DIPARTIMENTO
DI PSICOLOGIA
DINAMICA E CLINICA
SAPIENZA
UNIVERSITÀ DI ROMA

I.R.C.C.S. Ospedale
Galeazzi - Sant'Ambrogio
Gruppo San Donato

Institute participating in the trial: IRCCS **Galeazzi-Sant'Ambrogio Hospital**
Protocol acronym: **PSYCHOFIBRO**

INFORMATION LEAFLET AND DECLARATION OF INFORMED CONSENT
for observational study in an adult patient capable of personally giving consent

Exploratory investigation of the psychosomatic and psychopathological characteristics of patients suffering from chronic pain associated with migraine, fibromyalgia and genito-pelvic pain: a s observational.

Dear Madam(s),
at our IRCCS Galeazzi-Sant'Ambrogio Hospital an observational study is being carried out entitled "Exploratory investigation of the psychosomatic and psychopathological characteristics of patients suffering from chronic pain associated with migraine, fibromyalgia and genito-pelvic pain: an observational study". The observational study is a study that intends to collect data from normal clinical practice without intervening by altering the normal diagnostic-therapeutic path of a patient.

This research is national, multi-centre (i.e. it will take place at multiple centres).
To carry out this research we need the collaboration and availability of people who, like you, satisfy the scientific requirements suitable for the evaluation that will be carried out. However, before you decide whether or not to give consent to participate, we ask you to read these pages carefully, taking all the time necessary, and to ask for clarifications if you do not understand well or need further clarifications. Furthermore, if you wish, you can ask your family or a trusted doctor for advice before deciding.

Please remember that this is a research project and that your participation is completely voluntary. You may withdraw from participating at any time.

PURPOSE OF THE STUDY

The present study aims to investigate the impact of chronic pain associated with specific clinical conditions, such as fibromyalgia, migraines, genito-pelvic pain, on the psycho-emotional well-being of patients.
The literature highlights how both fibromyalgia, migraines, genito-pelvic pain and oncological pain are conditions that are often associated with forms of pain that tend to persist over time. Chronic pain, defined by the literature as pain that lasts continuously for at least three months, has a significant negative impact on the quality of life of people who suffer from it. Among the negative symptoms that worsen the clinical picture of these pathologies are

University of Rome "La Sapienza"
VAT number 02133771002 – Tax code 80209930587
Department of Dynamic and Clinical Psychology
Via degli Apuli, 1 00185 - Rome
T (+39) 06 49917

experience: fatigue, poor sleep quality, cognitive problems (low concentration, memory difficulties), nausea, vomiting, hypersensitivity to visual stimuli, anxious/depressed mood. In addition, the literature highlights a high percentage of psychological suffering
which worsens the underlying clinical picture. Therefore, in order to improve the quality of care of patients suffering from fibromyalgia, migraine and genito-pelvic pain, it is considered essential to expand knowledge regarding the impact of the disease on psycho-physical and emotional well-being.

PROCEDURE If
you agree to participate in this study, you will be subjected to an initial interview to verify that your conditions meet the criteria required by the study.
On the occasion of this visit, Prof. Sarzi Puttini or his collaborators will inform you about this study, which involves carrying out the following phases:

- description of the research study and explanation regarding the compilation of the tests
- administration of questionnaires

Overall, the participant is required to commit to approximately 40 minutes. 5 centers will participate in this study for a total of 436 patients recruited, of which 108 enrolled at this facility. The research will take place for a part of the sample online, through the Google Modules platform (responsible Prof. Sarzi Puttini), and for another part in person.

At the end of the research you can ask for clarification on the study and ask to be informed of the results. The protocol of this study and this information sheet were drawn up in accordance with the Standards of Good Clinical Practice and the Declaration of Helsinki and were approved by the Ethics Committee_____
on _____

TOOLS USED
The protocol is composed of a battery of psychometric tests that investigate various psychological aspects. In particular, the collaboration requested of you involves completing the following questionnaires:

- Highly Sensitive Person Scale (HSP-12): investigates the theoretical framework of Sensory Processing Sensitivity, referring to an innate psychological trait that predisposes the subject to broader sensory processing of the information captured. This translates into an amplified sensitivity to external (e.g., auditory, visual) and internal (such as emotions and bodily sensations) sensory stimuli. The person is generally able to perceive a higher
number of details from the environment, to perceive stimuli as stronger (and sometimes more

annoying) compared to the average of the general population, as well as perceiving a stimulus at a lower activation threshold.

- Central sensitivity inventory (CSI): was developed to evaluate the symptomatic dimensions of central sensitivity syndrome. The scale evaluates the presence of psychological manifestations that often accompany the presence of central sensitivity syndrome. In this sense, the CSI is intended as a support (not diagnostic) tool
per se) to help the clinician identify the presence of the syndrome during diagnosis
which focuses on the psychological experience of the subject.
- List of Traumatic Experiences (TEC): the tool investigates 29 types of potential traumas and other potentially overwhelming events: loss of significant others, life-threatening illness or assault, foster care experience, emotional neglect, emotional abuse, physical abuse, sexual harassment, and sexual trauma.
- DSM-5 Personality Inventory: Assesses 5

domains of personality traits, including affect
negatives, detachment, antagonism, disinhibition and psychoticism (i.e. the presence of unconventional, strange, eccentric thoughts and behaviors not recognized by the culture to which one belongs), with each domain made up of 5 questions.

- Defense Mechanisms Value Scale - DMRS-SR-30: it is a based instrument
on the identification of 30 individual defenses arranged hierarchically in 7 levels based on similarity of function and level of adaptability. The DMRS provides a definition of each defense mechanism, a description of its intrapsychic function, and criteria for discriminating a defense from those that fall within the same level of functioning (mature, immature, and neurotic).

Optional questionnaires (the participant decides whether to complete them or not)

- Brief Symptom Inventory (BSI-18): contains the three six-item scales of Somatization, Depression, Anxiety and the Global Symptom Score (GSI).
- Quality of life: is a generic health survey developed that produces two measures for the assessment of self-perceived physical and mental health.
- Toronto Alexithymia Scale (TAS-20): is a self-administered questionnaire consisting of 20 questions that measure the difficulty of identifying and describing emotions.
- Female (FSFI) and Male (IIEF) Functional Functioning Index (optional):
differentiated questionnaire for women and men on sexual function (desire, arousal and orgasm and satisfaction).

The study will require a commitment of approximately 45 minutes.

Institute participating in the trial: IRCCS **Galeazzi-Sant'Ambrogio Hospital**
Protocol acronym: **PSYCHOFIBRO**

RISKS, DISCOMFORT AND SIDE EFFECTS

Participation in the study currently does not imply side effects or exposure to known risks and inconveniences. However, we do not exclude the possibility that the topics covered in the questions may generate discomfort or a sense of inadequacy. Furthermore, given the number of tests, the possibility that the participant may experience a condition of fatigue cannot be excluded. This discomfort and/or fatigue can be managed independently, giving the study participant the possibility to interrupt the compilation at any time.

Since this is an observational study, participation does not require the execution of investigations or treatments other than those expected in normal clinical practice, therefore specific insurance coverage is not provided.

It is reiterated that this interruption will not affect the patient's treatment path in any way.

If you are a woman of childbearing age and know that you are pregnant and/or breastfeeding, it is not considered a contraindication to participate in the study.

WHAT ARE THE BENEFITS YOU COULD RECEIVE BY PARTICIPATING IN THE STUDY?

No direct benefits are foreseeable for you from participation in this study, but your participation will allow us to acquire additional information about the pathology you are suffering from and the related treatment, information which may also be useful for future patients.

OTHER USEFUL INFORMATION

TYPE OF RETURN EXPECTED

The data collection will allow us to have a general picture of the impact that chronic pain, inserted in a context of illness such as fibromyalgia, migraines and genito-pelvic pain, can have on psycho-physical and emotional well-being of people. The evaluation of the information collected will be reported and examined in a document, accessible to all research participants who request it and to the scientific community. The results of the study will be used for research purposes and not for clinical purposes and will be used, in aggregate and anonymous form, for publications and for possible participation in scientific conferences to which they belong.

PROCEDURES FOR WITHDRAWING PARTICIPATION IN RESEARCH

Participation is completely voluntary and you can decide to withdraw from the research at any time. Likewise, the Promoter may decide to interrupt the study or may suspend your participation (for example due to failure to complete the questionnaires).

University of Rome "La Sapienza"
VAT number 02133771002 – Tax code 80209930587
Department of Dynamic and Clinical Psychology
Via degli Apuli, 1 00185 - Rome
T (+39) 06 49917

Institute participating in the trial: IRCCS **Galeazzi-Sant'Ambrogio Hospital**
Protocol acronym: **PSYCHOFIBRO**

CONFIDENTIALITY
All your data will be encoded and recorded in computerized format. You will be assigned a personal numeric or alphanumeric code which will not allow you to be identified (pseudonymisation1). Regarding the processing of personal data, you can refer to the information for the expression of consent to the processing of personal data, which will be delivered to you separately.
The data collected will be processed in accordance with privacy laws and in compliance with Legislative Decree 30 June 2003 n. 196 “Code regarding the protection of personal data” and the European Privacy Regulation EU 2016/679 (GDPR), guaranteeing the anonymity of the participants. The privacy of the participants will be guaranteed by assigning a code to the subject, and the sensitive material will be kept by the Research Manager, Prof. Sarzi Puttini, at the Rheumatology department of the IRCCS Galeazzi-Sant'Ambrogio Hospital. The data will be kept for a period useful for the processing of statistical analyzes and the promotion of related scientific material. During this period, the participant has the right to request access, rectification or deletion of personal data.

FINANCING
There is currently no funding available to support the research.

WHO ORGANIZES AND PROMOTES THIS STUDY?
The study is promoted by the Department of Dynamic, Clinical and Health Psychology - Sapienza University - Rome.

We remind you that if you need clarification on any aspect of the experimental procedure, the Researcher, the Research Manager and any collaborators are at your complete disposal. For any doubts you can contact the research manager Prof. Sarzi Puttini 02/83502647 - Rheumatology Operating Unit of the IRCCS Galeazzi Hospital -
Saint Ambrose.

Please tick the appropriate box

[1] Pseudonymisation means the processing of personal data in such a way that the personal data can no longer be stored be attributed to a specific data subject without the use of additional information, provided that such information additional data are stored separately and subject to technical and organizational measures to ensure that such data personal data are not attributed to an identified or identifiable natural person (Article 4, point 5) of the GDPR (5).

Institute participating in the trial: IRCCS **Galeazzi-Sant'Ambrogio Hospital**
Protocol acronym: **PSYCHOFIBRO**

Participation in the study

I, the undersigned (name and surname……I declare that I have received from Dr. (name and surname)…… …….. exhaustive explanations regarding the request to participate in the study in question, as reported in the information sheet attached here, a copy of which was given to me sufficiently in advance.

Date…….Signature of the subject…….....

Date…….Signature of the guardian and/or legal representative of the subject……

I have read and understood the information (or had it read to me) since I had _____. I have the opportunity to ask questions about the research and the answers were comprehensive.

Yes ○ No ○

I understand that participating in this study includes the collection of information through the questionnaires I completed.

Yes ○ No ○

Risks associated with study participation

I am aware that participating in the study includes the following risks: discomfort or sense of inadequacy, fatigue.

Yes ○ No ○

Use of information in the study

Institute participating in the trial: IRCCS **Galeazzi-Sant'Ambrogio Hospital**
Protocol acronym: **PSYCHOFIBRO**

I am aware that the information I have provided will be used to obtain a general picture of the impact that chronic pain, in the context of a disease such as fibromyalgia, migraines and genito-pelvic pain, can have on psychological well-being -physical and emotional of people.
Furthermore, the evaluation of such information will be reported and examined in a document, accessible to all research participants who request it and to the scientific community and can be used for participation in scientific conferences to which they belong.

Yes ○ No ○

I understand that personal information collected about me that may be identifying [for example, my name or where I live] will not be shared outside of the research team.

Yes ○ No ○

I agree that the information provided may be expressly cited in research reports.

Yes ○ No ○

I, the undersigned …….. agree to participate in the research

Date…… Patient signature……..

For participants who are unable to write/ read or understand the consent in the Italian language:

I witnessed the careful reading of the informed consent with the potential participant and the subject had the opportunity to ask questions. I confirm that the subject freely provided his own
consent.

Institute participating in the trial: **IRCCS Galeazzi-Sant'Ambrogio** Hospital
Protocol acronym: **PSYCHOFIBRO**

Name and surname of witness [printed] ……

Date……
Witness signature……..

Doctor

I have carefully read the information sheet to the potential participant and, to the best of my ability, ensured that the participant understood what they freely consented to.

Name and surname of doctor [printed] ……

Date…… Doctor's signature……..