Universitat de Girona
Facultat de Medicina

FINAL DEGREE PROJECT

ASSESSMENT OF PATIENT-CENTRED CARE AND ITS IMPACT ON HEALTH CARE QUALITY

A MULTICENTRED PROSPECTIVE COHORT STUDY

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JANUARY 2021

The good physician treats the disease;
the great physician treats the patient who has the disease.

William Osler

I would like to show my sincere thanks to Dr. Ferran Cordón. An example to follow as a professional and as a person. For his unconditional support and involvement.

Eternal thanks to my great friend Anna Albiol for helping me with the language, to Carlos García for his creativity, to Marc Arques for always being willing to help, to Joan Esteban for never letting go of my hand and to my family for always believing in me and never leaving me alone.

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ABREVIATIONS

eCap: Estació Clínica d'Atenció Primària

EQA: Estàndards de Qualitat Assistencial

FCM: Family and Community Medicine

ICS: Institut Català de la Salut

PCC: Patient-centred care

PHC: Primary Health Care Centre

SEMFyC: Sociedad Española de Medicina Familiar y Comunitària

SISAP: Seguiment d'Indicadors Clínics dels Professionals d'Atenció Primària

SPSS: Statistical Package for Social Sciences

T2DM: Type 2 Diabetes Mellitus

ABSTRACT

BACKGROUND

For several decades now, a "patient-centred" clinical approach has been used in primary care consultations. However, although an integrative model of the concept has been established, it still lacks conceptual clarity and there is a great deal of divergence in its assessment so most of the instruments value only part of the principles on which “Patient-Centred Care” is based. This leads to heterogeneous results in terms of the effectiveness of patient-centred interventions and, above all, to the difficulty of applying patient-centred care by medical professionals.

OBJECTIVES

The aim of this study is to objectively determine which medical professionals provide patient-centred care (PCC) and which do not using tools that assess PCC. And, once this has been determined, compare the adherence to treatment and the results of the clinical parameters in chronic pathologies (High Blood Pressure, Type 2 Diabetes Mellitus and Respiratory disease), the adequacy of treatment in acute pathologies (acute urinary tract infection, acute low back pain and acute pharyngitis and tonsillitis) and patient satisfaction (randomly selected) for 1 year between both groups.

DESIGN

It is a multicentric prospective cohort study. Based on the analysis of clinical interviews at doctor-patient appointments by external observers, two groups will be formed: professionals who provide "patient-centred care" and professionals who do not. Once the two groups have been divided, each consisting of 49 medical professionals, the results obtained by doctors, in relation to the patients and their pathologies, on different variables will be analysed over the course of one year. The variables analysed will be adherence to treatment and clinical parameters in chronic pathologies, adequacy to treatment in acute pathologies and patient satisfaction in randomised patients for each doctor.

METHODS

The clinical interviews will be analysed based on the CICCA scale by external observers previously trained for this purpose. In addition, the doctors themselves will answer, after having been video-taped, two questionnaires: a dichotomous one and the PPOS scale. The comparison of the results will be used to determine whether patient-centred care is actually being implemented in relation to the doctor's belief in the type of care he or she is providing.

The results of the variables to be compared between the group of doctors who provide "patient-centred care" and the group who do not, will be obtained from different systems depending on the variable analysed. Adequacy to treatment and clinical parameters will be obtained from the EQA (standards of care quality), extracted from the Sisap-eCap programme, and from the Therapeutic Guide in Primary Care. Adherence to treatment will be obtained based on the SIRE management of the eCAP programme, from 10 randomised patients from each doctor and chronic pathology under study. Patient satisfaction will be determined based on telephone surveys (Baker questionnaire) conducted with random patients from each doctor under study.

PARTICIPANTS

Physicians, who meet the inclusion criteria, from the participating Primary Health Care centres of the Girona Health Region, who were randomly selected from all those who accepted the proposal to participate in the study.

KEY WORDS: Patient-Centred Care, Primary Health Care, doctor-patient relationship, patient satisfaction, adherence to treatment, CICCA scale

INTRODUCTION

1. THE IMPORTANCE OF INTERPERSONAL COMMUNICATION IN THE DOCTOR-PATIENT RELATIONSHIP IN PRIMARY CARE

"Talk is the main ingredient in medical care and it is the fundamental instrument by which the doctor-patient relationship is crafted and by which therapeutic goals are achieved" (1). From this point of view, it can be considered that one of the most important aspects in the doctor-patient relationship is the communication that is established between both parties, since it is the main tool for exchanging information (1) and the main component of medical care (2).

The clinical interview is the main element through which the doctor-patient relationship and communication between both is established (3,4). Smith et al. state that the clinical interview provides the necessary data for the diagnosis. In fact, they believe that it provides more diagnoses than physical examination and laboratory tests combined (4).

The main objective of doctor-patient communication is the two-way **exchange of information**. Information is needed to draw up a correct medical history and to be able to provide an accurate diagnosis and therapeutic plan. And, the patients need to know and understand their "problem"(1). The essay by Tor in the Singapore Medical Journal (2001) (5) noted an increase in patient demand for autonomy, fundamental ethical principle in the medical context (6), and self-determination. In this regard and according to the concept of two-way exchange of information, where collaborative communication has to be established, another of the new purposes of medical communication can be related: **shared decision making.** In order to do so, a good interpersonal relationship must be established using **effective communication**, that which achieves through the communicative form and skills, the purpose of what is to be transmitted or received (7).

The doctor's ultimate objective, through the clinical interview, is to provide information on the diagnosis and prognosis of the diagnosed pathology if necessary, to inform and make decisions on the treatment to be followed, responding in the most appropriate way to the patient's emotions (2,8), having previously made a psychosocial approach to the elements of the environment that may affect the patient's symptoms, since a poor identification of these may lead to errors in diagnosis and/or treatment (9).

Successful **information exchange** has to ensure that the doctor enables the discussion and negotiation with the patient of different treatment options adapted to the context of the situation, taking into account the patient's concerns and experiences and preference for outcomes, enabling shared decision making between doctor and patient (2). Chin (2001) explains that even experience-based treatment options have to give way to other options based on patients' values and obligations and that only they know about (5). Walter et al. determines that many patients want to receive accurate information that will help them make important decisions about their quality of life. On the other hand, there are other people who avoid or minimise the receipt of information despite adhering to the treatment (10).

It should be noted that effective communication has been considered one of the basic clinical competencies of medical learning for only two decades, since there was no scientific evidence of its relevance in this field until then. Moore et al. refers to effective communication in medicine as a set of skills acquired in order to improve patient health (11).

The **communication and relationship skills** that lead to effective communication, according to literature, are 1) Respect for and attention to the patient, taking into account both verbal and non-verbal communication (12) 2) Trust management. Chin (2001) states that "patients generally view trust as an interactive process, requiring care, concern and compassion, with listening as a central focus" (5). 3) The literature

(2) identifies empathy as "one of the most powerful ways of providing this support to reduce patients' feelings of isolation and validating their feelings or thoughts as normal and to be expected". Empathy is specifically cognitive, that is, the ability to understand feelings and see things from the other person's perspective. It should not be confused with sympathy, although sometimes these two concepts are correlated, since the latter has an affective part that implies the ability to feel the feelings/experiences of another person (13). Therefore, a sympathetic doctor shares his or her emotions with patients, which may affect objectivity in diagnosis and treatment. Meanwhile, the empathic doctor transmits understanding to the patients by maintaining sympathy at an affective distance so that there is an emotional balance that does not interfere with clinical neutrality, and so that communication can be further deepened (9).

2. PATIENT-CENTREDNESS CLINICAL METHOD

The concept of "person-centred medicine“ was first introduced by Enid Balint in the mid-fifties (14) in contrast to "disease-centred medicine" (15). He described **patient-centredness** as a way of understanding the patient as a unique human being (16). At the end of the seventies, Engel pointed out the need for a biopsychosocial model in response to the hitherto dominant, paternalistic and disease-centred biomedical model. Epstein et al. mentioned the fundamental aspects of the biopsychosocial perspective proposed by Engel: 1) It stimulates a more integral knowledge of the patient and his/her environment 2) Interaction of three factors: biological, psychological and social 3) It recognises the central role of the therapeutic relationship in the course of events 4) It optimises teamwork 5) It incorporates the health professional as another piece of the system that also has to be cared for (17).

In the mid-eighties, a decade of constant social change against authoritarianism and a constant struggle by patients for greater individualisation, Stewart et al, based on the Balint's idea and influenced by the biopsychosocial model proposed by Engel, developed “**the patient-centered clinical method”.** In fact, he drew up one of the

most comprehensive definitions of the model of patient-centred care (PCC): 1) Exploring the condition and the experience (impact and expectations) of the patient's condition 2) Understanding the person by taking into account additional aspects of the patient's situation in a close context, such as social support, or distant, such as the patient's culture 3) Defining the problem and reaching a common agreement on the objectives of treatment 4) Improving the doctor-patient relationship through trust and empathy (*Figure 1* (18)) 5) Preventing and promoting health 6) "Being realistic" about personal limitations and resources (14,16,19).

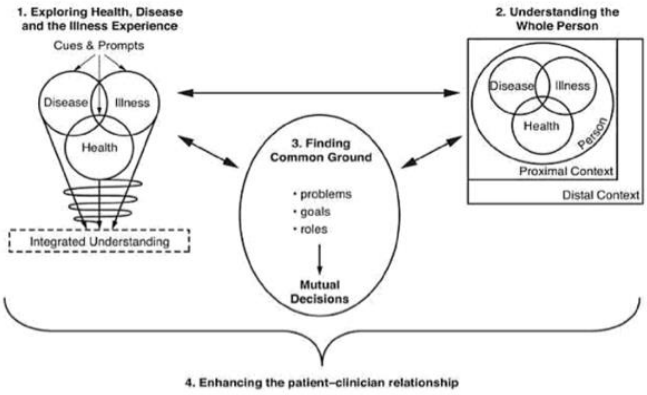

FIGURE 1. *The patient-centered clinical method: four interactive components*.

Despite the value given to this model of clinical care, Mead and Bower, at the beginning of the 21st century, realised the lack of a universal definition of this concept, which was hindering its development. Following an exhaustive review of the literature published so far, they set out the 5 dimensions that PCC had to address 1) Applying Engel's biopsychosocial model 2) Taking into account the patient's situation, understanding the "patient as a person". In other words, the deterioration of a particular function in one patient may have different consequences from another patient. 3) Sharing power and responsibility between the doctor and the patient through correct information of the patient to involve him/her in medical decision-making 4) Creating a good doctor-patient relationship: "therapeutic alliance" 5) Understanding the "doctor as a person", i.e. taking into account that the mentality, mood and personality of the doctor affect the permanent relationship with the patient and the decisions made during a consultation (16).

In 2001, the US Institute of Medicine (IOM) defined PCC as "*health care that establishes a partnership between professionals, patients and their families to ensure that clinicians and systems provide care according to patients' needs, values and preferences*"(15).

Thus, the theoretical conceptualisation of "patient-centred" is quite clear but there is a lack of consensus on the dimensions covered by PCC. This translates into a lack of clear criteria for its measurement, unclear results on the effectiveness of patient-centred interventions and difficulties in implementing this type of care. In 2014, Scholl et al. (20) systematically analysed the patient-centred concept and managed to integrate all the principles that characterise the patient-centred model, which we have been explaining so far, without being independent of each other. Thus, at present, the dimensions involved in patient-centred care are 3 (*Figure 2* (20)*)*:

- PRINCIPLES

    1) **Essential characteristics of the clinician:** either towards the patient such as empathy, honesty and respect, or towards oneself such as self-reflection and limited self-disclosure. Qualities that need to be associated with evidence-based medicine.
    2) **Clinician-patient relationship**: essential principle of PCC characterised by a reciprocal relationship based on trust and mutual understanding of roles and responsibilities.
    3) **Patient as a person**: taking into account the preferences, feelings, values and expectations of each patient. Therefore, both the condition and the experience must be explored, which implies a recognition of the uniqueness of each patient.
    4) **Biopsychosocial perspective**: understanding the patient's condition in its biological, psychological and social context. This requires the doctor to focus on non-medical aspects and to understand the person (personal

history) in both a proximal (family, social support) and a distal context (culture and community) and to focus on the patient's quality of life.

- ENABLERS

1) **Clinician-patient communication**: range of verbal and non-verbal communication skills. Among them, the most prominent in the literature are the use of open-ended questions, summary of important information, nodding and making eye contact.
2) **Integration of medical and non-medical care**: to provide patient support services with emphasis on therapies and complementary medicine required by the patient according to his/her non-medical requirements.
3) **Teamwork and teambuilding**
4) **Access to both primary and specialised care**
5) **Continuity of care**

- ACTIVITIES

1) **Reciprocal information and involvement of the patient in care**: the clinician must encourage the patient to actively participate in the consultation and thus be able to share his/her information (symptoms, concerns...) in order to offer PCC with all the requirements. At the same time, the clinician also has to ensure that the patient receives full information, from prevention to treatment of the pathology, respecting the patient's information preferences, to engage the patient in decision-making.
2) **Sharing power and responsibility**: common decision-making can only be done through the exchange of information. In this regard, the patient's self-responsibility can also be promoted to solve his/her health problems and to adopt measures to improve it by supporting the patient's autonomy.
3) **Physical support:** ensuring the patient's physical comfort.

4) **Emotional support**: paying attention to the distress that a pathology can produce regarding the patient's physical state, treatment and/or prognosis. Prescribing medication or psychotherapy to improve the patient's wellbeing if necessary and managing uncertainty by giving information.

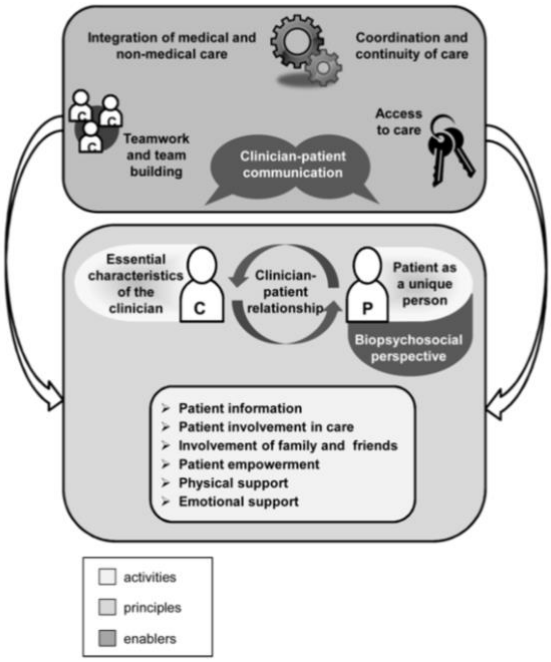

FIGURE 2. *Current dimensions involved in patient-centred care*

Thus, the concept of "patient-centred" has evolved from being a theoretical element to being considered, nowadays, a central value in quality health care. It has evolved from depending on policy and practice developments to promote it at a legislative level, to being regulated within the framework of health care and being defended in medical education on an international basis (20). Therefore, as Primary Care (PC) is the basis of the national health system, PCC should become the core value of Family and Community Medicine (FCM).

3. RATIONALE

The quality of care is one of the basic pillars of the health system. Starfield B. demonstrated how countries with quality Primary Care have more efficient health systems. In fact, Primary Care takes care of and solves 90% of health problems (21). It is therefore necessary that the main axis of the health system is Primary Care. The Spanish public health system guarantees universal access for all citizens and allows everyone to have a family doctor with whom they can manage their health problems (22). Therefore, guaranteeing a unanimous quality of care in PC consultations is essential.

As a result of multiple systematic reviews of the concept of PCC, it has been possible to establish, as previously mentioned, an integrative model of PCC. But this does not explicitly lead to improved health outcomes in its application. In fact, according to Scholl et al.'s systematic review, there's literature that agrees that PCC suggests a potentially beneficial effect on intermediate an final medical outcomes while there are other authors who agree that evidence of PCC effects is no just clear (20). Another view that needs to be taken into account is that most studies that have investigated the effect of the doctor-patient relationship, based on PCC, on clinical outcomes are observational studies so they cannot assess causality (23).

However, despite an empirical and not very established understanding of the effects of PCC, there is still a commitment to it at both the political and educational levels (15). The ambiguity regarding the exact meaning of the term and the optimal method of measurement, as well as the demonstration of a causality of this effect, compared to those that do not focus as much on the patient as on the disease, has made us set the objectives of this study.

This study aims to evaluate the clinical approach used by professionals in Primary Care consultations using tools that assess PCC and to analyze the clinical outcomes obtained afterwards, such as adherence and adequacy to treatment, clinical

parameters and patient satisfaction, comparing those professionals who adopt a more patient-centred approach and those who do not.

An objective assessment of the advantages of the "patient-centred model" and the establishment of fixed assessment criteria could be an investment in the future for the improvement of quality of care and the health outcomes, as through the training of medical professionals and students with PCC skills it would lead to a homogenisation of the services provided by all medical professionals.

According to data from the INE (Spanish National Institute of Statistics), the incidence of chronic illnesses is up to 50% among people over 65. Above all, cardiac pathologies, diabetes, arthrosis and high blood pressure, the latter two affecting 1 out of 2 patients over 65 (24). And, according to the 2017 National Health Survey, 60.0% of men and 68.2% of women over the age of 15 have some chronic health condition or problem, increasing the percentages as age increases (25). In addition, chronic diseases are currently the main factor in morbimortality at state level. Given the high incidence of these diseases, it is necessary to implement strategies for their prevention and control. The General Law of Public Health (26) has developed health strategies to prevent and control chronic diseases and other problems of special relevance to public health. At Primary Care level, it would be advisable to determine whether improving the quality of care based on a doctor-patient relationship centred on the latter, compared with other care methods used by different professionals, would be a good starting point to encourage patients' adherence to primary prevention of chronic diseases, and whether this would lead to improved clinical parameters, stability or, at least, a slowdown and control of the evolution of these diseases, ensuring a better quality of life for these patients (27).

We have chosen three chronic diseases because of their relevant incidence in our environment. In fact, it has been found that 80% of the population suffers from back pain at some point in their lives, the most frequent being low back pain from a variety of causes and a major reason for time off work, both in men and women. 19.8% of the Spanish population suffers from diagnosed high blood pressure and it is believed

that the number is higher because many of the cases are undiagnosed. According to the WHO, high blood pressure causes 45% of deaths from heart disease and 51% of deaths from cardiovascular accidents(28). The incidence of Diabetes Mellitus is around 7.8%, (25) but the Spanish Diabetes Federation states that almost 14% of Spanish adults suffer from Diabetes Mellitus and therefore half are undiagnosed. Type 2 Diabetes is the most common type of Diabetes Mellitus, being up to 10 times more common tan type 1 Diabetes (29).

Besides working on the chronic pathologies mentioned above, we aim to assess the adequacy of treatment in the most common acute pathologies in Primary Care as we believe that the assessment of the use of the Therapeutic Guides of scientist societies by professionals it could be redundant to analyze if those who apply PCC make more and better use of them compared to those who do not.

José Maria Cots, coordinator of the Infectious Diseases Group of the Spanish Society of Family and Community Medicine, listed the 10 most frequently treated pathologies in Primary Care in Spain. These include acute pharyngitis and tonsillitis, urinary tract infection and exacerbations of chronic obstructive pulmonary disease (30).

HYPOTHESES

MAIN HYPOTHESIS

- A doctor-patient relationship characterised by the patient-centred model could favourably condition, in terms of effectiveness and efficiency, the adherence to treatment, the evolution of the disease and the satisfaction of patients presenting with a specific pathology in Primary Health Care Centres (PHC).

SECONDARY HYPOTHESIS

- Patient-centred medicine is a widely known but non-standardised concept, thus most professionals believe they are applying patient-centred medicine in their practices, but reality is quite different.

OBJECTIVES

MAIN OBJECTIVES

- To determine whether the patient-centred approach, compared to other models of clinical care, improves adherence and adequacy to treatment, clinical parameters and patient satisfaction in the population over 18 and under 80 who attend to PHC.
- To compare the results obtained between the two models of approach on clinical parameters and adherence to treatment in relation to the following chronic pathologies:
    - Type 2 Diabetes Mellitus (T2DM)
    - High blood pressure
    - Respiratory pathology
- To compare the results obtained between the two models of approach on adequacy to treatment in relation to the following acute pathologies:
    - Acute pharyngitis and tonsillitis
    - Acute low back pain
    - Acute urinary tract infection

SECONDARY OBJECTIVE

- To evaluate the degree of perception to which doctors believe they are providing PCC and the degree to which they are actually providing it.

METHODOLOGY

1. STUDY DESIGN

This study consists of two parts:

I. The first part of the study is based on a cross-sectional descriptive study that will evaluate, by means of video-recording, the type of medical care carried out by doctors in Primary Care consultations in order to be able to subsequently differentiate between those who provide PCC and those who do not.

II. Based on the results obtained, the second part of the study, which is based on a multicentred prospective cohort study will compare, depending on the clinical care of the professionals (PCC o non-PCC), the effectiveness and efficiency objectives between patients who have received PCC and those who have not.

The Primary Care Centres from which the professionals and patients will be chosen are those of the Health Region of Girona (*Figure 3 (31)*) and can be found at the following link: https://catsalut.gencat.cat/web/.content/minisite/catsalut/coneix_catsalut/memories-activitat/regions-sanitaries/girona/memoria-rsgirona-2017.pdf

FIGURE 3. ***Primary Health Care Centres. Girona Health Region.***

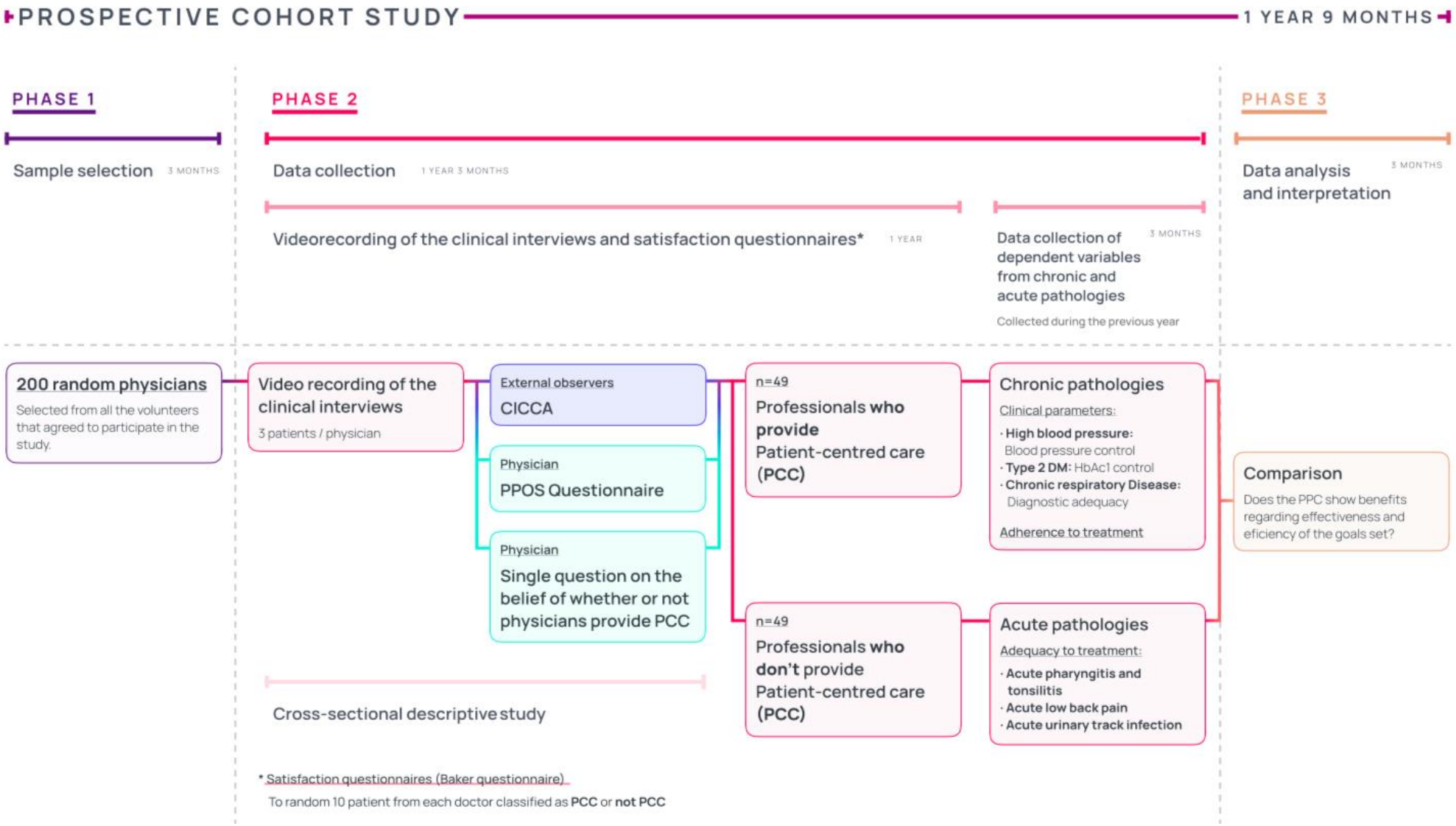

TABLE 1. ***Summary of study design***

2. STUDY POPULATION

The population considered are all those specialists in FCM who are part of the Health Region of Girona, both belonging to the Catalan Health Institute (ICS) and to other providers, and once they have confirmed that they want to be part of the study, they have been randomly selected.

The list of professionals will be requested from each of the provider entities and will be chosen at random from the database obtained.

INCLUSION CRITERIA

- All the specialists in FCM in the Health Region of Girona.
- Professionals who agree to participate in the study and sign the informed consent.
- Good knowledge of the Catalan and/or Spanish language.
- To carry out the video-recording, we will select those patients over 18 and under 80 years of age who agree to participate in the study and sign the informed consent.
- To assess patient satisfaction, we will select those patients over 18 and under 80 years of age who agree to participate in the study and whose doctors are part of the study.
- In order to study the adequacy of the treatment, we will select the patients of the participating professionals who present the acute pathologies determined for the study (urinary tract infection, acute low back pain and acute pharyngitis and tonsillitis).
- To assess the results of the clinical parameters and adherence to treatment we will select patients with less than 3 of the chronic pathologies included in the study (T2DM, high blood pressure and respiratory disease), and diagnosed within at least two years from the start of the study.

EXCLUSION CRITERIA

- Resident Medical Interns
- Professionals who do not agree to participate in the study and do not sign the informed consent.
- Medical consultations of a bureaucratic nature such as updating medication, temporary incapacity for work or drawing up medical reports or certificates.
- People with poor knowledge of the Catalan and/or Spanish language.
- To carry out the video-recording, we will exclude those patients under 18 and over 80 years of age, patients with cognitive impairment and patients unable to respond for themselves, and/or who don't agree to participate in the study and doesn't sign the informed consent.
- To assess patient satisfaction, we will exclude those patients under 18 and over 80 years of age, those who do not agree to participate in the study, patients with cognitive impairment and patients unable to respond for themselves.
- With regard to the analysis of clinical parameters* and adherence to treatment, we will exclude multipathological patients with more than two of the chronic diseases under study.

**All the inclusion and exclusion criteria that are predetermined by the EQA (standards of care quality) from the Sisap-eCap (monitoring of clinical indicators of primary care professionals-primary care clinical station) programme, for the control of the clinical parameters and adequacy to treatment, are found in section 4 (study variables and measuring instruments) classified within each corresponding variable.*

3. SAMPLING

SAMPLE SIZE

To calculate the sample size we have used the following formula, $n = \frac{2(Z_\alpha + Z_\beta)^2 * S^2}{d^2}$ where:

- n = subjects needed in each of the samples
- Z_a = Z value corresponding to the desired risk
- Z_b = Z value corresponding to the desired risk
- S^2 = Variance of the quantitative variable held by the control or reference group.
- d = Minimum value of the difference to be detected (quantitative data)

This formula is designed to compare two averages, since we are dealing with a study based on contrasting hypotheses.

We would like to consider that the influence of a PCC achieves 5 more points in the patient satisfaction (d) compared to a non-patient centred care (unilateral hypothesis). We have chosen the dependent variable "patient satisfaction" because we consider that at the level of health management it is one of the optimal requirements to carry out any project.
From previous studies we know that the standard deviation (S) of patient satisfaction using the Baker questionnaire is 8.49 (32). We accept a risk of 0.05 and wish to have a statistical power of 90% to detect differences if they exist.

The values used for Za and Zb have been selected from the most frequently used parameters in statistics on the basis of the statistical objectives we have set ourselves: by accepting a risk of 0.05 and having posed a unilateral hypothesis, the value that the statistic specifies for Za is 1.645. And, by desiring a statistical power of 90%, we are accepting a beta risk of 0.10, so the value of Zb is 1.282.

$$n = 2\,(1.645+1.282)^2 * S^2 / 5^2$$
$$n = 2\,(2,927)2 * 8,49^2 / 5^2$$
$$n = 2\,(8,567) * 8,49^2 / 5^2$$
$$n = 17,134 * 8,49^2 / 5^2$$
$$n=17,134*72,08/5^2$$
$$n=49$$

Therefore, **we need 49 professionals per group.**

The statistics determine the sample population we need for each group (n=49): professionals who provide PCC and professionals who do not. The sum of the two "n" for each group is the result of the total sample population (n=98). Therefore, all volunteer doctors who want to take part in the study will be randomised to achieve the desired total sample.

However, we assume that the distribution between the two groups will not be equal, so we will randomly start from a total sample of 200* volunteer doctors. From the total of this sample, we need to obtain a specific number of professionals who provide PCC and another group who do not, according to the value that the statistics have determined for us (n=49). Therefore, video-recordings will be made, analysed by external observers according to the CICCA scale, and the doctors in the total randomised sample will be classified between PCC and non-PCC until the desired sample is obtained for each group. As soon as we reach the desired sample for a group, the remaining physicians who agreed to participate and who are classified in the same group according to the results of the CICCA scale assessed by the observers, will be excluded from the sample. And, if on the basis of the total sample obtained from randomisation, more sample is needed to obtain the required sample for one of the two groups, a new randomisation will be made among those doctors who agreed to participate in the study but were not randomly chosen.

**It should be noted that the total number of randomised professionals, will also depend on the number of doctors who volunteer to participate in the study. However, we have considered that, ideally, this would be a good starting point to obtain the desired sample per group in each case.*

A probabilistic simple random sampling will be used for this study.

The professionals who will enter the study will be all those, randomly selected from among the ones who have accepted to join the study, from the Girona Health Region, who do not meet the exclusion criteria.

4. STUDY VARIABLES AND MEASURING INSTRUMENTS

INDEPENDENT VARIABLE

- IMPLEMENTATION OF THE PCC MODEL

Patient-centred care is a continuous quantitative variable that will be objectified by an external video-recorded assessment based on the analysis of doctor-patient interaction by external observers, previously trained for this purpose, using the **CICCA scale** (*see ANNEX 1*), an instrument designed to assess the doctor-patient clinical relationship. It consists of 29 items grouped into 3 tasks: 1) connecting with the patient 2) identifying and understanding the patient's health problems 3) agreeing with the patient on problems, decisions and actions as well as helping the patient to understand, choose and act. These items are scored on a 4 category Likert-type *rating scale* (Np: "Not applicable" - 0: "Very little or hardly applicable" - 1: "Acceptable" - 2: "Almost or fully applicable"), which provides greater ability to discriminate and therefore to provide information. The maximum score that can be obtained is 58 points. The clinical relationship on which the CICCA scale is based is defined by a series of elements that generally embrace the principles of Patient-Centred Care. These include biopsychosocial assessment, communication skills to create a "therapeutic alliance" as well as non-verbal communication and affectivity used by the professional to take into account the patient as a person and involve them in decision-making (33).

Bearing in mind the basic principles of the patient-centred clinical care model, we have selected the questions of the questionnaire that will have a greater statistical weight in deciding which professionals make PCC and which do not. As far as the "**Essential characteristics of the clinician**" principle is concerned, the reference question is number 5. Questions 8, 25, 26 and 29 will be the representative ones as regards the second principle, "**Clinician-patient relationship**". Question 13 is representative of the **"Patient as a person"** principle. Finally, the most representative questions of the fourth principle, "**Biopsychosocial perspective**", are questions 14 and 18. These 8 questions will have to receive a score ≥1 in at least 1 of the 3 interviews analysed by the observers in order to be classified as PCC professionals.

Patient-centred care is also determined subjectively through a single question to professionals *(see ANNEX 2),* being in this case a nominal qualitative variable, so that they can express, by means of “yes”, “no” or “don’t know”, whether they consider that they apply the PCC model. Furthermore, by means of the resolution of the **PPOS** questionnaire (Patient-Professional Orientation Scale) *(see ANNEX 3)*, which consists of 18 items grouped in two subscales of 9 items each and being in this case a continuous quantitative variable, the application of the patient-centred model will be measured objectively from the point of view of the professional. In the first part of the questionnaire the dimension of sharing information, decisions and power with their patients is assessed. And, in the second subscale, the treatment of patients by professionals as whole persons is valued. The scale is scored on a Likert scale of 1-6 (1: "strongly disagree" and 6: "strongly agree"). A higher score on the PPOS is associated with more patient-centred behaviour in the consultation (34), bearing in mind that the maximum score that can be achieved is 108 points.

Once the analysis of the clinical interview has been carried out using the CICCA scale, the external observers will compare the result obtained with the assessment made by the professional him/herself using the PPOS scale and the single question on whether he/she provides PCC. The aim is to check whether there is a coincidence

between the doctor's belief and the reality detected by the observers. In addition, we will obtain greater validity of the result in case of concordance between the results of the three instruments and, in the case of discrepancy, the result obtained from the CICCA scale will be considered more reliable, as it is carried out by external observers trained for this purpose.

DEPENDENT VARIABLE

- PATIENT SATISFACTION

Patient satisfaction is a continuous quantitative variable that is assessed by means of the **Baker** questionnaire *(see ANNEX 4)* validated in both the Spanish and Catalan versions. The questionnaire consists of 18 items scored on a 5-point Likert scale: 1) totally disagree - 5) totally agree, with a maximum score of 90 points. Three dimensions are taken into account: general satisfaction, remedies offered by the professional, time dedicated to the consultation and depth of the relationship with the professional (32).

→ From the two dependent variables (adherence to treatment and clinical parameters) discussed below, data will be collected from **eCap** (primary care clinical station), the computerised clinical history programme used by primary care professionals that incorporates, among others, the shared clinical history projects of Catalonia (35). They will be studied to analyse the control of the chronic pathologies selected for the study (T2DM, high blood pressure, respiratory disease) in order to compare them between those professionals classified as having ACP and those who do not:

- ADHERENCE TO TREATMENT

Adherence to treatment is a qualitative dichotomous variable expressed by yes or no. It will be studied in those patients with the chronic pathologies that are part of the study's inclusion criteria.

Through eCap we will access the medication plan of the selected patients and go to the **SIRE Management** section. Once there, it is possible to access the medication dispensing system where we can see if the patient is taking his or her medication. The treatment will be considered to have been complied with if the patient has been collecting the medication in >90% of cases during 1 year.

- CLINICAL PARAMETERS

The clinical parameters we use are continuous quantitative variables. They will be analysed in those patients with the aforementioned chronic pathologies who meet the inclusion criteria.

The **Sisap** (monitoring of clinical indicators of primary care professionals) can be accessed through eCap. And, through the Sisap, we will be able to look at the **EQA** (standards of care quality) which will determine the results of the clinical parameters of the pathologies under study as well as the criteria for exclusion and inclusion of patients for each of them. Therefore, it will be through the EQA that we will extract the clinical results obtained by each professional with respect to all their patients with the chronic pathologies that we have selected to carry out the study.

The clinical parameters that we will take into account are the following (*we have collected all the next information through the eCAP of the CAP Montilivi 3, to which there is no access from a private computer*):

- **T2DM**
  - The variable we use to study it is glycated haemoglobin (HbA1C)
  - HbA1C control is defined as:
    Percentage of the population aged between 14 and 80 years diagnosed with DM2 where the last determination of glycated haemoglobin during the assessment period is less than or equal to 8% (at least one HbA1C determination in the last 12 months, the last of which is less than or equal to 8%).
  - Period: last 12 months

- Formula: (Numerator/Denominator) x100
  - Numerator: definition of HbA1C control
  - Denominator: assigned population assisted over 14 and under 80 years old, with diagnosis of T2DM.
- Exclusion criterion: patients with haemoglobinopathies

- **HIGH BLOOD PRESSURE**
  - The variable we use to study it is blood pressure.
  - Blood pressure control is defined as:
    Percentage of population aged between 14 and 80 years diagnosed with high blood pressure where the average of the last 3 blood pressure measurements during the assessment period is 150/95 (or ≤ 160/95 if the population is 60 or older).
  - Period: 12 months
  - Formula: (Numerator/Denominator) x100
    - Numerator: definition of blood pressure control
    - Denominator: Assigned population over 14 and under 80 years old, with a diagnosis of high blood pressure.
  - Exclusion criterion: All those patients with high blood pressure that are included in the other indicators, i.e. with the diagnosis of ischemic heart disease or stroke or DM or chronic renal disease.

- **RESPIRATORY DISEASE (CHRONIC RESPIRATORY OBSTRUCTION)**
  - The variable we use to study it is its diagnostic adequacy.
  - The diagnostic adequacy of respiratory disease includes the following sub-indicators:
    - **Concordance with the use of bronchodilators.**
      It is defined as the percentage of patients treated with bronchodilators who have a chronic respiratory obstruction or diagnosis of bronchial hyperactivity.

→Formula: Numerator/Denominator

Numerator: patients of the denominator who have a chronic respiratory obstruction or diagnosis of bronchial hyperactivity

Denominator: patients on active treatment with bronchodilators and who have been undergoing treatment for at least 3 months.

Denominator exclusion criteria:

- Patients diagnosed with sarcoidosis.
- Patients diagnosed with lung cancer. Patients diagnosed with respiratory insufficiency.

- **Diagnostic adequacy of chronic obstructive pulmonary disease (COPD)**

  It is defined as the percentage of the population over 14 years of age with a new diagnosis of COPD in the last year who have an FEV1/FVC index determination below 0.7 on the post-bronchodilator test.

  →Formula: numerator/denominator * Expected prevalence

  Numerator: Population included in the denominator that has a FEV1/FVC index determination below 0.7 in the post-bronchodilator test, 12 months before or 6 months after diagnosis.

  Denominator: Population over 14 years of age with a new diagnosis of COPD in the last year.

  Denominator exclusion criteria:

  - Dementia
  - Mental retardation
  - Home health care
  - Tracheostomy
  - Institutionalised patients with dementia

- **Diagnostic adequacy of asthma**

  It is defined as the percentage of patients with a new diagnosis of asthma in the last year who have undergone a spirometry with bronchodilator test.

  → Formula: Numerator/Denominator

  Numerator: Patients included in the denominator who have undergone a spirometry with bronchodilator test in the 12 months before or 6 months after the diagnosis of asthma.

  Denominator: Patients with a new diagnosis of asthma in the last year.

  Denominator exclusion criteria:

  - Dementia
  - Mental retardation
  - Home health care
  - Institutionalised patients with dementia

- **Diagnostic criteria for chronic respiratory obstruction**

  It is defined as the percentage of patients with an obstructive spirometry that have been diagnosed with chronic respiratory obstruction (COPD, Asthma, Bronchiectasis).

  → Formula: Numerator/Denominator

  Numerator: patients included in the denominator who have been diagnosed with chronic respiratory obstruction.

  Denominator: patients with an obstructive spirometry.

  Denominator exclusion criteria:

  - Incorrect or non-valuable spirometry

- **Specification of the severity degree of asthma**

  It is defined as the percentage of patients diagnosed with asthma with a recorded severity degree (mild intermittent/frequent or moderate persistent/severe persistent).

→ Formula: Numerator/Denominator

Numerator: patients diagnosed with asthma with recorded severity

Denominator: patients diagnosed with asthma

- **Specification of the functional degree of COPD**

  It is defined as the percentage of patients with COPD who have specified functional status (stage Y, II, III or IV GOLD)

  →Formula: Numerator/Denominator

  Numerator: patients who have specified the functional degree

  Denominator: patients diagnosed with COPD

  Denominator exclusion criteria:

  - Patients diagnosed with dementia
  - Patients with tracheostomy

- ADEQUACY TO TREATMENT

Adequacy to treatment is a qualitative dichotomous variable in the analysis that will be carried out on those patients with acute pathologies that meet the criteria for inclusion in the study (urinary tract infection, pharyngitis and acute tonsillitis and acute low back pain). What we determine is the correct application of the treatment by the medical professional, since, in this case, it would be difficult to control the variables studied in chronic pathology and assess whether they really depend on the application of PCC or not.

In acute low back pain, the suitability of the treatment will be measured based on the determination of the application by the medical professionals of the **"Therapeutic Guide in Primary Care** (36)**"** that the SEMFyC (Family and Community Medicine Spanish Society) makes available to Family and Community Medicine doctors.

- **ACUTE LOW BACK PAIN**:

  Treatment of choice: Paracetamol

  Adult dose: 0.5-1g/4-6h orally (max. 4g/d; in the elderly or in case of severe kidney failure, max. 3g/d; and in case of liver failure, max. 2g/d).

  Alternative treatment:

  - Severe pain or no improvement:
    - Ibuprofen (adult dose: 400-600mg/6-8h vo (orally))
  - Muscle contracture and/or difficulty in sleeping and/or associated anxiety:
    - Prescribe diazepam (adult dose: 5mg/12-24h)

On the other hand, in the case of urinary tract infections and acute pharyngitis and tonsillitis we will collect the results through the **Sisap-eCap** as we have done previously in the clinical parameters of chronic pathologies.

- **URINARY TRACT INFECTION**

  Adequacy for treatment of urinary tract infections is defined as the percentage of new diagnoses of urinary tract infection in women treated between 14 and 90 years of age with appropriate antibiotic treatment.

  →Formula: Numerator/Denominator * Detection

  Numerator: population of the denominator with appropriate antibiotic treatment within the first 7 days from diagnosis (or 7 days before): Phosphomycin, phosphomycin trometamol, nitrofurantoin.

  Denominator: new diagnoses of urinary tract infection (both active and closed) in treated women between 14 and 90 years of age.

  Denominator exclusion criteria:

  - Recurrent cystitis (2 or more in 6 months, or 3 or more a year)
  - Pregnancy
  - Pyelonephritis
  - Renal lithiasis

- **ACUTE PHARYNGITIS AND TONSILLITIS**

  Adequacy for treatment of acute tonsillitis and pharyngitis is defined as the percentage of new episodes of acute tonsillitis or acute pharyngitis in people between 14 and 90 years of age who are not treated with antibiotics or are treated with penicillin.

  →Formula: Numerator/Denominator * Detection

  Numerator: patients who within 7 days of diagnosis meet the following conditions:

  - Without antibiotic treatment or
  - With penicillin treatment or
  - With amoxicillin clavulanic treatment if the tonsillitis is recurrent. Tonsillitis is considered to be recurrent when the patient has the open diagnosis of recurrent tonsillitis or if the sum of the following concepts is equal to or greater than 5:
    - Number of episodes of acute tonsillitis in the last year either open or closed.
    - Number of drugs or clinical courses in the last year linked to acute or recurrent tonsillitis not associated with the opening of a health problem.
  - With clarithromycin, josamycin or clindamycin treatment if the patient is allergic to penicillin.

  Denominator: New episodes of acute tonsillitis in people between 14 and 90 years of age. New episode is defined as follows:

  - A new health problem is opened up.
  - There is a course or a prescription linked to the health problem 3 months away from the previous one.

SECONDARY VARIABLES

→ PATIENT VARIABLES

- **SEX**

Sex is a nominal categorical qualitative variable (male/female/other). This variable will be collected through the initial cells of the CICCA scale questionnaire to be answered by the observers in the clinical interviews.

- **AGE**

Age is a discrete, quantitative variable measured on a 4-range age scale (<25, 25-39, 40-64 and 65-80 years of age). Different studies have shown that there is more PCC in older patients (14). This variable will be collected by the professional by entering it into the study database once the patient has signed the informed consent.

- **EDUCATION**

Education is a nominal categorical variable (*low level*: primary and secondary education, *upper-middle level:* high school and *high level*: advanced professional training/university). The level of education can determine the quality of the doctor-patient relationship in terms of willingness to make common decisions, biopsychosocial sphere and information preference, as well as adherence to treatment. This variable will be collected by the professional by entering it into the study database once the patient has signed the informed consent.

- **CHRONICITY OF THE PATHOLOGY**

This is a nominal dichotomous qualitative variable (acute or chronic). The chronicity of the pathology can be involved in the doctor's ability to provide more patient-centred care because of the possible follow-up of the patient at the consultation. In fact, it has been found that there are higher levels of concentration when it comes to known patients (14).
This variable will be collected through the initial cells of the CICCA scale questionnaire to be answered by the observers in the clinical interviews.

→ DOCTOR VARIABLES

- **AGE**

Age is a discrete, quantitative variable measured on a 4-range age scale (24-35, 35-45, 45-60, >60 years of age). It is important to keep this in mind as experience may or may not favourably condition a greater application of PCC, and new training models may have a greater impact on the application of this model. This variable will be collected by the professional by entering it into the study database once he or she has signed the informed consent.

- **SEX OF THE DOCTOR**

Sex is a nominal categorical qualitative variable (male/female/other). It must be considered whether gender conditions a greater predisposition to patient-centred care. In fact, some studies have found that women have a more patient-centred behaviour (14). This variable will be collected through the initial cells of the CICCA scale questionnaire to be answered by the observers in the clinical interviews.

- **MEDICAL STATUS** *(specialist in FCM with a permanent position or an interim position)*

Medical status is a binary nominal categorical qualitative variable (permanent or interim position) that can influence the application of the "patient-centred care" model due to the fact of having or not having a permanent position. This variable will be collected by the professional by entering it into the study database once he or she has signed the informed consent.

- **TIME SPENT WORKING IN THE CORRESPONDING PHC**

The amount of time a professional has worked in a particular centre is a discrete quantitative variable measured on a 3-range scale (<1 year, 1-5 years and >5 years) that could influence PCC due to the fact that, the more years worked, the more knowledge about patients and their environment and, possibly, the more confidence. This variable will be collected by the professional by entering it into the study database once he or she has signed the informed consent.

- **AVERAGE NUMBER OF DAILY VISITS**

The average number of visits per day is a discrete quantitative variable measured in 3 ranges (<20 visits/day, 20-40 visits/day, >40 visits/day).
This data will be extracted from the records of the supplier entities.

→ VISITS VARIABLE

- **AVERAGE TIME PER VISIT**

The average time of the visit is a discrete quantitative variable measured in 3 ranges (<10 minutes, 10-20 minutes, >20 minutes). This variable could make PCC difficult or easy to implement.
This variable will be collected through the initial cells of the CICCA scale questionnaire to be answered by the observers in the clinical interviews.

→ GEOGRAPHICAL AREA VARIABLE

- **GEOGRAPHICAL AREA**

The geographical area is a nominal categorical qualitative variable measured according to whether the medical practice is in a rural or urban area.
This data will be extracted from the division that we will make between the primary care centres corresponding to the Health Region of Northern and Southern Girona and the proportion of inhabitants that live in the area corresponding to the designated primary care centre.

5. DATA COLLECTION

From among all those doctors who, after receiving the information sheet regarding the study, have confirmed their participation, a random selection of 200 volunteer professionals will be made according to the size of the sample provided by the statistics, as explained above *(sample size).*

Once selected, they will be notified of the selection and the corresponding information on the next steps to be taken in the study. Also, they will have to sign the informed consent and fill in the database with the following variables about themselves:

- Name
- Age
- Medical status
- PHC where they work
- Time spent working in the PHC

Patients who meet the inclusion criteria will be given an explanatory sheet for the study and the informed consent form which they will have to sign if they agree to participate in the study. If so, the doctor will collect the following information about the patient in the study database:

- Age
- Education

Once this information has been collected, the clinical interview will be recorded and conducted. The information from the clinical interviews will be collected through video-recordings of the medical consultations of patients and doctors who meet inclusion criteria and have agreed to take part in the study. Subsequently, they will be analysed by contracted external observers from two different scientific fields: the health field and the social science field. Each recording will be uploaded to the database in the section of the medical professional under study together with the results of the CICCA scale analysed by the observers and the comparison they will make between the results of this scale and the two questionnaires answered by the same doctor once the recordings of his 3 consultations with patients will be finished.

At the end of the video recording of each doctor's clinical interviews, an e-mail will be sent to the physicians with two questionnaires to answer. The questionnaires they will receive will be as follows:

- Single question on the belief of whether or not they provide PCC.
- The PPOS questionnaire which will assess their response objectively, but from their point of view as to their belief in the application of the "patient centred model".

The coordinators of the study will carry out the satisfaction assessment by telephone based on the Baker questionnaire (*see ANNEX 4.1.).* Ten random patients, who meet the criteria for inclusion and none for exclusion from those specified in the study, will be chosen from each of the doctors classified as PCC or not PCC. They will be given a brief explanation of the reason for the call and be asked if they wish to take part. Then the questionnaire questions will be asked.

Both the principal investigator and the study coordinators will collect the rest of the dependent variables:

- Information on clinical parameters of patients with chronic pathologies that follow the inclusion criteria will be extracted from the Sisap-eCap programme one year after the start of the study.
- The information on adherence to treatment will be extracted from the eCAP in the SIRE Management section for 10 randomised patients for each chronic disease under study and for each physician classified in one of the two groups.
- Adequacy to the treatment we studied in the case of acute pathologies that follow the study's inclusion criteria will be analysed on the basis of:
    - The proposals of SEMFyC's **"Therapeutic Guide in Primary Care"** in comparison with the therapy determined by the doctor for the specific patient, in the case acute low back pain.
    - Results extracted from the Siscap-eCap application for urinary tract infection and acute pharyngitis and tonsillitis.

STATISTICAL ANALYSIS

The statistical plan will be carried out by a statistical analyst using the SPSS (Statistical Package for Social Sciences) programme.

We will ask the statistical analyst for the following activities:

- Describe and analyse the sample based on the information collected by CICCA scale.
- Determine if there are statistically significant differences between the results of the questionnaires answered by the professionals with respect to whether they believe that they are providing patient-centred care and the results extracted through its analysis scale (CICCA scale).
- Describe and analyse the independent variable (physicians who provide PCC and those who do not) according to the secondary variables.
- Describe and analyse the results obtained from all the dependent variables depending on the independent and secondary variables.
- Compare the patient satisfaction results between those professionals who have been shown to provide PCC and those who have not and determine the statistical difference.
- To compare the results obtained, after one year, of the clinical parameters and the adherence to treatment of the chronic pathologies established as criteria for inclusion in this study for the sample of professionals in the group who provide PCC compared to those who do not and to determine, if necessary, the statistical difference.
- Compare the professionals who provide PCC and those who do not, the correct use of clinical practice guidelines for acute pathologies established as criteria for inclusion in this study and determine the possibility of statistical differences.

UNIVARIATE ANALYSIS

In univariate analysis, the variables will be defined as either quantitative or qualitative:

- For quantitative variables we will use means.
- For qualitative variables, we will use percentages or proportions.

BIVARIATE ANALYSIS

- To compare qualitative variables, using percentages, we will use Chi-Square test (χ^2).
- To compare quantitative variables, using means, we will use T student.

MULTIVARIATE ANALYSIS

The multivariate analysis will be carried out to adjust the result of the main independent variable to the secondary and dependent variables.

To analyse how variables can influence patient-centred care (independent variable), a logistic regression model will be used to fit all of them, which will give an important weight to encompass everything that could influence PCC.

WORK PLAN AND CHRONOGRAM

1. WORK PLAN

The study is expected to last approximately 2 and a half years (March 2021-August 2023). All the activities included in this study are structured in 6 stages:

First stage: *PREPARATION* **-** 3 months (March-May 2021)

- Elaboration of the protocol and review of possible errors.
- As this is a study involving patients and the use of their clinical data as well as the video recording of doctors and patients, it will be necessary to present the project to the Ethics Committee of Clinical Investigation (CEIC) to request approval.

Second stage: *EXPLANATION AND COORDINATION* **-** 2 months (June-July 2021)

- An e-mail will be sent *(see ANNEX 5)* to all the directors of the Health Region of Girona, with the aim of providing all the information regarding the protocol. The procedure, the work plan and the objectives we are pursuing will be explained, and confirmation of their participation in the study will be requested.
- General approval for the study to be carried out in the different Primary Care Centres of the area after receiving all the information.
- Hiring of the coordinators of the Northern and Southern Health Region and study coordinators, assistants to the investigator, to carry out the protocol, from the different health institutions.
- The coordinators will be organised in such a way as to guarantee the recording of 3 consultations of each doctor participating in the study in all the participating primary care centres in the Health Region of Girona. Thus, there will be two working groups to facilitate logistics: one at the level of the Health

Region of Southern Girona and one at the level of the Health Region of Northern Girona.

- Recruitment of the observers (4 psychologists, 4 doctors from other PHC and 4 sociologists)
- Training of observers in interview analysis following the model of the CICCA scale.

Third stage: *SAMPLE SELECTION* **-** 3 months (August-October 2021)

- A list of all the professionals will be requested from each of the provider entities that have agreed to participate in the study.
- An e-mail will be sent *(see ANNEX 6)* to all the doctors from the provider entities who have agreed to take part in the study, in order to provide all the information regarding the protocol. The procedure, work plan and objectives we are pursuing will be explained and confirmation of their participation in the study will be requested.
- From among all the professionals who agree to take part in the study, participants will be randomly selected based on the total sample required to conduct the study (*explained in sample size*)
- They will be informed of their selection via email and, through the same email, they will be provided with informed consent *(see ANNEX 7)* and they will be given the database to enter their data and those of the patients about the secondary variables required in the study in those consultations that are video recorded (*set out in the data collection section*).

Fourth stage*: DATA COLLECTION* – 1 year and 3 months (November 2021-February 2023)

- The coordinators of the different Health Regions will distribute the study coordinators into two groups. Each of the groups will be assigned a part of the health centres participating in the study. This will ensure that a minimum

of 3 consultations per professional can be made at random in the same day from the total sample of participating doctors.

PATIENTS RECRUITMENT AND VIDEO RECORDINGS (for 1 year):

- At the consultation, the doctors participating in the study will recruit patients who meet the inclusion criteria and none of the exclusion criteria. They will have to be given an explanatory document with all the details of the project *(see ANNEX 8)* and will be included in the study once the objective of the study has been understood and the informed consent signed *(see ANNEX 9).*
- Once the informed consent has been signed, the coordinating researcher will place the camera and the video recording of the consultation will begin.
- The video-recordings of the consultations will become part of the database after they are carried out. Thus, from the moment the study begins, the observers can begin to make their analysis following the CICCA scale, and classifying the professionals according to the clinical care they provide (PCC or non-PCC) until they reach the desired sample for each group.
- Once the 3 video recordings corresponding to each doctor have been completed, the physician will receive by e-mail two questionnaires to answer (one on the subjective assessment of whether they provide PCC or not through a single question and another test (PPOS) that will objectively evaluate the same concept, both from your point of view).

RANDOM PATIENT SELECTION TO RESPOND TO THE BAKER QUESTIONNAIRE (for 1 year):

- During this year, the video-recordings of each of the doctors selected at random and subsequently included, by means of the evaluation of their clinical interview, in the "PCC" or "non-PCC" groups will be made. Ten randomly selected patients will be asked to complete the Baker questionnaire, through which we will analyse the patients' satisfaction with the care received by the doctor in question, by telephone.

COLLECTION OF THE DATA OBTAINED WITH RESPECT TO THE DEPENDENT VARIABLES RELATED TO ACUTE AND CHRONIC PATHOLOGIES (for 3 months)

Once we have randomised the sample of doctors needed (who had previously agreed to take part in the study), approximately at the beginning of November 2021, until a year later (November 2022), we will consider the period of time that we will take into account to determine the results obtained by the professionals with regard to the dependent variables related to acute and chronic pathologies.

- Therefore, from November 2022 until February 2023, we will collect the results of the clinical parameters and adequacy of treatment for all patients, of each of the physicians in the sample, with the chronic and acute pathologies studied in this protocol through the Sisap-eCap programme. Adherence to treatment of each of the aforementioned chronic pathologies will also be determined but, in this case, 10 patients will be randomly selected for each of the diseases and each doctor.

***Fifth stage*:** *DATA ANALYSIS AND INTERPRETATION* – 3 months (March– May 2023)

- Once the data have been collected, they will be organised for subsequent analysis by a professional statistician.
- The research team will discuss, analyse and interpret the statistical results obtained.

Sixth stage: *PUBLICATION AND DISSEMINATION OF THE RESEARCH FINDINGS* – 3 months (June-August 2023)

- The results obtained will be presented in an article with the corresponding structure.
- The article will be sent to different journals for publication.
- Dissemination of the findings in conferences and congresses related to Primary Care.
- If they so wish, patients will receive the article with the published results.

2. MEMBERS OF THE TEAM

Main investigator: Responsible for the elaboration of the protocol, communication with the different centres involved, coordination and training of the research team, supervision of the study, interpretation of the results and drafting of the conclusions. He or she will also be responsible for collecting the variables required by the study in the Sisap-eCap programme.

General Coordinators: There will be a coordinator from the Health Region of Southern Girona and a coordinator from the Health Region of Northern Girona responsible for managing the organisation in each of them and resolving any problems or doubts that may arise during the period in which the study is being carried out. In addition, they will be able to communicate with the main researcher if necessary.

Study coordinators: They will guarantee the video-recording of the consultations of the doctors included in the study by the different heads of the Health Region of Girona and will be in charge of the telephone calls to be able to carry out the satisfaction questionnaire with the patients, who have been chosen at random. They will also be responsible for collecting the variables required by the study in the Sisap-eCap programme.

Co-investigators:

- Family medicine doctors: they will provide the information sheet on the study to the patients who meet the inclusion criteria and none of the exclusion criteria, and will provide the informed consent. If they agree to take part in the study, they will inform the study coordinators, who will then start the video-recording.
- Statistical analyst: responsible for the statistical analysis of the results of the study.

- External observers: responsible for the assessment, using the CICCA scale, of the clinical interviews recorded by the professionals and to compare the results with the questionnaires completed by the doctors. There will be observers from the area of social sciences (4 sociologists with expertise in communication skills) and the area of health sciences (4 doctors and 4 psychologists). There must be at least one from each area in each interview analysis.

3. CHRONOGRAM OF THE GLOBAL PROJECT

DATE	JAN- FEB		MAR-APR		MAY-JUN		JUL-AUG		SET-OCT		NOV-DEC		JAN- FEB		MAR-APR		MAY-JUN		JUL-AUG		SET-OCT		NOV-DEC		JAN- FEB		MAR-APR		MAY-JUN		JUL-AUG		SET-OCT		NOV-DEC	
1. PREPARATION																																						
1.1. Protocol elaboration																																						
1.2. CEIC evaluation																																						
2. EXPLANATION AND COORDINATION																																						
2.1. Informative e-mail to PHC directors																																						
2.2. Centre approval																																						
2.3. Hiring and organizing coordinators																																						
2.4. Recruitment and formation of observers																																						
3. SAMPLE SELECTION																																						
3.1. Reception of the list of professionals																																						
3.2. Delivery of an informative email to all professionals																																						
3.3. Random choice of volunteer professionals																																						
3.4. Delivery of informed consent																																						
4. DATA COLLECTION																																						
PATIENTS RECRUITMENT AND VIDEO RECORDINGS																																						
4.1. Delivery of the explanatory document and informed consent																																						
4.2. Video recordings of the clinical interview																																						
4.3. Delivery the PPOS and the single question to the physicians after the video recordings																																						
4.4. Analysis of the interview based on the CICCA scale																																						
SATISFACTION QUESTIONNAIRE																																						
4.5. Random selection of 10 patients from each doctor																																						
4.6. Completion of the Baker questionnaire by telephone																																						
DATA COLLECTION OF DEPENDENT VARIABLES																																						
CHRONIC PATHOLOGIES																																						
4.7. Collection of the results of the clinical parameters through eCap																																						
4.8. Collection of the results of the adherence to treatment through eCap																																						
ACUTE PATHOLOGIES																																						
4.9. Collection of the results of adecuacy to treatment																																						
5. DATA ANALYLIS AND INTERPRETATION																																						
5.1. Data analysis																																						
5.2. Results interpretation																																						
6. PUBLICATION AND DISSEMINATION OF THE RESEARCH FINDINGS																																						
6.1. Article elaboration																																						
6.2. Article publication																																						
6.3. Divulgation																																						

TABLE 2. ***Chronogram of the global project***

BUDGET

The budget of this study includes all the possible expenses that would be necessary to carry it out, considering personnel expenses, necessary purchases to carry out the data collection and other costs such as publication expenses.

1. PERSONNEL EXPENSES

The personnel to be hired additionally for the research project are:

- **A statistical analyst**:
  - Calculating a 40€ hourly rate and a 40-hour task for analysing all data, it would sum up to 1600€.
- **A specialist in CICCA scale** that will form, according to this method, the observers.
  - We've calculated a training of 8 hours, at a 15€ hourly rate, which would cost 120€.
- **12 external observers for the clinical interviews**

  We must take into account that we start with a total sample of 200 medical professionals to obtain a sample for each of the two groups of "n=49". Therefore, as we intend to analyse each professional in 3 different clinical interviews, it adds up to a total of 600 interviews that will have to be analysed. (this number of interviews could be higher or lower depending on the number of professionals we need to get the sample of each group).

  At least two observers are needed for each interview analysis, and each group of two observers will analyse an average of 33-34 professionals with their corresponding three clinical interviews (99-102 interviews, respectively). The minimum duration of the visit is estimated at 10 minutes. This means that it will take approximately 1 hour and 30 minutes to complete the interview analysis using the CICCA scale, comparing the results with the questionnaires provided by the professionals and classifying them into the CCP or non-CCP group.

- Each group of observers (6 groups of 2 observers each) will take 150 hours to analyse 100 interviews. A 10€ hourly rate adds up to a total cost of 18.000 €.

- **4 study coordinators**
  - A total of 980 satisfaction interviews must be carried out by telephone (a total of 245 interviews per coordinator) with a duration of approximately 20 minutes each, which is equivalent to 82 hours of work per coordinator. This means a cost, which has to be paid at an hourly rate of 10€, of 3280€.
  - In addition, we must take into account that they will also be in charge of collecting the data from the other variables.
    - Regarding the adherence to treatment, 10 random patients are selected for each professional and each chronic pathology under study (we have a total of 3 pathologies for 10 random patients from each of them, making a total of 2940 patients to follow up). It is estimated that it will take 10 minutes per patient to collect and enter the results into the data base. Each study coordinator will follow up 735 patients, at a rate of 10 minutes per patient, for a total of 123 hours. I would be the equivalent of 4920€.
    - Regarding the adequacy of treatment and clinical parameters of all acute (except for acute low back pain*) and chronic diseases, respectively, the results of which are determined by the EQA of the Sisap-eCap programme, it has been calculated that it takes 15 minutes to collect and enter the results of these two variables for each doctor. Thus, each study coordinator will collect the results of the variables from a group of 25 professionals, and it will take a total of 6 hours to obtain all of them. This means a total cost of 240 euros.

**The adequacy of treatment of acute low back pain will be analysed by the main investigator without any additional cost.*

***All calls and data collection will be done from the Health Care Centres where the study coordinators come from, as well as the working areas, without any additional costs.*

2. EXECUTION EXPENSES

- The articles and publications consulted for the development of this study have not had any additional cost.
- As the patient satisfaction surveys will be done by telephone, the data will be introduced directly into the database. Moreover, the surveys that the professionals will answer as well as the CICCA scale on which the observers will be based will be sent by e-mail and there will be no additional costs for printing them.
- The petro used by the study coordinator when travelling to the different PHC in the Girona Health Region in order to carry out the video recording will be paid at 0.50 cents per km. One group (of two study coordinators) will go to the Northern Health Region and the other group to the Southern Health Region. For this we have calculated an average of 1000 km/group, which sums up to a petrol cost of 500 euros/group, a total amount of 1000 euros.
- The study coordinator's diets must also be taken into account. If the medical consultations of approximately 200 professionals are to be recorded, assuming that every 3 doctors are from the same health centre, it can take approximately 70 days to obtain all the video recordings throughout the year. If we add up the expenses of each coordinator (15€) it means a cost of 2800€.

3. PREPARATION EXPENSES

- It will be necessary to buy 4 video recording cameras with a built-in microphone, which will be distributed among the 4 study coordinators. Each camera costs approximately 50 euros, bringing the total cost to 200 euros.

4. PUBLICATION EXPENSES

- When publishing the results of the study in a journal article we will assume the costs of reviewing, editing, formatting and preparing the digital data, which will cost approximately 2000€.
- Moreover, we would like to present it at a National Congress, where the expenses involved will be approximately 1000€.

The different expenses are summarized in *Table 3* below:

TYPE OF COST		UNIT COST	HOURS/UNIT	TOTAL
PERSONNEL EXPENSES				
Statistical analyst		40€	40 hours	1.600€
Specialist in CICCA scale		15€	8 h.	120€
12 External Observers		10€	150 h./person	18.000€
4 Study coordinators	Satisfaction questionnaire	70€	82 h./p.	3.280€
	Data collection (adherence to treatment)		123 h./p.	4.920€
	Data collection (clinical parameters and adequacy to treatment)		6 h./p.	240€
EXECUTION EXPENSES				
Travel by car		0,50 cents/km	2000km	1.000€
Study coordination diets		15€	280 diets	4.200€
Questionnaires		-	-	NO COST
PREPARATION EXPENSES				
Video-recording cameras		50€	4 units	200€

PUBLICATION EXPENSES			
Article publication	2000€	-	2.000€
National Congress	1000€	-	1.000€
MISCELANOUS COSTS			
10% of the total amount			3656€
TOTAL			40.216€

TABLE 3. ***Budget of the prospective cohort study "Assessment of patient-centred care and its impact on quality of care"***

ETHICAL AND LEGAL CONSIDERATIONS

This protocol will be carried out in accordance with the requirements expressed in the document "*Declaration of Helsinki of Ethical Principles for Medical Research Involving Human Subjects*" revised by the World Health Association on October 2013 and *ministerial order SAS/3470/2009* defined in the current Spanish legislation related to the conduct of observational studies.

Furthermore, it will be presented to the Ethics and Clinical Research Committee (CEIC) of the *"Fundación Instituto Universitario para la Investigación en Atención Primaria de Salud Jordi Gol i Gurina"* (IDIAP JGol) for the evaluation and approval of the legal aspects of this project. If there are any suggestions in this regard, the study will be modified as necessary.

We will need the approval of the heads of the Girona Health Region who will participate in the research project to be able to take part in the study and a coordination team willing to carry it out. Each member of the research team will have to sign a declaration stating that they have read and approved the final protocol and that they agree with the national and international ethical aspects of the research.

Participation in this study is voluntary. All patients and medical professionals will be fully informed before taking part in the study and will be required to sign an informed consent form, in accordance with Law 41/2002 regulating *Patient Autonomy and Health Documentation and Information-Related Rights and Obligations.* If the patient or doctor wishes to withdraw his or her informed consent, he or she may do so at any time without giving any explanation.

The transfer and the processing of personal data required in the study as well as their confidentiality will obey the *EU regulation 2016/679* of the *European Parliament and the Council of 27 April 2016* repealing *Directive 95/46/EC (General Data Protection Regulation)* and the *Organic Law 3/2018 of 5 December, on Personal Data Protection and Guarantee of Digital Rights,* in the protection of individuals with respect to all content related to the

confidentiality of personal data and the anonymity of participants. This also guarantees the right to consult, modify and delete all personal information from the records.

The above law also guarantees that all personal data used will remain anonymous after being entered and processed in the database, that they will only be used for the development of the study and that they will be available exclusively to the research team.

LIMITATIONS OF THIS STUDY

- In a prospective study, withdrawals and losses are to be expected that may modify our study and produce a selection bias. The withdrawal of some professionals once the definitive sample has been randomised and obtained could lead to them. The greatest loss of professionals may occur in the performance of the tests once the study has begun. To try to minimise the loss, reminders will be sent via e-mail.
- We may find, as already explained in the measurement of the sample, that with the total random sample from which we start (based on volunteer doctors), we may be able to get the full sample for one group but not for the other (PCC or non-PCC) if the differentiation obtained through the CICCA scale that the observers are using in the clinical interviews indicates so.

  Then, at the end of the first random sample of total doctors needed, we would proceed to repeat the same procedure as the first time: of the doctors who confirmed their willingness to participate in the study and who were randomly excluded, a new sample of total doctors would be randomised and the initial procedure of analysing the clinical interviews would be followed until the sample required by the incomplete group was obtained. All those classified in a group that was already complete would be excluded.
- It could also happen that, instead of having to enlarge the randomised sample, we might not have enough volunteers to fill both groups.
- The loss of follow-up of chronic patients by the professional, during the year of data collection and for various reasons, could affect the final results obtained with respect to clinical variables and adherence to treatment, causing a selection bias.
- There may be inter-observer differences in terms of interview analysis using the CICCA scale. To avoid this, observers will be trained according to the CICCA scale and there will have to be at least 2 observers analysing each

interview and coming from two different professional fields (social and medical).

- Another limitation is the duration of the study, the logistics for carrying it out and the human's resources needed, with a consequent methodological complication.
- A non-negligible limitation of the study is the large number of interviews that will have to be analysed, approximately 600 if the 200 professionals from which we intend to start are necessary, and the possible difficulty in finding patients who accept to be videorecorded.
- The fact that the professionals know that they are being recorded to analyse the clinical interview and that a cohort study is being carried out through which different variables will be analysed could condition a different "attitude" which would lead to an information bias. For this reason, we will try to provide clear information in the doctors' information sheets but with few details about the study and to pass the questionnaires on whether they consider that they provide PCC or not, after having recorded their 3 medical consultations.

  Furthermore, to avoid this limitation, it is also planned to compare the results obtained at the end of the study with those of the previous year, retrospectively, to see if there is a difference. If there is a difference, it will be assessed whether the fact of knowing that they entered the study may have influenced it.

IMPACT ON THE NATIONAL SYSTEM

During medical training, the degree of emphasis given to the disease is not the same as that given to the patient. By this we mean that the priority focus of the university degree is to diagnose and treat all those pathologies that may appear in the different organs that make up the human being. On the other hand, the subjects related to communication skills and clinical interviews are quite disguised. In medicine, the disease is as important as the patient who suffers it. Obviously, having medical knowledge is important, but to what extent is it important if we leave aside other aspects related to the patient that may end up influencing the pathology?

Every patient is unique, with concerns, worries and problems. A patient-centred model has been considered to be in place for some decades now (16). But is that really the case? The present study aims to assess objectively whether patient-centred medicine is really being implemented, but also subjectively with the intention of demonstrating that, as the literature has already stated, the concept of patient-centred medicine is a vague one (15) and is possibly believed to be implemented but not to its fullest extent. The comparison between the results obtained through the CICCA scale and the results of the questionnaires answered by the professionals themselves will help us to finish answering this belief.

Therefore, from the evaluation items of the validated and used questionnaire (CICCA) used in this study and based on the basic principles determined by the literature on PCC, some parameters to be taken into account and applied in any Primary Care consultation could be determined. In this regard, and if it is proven that PCC has significant clinical benefits for the patient, university training would play a fundamental role by implementing a specific training model with specific principles that can be adapted to any patient, which would guarantee PCC in a unanimous manner among all medical professionals. This unanimity in the form of care by health professionals would allow us to find a balance in the health system, avoiding mistrust of the health system, without differences between professionals and with the benefit

of a quality system in which all patients could be treated equally regardless of the professional chosen.

In addition, variables such as visiting time and number of visits made by doctors in primary care and how this influences the application of the above model will have to be taken into consideration. This could show the impact on the quality of health care and could be significant in the implementation of new policies to regulate it in terms of educational matters.

We have no doubt that better quality of care translates into greater satisfaction for patients who receive it. By this we mean that, if medical care of these characteristics were to be imposed, along with everything that it entails beyond the consultation itself, Primary Care, the basis of our National Health System, would be favoured in every way; from the improvement of the working conditions of the medical professionals themselves to a significant impact on the health and well-being of the population.

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ANNEXES

1. CICCA SCALE

DATOS GLOBALES:

PROYECTO: CLAVE: OBSERVADOR:

Tiempo total de consulta (s y min): ☐☐☐	Hasta explorar (S): ☐☐	Exploración (s): ☐☐		
Profesional: M ☐ F ☐	Tipo: Med. ☐	Resi. ☐	Enfer. ☐	Est. ☐
Motivo de consulta: Pral.:	2)	3)		
Especialidad /Año / Curso	Docente: Sí ☐ No ☐	Proceso: Agudo ☐ Crónico ☐		
Paciente: M ☐ F ☐ / Re. ☐ Es. ☐	Acompaña: Sí ☐ No ☐	Visita: Inicial ☐ Revisión ☐		

TAREA 1.ª CONECTAR	Np	0	1	2
1.-¿En qué medida el profesional recibe adecuadamente al paciente?				
2.-¿En qué medida el profesional hace un uso del ordenador u otros registros de forma que no altera la comunicación?				
3.-¿En qué medida el profesional se muestra cortés y amable durante la entrevista?				
4.-¿En qué medida el lenguaje no verbal del profesional es el adecuado?				
5.-¿En qué medida el profesional muestra empatía en los momentos oportunos?				
6.-¿En qué medida el profesional cierra adecuadamente la entrevista con el paciente?				
TAREA 2.ª IDENTIFICAR Y COMPRENDER LOS PROBLEMAS				
7.-¿En qué medida el profesional ha mostrado una reactividad adecuada?				
8.-¿En qué medida el profesional facilita el discurso del paciente?				
9.-¿En qué medida el profesional establece y mantiene a lo largo de la entrevista un contacto visual-facial adecuado?				
10.-¿En qué medida el profesional capta y responde a las pistas ofrecidas por el paciente?				
11.-¿En qué medida el profesional emplea preguntas abiertas?				
12.-¿En qué medida el profesional ha explorado la idea que tenia el propio paciente sobre el origen y/o la causa de su síntoma o proceso?				
13.-¿En qué medida el profesional ha explorado las emociones y los sentimientos que el síntoma o proceso ha provocado al paciente?				
14.-¿En qué medida el profesional ha explorado cómo afecta al paciente su síntoma o proceso en su vida diaria, entorno sociofamiliar o laboral?				
15.-¿En qué medida el profesional ha explorado las expectativas que el paciente tiene para esta consulta?				
16.-¿En qué medida el profesional ha explorado el estado de ánimo del paciente?				
17.-¿En qué medida el profesional ha explorado posibles acontecimientos vitales estresantes para el paciente?				
18.-¿En qué medida el profesional ha explorado el entorno sociofamiliar?				
19.-¿En qué medida el profesional ha explorado factores de riesgo o realizado actividades preventivas no relacionadas con la demanda?				
20.-¿En qué medida el profesional ha resumido la información que ha obtenido del paciente?				

TAREAS 3.ª y 4.ª ACORDAR Y AYUDAR A ACTUAR	Np	0	1	2
21.-¿En qué medida el profesional trata de explicar el proceso o el síntoma principal presentado por el paciente?				
22.- ¿En qué medida el profesional trata de explicar la evolución que puede seguir el proceso?				
23.- ¿En qué medida el profesional ofrece una información adaptada a los problemas y necesidades que tiene el paciente?				
24.- ¿En qué medida el profesional ofrece la información de forma clara?				
25.- ¿En qué medida el profesional da la oportunidad al paciente de participar en la toma de decisiones de la consulta animándolo?				
26.- ¿En qué medida el profesional permite que el paciente exprese sus dudas?				
27.- Si se produce alguna discrepancia o desacuerdo entre el profesional y el paciente, ¿en qué medida el profesional busca el acuerdo (entrando en discusión y considerando las opiniones del paciente?				
28.- ¿En qué medida el profesional comprueba que el paciente ha comprendido la información suministrada?				
29.- ¿En qué medida el profesional consigue compromisos explícitos por parte del paciente respecto al plan a seguir?				

NP: No procede. (0): Muy escasamente o Escasamente; (1): Aceptablemente; (2): Casi totalmente o Totalmente

He revisado la cumplimentación de todos los ítems _____ ☐☐

PUNTUACION TOTAL / n.º ítems con NP ☐☐☐☐

Comentarios y notas:

ABREVIATURAS: M: Masculino; F: Femenino; Med.: Médico; Resi.: Residente; Enfe.: Enfermera; Est.: Estudiante; Re.: Real; Es.: Estandarizado; Acompaña.: Acompañante

(*) CICAA es acrónimo de: Conectar, Identificar y Comprender, Acordar y Ayudar

2. SINGLE QUESTION ON THE BELIEF OF WHETHER OR NOT PHYSICIANS PROVIDE PATIENT-CENTRED CARE

La següent pregunta que li plantegem es basa amb la creença de si vostè, en la consulta mèdica, fa una "Atenció Centrada en el Pacient".

Emmarqui amb un cercle una de les possibles respostes que es plantegen per la següent pregunta.

→ Creu vostè, com a metge/ssa especialista en Medicina de Família i Comunitària que aplica en les seves consultes una "Atenció Centrada en el Pacient"?

- Si
- No
- No ho sé

La siguiente pregunta que le planteamos se basa en la creencia de si usted, en la consulta médica, hace una "Atención Centrada en el Paciente".

Redondee una de las posibles respuestas que se plantean para la siguiente pregunta:

→ Considera usted, como medico/a especialista en Medicina de Familia y Comunitaria que aplica en sus consultas una "Atención Centrada en el Paciente" de acuerdo con los 4 principios básicos que la caracterizan?

- Sí
- No
- No lo sé

3. PATIENT-PRACTITIONER ORIENTATION SCALE (PPOS)

Mitjançant aquest qüestionari podrem valorar, objectivament però des del seu punt de vista, si vostè fa una atenció mèdica basada en el model "atenció centrada en el pacient". Per favor, contesti totes les preguntes amb màxima sinceritat marcant només una resposta per a cada pregunta.

A través de este cuestionario podremos valorar, objetivamente pero des de su punto de vista, si usted realiza una atención médica basada en el modelo "atención centrada en el paciente". Por favor, responda todas las preguntes con máxima sinceridad señalando solamente una respuesta por cada pregunta.

		Strongly Disagree *Muy en Desacuerdo* 1	**Moderately Disagree** *Moderada-mente en desacuerdo* 2	**Slightly Disagree** *Un poco en desacuerdo* 3	**Slightly Agree** *Un poco de acuerdo* 4	**Moderately Agree** *Moderada-mente de acuerdo* 5	**Strongly Agree** *Muy de acuerdo* 6
1.	The doctor is the one who should decide what gets talked about during a visit. *El médico es el que debería decidir de que es lo que se habla durante una visita.*	○	○	○	○	○	○
2.	Although health care is less personal these days, this is a small price to pay for medical advances. *Aunque hoy en día el cuidado médico es menos personal, esto es un precio pequeño que pagar por todos los adelantos (de la medicina).*	○	○	○	○	○	○
3.	The most important part of the standard medical visit is the physical exam. *La parte más importante de una visita médica regular (estándar, corriente) es el examen físico.*	○	○	○	○	○	○

		Strongly Disagree *Muy en Desacuerdo* 1	Moderately Disagree *Moderada-mente en desacuerdo* 2	Slightly Disagree *Un poco en desacuerdo* 3	Slightly Agree *Un poco de acuerdo* 4	Moderately Agree *Moderada-mente de acuerdo* 5	Strongly Agree *Muy de acuerdo* 6
4.	It is often best for patients if they do not have a full explanation of their medical condition. *A menudo, es mejor para los pacientes si no reciben una explicación completa de su condición médica.*	○	○	○	○	○	○
5.	Patients should rely on their doctors' knowledge and not try to find out about their conditions on their own. *Los pacientes deberían confiar en el conocimiento de sus médicos y no tratar de informarse acerca de sus condiciones por sus propios medios.*	○	○	○	○	○	○
6.	When doctors ask a lot of questions about a patient's background, they are prying too much into personal matters. *Cuando los médicos hacen muchas preguntas sobre los antecedentes del paciente, se están metiendo mucho en asuntos personales.*	○	○	○	○	○	○
7.	If doctors are truly good at diagnosis and treatment, the way they relate to patients is not that important. *Si los médicos son verdaderamente buenos en el diagnóstico y el tratamiento, la manera como se relacionan con el paciente no es tan importante.*	○	○	○	○	○	○
8.	Many patients continue asking questions even though they are not learning anything new. *Muchos pacientes continúan haciendo preguntas aun cuando ne están aprendiendo nada nuevo.*	○	○	○	○	○	○
9.	Patients should be treated as if they were partners with the doctor, equal in power and status. *Los pacientes deberían ser tratados como si fueran socios del médico, igual en posición (estado) y poder.*	○	○	○	○	○	○
10.	Patients generally want reassurance rather than information about their health. *En vez de información sobre su salud los pacientes generalmente quieren que los reaseguren.*	○	○	○	○	○	○
11.	If a doctor's primary tools are being open and warm, the doctor will not have a lot of success. *Si los instrumentos principales del médico son el ser abierto y cálido, el médico no tendrá mucho éxito.*	○	○	○	○	○	○
12.	When patients disagree with their doctor, this is a sign that the doctor does not have the patient's respect and trust. *Cuando los pacientes están en desacuerdo con sus médico, esta es una señal que el médico no tiene el respeto ni la confianza del paciente.*	○	○	○	○	○	○
13.	A treatment plan cannot succeed if it is in conflict with a patient's lifestyle or values. *Un plan de tratamiento no puede tener éxito si está en conflicto con el estilo de vida o los valores del paciente.*	○	○	○	○	○	○
14.	Most patients want to get in and get out of the doctor's office as quickly as possible. *La mayoría de los pacientes quieren entrar y salir de la oficina del médico lo más rápido posible.*	○	○	○	○	○	○

		Strongly Disagree *Muy en Desacuerdo* 1	**Moderately Disagree** *Moderada-mente en desacuerdo* 2	**Slightly Disagree** *Un poco en desacuerdo* 3	**Slightly Agree** *Un poco de acuerdo* 4	**Moderately Agree** *Moderada-mente de acuerdo* 5	**Strongly Agree** *Muy de acuerdo* 6
15.	The patient must always be aware that the doctor is in charge. *El paciente debe estar siempre consciente de que el médico es el que esta a cargo.*	○	○	○	○	○	○
16.	It is not that important to know a patient's culture and background in order to treat the person's illness. *No es tan importante conocer la cultura y los antecedentes del paciente para tratar la enfermedad de la persona.*	○	○	○	○	○	○
17.	Humor is a major ingredient in the doctor's treatment of the patient. *El humor es un ingrediente importante en el tratamiento que provee el médico al paciente.*	○	○	○	○	○	○
18.	When patients look up medical information on their own, this usally confuses more than it hleps. *Cuando los pacientes buscan información por su cuenta, esto usualmente confunde más que ayuda.*	○	○	○	○	○	○

Comments: *Comentarios:*

4. BAKER QUESTIONNAIRE

1. Estoy totalmente satisfecho de la visita con este médico/enfermera.
2. El médico/enfermera ha puesto mucha atención en examinar todos los problemas.
3. Seguiré los consejos del médico/enfermera porque creo que son muy acertados.
4. Me he sentido cómodo hablando con el médico/enfermera sobre temas muy personales.
5. El tiempo que he pasado con el médico/enfermera ha sido algo corto.
6. El médico/enfermera me ha dado una información completa sobre mi tratamiento.
7. Algunos aspectos de la consulta con el médico/enfermera podrían haber sido mejores.
8. Hay algunas cosas que el médico/enfermera no sabe de mí.
9. El médico/enfermera ha escuchado con mucha atención todo lo que le he dicho.
10. Pienso que el médico/enfermera me ha tratado de manera personalizada.
11. El tiempo que he estado con el médico no ha sido suficiente para comentarle todo lo que deseaba.
12. Después de la visita con el médico/enfermera entiendo mucho mejor mi problema de salud.
13. El médico/enfermera se ha interesado por mí no sólo a causa de mi enfermedad, sino también como persona.
14. El médico/enfermera lo sabe todo sobre mí.
15. Creo que el médico/enfermera sabía realmente lo que yo estaba pensando.
16. Me hubiera gustado estar más tiempo con el médico/enfermera.
17. No estoy del todo satisfecho con la visita al médico.
18. Me resultaría difícil hablar con el médico/enfermera sobre temas personales.

4.1. INFORMATION FOR STUDY COORDINATORS ABOUT "BAKER QUESTIONNAIRE"

A continuació apareix el qüestionari que haureu de fer, via telefònica, als 10 pacients seleccionats aleatòriament, de tots els metges en estudi, en relació a la seva satisfacció envers la consulta mèdica amb el seu/seva Metge/ssa de Família. En els següents links podreu accedir i contestar directament les respostes que us contestin els pacients. Llegiu amb atenció el qüestionari abans de realitzar la trucada telefònica i completeu la informació que es demana a l'inici.

A continuación aparece el cuestionario que deberéis hacer, vía telefónica, a 10 pacientes seleccionados aleatoriamente, de todos los médicos en estudio, en relación a su satisfacción respecto la consulta médica con su Médico/a de Familia. En los siguientes links podréis acceder y contestar directamente las respuestas que os contesten los pacientes. Leed con atención el cuestionario antes de realizar la llamada telefónica y completad la información que se os pide al inicio.

BAKER QUESTIONNAIRE (Catalan version)

https://docs.google.com/forms/d/e/1FAIpQLSflWGIRHSJixoXzTRiLDzC7A6WU1JxsHbVNmRKZ_1JBbXCm0Q/viewform?vc=0&c=0&w=1&flr=0&gxids=7628

BAKER QUESTIONNAIRE (Spanish version)

https://docs.google.com/forms/d/e/1FAIpQLSfm0tOXyEGb21lHgj0LVRKDB_Piys4A4i4Ifn_1iemozyXFeQ/viewform?vc=0&c=0&w=1&flr=0&gxids=7628

5. EXPLANATORY DOCUMENT FOR THE DIRECTORS OF THE PRIMARY HEALTH CARE CENTRES

CATALAN VERSION

FULL D'INFORMACIÓ A ELS/LES DIRECTORS/ES DELS CENTRES D'ATENCIÓ PRIMÀRIA DE LA REGIÓ SANITÀRIA DE GIRONA

Nom de l'estudi: Avaluació de l'Atenció Centrada en el/la pacient i la seva repercussió en la qualitat assistencial

Investigador/a principal:

Benvolgut/da,

Ens dirigim a vostè per informar-lo sobre l'estudi d'investigació que estem portant a terme en els CAP de la Regió Sanitària de Girona i en el que ens agradaria que el CAP que dirigeix en formés part.

La nostra intenció és que vostè rebi la informació correcta i suficient per què pugui avaluar i decidir si el CAP que regeix, així com els metges/sses i pacients del mateix, formi part d'aquest estudi. Llegeixi aquest full informatiu amb atenció i, si li queden dubtes, li aclarirem seguidament.

PARTICIPACIÓ VOLUNTÀRIA

La participació en aquest estudi és voluntària per tothom qui en vulgui formar part. En cas que decideixi que el seu CAP formarà part de l'estudi, als metges/sses que treballin en aquest i que segueixin criteris d'inclusió se'ls enviarà un full informatiu per què puguin decidir si participen o no. També podran canviar la seva opinió un cop hagin acceptat i retirar el seu consentiment en qualsevol moment sense que això els afecti en cap aspecte.

DESCRIPCIÓ I OBJECTIUS DE L'ESTUDI

L'informem que aquest projecte ha estat prèviament aprovat pel Comitè d'Ètica i d'Investigació Clínica (CEIC) de la IDIAP JGol.

Per portar a terme aquest estudi es necessiten inicialment 200 metges/sses especialistes en Medicina de Família i Comunitària de la Regió Sanitària de Girona

que, un cop llegit el full informatiu de l'estudi i confirmada la seva participació, se'n farà una selecció aleatòria de 200 professionals entre tots els voluntaris inicials.

L'objectiu de l'estudi és valorar el tipus d'abordatge clínic que realitzen els professionals mèdics amb els pacients per tal de poder objectivar la seva influència i els possibles beneficis respecte la qualitat assistencial. Per poder valorar-ho serà necessari vídeo-gravar 3 consultes diferents amb 3 dels seus pacients.

BENEFICIS I RISCOS DE L'ESTUDI

La participació dels seus professionals així com la dels pacients serà important per poder determinar com l'abordatge clínic pot condicionar la qualitat assistencial. I, tenint en compte que, una milloria en la qualitat assistencial es correlaciona amb una satisfacció major per part dels usuaris, l'Atenció Primària es podria veure afavorida en tots els sentits.

El present estudi no presenta riscos ni per als professionals ni per als pacients.

Si vostè ho desitgés, se li facilitaria un resum dels resultats de l'estudi.

CONFIDENCIALITAT/PROTECCIÓ DE DADES PERSONALS

Sol·licitem el seu permís per poder dur a terme l'estudi en el CAP que regeix en l'actualitat. Tots els processos realitzats tant amb els professionals mèdics com amb els pacients es trobaran protegits sota la "Llei Orgànica 3/2018, 5 de desembre, de Protecció de Dades personals i Garantia dels Drets Digitals".

DESPESES I COMPENSACIÓ ECONÒMICA

La participació en aquest estudi és voluntària. Per tant, si es decideix participar-hi, no rebrà cap compensació econòmica. La participació en l'estudi no suposarà cap despesa.

CONTACTE

En cas que estigui d'acord en què el seu CAP formi part d'aquest estudi, respongui aquest e-mail indicant en el concepte el nom del seu CAP (ex. DIRECTOR/A CAP MONTILIVI 3) i en el text la seva decisió.

En cas de qualsevol dubte o pregunta, ara i/o durant la realització de l'estudi, podrà posar-se en contacte amb el responsable i coordinador d'estudi.

HOJA DE INFORMACIÓN A LOS/LAS DIRECTORES/AS DE LOS CENTROS DE ATENCIÓN PRIMARIA DE LA REGIÓN SANITARIA DE GIRONA

Nombre del estudio: Avaluación de la Atención Centrada en el/la paciente y su repercusión en la calidad asistencial

Investigador/a principal:

Bienvenido/da,

Nos dirigimos a usted para informarle sobre el estudio de investigación que estamos llevando a cabo en los CAP de la Región Sanitaria de Girona y en el que nos gustaría que el CAP que usted dirige formase parte.

Nuestra intención es que usted reciba la información correcta y suficiente para así poder evaluar y decidir si el CAP que rige, así como los médicos/as y los pacientes de estos, forme parte de este estudio. Lea esta hoja informativa con atención y, si li quedan dudas, se lo aclararemos seguidamente.

PARTICIPACIÓN VOLUNTARIA

La participación en este estudio es voluntaria para todo aquel que quiera formar parte. En caso de que decida que el CAP que dirige forme parte del estudio, los médicos/as que trabajan en este y que siguen criterios de inclusión se les enviará una hoja informativa para que puedan decidir si participan o no. También podrán cambiar su opinión una vez hayan aceptado y retirar su consentimiento en cualquier momento sin que esto les afecte en ningún aspecto.

DESCRIPCIÓ I OBJECTIUS DE L'ESTUDI

Le informamos que este proyecto ha estado previamente aprobado por el Comité de Ética y de Investigación Clínica (CEIC) de la IDIAP JGol.

Para llevar a cabo este estudio se necesitan inicialmente 200 médicos/as especialistas en Medicina de Familia y Comunitaria de la Región Sanitaria de Girona que, una vez hayan leído la hoja informativa del estudio y confirmada su participación, se hará una selección aleatoria 200 profesionales entre todos los voluntarios iniciales.

El objetivo del estudio es valorar el tipo de abordaje clínico que realizan los profesionales médicos con los pacientes para poder objetivar su influencia y los posibles beneficios respecto la calidad asistencial. Para poder valorarlo será necesaria video-gravar 3 consultas diferentes con 3 de sus pacientes.

BENEFICIOS Y RIESGOS DEL ESTUDIO

La participación de sus profesionales, así como la de los pacientes, será importante para poder determinar como el abordaje clínico puede condicionar la calidad asistencial. Y, teniendo en cuenta que, una mejoría en la calidad asistencial se correlaciona con una mayor satisfacción por parte de los usuarios, la Atención Primaria se podría ver favorecida en todos los sentidos.

El presente estudio no presenta riesgos ni para los profesionales ni para los pacientes.

Si usted lo desea, se le felicitaría un resumen de los resultados del estudio.

CONFIDENCIALIDAD/PROTECCIÓN DE DATOS PERSONALES

Solicitamos su permiso para poder llevar a cabo el estudio en el CAP que dirige actualmente. Todos los procesos realizados tanto con los profesionales médicos como con los pacientes se encuentran protegidos por la “Ley Orgánica 3/2018, 5 de diciembre, de Protección de Datos Personales y Garantía de los Derechos Digitales”.

GASTOS Y COMPENSACIÓN ECONÓMICA

La participación en este estudio es voluntaria. Por lo tanto, si se decide participar, no recibirá ninguna compensación económica. La participación en el estudio no supondrá ningún gasto.

CONTACTO

En caso de que esté de acuerdo con el hecho de que su CAP forme parte del estudio, responda este e-mail indicando en el concepto el nombre de su CAP (ej. DIRECTOR/A CAP MONTILIVI 3) y en el texto su decisión.

En caso de cualquier duda o pregunta, ara y/o durante la realización del estudio, podrá ponerse en contacto con el responsable y coordinador del estudio.

6. EXPLANATORY DOCUMENT FOR THE PHYSICIANS

CATALAN VERSION

FULL D'INFORMACIÓ PER EL/LA METGE/SSA

Nom de l'estudi: Avaluació de l'Atenció Centrada en el/la pacient i la seva repercussió en la qualitat assistencial

Investigador/a principal:

Benvolgut/da,

Ens dirigim a vostè per informar-lo sobre l'estudi d'investigació que estem portant a terme en els CAP de la Regió Sanitària de Girona i en el qual se'l convida a participar.

La nostra intenció és que vostè rebi la informació correcta i suficient per què pugui avaluar i decidir si vol participar en aquest estudi. Llegeixi aquest full informatiu amb atenció i, si li queden dubtes, li aclarirem seguidament.

PARTICIPACIÓ VOLUNTÀRIA

Vostè ha de saber que la seva participació en aquest estudi és voluntària. Pot decidir no participar o canviar la seva opinió un cop hagi acceptat i retirar el seu consentiment en qualsevol moment sense que això li afecti a vostè com a sanitari/a.

DESCRIPCIÓ I OBJECTIUS DE L'ESTUDI

L'informem que aquest projecte ha estat prèviament aprovat pel Comitè d'Ètica i d'Investigació Clínica (CEIC) de la IDIAP JGol.

Per portar a terme aquest estudi es necessiten 200 metges/sses especialistes en Medicina de Família i Comunitària de la Regió Sanitària de Girona que, un cop llegit el full informatiu de l'estudi i hagin confirmat la seva participació, es farà una selecció aleatòria de 200 professionals entre tots els voluntaris inicials.

L'objectiu de l'estudi és valorar el tipus d'abordatge clínic que realitza el professional mèdic amb els pacients per tal de poder objectivar la seva influència i els possibles beneficis respecte la qualitat assistencial. Per poder valorar-ho serà necessari vídeo-gravar 3 de les seves consultes amb 3 dels seus pacients.

BENEFICIS I RISCOS DE L'ESTUDI

Es possible que d'aquest estudi vostè no obtingui un benefici immediat però la seva participació és important per poder determinar com l'abordatge clínic pot condicionar la qualitat assistencial.

El present estudi no presenta riscos ni per a pacients ni per als professionals.

Si vostè ho desitgés, se li facilitaria un resum dels resultats de l'estudi.

CONFIDENCIALITAT/PROTECCIÓ DE DADES PERSONALS

Sol·licitem el seu permís per fer la vídeo-gravació de la seva consulta amb el/la seu/seva pacient. Les dades extretes seran utilitzades únicament amb la finalitat de portar a terme l'estudi, de forma confidencial i anònima, sense accés a les mateixes per tercers, i un cop analitzada l'entrevista clínica i obtinguts els resultats, les vídeo-gravacions seran eliminades d'acord la llei vigent "*Llei Orgànica 3/2018, de 5 de desembre, de Protecció de Dades Personals i Garantia dels Drets digitals".*

En la publicació dels resultats es conservarà sempre l'anonimat dels pacients i metges.

Si vostè decideix retirar el consentiment per a participar en aquest estudi, cap de les seves dades seran utilitzades per realitzar l'estudi.

DESPESES I COMPENSACIÓ ECONÒMICA

La participació en aquest estudi és voluntària. Per tant, si vostè decideix participar, no rebrà cap compensació econòmica. La participació en l'estudi no li suposarà cap despesa.

CONTACTE

En cas de qualsevol dubte o pregunta durant la realització d'aquest estudi, podrà posar-se en contacte amb el responsable i coordinador d'estudi.

Tant si vostè està disposat a participar en l'estudi com si no, respongui aquest e-mail indicant en el concepte el seu nom complet i el CAP on treballa (ex. MARIA COTAINA RECIO CAP MONTILIVI 3) i indiqui en el text la seva decisió.

En cas de voler participar, quan es faci l'aleatorització de tots els voluntaris, si ha estat seleccionat, se li farà arribar (al llarg del Setembre o Octubre d'aquest mateix any) un document amb el consentiment informat i les instruccions a seguir a partir d'aquell moment).

HOJA INFORMATIVA PARA EL/LA MÉDICO/A

Nombre del estudio: Avaluación de la Atención Centrada en el/la paciente y su repercusión en la calidad asistencial.

Investigador/a principal:

Bienvenido/a,

Nos dirigimos a usted para informarle sobre el estudio de investigación que estamos llevando a cabo en los CAP de la Región Sanitaria de Girona y en el cual se le invita a participar. Lea esta hoja informativa con atención y después le aclararemos cualquier duda que le pueda surgir.

Nuestra intención es que usted reciba toda la información correcta y suficiente para poder avaluar y decidir si quiere participar en este estudio. Lea esta hoja informativa con atención y después le aclararemos cualquier duda que le pueda surgir.

PARTICIPACIÓN VOLUNTARIA

Usted tiene que saber que su participación en este estudio es voluntaria. Puede decidir no participar o cambiar su opinión una vez haya aceptado y retirar su consentimiento en cualquier momento sin que esto le afecte a usted como sanitario/a.

DESCRIPCIÓN Y OBJECTIVOS DEL ESTUDIO

Le informamos que este proyecto ha estado previamente aprobado por el Comité de Ética y de investigación Clínica (CEIC) de la IDIAP JGol.

Para llevar a cabo este estudio se necesitan inicialmente 200 médicos/as especialistas en Medicina de Familia y Comunitaria de la Región Sanitaria de Girona que, una vez leída la hoja informativa del estudio y hayan confirmado su participación se hará una selección aleatoria de 200 profesionales entre todos los voluntarios iniciales.

El objetivo de este estudio es valorar el tipo de abordaje clínico que realiza el profesional médico con los pacientes para poder objetivar su influencia y los

posibles beneficios respecto la calidad asistencial. Para poder valorarlo será necesario video grabar 3 de sus consultas con 3 de sus pacientes.

BENEFICIOS Y RIESGOS DEL ESTUDIO

Es posible que de este estudio usted no obtenga un beneficio inmediato pero su participación es importante para poder determinar como el abordaje clínico puede condicionar la calidad asistencial.

El presente estudio no presenta riesgos ni para pacientes ni profesionales.

Si usted lo desea, se le facilitaría un resumen de los resultados del estudio.

CONFIDENCIALIDAD/PROTECCIÓN DE DATOS PERSONALES

Solicitamos su permiso para hacer la videograbación de su consulta con su paciente. Los datos extraídos serán utilizados únicamente con la finalidad de llevar a cabo el estudio, de forma confidencial y anónima, sin acceso a las mismas por terceros, y una vez analizada la entrevista clínica y obtenidos los resultados, las videograbaciones serán eliminadas de acuerdo con la ley vigente "*Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y Garantía de los Derechos digitales"*.

En la publicación de los resultados se conservará siempre el anonimato de los pacientes y médicos/as. Si usted decide retirar el consentimiento para participar en este estudio, ninguno de sus datos será utilizado para realizar dicho estudio.

GASTOS Y COMPENSACIÓN ECONÓMICA

La participación en este estudio es voluntaria. Por tanto, si usted decide participar, no recibirá ninguna compensación económica. La participación del estudio no le supondrá ningún gasto económico.

CONTACTO

En caso de cualquier duda o pregunta durante la realización de este estudio, podrá ponerse en contacto con el responsable y coordinador del estudio.

Tanto si usted está dispuesto a participar en el estudio como si no, responda a este email indicando en el concepto su nombre completo y el CAP donde

trabaja (ej. MARIA COTAINA CAP MONTILIVI 3) e indicando en el texto su decisión.

En caso de querer participar, cuando se haga la aleatorización de todos los voluntarios, si usted ha sido escogido, se le hará llegar (a lo largo del Septiembre o Octubre de este mismo año) un documento con el consentimiento informado y las instrucciones a seguir a partir de aquel entonces.

7. INFORMED CONSENT SHEET FOR THE PHYSICIANS

CATALAN VERSION

DOCUMENT DE CONSENTIMENT INFORMAT DE EL/LA METGE/SSA

TÍTOL DE L'ESTUDI: Avaluació de l'Atenció Centrada en el/la pacient i la seva repercussió en la qualitat assistencial

INVESTIGADOR/A PRINCIPAL: .....

CENTRE ATENCIÓ PRIMÀRIA: .....

Jo, el/la Dr/Dra. ..... Amb DNI ..... Afirmo que,

- He rebut una còpia del consentiment informat i llegit el full informatiu que se m'ha lliurat.
- He pogut fer totes les preguntes necessàries respecte a l'estudi i han estat respostes de manera satisfactòria.
- He rebut la informació sobre les característiques i objectius de l'estudi i estic d'acord amb tota la informació rebuda en el document explicatiu.
- He estat informat per el/la investigador/a ..... de les implicacions i la finalitat de l'estudi.
- Entenc que la meva participació és voluntària.
- Estic d'acord amb que les meves dades siguin utilitzades per l'equip d'investigació per a fins relacionats amb l'estudi tot respectant la Llei de Protecció de Dades.
- Autoritzo la realització de la vídeo-gravació de la meva consulta entenent que serà només utilitzada per a fins relacionats en l'estudi, tot respectant la Llei de Protecció de Dades, i les imatges seran eliminades en finalitzar la seva anàlisis.
- Sé que es mantindrà la confidencialitat de les meves dades i es respectarà l'anonimat.
- Dono el meu consentiment de manera voluntària i sé que sóc lliure de retirar-me de l'estudi en qualsevol moment del mateix.

---------- ---------- ----------

(Data) (Nom i cognoms del/la professional) (Signatura del/la professional)

Confirmo que he explicat a el/la metge/ssa el caràcter i el propòsit de l'estudi.

(Signatura de el/la investigador/a)

DOCUMENTO DE CONSENTIMIENTO INFORMADO DE EL/LA MÉDICO/A

TÍTULO DEL ESTUDIO: Avaluación de la Atención Centrada en el/la Paciente y su repercusión en la calidad asistencial

INVESTIGADOR/A PRINCIPAL: ....

CENTRO ATENCIÓN PRIMARIA: .....

Yo, el/la Dr/Dra ..... Con DNI .....
Afirmo que,

- He recibido una copia del consentimiento informado y leído la hoja informativa que se me ha librado.
- He podido hacer todas las preguntas necesarias respecto al estudio y han sido respondidas de manera satisfactoria.
- He recibido la información sobre las características y objetivos del estudio y estoy de acuerdo con toda la información recibida en el documento explicativo.
- He sido informado por el/la investigador/a ..... de las implicaciones y la finalidad del estudio.
- Entiendo que mi participación es voluntaria.
- Estoy de acuerdo con que mis datos sean utilizados por el equipo de investigación para fines relacionados con el estudio respetando la Ley de Protección de Datos.
- Autorizo la realización de la videograbación de mi consulta entendiendo que será solo utilizada para fines relacionados en el estudio, respetando la Ley de Protección de Datos, y las imágenes serán eliminadas al finalizar su análisis.
- Sé que se mantendrá la confidencialidad de mis datos y se respetará el anonimato.

- Doy mi consentimiento de manera voluntaria y sé que soy libre de retirarme del estudio en cualquier momento de este.

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(Fecha) (Nombre y Apellidos del/la professional) (Firma del/la professional)

Confirmo que he explicado a el/la médico/a el carácter y el propósito del estudio.

(Firma del/la investigador/a)

8. EXPLANATORY DOCUMENT FOR THE PATIENTS

CATALAN VERSION

FULL D'INFORMACIÓ PER EL/LA PACIENT

Nom de l'estudi: Avaluació de l'Atenció Centrada en el/la pacient i la seva repercussió en la qualitat assistencial

Centre assistencial:

Investigador/a principal:

Benvolgut/da,

Ens dirigim a vostè per informar-lo sobre l'estudi d'investigació que estem portant a terme en els CAP de la Regió Sanitària de Girona i en el qual se'l convida a participar.
La nostra intenció és que vostè rebi la informació correcta i suficient per què pugui avaluar i decidir si vol participar en aquest estudi. Llegeixi aquest full informatiu amb atenció i després li aclarim qualsevol dubte que li pugui sorgir.

PARTICIPACIÓ VOLUNTÀRIA

Vostè ha de saber que la seva participació en aquest estudi és voluntària. Pot decidir no participar o canviar la seva opinió un cop hagi acceptat i retirar el seu consentiment en qualsevol moment sense que això alteri la relació amb el/la seu/seva metge/ssa i la seva atenció sanitària.

DESCRIPCIÓ I OBJECTIUS DE L'ESTUDI

L'informem que aquest projecte ha estat prèviament aprovat pel Comitè d'Ètica i d'Investigació Clínica (CEIC) de la IDIAP JGol.

En aquest estudi participaran 98 metges/sses especialistes en Medicina de Família i Comunitària de la Regió Sanitària de Girona que, en primer lloc, hagin decidit formar-ne part i que, posteriorment, hagin estat seleccionats/des de forma aleatòria entre tots els/les voluntaris/es. Tots/es aquells/es pacients de els/les professionals escollits/des aleatòriament podran formar part de l'estudi si compleixen els criteris de selecció.

L'objectiu de l'estudi és valorar el tipus d'abordatge clínic que realitza el professional mèdic amb els pacients per tal de poder objectivar la seva influència i els possibles beneficis respecte la qualitat assistencial. Per poder valorar-ho serà necessari vídeo gravar la seva consulta. Així que, en el moment que vostè confirmi la seva participació es procedirà a fer una vídeo gravació de la seva consulta per ser posteriorment analitzada.

BENEFICIS I RISCOS DE L'ESTUDI

Es possible que d'aquest estudi vostè no obtingui un benefici immediat però la seva participació és important per poder determinar com l'abordatge clínic pot condicionar la qualitat assistencial.
Donat que no es realitza cap intervenció sobre els participants no es preveuen riscos ni inconvenients de la seva participació en aquest estudi.

Si vostè ho desitgés, se li facilitaria un resum dels resultats de l'estudi.

CONFIDENCIALITAT/PROTECCIÓ DE DADES PERSONALS

Sol·licitem el seu permís per fer la vídeo-gravació de la seva consulta amb el/la seu/seva Metge/ssa de Família. Les dades extretes seran utilitzades únicament amb la finalitat de portar a terme l'estudi, de forma confidencial i anònima, sense accés a les mateixes per tercers, i un cop analitzada l'entrevista clínica i obtinguts els resultats, les vídeo-gravacions seran eliminades d'acord la llei vigent "*Llei Orgànica 3/2018, de 5 de desembre, de Protecció de Dades Personals i Garantia dels Drets digitals".*

En la publicació dels resultats es conservarà sempre l'anonimat dels pacients. Si vostè decideix retirar el consentiment per a participar en aquest estudi, cap de les seves dades seran utilitzades per realitzar l'estudi.

DESPESES I COMPENSACIÓ ECONÒMICA

La participació en aquest estudi és voluntària. Per tant, si vostè decideix participar, no rebrà cap compensació econòmica. La participació en l'estudi no li suposarà cap despesa.

CONTACTE

En cas de qualsevol dubte o pregunta durant la realització d'aquest estudi, podrà posar-se en contacte amb el responsable i coordinador d'estudi:

HOJA INFORMATIVA PARA EL/LA PACIENTE

Nombre del estudio: Avaluación de la Atención Centrada en el/la paciente y su repercusión en la calidad asistencial.

Centro asistencial:

Investigador/a principal:

Bienvenido/a,

Nos dirigimos a usted para informarle sobre el estudio de investigación que estamos llevando a cabo en los CAP de la Región Sanitaria de Girona y en el cual se le invita a participar. Lea esta hoja informativa con atención y después le aclaramos cualquier duda que le pueda surgir.

Nuestra intención es que usted reciba toda la información correcta y suficiente para poder avaluar y decidir si quiere participar en este estudio. Lea esta hoja informativa con atención y después le aclararemos cualquier duda que le pueda surgir.

PARTICIPACIÓN VOLUNTARIA

Usted tiene que saber que su participación en este estudio es voluntaria y puede decidir no participar o cambiar su opinión una vez haya aceptado y retirar su consentimiento en cualquier momento sin que esto altere la relación con su médico/a y su atención sanitaria.

DESCRIPCIÓN Y OBJETIVOS DEL ESTUDIO

Le informamos que este proyecto ha estado previamente aprobado por el Comité de Ética y de investigación Clínica (CEIC) de la IDIAP JGol.

En este estudio participaran 98 médicos/as especialistas en Medicina de Familia y Comunitaria de la Región Sanitaria de Girona que, primero hayan decidido formar parte de él y que, posteriormente, hayan estado seleccionados de forma aleatoria entre todos/as los/las voluntarios/as. Todos/as aquellos/as pacientes de los/las profesionales elegidos/as aleatoriamente podrán formar parte del estudio si cumplen los criterios de selección.

El objetivo de este estudio es valorar el tipo de abordaje clínico que realiza el profesional médico con los pacientes para poder objetivar su influencia y los posibles beneficios respecto la calidad asistencial. Para poder valorarlo será necesario video grabar su consulta. Así que, en el momento en que usted confirme su participación, se procederá a hacer una video grabación de su consulta para ser posteriormente analizada.

BENEFICIOS Y RESGOS DEL ESTUDIO

Es posible que de este estudio usted no obtenga un beneficio inmediato pero su participación es importante para poder determinar como el abordaje clínico puede condicionar la calidad asistencial.
El hecho de que no se realice ninguna intervención sobre los participantes hace que no haya riesgos ni inconvenientes de su participación en este estudio.

Si usted lo desea, se le facilitaría un resumen de los resultados del estudio.

CONFIDENCIALIDAD/PROTECCIÓN DE DATOS PERSONALES

Solicitamos su permiso para hacer la videograbación de su consulta con su Médico/a de Familia. Los datos extraídos serán utilizados únicamente con la finalidad de llevar a cabo el estudio, de forma confidencial y anónima, sin acceso a las mismas por terceros, y una vez analizada la entrevista clínica y obtenidos los resultados, las videograbaciones serán eliminadas de acuerdo con la ley vigente "*Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y Garantía de los Derechos digitales"*.

En la publicación de los resultados se conservará siempre el anonimato de los pacientes. Si usted decide retirar el consentimiento para participar en este estudio, ninguno de sus datos será utilizado para realizar dicho estudio.

GASTOS Y COMPENSACIÓN ECONÓMICA

La participación en este estudio es voluntaria. Por tanto, si usted decide participar, no recibirá ninguna compensación económica. La participación del estudio no le supondrá ningún gasto económico.

CONTACTO

En caso de cualquier duda o pregunta durante la realización de este estudio, podrá ponerse en contacto con el responsable y coordinador del estudio.

9. INFORMED CONSENT SHEET FOR THE PATIENTS

CATALAN VERSION

DOCUMENT DE CONSENTIMENT INFORMAT DE EL/LA PACIENT

TÍTOL DE L'ESTUDI: Avaluació de l'Atenció Centrada en el/la Pacient i la seva repercussió en la qualitat assistencial.

INVESTIGADOR/A PRINCIPAL: .....

CENTRE ATENCIÓ PRIMÀRIA: .....

Jo, el/la Sr/Sra ..... Amb DNI ..... Afirmo que,

- He rebut una còpia del consentiment informat i llegit el full informatiu que se m'ha lliurat.
- He pogut fer totes les preguntes necessàries respecte a l'estudi i han estat respostes de manera satisfactòria.
- He rebut la informació sobre les característiques i objectius de l'estudi i estic d'acord amb tota la informació rebuda en el document explicatiu.
- He estat informat per el/la investigador/a ..... de les implicacions i la finalitat de l'estudi.
- Entenc que la meva participació és voluntària.
- Estic d'acord amb que les meves dades siguin utilitzades per l'estudi indicat de forma anònima.
- Accepto que les dades de la meva història clínica siguin utilitzades per l'equip d'investigació per a fins relacionats amb l'estudi tot respectant la Llei de Protecció de Dades.
- Autoritzo la realització de la vídeo-gravació de la meva consulta entenent que serà només utilitzada per a fins relacionats en l'estudi, tot respectant la Llei de Protecció de Dades, i les imatges seran eliminades en finalitzar la seva anàlisis.
- Sé que es mantindrà la confidencialitat de les meves dades i es respectarà l'anonimat.
- Dono el meu consentiment de manera voluntària i sé que sóc lliure de retirar-me de l'estudi en qualsevol moment del mateix.

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(Data) (Nom i cognoms del/la participant) (Signatura del/la participant)

Confirmo que he explicat a el/la pacient el caràcter i el propòsit de l'estudi.

(Signatura de el/la investigador/a)

DOCUMENTO DE CONSENTIMIENTO INFORMADO DE EL/LA PACIENTE

TÍTULO DEL ESTUDIO: Avaluación de la Atención Centrada en el/la Paciente y su repercusión en la calidad asistencial

INVESTIGADOR/A PRINCIPAL: .....

CENTRO ATENCIÓN PRIMARIA: .....

Yo, el/la Sr/Sra ..... Con DNI .....
Afirmo que,

- He recibido una copia del consentimiento informado y leído la hoja informativa que se me ha librado.
- He podido hacer todas las preguntas necesarias respecto al estudio y han sido respondidas de manera satisfactoria.
- He recibido la informaciǿn sobre las características y objetivos del estudio y estoy de acuerdo con toda la información recibida en el documento explicativo.
- He sido informado por el/la investigador/a ..... de las implicaciones y la finalidad del estudio.
- Entiendo que mi participaciǿn es voluntaria.
- Estoy de acuerdo con que mis datos sean utilizados por el estudio indicado de forma anónima.
- Acepto que los datos de mi historia clínica sean utilizados por el equipo de investigaciǿn para fines relacionados con el estudio respetando la Ley de Protección de Datos.
- Autorizo la realización de la videograbación de mi consulta entendiendo que será solo utilizada para fines relacionados en el estudio, respetando la Ley de Protección de Datos, y las imágenes serán eliminadas al finalizar su análisis.
- Sé que se mantendrá la confidencialidad de mis datos y se respetará el anonimato.

- Doy mi consentimiento de manera voluntaria y sé que soy libre de retirarme del estudio en cualquier momento de este.

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(Fecha) (Nombre y Apellidos del/la participante) (Firma del/la participante)

Confirmo que he explicado a el/la paciente el carácter y el propósito del estudio.

(Firma del/la investigador/a)