Effects of an ACT-based Psychological Treatment in Patients with Chronic Kidney Disease

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Informed consent form

INFORMED CONSENT FORM TO PARTICIPATE IN THE RESEARCH:

"Effects of an ACT-based Psychological Treatment in Patients with Chronic Kidney Disease"

We would like to invite you to participate in a clinical research study. Our intention is that you receive correct and enough information so that you can evaluate whether or not you want to participate in this study. Please read this information sheet carefully. The staff involved in the conduct of this study will be available to answer any questions you may have at the time and after the explanation of the study. In addition, you can consult with the people you consider appropriate. The study has been approved by the corresponding Research Ethics Committee, in accordance with current legislation, and conforms to the standards of Good Clinical Practice in accordance with the latest update of the Declaration of Helsinki (64th General Assembly, Fortaleza, Brazil, October 2013) and Law 14/ 2007, of July 3, 2007, on Biomedical Research.

To decide to participate, you must understand the purpose of the study. The information you need is contained in this Information Sheet, which is provided for you to read carefully. If you wish to participate after having read it and having clarified your doubts with the research staff, you will be asked to sign the Informed Consent and you will be provided with a copy of it.
You should know that your participation in this study is voluntary and that you may decide not to participate or to change your decision and withdraw your consent at any time, without altering your relationship with your physician or harming your treatment.

WHAT DOES IS THIS STUDY ABOUT?

The objective of the study is to analyze the effect of a psychological intervention based on Acceptance and Commitment Therapy in patients with Chronic Kidney Disease undergoing haemodialysis treatment. This is a second phase of a larger research project to study and address the psychosocial needs of chronic kidney patients. It is possible that you participated in the first phase of this study by completing some questionnaires on psychological aspects of the disease, and that in view of the results (a high score in anxiety and depression) we have considered contacting you to invite you to this second phase of intervention. The therapy will be delivered by a general health psychologist specialized in this therapy.

On the first visit, the researcher will conduct an initial evaluation interview with questions and questionnaires. If you do not meet the proposed inclusion criteria, you will not be able to take part in this study. If you meet the inclusion criteria, you will receive an individual psychological intervention directed by a psychologist-researcher. You will receive the psychological intervention now or after 5 months, depending on the group to which you are assigned. Assignment to one or the other group will be completed randomly. Psychological intervention will provide you with tools so that you can live more effectively with your anxiety, sadness and other emotions. The therapy will include training in various skills for managing difficult emotions that have been shown to be useful in previous studies for supporting chronically ill people. It will also include personal work to clarify what is most important to you in life and to learn to have a more active daily life. The intervention will be administered over eight sessions during your dialysis attendance (one weekly session over two months). Likewise, to assess the effect of the intervention, you will have to complete some questionnaires related to psychological aspects of the disease, therapeutic adherence to drugs and quality of life at three different times: at the beginning of your participation, at the end of psychological therapy and three months later. Likewise, to assess the effect of the intervention, we will ask you to install an app on your own smartphone that is very easy to use, which will allow us to monitor your mood more continuously.

In the event that the detected symptoms of anxiety or depression require medical intervention, the intervention will be coordinated through the main researcher (Dr. M.D.Arenas). If the follow-up assessment assesses that you may require additional psychological intervention, you will be offered the possibility of being referred to a psychologist from the FRIAT Foundation.

In relation to your kidney disease, you will be treated in the same way whether you decide to participate or not, since decisions about your treatment are made by the doctor treating you. The only difference if you participate is that you will be randomly assigned to one of the two groups: receive the psychological intervention that we have explained to you immediately or continue it after 5 months.

If you decide to participate, the data collected from your medical history that is relevant to the study and through questionnaires will be coded for subsequent statistical analysis and publication of general results (always maintaining patient confidentiality).

This study aims to include approximately 104 patients like you.

BENEFITS AND RISKS RELATED TO YOUR PARTICIPATION IN THE STUDY

You may not benefit directly from participating in this study. However, we hope that the results of this study will contribute to a better understanding of the psychological state of dialysis patients, so that interventions can be designed to improve their quality of life and psychological health. You will not be subjected to any extraordinary risk by participating in the study, as no extraordinary tests are planned.

CONFIDENTIALITY AND DATA PROTECTION

By signing the document called INFORMED CONSENT that accompanies this INFORMATION SHEET, you declare that, in accordance with current legislation on data protection, you expressly consent to the processing of your data for participation in the study.

The institution participating in the study and co-responsible for the processing of your personal data will be the Fundación Renal Iñigo Alvarez de Toledo, whose corporate name is FUNDACIÓN RENAL IÑIGO ALVAREZ DE TOLEDO, along with Instituto de Investigación en Salud-Fundación Jiménez Díaz IIS-FJD, which will process your data for the exclusive purpose of carrying out the identified study. Likewise, the co-promoting entity of the study, the Fundación Renal Iñigo Alvarez de Toledo, whose corporate name is FUNDACIÓN RENAL IÑIGO ALVAREZ DE TOLEDO, along with Instituto de Investigación en Salud-Fundación Jiménez Díaz IIS-FJD, will be responsible for your data, once they have been dissociated.

The legitimate basis for the processing of your data is your express consent expressed in this document. Your data will be kept while the study is being carried out, as well as subsequently for a maximum period of 5 years to meet the legal obligations that may have arisen from the relationship. With regard to data processed for scientific research purposes, the Control Authorities of the Spanish Autonomous Communities may, at the request of the data controller and in accordance with the procedure established by regulation, agree to keep certain data in full, taking into account the historical, statistical or scientific values in accordance with the legislation applicable to each case.

Access to your personal information will be restricted to the study doctor and his/her collaborators, health authorities, Research Ethics Committee and the sponsor's monitors and auditors, who will be subject to the duty of secrecy inherent to their profession, when required, to check the data and procedures of the study, but always maintaining the confidentiality of the same in accordance with current legislation (Regulation (EU) 2016/679 of the European

Parliament and of the Council of 27 April 2016 on Data Protection (RGPD), on the Protection of Personal Data, Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights, and the provisions in this regard contemplated in Law 41/2002, of November 14, basic regulating the Autonomy of the patient and the rights and obligations regarding information and clinical documentation, as well as any current and applicable regulations). Therefore, your identity will not be released to any person or your data communicated to third parties except in case of medical emergency or legal requirement.

Finally, you may withdraw the consent given and exercise your rights of access, rectification, deletion, limitation of the processing of your data, opposition and portability, for which you should contact the patient care service of the health center where the study was conducted, or by mail addressed to "Patient Care Service" of the center, with the reference "data protection rights", identifying yourself as a participant in the study and providing a photocopy of your ID card or equivalent document and indicating the right you wish to exercise.
For any questions regarding the processing of your data, please contact our DPO at DPO@fjd.es.
In addition, we inform you of the possibility of filing a complaint with the competent supervisory authority, in accordance with the procedure that corresponds to the specific case".

PUBLICATION OF THE RESULTS

The results of this study will be published, according to one of the channels accepted by the scientific community, maintaining in all cases the confidentiality and rights of the participants. Data that allow the identification of the participants will not be published in any circumstances.

FINANCIAL SETTLEMENT

This study is an independent initiative of researchers at Instituto de Investigación Sanitaria Fundación Jiménez Díaz, Fundación Renal Iñigo Álvarez de Toledo and Universidad Europea, which has no specific source of finance or profit motive. Neither the investigator, nor the patients, nor the centers will receive financial compensation for their participation in the study. Nor their participation in the study will involve any expense for you.

OTHER RELEVANT INFORMATION

Any new information concerning the study that may affect your ability to participate in the study that could be discovered during your participation, will be communicated to you by your study doctor as soon as possible. You should also be informed that you may be excluded from the study if the study sponsor or investigators deem it appropriate.

At this point we give you the opportunity, if you have not already done so, to ask any questions you may have. The research team will respond to the best of their ability. If you have any questions about any aspect of the study or would like to discuss any aspect of this information, please do not hesitate to ask members of the research team. If you require further information about this study you can contact the Principal Investigator of the project, Dra M. Dolores Arenas Jiménez at his email address mdarenas@friat.es or with the Principal Investigator of the center (add name here) at their email address (add address here).

In case you decide to participate in the study once you have read this information and clarified your concerns, you must sign an informed consent form.

DECLARATION OF CONSENT

STUDY TITLE: " Effects of an ACT-based Psychological Treatment in Patients with Chronic Kidney Disease"

PROMOTER: Fundación Renal Iñigo Álvarez de Toledo and Instituto de Investigación Sanitaria Fundación Jiménez Díaz

SCIENTIFIC COORDINATOR OF THE STUDY AND CHIEF RESEARCHER at Fundación Renal Iñigo Álvarez de Toledo: Dr. M. Dolores Arenas Jiménez.

I ……. With ID number…… declare:

Dr…… has informed me about the present study:

1. That I am of legal age and that I have read and understood all the oral and written information in relation to the participation in the aforementioned project.
2. I have had the opportunity to discuss and ask about this information and I have received the appropriate answers from one of the members of the research team in charge of this study.

3. I have been enough informed about this study

4. I understand that I voluntarily consent to participate in this study

5. I understand that I am free to withdraw from the study at any time during the study, for any reason and without having to give any explanation and without any impact on my medical care

I consent to participate freely in the study in the terms expressed above.

In Madrid, on the ___ of _____ of 20__

Patient Signature: PI Signature:

Date: Date: