

# Biopsychosocial characteristics of patients with fibromyalgia / chronic widespread pain. A cross-sectional review of depersonalized data from the German Pain e-Registry. (F-type Pain)

**First published:** 22/11/2021

**Last updated:** 22/11/2021

Study

Finalised

## Administrative details

### EU PAS number

EUPAS44365

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### Study ID

44366

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### DARWIN EU® study

No

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### Study countries

☐ Germany

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## Study description

Fibromyalgia (FM), respective the chronic widespread pain syndrome (CWSP) is a medical condition characterized by chronic widespread pain and a heightened pain response to pressure. Other symptoms include tiredness to a degree that normal activities are affected, sleep problems, and cognitive dysfunctions. Some people also report restless legs syndrome, bowel or bladder problems, numbness and tingling and sensitivity to noise, lights or temperature. Patients with fibromyalgia are more likely to suffer from depression, anxiety and posttraumatic stress disorder. To gain further insight into the prevalence and biopsychosocial consequences of FM in patients we evaluated anonymized real-world data derived from routine medical care in pain centers within the German Pain e-Registry (GPeR), a national web-based registry developed in cooperation with the German Pain Association (Deutsche Gesellschaft für Schmerzmedizin) and the German Pain League (Deutsche Schmerzliga).

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## Study status

Finalised

# Research institutions and networks

## Institutions

**Institute for Neurological Sciences (IFNAP)**

**First published:** 01/02/2024

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**Institution**

## Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Michael Ueberall

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 08/10/2021

Actual: 08/10/2021

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**Study start date**

Planned: 11/10/2021

Actual: 11/10/2021

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**Data analysis start date**

Planned: 18/10/2021

Actual: 18/10/2021

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**Date of final study report**

Planned: 22/11/2021

Actual: 22/11/2021

## Sources of funding

- Other

## More details on funding

German Pain Association, IFNAP - private Institute of Neurological Sciences

## Regulatory

**Was the study required by a regulatory body?**

No

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition

Other

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**Study topic, other:**

Disease/Epidemiology study

**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To assess the extend of the biopsychosocial burden in patients with FM/CWSP

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medical condition to be studied**

Fibromyalgia

## Population studied

**Short description of the study population**

Anonymized real-world data of patients derived from routine medical care in pain centers within the German Pain e-Registry (GPeR), a national web-based registry developed in cooperation with the German Pain Association (Deutsche Gesellschaft für Schmerzmedizin) and the German Pain League (Deutsche

Schmerzliga).

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### **Age groups**

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

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### **Special population of interest**

Other

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### **Special population of interest, other**

Fibromyalgia

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### **Estimated number of subjects**

15000

## Study design details

### **Data analysis plan**

Biometric analyses will be performed using the descriptive procedures suitable for the respective data format. Mean data will be presented with standard deviation or 95% confidence intervals (CI), proportions expressed in percent (%) and if necessary, adjusted for the number of patients with available data (a%). For statistical between subcohort comparisons Pearson's chi-square test and Wilcoxon's signed rank test will be performed using a two-sided significance level of 0.05. All comparisons will be exploratory, therefore neither significance levels will be adjusted for multiplicity nor confirmatory analyses performed. All analyses will be conducted with PASW Statistics version 18.

## Data management

## **Data sources (types)**

Other

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## **Data sources (types), other**

German Pain e-Registry

# Use of a Common Data Model (CDM)

## **CDM mapping**

No

# Data quality specifications

## **Check conformance**

Unknown

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## **Check completeness**

Unknown

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## **Check stability**

Unknown

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## **Check logical consistency**

Unknown

# Data characterisation

## **Data characterisation conducted**

No