Cover Letter

ClinicalTrial.gov

Here by we present the data from the Clinical Trial that it is being carrying out in Argentina using a Dietary Supplement based on sea urchin eggs with Echinochrome A.

We present the formal Information, Protocol and Informed Consent in this Document.

Formal Information:

Clinical Trial at Hospital Santojanni in Argentina

Approved by Ethic Committee of the Hospital

Approval´s Number: 5832

Date of approval: September 22th of 2021

Title: COVID-19 Sequelae: Treatment and Monitoring. A Dietary SupplementBased on Sea Urchin Eggs With Echinochroma A

Support by a Grant from the Ministry of Science, Technology and Innovation of Argentina.

PROTOCOL

COVID-19 Sequelae: Treatment and Monitoring. A Dietary Supplement Based on Sea Urchin Eggs With Echinochroma A

INTRODUCTION

It is estimated that 20% of patients hospitalized for COVID-19 will have persistent symptoms after 5 weeks and 10% after 12 weeks. However, in non-hospitalized patients it was found that between 32.6% and 87.4% present at least one persistent symptom after months of having suffered from COVID-19. To signs and symptoms that began during COVID-19 infection or after her, and last beyond 12 weeks from the date of onset of symptoms, and not can be explained by alternative diagnosis is called persistent COVID. The The importance of this syndrome was warned by the WHO on October 30, 2020 by its Director General due to the number of people with this condition and the effects on their health. However, it only physical symptoms are considered and the mental health of patients is not included, although addressing this appearance is an integral part of your ref health. Being multisystemic, this syndrome requires an approach multidisciplinary, capable of studying physical, cognitive, psychological and social aspects. So far, it is known that persistent COVID syndrome can have disabling consequences for prolonged periods. These sequelae can involve a wide variety of symptoms, from extreme fatigue, muscle and joint pain, shortness of breath, palpitations, loss permanent loss of taste and smell, gastrointestinal upset, and problems with attention, memory, and cognition. However, the exhaustive understanding of the syndrome, its monitoring and the search for treatments singles have not yet been determined. The Decentralized Medical Trials Manual of the Association of Research Organizations Clinic (ACRO) recommends decentralized medical testing or partially decentralized, organized around the patient. Decentralization refers to monitoring of patients from their place of residence to prevent them from going to health centers in regular way. The decentralization can be total or partial depending on whether duringthe treatment they never go to a health center or do so occasionally. These types of studies canbe carried out through the use of telemedicine and artificial intelligence tools, the use of remotevisits and visits to the patient's home to carry out the collection of biological samples necessaryfor carry out the study. On the other hand, the design around the patient is intended to be friendly and allow the patient's perspective to be at the heart of the study, considering the patient's well-being from a comprehensive perspective (clinical and psychological). This approach allows the patient to know their perspective of physical and emotional health and feelaccompanied throughout the clinical study, which improves patient adherence to the clinical trial. There are no specific treatments yet for persistent COVID syndrome, and given the range of symptoms persistent, treatments should focus on generating a systemic improvement of thepatient, especially for improve her quality of life. Echinochroma A (EchA) is a pigment derived from sea urchins which is known for its antioxidant power and its proven benefits for human health, especially heart disease and inflammatory pathologies. Oral administration of EchA in patients with syndrome Persistent COVID can bring many benefits: reduced inflammation, elimination of ROS and the induction of glutathione (GSH) pathways, among the most prominent. Also, due to the pharmacological activities of EchA, its low level of toxicity and high bioavailability, is hypothesized which will contribute highly positive clinical benefits to patients with sequalae from COVID. Therefore, the objective of this project is to carry out a partially decentralized study around the patient with COVID-19 sequalae from a multidisciplinary perspective, with an intervention when administering a Dietary supplement based on sea urchin roe rich in Echinochrome A.

Objectives and Hypothesis

1 To perform an outpatient treatment with a Dietary supplement based on sea urchin roe rich in Echinochrome A in patients with sequalae from COVID-19.

a - H1-1: The Dietary supplement improves the clinical status of patients with COVID-19 sequelae

Justification: Treatment with the Dietary supplement rich in Echinochrome A is expected to activate the metabolism of glutathione, improves the functioning of the mitochondria, decreasing the cellular oxidation state and general inflammation of the endothelium, generating an improvement in the clinical status of patients and reducing your recovery time.

b - H1-2: The Dietary supplement based on sea urchin roe rich in Echinochrome A reduces the recovery time of patients with sequelae from COVID-19

Justification: Treatment with the Dietary supplement by activating the metabolism of glutathione and decrease cell oxidation and inflammation of the endothelium, reduces recovery time of the patient.

2 Perform a multidisciplinary follow-up of the evolution of the patient with COVID sequalae, involving clinicians, pulmonologists, neurologists, counselors, biochemists and Researchers.

a - H2-1: The multidisciplinary approach allows a deep understanding of the symptoms of the sequalae from COVID and its evolution

Justification: This approach will allow for a comprehensive analysis. Can be tracked simultaneous clinical, neurological, neurological, cardiological, psychological, biochemical approach, with a adequate analysis of the data, allowing a deeper understanding of the symptoms.

b - H2-2: The multidisciplinary approach generates high adherence to the study and allows a emotional accompaniment of patients, improving their mood Justification: the multidisciplinary approach will allow comprehensive monitoring of patients and increase knowledge about the persistent symptoms found in the patients with sequalae from COVID-19. In addition, psychological support will increase the patient's adherence to treatment and will improve your emotional state when accompanied.

3 Follow up with patients on a daily basis using a partially decentralized through the use of telemedicine in patients with the COVID sequalae.

a - H3-1: The partially decentralized approach by telemedicine allows a daily follow-up of the symptoms of patients with sequalae from COVID, thus relieving the health system

Justification: Daily telemedicine follow-up will decrease the frequency with which patients approach or communicate with doctors, relieving the daily tasks of health personnel and administrative work that normally involves a medical test, obtaining high-quality data anyway.

b - H3-2: The partially decentralized by telemedicine allows the emotional accompaniment of the patients increasing their adherence to the study and improving their mood and emotional state.

Justification: The decentralized design is focused on the well-being of the patient, providing a daily accompaniment by telemedicine and emotional weekly. In addition, patients can Communicate through the telemedicine system in case of doubts or concerns, providing greater

security. As well as they will be able to have access when requesting it of their progress to be able to understand how they evolve the consequences.

Partially decentralized design focused on the patient.

It is proposed to make a partially decentralized design around the patient following the ACRO recommendations. These studies use digital technologies to optimize resources of the health system and to allow the patient to have daily contact with the objective to accelerate the production of results and create an efficient dynamic of the research process. This type of design puts the patient at the heart of interactions and allows for more efficient bonding of all the actors involved. In this case, the patient with symptoms of persistent Covid-19 is detected in the Hospitals, the treatment is offered to the patient according to medical criteria, the patient's file is filled out with the clinical history and through informed consent, the participant is recruited in this comprehensive care model with intervention. We proceed to complete the Digital Entry Form of the patient where their data is uploaded and a photo of the informed consent document is attached signed, the group of CONICET-UNPSJB Researchers receives the information about the patient and by randomized algorithm, the delivery of the nutraceutical or the placebo is determined and sent to the patient's address along with pertinent information. The ID of each patient in the entire Health System telemedicine will be your ID. Once loaded, the link of the digital self-tests will be sent to your WhatsApp designed for this study, which the patient must complete and send daily as a health report and you can use it whenever she needs it. SKYMED is governed by Law 25,326 on Data Protection Personal and Law 26,529 of the Right of the Patient and has the due Confidentiality Agreements that protect and commit all parties in your application during the use of the platform. Starting from that moment the Muñiz Hospital Hemostasis Team and the Team of Psychological Consultants Receive patient information. From here, through the calendar of the telemedicine system SKYMED organizes shifts for each patient with Hospital Muñiz for blood collection, interviews with the psychological accompaniment and the medical follow-ups by the different doctors and hospitals involved. The patient fills out the form every day and this information can be monitored instantly. If the patient has symptoms that show deterioration, sends an alert to the medical team through the triage system that SKYMED has based on artificial intelligence. The patient has an instant messaging interface to make inquiries during the treatment in addition to the weekly interviews with the team of psychological consultants and the Monthly visits to hospitals. The evolution of the patient is carried out weekly and at the end of the study the results are already very advanced to be able to conclude on them. This approach seeks to accompany the patient throughout the medical study from a multidisciplinary, considering the practical aspect of decentralization with the emotional care that patients with persistent COVID syndrome require.

The SKYMED telemedicine system has been used successfully for a year in Chubut (Lago Puelo) and uses the key performance indicators (KPIs) established by the WHO for the care of COVID-19, in order for the doctor to evaluate the patients, and, with the help of the artificial intelligence digital technology, early detection of symptoms that are considered within a serious picture to send alerts to the health system. For this particular study, it was adapted the system with a design and interface or dashboard based on the KPIs specified by the team medical, scientific and psychological consultants, for the monitoring of the participants, the collection and data processing, and immediate accessibility to the results in the interface on a cell phone, tablet or PC of patients with COVID-19 sequalae. Since there are very few scales around the patient that adequately reflect the clinical situation of patients with sequalae from COVID-19 and that

evaluates its evolution in a comprehensive way to integrate symptom monitoring so that in-depth symptom assessment is possible; It will be used a brief and easy-to-use self-report questionnaire that will consist of different scales to perform a comprehensive assessment and can be used for repeated measurements over time to monitor the progress. The scales were selected according to the recommendations of Sanz Almazán et al (2021), who analyzed which would be the most appropriate scales to assess persistent symptoms that found in the persistent COVID syndrome, as well as its limitations and possible improvements. So daily clinical data will be evaluated. The questionnaire that assesses mood will have a psychoeducational functionality in itself since it will provide self-exploration and self-management tools emotional that will be answered 2 times a week.

In SKYMED, the patient completes the entire questionnaire at the indicated frequency. The system sends reminders to take the surveys at different times of the day and/or week to ensure your compliance. In turn, doctors, psychological and biochemical consultants can upload the information that they collect per patient. The scientists of the team will carry out the analyzes on a weekly basis during the study as the data is collected by the SKYMED system. The final report will be once the study is completed.

The psychological accompaniment will be carried out through a weekly virtual Zoom meeting of 30 minutes during the three months of treatment with the psychological consultant, in which he will be given accompaniment and emotional support hoping to sustain their adherence to it (Centered Approach in the Person. Likewise, face-to-face evaluations will be carried out with specialist doctors, at the beginning of the medical test and once a month after beginning the treatment, until its completion. In these evaluations will carry out a complete clinical and psychological study. Face-to-face evaluations are also carried out with the specialists, at the beginning of the medical test and once a month after starting the treatment, until its completion. In these evaluations, a complete clinical study will be carried out, evaluating the presence of cough, chest pain, dyspnea by mMRC scale, quality of life by EuroQOL scale, spirometry will be performed (FVC, FEV1, FEV1/FVC), the walk test of 6 minutes, a HRCT of the Chest, an electrocardiogram, the evaluation of fatigue measured with the MFI scale, the cognitive evaluation will be carried out with the MMSE (minimental State) scale, ACE-R (Addenbrooke's Cognitive Examination), attention by San of Digits forward, Digits and signs (WAIS-III), Trial Making A and Stroop Test; executive function with Trial Making B, word generation (phonological verbal fluency), FAB (Frontal Assessment Battery), clock test (on command) and analogies (WAIS-III); Language will be evaluated with the Boston Nomination Test and through semantic verbal fluency; Verbal Memory will be evaluated by the RAVLT test (Rey auditory verbal learning test), Visual Memory with the Rey Figure (evocation and recognition), Visuospatial ability with the Rey Figure (copy) and the clock test (Copy) and Mood assessment with the Beck Inventory. Finally, blood samples will be taken from the patients to perform a complete blood count, platelets, white blood cells and formula in absolute and relative values, C-Reactive Protein, Ferritin, D-Dimer and Von Willebrand Factor.

SKYMED telemedicine

The telemedicine System and Remote Patient Control SKYMED complies with the quality standards established in the Design Quality Manual for ACRO Decentralized Clinical Trials (Association of Clinical Research Organizations for its acronym in English), regarding the possibility of entering data by the patient and the equipment intervening remotely, as well as

that the system is subject to the laws and regulations of data protection and privacy that regulate these types of data released. It also meets the Total Quality Control standards, having been tested with constant improvement in use for 13 months for COVID-19 control, providing connectivity and solid infrastructure because it ensures the integrity and security of electronic records, accuracy and precision of measurements, technological solutions are fit for purpose. In addition, a user manual is provided where the flow and collection of data is described, it has backup backup of the entire system, storage, filing and availability for retrieval of source documents and information electronics during and after the test. On the other hand, there is a management plan in case of failure for all the parties, they are trained to use the system and adequate support is provided to all parties, articulating the investigators in a clear manner the procedures for decentralized clinical trials, it is added efficiency, cost savings by reducing waste and contributes to reducing climate change. The risk is minimized because: users are restricted with the use of unique and non-transferable credentials for entry into the system; there is no resistance to change because users and participants are willing to the use already proven in effectiveness of SKYMED, interfaces of known use and easy access are used, and alternative plans exist if a participant is unable to access for any reason; assistance is provided permanent technique to ensure effectiveness in the design of the system infrastructure; the system has optimal technological interoperability and data integration; constant training is given to new processes to all users; the best security standard is provided with the best provider technological; there is an optimal governance structure; It has a large data loading space that prevents system overload; SKYMED lowers costs and provides efficiency in studies focused on the patient minimizing the administrative work of the evaluation team and providing access to information processed and reliable for strategic decision making 24 hours a day, 7 days a week.

Ethical and environmental safeguard

This research project will not affect human rights nor will it be the cause of any eventual damage to the environment, animals and/or future generations. All work done previously carried out in compliance with the Biosafety and Environmental Safety Standards in force, so its realization will not have any impact on the environment. Biological material (blood samples human) will be processed in a biological safety cabinet and all the elements and reagents used properly discarded following the standards indicated by the Health and Safety Committee of the Hospital F. J. Muñiz. In this sense, the Hospital has a pathological waste management service. On the other hand, the methodology included in this project has been endorsed by the Ethics Committees of the hospitals.

Physicians will invite patients and/or their immediate family members to participate in the research study, explaining in a detailed and understandable way the characteristics of the study and future studies related to sequelae in COVID-19. Informed consents are approved by the Committees of Ethics and/or Teaching and Research of the Hospitals involved. In Argentina there is a law that protects personal information (Law No. 25,326 on Data Protection Personal) that establishes the integral safeguard of data settled in files or records, be they public or private, to guarantee the right to honor and privacy of people. When is made reference to "Client's personal data" is about the personal data of which the Institutions authorized are controllers and that OcusCloud processes in the course of providing the SaaS (Software as a service) SkyMeD. The terms "controller", "processor", "process", "processed", processing" and "personaldata" used, are defined according to the Union Directive 95/46/EC European Union, except as defined by the corresponding data protection legislation. OcusCloud guarantees under the

clauses of a confidentiality agreement, in all media / systems that are under its control and guardianship, the implementation of the technical and organizational measures that are necessary to protect the data provided. There is also Law 26,529 of the Right of the Patient, in force since February 2010, which regulates the civil relations between the patient with the doctors and with the institutions of Health and legislates on the information that the doctor must give and that the patient must receive regarding clinical documentation. The information and clinical documentation of the patient has the due protection of its privacy and the confidentiality of its sensitive data. This includes the statistical secrecy, in relation to the development of databases in the health system, by which the statements and/or individual information may not be communicated to third parties or used, disseminated or published in such a way as to allow the person or entities to be identified. sensitive data related to the patient are protected by confidentiality and privacy as well as by the data from the investigation. Only researchers will have access to this information directly related to the trial and the members of the Teaching and Research Committees and/or Hospital Ethics. All adverse effects will be reported to the Ethics Committees instantly according to current national laws, whether or not associated with the administered product. The researchers participating in this project know and carry out the safeguards provided for in all ethical, legal and legal requirements, establishedin the National bioethical standards -ANMAT provision 5330/97- and International -NurembergCode, declaration of Helsinski version 2008 and its modifications, universal declaration on the human genome and human rights approved by the General Conference of UNESCO 2005 and according to the regulations of the International Declaration on the human genetic data UNESCO2003, the Universal Declaration on Bioethics and guidance for Human Health Research (GISH), resolution 1480/2011 MSN. The counselors involved they know and follow the rules of the Professional Code of Ethics of the Argentine Association of Counseling.

INFORMATION FOR THE PARTICIPANT AND WRITTEN INFORMED CONSENT FORM

COVID-19 Sequelae: Treatment and Monitoring. A Dietary Supplement Based on Sea Urchin Eggs With Echinochroma A.

Location: Hospital Santojanni.

Responsible MD: Dr. Fernando Saldarini

Telephone: 011 3703-0712

Address: Pilar 950, Buenos Aires

Dear Participant

You have been invited to participate in a basic science research study where you want to study that Echinochroma A extracted from sea urchin roe alleviates the symptoms of COVID 19 with comorbidities. This research is different from healthcare practice, however, it is combined with it as we will use your clinical data obtained from healthcare for this research work. Before deciding whether or not to take part, it is important for you to know why the study is being done and what it will involve. Please take some time to read this information. If you wish, discuss this with family members, friends, your personal doctor, or your study doctor. Please ask if anything is not clear or if you would like more information.

Why is this study being done?

The SARS-CoV-2 virus caused the COVID-19 pandemic very quickly. This virus is new, highly contagious and has caused almost 3 million deaths globally to date, especially patients with comorbidities. The pathogenesis produced by the viral infection caused by SARS-CoV-2 in humans is still unclear and there is no effective treatment to prevent contagion or treat the disease. In severe cases, the virus induces the Cytokine Storm Syndrome characterized by the massive release of cytokines, being the main cause of death among patients infected with COVID-19. During the Cytokine Storm, pro-inflammatory cytokines are released in excess, resulting in overwhelming systemic inflammation, hemodynamic instability, multi-organ dysfunction, sepsis, fever, hyperferritinemia, and, in many cases, death. COVID-19 patients with pre-existing comorbidities may present with Cytokine Storm and coagulopathies that may progress to a severe stage. Therefore, the objective of this study is to be able to provide a nutraceutical to patients on an outpatient basis that prevents cases from getting worse and having to be hospitalized in the health system. Thus obtaining two results simultaneously: the benefit to the person and the health system. Having already spent more than a year since the start

of the pandemic, facing an imminent second wave and with the precarious health system in our province and extremely in demand; We hope that our development from the scientific system and with the accompaniment of the private sector can be beneficial.

Who can participate in this study?

Persons over 18 years of age with a positive diagnosis of COVID-19 determined by PCR or other commercial or public health assay in any sample and have one with comorbidity

What does this study include?

If you choose to participate, you will need to fill in your details in the SkyMed Telemedicine System. The data that will be requested to start is sex, age, weight, comorbidity and contact data. A blood sample will be obtained to study the concentration of the CR protein, proinflammatory cytokines IL-6 and TNF-α, total peroxidase activity, total oxidant activity, free radicals in plasma, the proportion of CD95+ and the HLA-DR antigen. The SkyMed System is governed by Law 25,326 on the Protection of Personal Data and Law 26,529 on the Right of the Patient.

What is being investigated to help people with covid 19 with comorbidity?

The purpose of this study is to test whether Echinochroma A can be used in the treatment of COVID-19 to relieve symptoms in patients with comorbidities. The information obtained from your data, including, does not imply that it has direct relevance to you or your family, since it is an investigation that must be repeated before drawing definitive conclusions. However, it can be useful in the course of the disease.

How many people will participate in this study?

Approximately a number of not less than 70 people, with a diagnosis of COVID-19 and comorbidities. Half will be administered Echinochroma A and the other half a double-blind placebo.

Are there any risks or discomforts involved?

Pain or discomfort in drawing blood. In some cases, a hematoma may appear at the site of the blood draw. Some people feel faint when blood is drawn.

Are there any benefits?

This study could benefit your health status when you are infected with COVID-19. In addition, the fact of voluntarily participating in the study allows you to have access to the information on the results of the determinations that are made. Also, you have the right to decide not to be informed about your results. In both cases, you must inform SkyMed of your decision to know or not know about your results**.**

Payment to participants / expenses / costs

There will be no cost to you for any laboratory tests or procedures. You will not receive any payment for participating in this study.

Funding source:

Ministry of Science, Technology and Productive Innovation of the Argentine Nation.

Voluntary participation/withdrawal from the study

Your participation in this study is voluntary. If you decide to participate, you will be asked to sign the informed consent at the end of this document and keep a copy of it and this information sheet. You have the right not to participate. Likewise, you have the right to withdraw your consent at any stage of the investigation, without suffering any discrimination, penalty or prejudice. You must report through SkyMed if you decide to do this. Your decision not to participate in this study or to discontinue your participation in the study will not affect your current or future health care, or any other benefits to which you are entitled in any way. If you withdraw from the study, your data will not be used. The signing of this informed consent does not imply the loss of the rights that legally correspond to you according to the laws in force in Argentina.

Confidentiality

If you decide to participate in the study, you will be asked for personal information. For your security, in Argentina there is a law that protects this information (Law No. 25,326 on the Protection of Personal Data). This Law also gives you the right to have access to all the data collected about you in the study. The doctors and staff of the study, as well as the Research Ethics Committee of the Hospital that reviewed this study, and the Research Ethics Committee of the MSGCBA may have access to your personal information if they consider it necessary and are obliged to respect the law that protects your personal information. In this written consent, it is stated that the data obtained will be handled with absolute confidentiality, with only the research team, the Teaching Committee and the Research Ethics Committee of the institution having access to them. In the event that the data is presented at congresses or published in national or international publications, the identity of each participant will be fully protected. The identification of the sample will

only be possible to recognize by the principal investigator, since the sample is coded by encrypting it with the patient's initials and an internal reception number of the laboratory.

Who should I contact with any questions?

- If you wish to ask any questions related to the nature of the research during the study, please contact those responsible for the study through SkyMed.

- If you have questions about your rights as a research subject or about your participation in the study, you can contact: Dr. Alejandra Oviedo. RESEARCH ETHICS COMMITTEE CEI SANTOJANNI, ceisantojanni@gmail.com, PHONE. 011 46305848

INFORMATION FOR THE PARTICIPANT AND WRITTEN INFORMED CONSENT FORM

COVID-19 Sequelae: Treatment and Monitoring. A Dietary Supplement Based on Sea Urchin Eggs With Echinochroma A.

Location: Hospital Santojanni.

Responsible MD: Dr. Fernando Saldarini

Telephone: 011 3703-0712

Address: Pilar 950, Buenos Aires

I declare that I have been invited to participate in the research study on COVID-19 Sequelae: Treatment and Monitoring. A Dietary Supplement Based on Sea Urchin Eggs With Echinochroma A. 2.6

I have received information from Dr/a… .....(name and surname) about this research study and I have been able to ask questions, which were answered satisfactorily. I have understood the information received from the research study. I understand that my participation is voluntary and that I can withdraw from the study at any time, without giving reasons, and without affecting the health care that I should receive if I do not participate or withdraw from the research study. I agree to participate in this research, keeping a copy of the information sheet and the informed consent form for myself.

- Signature of the participant Name and surname:

DNI Nº:

Place and date:

- Signature of the witness** Name and surname:

DNI Nº:

Place and date:

- Signature of the researcher Name and surname:

DNI Nº:

Place and date:

As Principal Investigator and/or collaborator of the study, I agree to comply with the approved protocol, Law 3301, its Regulatory Decree, and any other regulation related to the Research protocol, adjusting to the universally proclaimed and cited ethical values and principles. in this Law and to respect the rights of the subjects participating in this research study during the conduct of this study.

** The witness must be present at the moment when the researcher and/or the person who obtains the informed consent explains its content to the participant.

INFORMED CONSENT FOR THE PARTICIPANT IN THEIR MONITORING, SUPPORT AND EMOTIONAL SUPPORT BY A PSYCHOLOGICAL CONSULTANT

COVID-19 Sequelae: Treatment and Monitoring. A Dietary Supplement Based on Sea Urchin Eggs With Echinochroma A.

Name and Surname of the Participant Patient/Consultant: ……

DNI: ……

Contact cell phone: …… Third person contact information …….

Please read this document carefully, it may contain phrases or words that you cannot understand. If so, please ask the treating professional to explain in detail any information that you do not clearly understand. By signing this document, you will be accepting its content and giving your consent to the conditions detailed here.

Characteristics of Follow-up, Accompaniment and Emotional Containment

Follow-up and accompaniment will be carried out with the orientation of the Person-Centered Approach from the Psychological Consultancy/Counseling for emotional support for psychoeducational purposes, prevention and promotion of the holistic well-being of the patient/consultant, as a joint work of the partially decentralized approach by telemedicine focused on the person who participates voluntarily and is selected for this study for being a patient with COVID-19 sequelae and aimed at attending to the reasons for consultation exposed. This agreement is between the patient involved in the study, hereinafter called Consultant and treating professional, hereinafter called Psychological Consultant.

Duration and Modality in the Follow-up, Accompaniment and Emotional Containment Process

1. The duration of the follow-up and accompaniment will be only and for the duration of the permanence of the consulting participant, in the present study (three months). The process is individual and will be developed within the framework of virtuality, using the SkyMed tool on the one hand, and the encrypted information videoconferencing platform/system (Zoom, Skype, Googlemeet) or messaging for personal use (WhatsApp on the other). /facetime).

A-When you contact the Psychological Consultant for the first time, you will receive a WhatsApp message in response where you will be asked for additional consent for the use of the videoconference or video call

B-Procedure in technological failures: The internet connection can be interrupted, both for the professional and for the patient/consultant. This circumstance is protocolized. Two scenarios can occur, mainly:

• The connection suffers interruptions or is not fluid, so it will be agreed to keep the meeting through a phone call or re-schedule it in order to have optimal communication.

• The connection is cut and it is not possible to resume it. You will be contacted by another means, audio or text, in order to notify that it is not possible to carry out the session and proceed to re-schedule it.

2. The frequency of the meetings will be weekly. Its duration will be 30 minutes, and there may be variations depending on what happens during the meeting.

3. The absence to 2 (two) consecutive meetings will be interpreted as an abandonment of the process. If you want to restart, you must contact SkyMed.

Cancellation of the Meeting

1. In order to maximize the effectiveness of care services, in follow-up, accompaniment and emotional support, I will make the listening space a high priority and I will not cancel meetings, except in cases of emergency. The Psychological Consultant lends his availability free of charge, please consider the commitment and valuation of this time informing of a possible cancellation of a meeting at least 24 hours in advance. If I connect late to a meeting, I understand that I will use only the time remaining in the scheduled meeting.

Emergency

1. Online meeting is not and does not cover emergency services. In the case of an emergency, I must dial the emergency number in my area, contact my doctor through SkyMed or go to the emergency room/call of any hospital closest to my place of residence.

Payment of Fees

1. Assistance is provided free of charge and I must not pay any monetary value to the professional Psychological Consultant.

Privacy and Confidentiality

1. Data related to follow-up care, accompaniment and emotional support follow the regulations mentioned above in the “INFORMATION FOR THE PARTICIPANT AND WRITTEN INFORMED CONSENT FORM”.

Supervision – Co-vision

1. In the event that some aspects of my professional care require the supervision of a supervising professional Psychological Consultant and/or Psychologist, you will be able to access my clinical history and personal information for treatment purposes, and I will be notified in advance. .

Clinical History-Reports

1. Through the SkyMed tool, I will complete a survey to provide information about my mood and emotional state during my participation in the study, and on the other hand, my Psychological Consultant may collect personal information about me to incorporate in my story clinic.

2. The documentation must be kept in a safe place for a minimum of 5 to 10 years after the last date of contact to be designated by the regulations of the Investigation.

Evolution of the Follow-up, Accompaniment and Emotional Containment Process

1. The process may be unilaterally interrupted by the consultant at the time he/she deems appropriate, informing the professional of this decision, who will assess whether this interruption may be detrimental to himself or third parties, reserving the right to notify the professional. who he considers responsible.

2. Confidentiality and due secrecy are guaranteed regarding the information received in professional practice, whose limit may only be violated for a just cause, in accordance with the provisions of the codes of ethics and current legal regulations, or before the possibility of harm to himself or third parties.

3. The consultant undertakes to comply with the indications that the treating professional gives him, in the case of considering necessary a medical, psychological and/or psychiatric interconsultation or a referral to another institution.

I hereby certify that:

● All the personal data that I have provided for the preparation of the clinical history are true.

● I have received sufficient information about the follow-up, accompaniment and emotional support that will be provided to me and I have understood all the requirements and conditions to carry it out.

● That I have been informed of the administrative conditions regarding the payment of fees.

- Signature of the participant Name and surname:

DNI Nº:

Place and date:

- Signature of the witness** Name and surname:

DNI Nº:

Place and date:

- Signature of the researcher Name and surname:

DNI Nº:

Place and date: