).

What are the possible benefits and risks of participating?
Benefits include helping researchers and policymakers better understand what makes care effective and accessible, especially for vulnerable patients. Participating centers may also benefit from feedback on how to improve teamwork and patient satisfaction.

There are no medical risks involved, as the study only collects survey responses and demographic information. All data will be collected anonymously and handled securely.

Where is the study run from?
The study is coordinated by the Institut Jean-François Rey (IJFR), in collaboration with the French Society of General Practice (SFMG) and academic partners such as the École des Hautes Études en Santé Publique (EHESP, Rennes) and the INSERM CEPIA research team.

When is the study starting and how long will it run?
November 2024 to June 2026

Who is funding the study?
The study is funded by the French Ministry of Health, through the Direction Générale de l'Offre de Soins (DGOS), as part of a grant awarded via the RESPIR (Regional Support for Research in Primary Care) for proposals managed by the GIRCI Île-de-France (Interregional Clinical Research and Innovation Group).

Who is the main contact?
Prof. Julien Le Breton, julien.lebreton@u-pec.fr

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
RESPIR-21-003

Study information

Scientific Title
Analysis of coordinated care organization in health centers: accessibility and quality of curative and preventive services

Acronym
EPIDAURE-2

Study objectives
Primary Objective
To assess the relevance of different organizational models in health centers — including modes of interprofessional cooperation, coordination, and regulation within teams, and the role of general practitioners — in delivering coordinated healthcare.

Secondary Objectives
- To evaluate the ability of these organizational models to provide care for socially vulnerable populations and to identify the factors associated with this capacity
- To assess the perceptions (experience, satisfaction) of healthcare professionals involved in these organizational models and identify associated factors
- To assess the perceptions (experience, satisfaction) of patients (those listed with a primary care physician) using these organizational models and identify associated factors

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 18/03/2025, Comité Ethique du CNGE (155 rue de Charonne, Paris, 75011, France; +33 (0)175622290; comite-ethique@cnge.Fr), ref: 740

Study design
Exploratory observational study using descriptive epidemiology to analyze organizational models in health centers

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Access to and quality of coordinated primary care, including care for socially vulnerable populations

Interventions
This is an observational, descriptive epidemiological study conducted in nine community health centers in the Île-de-France region, France. The study involves two participant populations:
1. Healthcare professionals (clinical and non-clinical staff) working in the centers.
2. Patients who consult with a general practitioner (GP) within these centers and have declared a GP at the center.

Participant involvement:
• Healthcare professionals will complete the SAPHORA-JOB questionnaire, which collects information on their professional characteristics, experience of coordination, and job satisfaction.
• Patients will complete the EUROPEP questionnaire, providing data on their healthcare experience and satisfaction, as well as sociodemographic information and social vulnerability (EPICES score).
No intervention is delivered as part of this study. All data are collected via self-administered or assisted questionnaires during routine care.
Participation does not alter clinical care pathways.
Duration of participation:
• For patients: A single-point questionnaire during the consultation period.
• For professionals: One-time data collection during the study period.
Total observation period: March 2025 – March 2026 (12 months total)
Total duration of follow-up for each participant: No follow-up; single timepoint only.

Intervention Type
Other

Primary outcome(s)
The relevance of organizational models in health centers will be assessed using the following tools:
1. Perceived job organization and coordination measured using the SAPHORA-JOB questionnaire among healthcare professionals at a single timepoint during the study period
2. Patient experience and satisfaction measured using the EUROPEP questionnaire among patients at a single timepoint during the study period

Key secondary outcome(s))
1. Perception and experience of healthcare professionals measured using the SAPHORA-JOB questionnaire at a single timepoint.
2. Perception and experience of patients measured using the EUROPEP questionnaire at a single timepoint.
3. Patients' social vulnerability measured using the EPICES score at a single timepoint.

Completion date
30/06/2026

Eligibility

Key inclusion criteria
Health Centers:
The study will include a total of 9 health centers in the Île-de-France region, with variation in organizational and remuneration models:
1. 2 centers with activity-based remuneration
2. 7 centers with fixed-salary remuneration

Patients:
1. Prospectively and randomly included during consultations.
2. Eligible patients are adults who have declared a primary care physician within the participating health center.

Healthcare Professionals:
All staff working in the participating centers during the study period will be included, whether medical or non-medical, clinical or non-clinical.

Participant type(s)
Patient, Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
120 years

Sex
All

Key exclusion criteria
Patients:
Patients who have not declared a primary care physician within the participating health center

Healthcare Professionals:
1. Professionals not working at the participating health centers during the study period
2. Temporary staff or visiting professionals with no regular activity in the center

Date of first enrolment
27/03/2025

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
France

Study participating centre
CMS La Courneuve
2 mail de l'égalité
La Courneuve
France
93120

Study participating centre
CMS Nanterre
8 Rue Jean-Baptiste Lebon
Nanterre
France
92000

Study participating centre
CMS Malakoff
74 Av. Pierre Larousse
Malakoff
France
92240

Study participating centre
CMS Arcueil
13 avenue du Chaperon Vert
Arcueil
France
94110

Study participating centre
CDS Richerand
4 Av. Richerand
Paris
France
75010

Study participating centre
CMS Champigny
5, rue de l’Abreuvoir
Champigny-sur-Marne
France
94500

Study participating centre
CMS Saint-Denis
14, rue Henri-Barbusse

Saint-Denis
France
93200

Study participating centre
CDS Edisson
44 Rue Charles Moureu
Paris
France
75013

Study participating centre
CDS Yvonne Pouzin
14 Rue Volta
Paris
France
75003

Sponsor information

Organisation
Institut Jean-François Rey

Funder(s)

Funder type
Government

Funder Name
Direction Générale de l’offre de Soins

Alternative Name(s)
DGOS

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
France

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Julien Le Breton, julien.lebreton@u-pec.fr.

Type of data that will be shared:
De-identified individual-level data from questionnaires completed by patients and healthcare professionals. This includes:
- Patient responses on care experience and satisfaction (EUROPEP questionnaire)
- Professional responses on team coordination and work experience (SAPHORA-JOB questionnaire)
- Social vulnerability data (EPICES score)
- Basic demographic characteristics

When the data will become available:
Within 6 months after publication of the main study results.

For how long the data will be available:
For a period of 2 years after publication.

Access criteria:
Data will be shared with qualified researchers affiliated with academic or healthcare institutions, upon submission and approval of a data access request outlining the proposed secondary analysis.

Mechanism for data access:
Requests should be submitted by email to the study contact. A data-sharing agreement (DSA) will be required to ensure data use complies with ethical, legal, and confidentiality obligations.

Consent and anonymisation:
All identifiable information will be fully anonymised before sharing. Participants have been informed of potential secondary data use during the consent process.

Ethical or legal restrictions:
Data sharing is subject to compliance with GDPR and French data protection laws. Any qualitative data will be reviewed to ensure full de-identification prior to release.

Additional comments:
The data will not be deposited in a public repository due to confidentiality considerations, but access can be granted on a case-by-case basis through controlled procedures.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes