

INFORMATION FOR PARTICIPANTS AND INFORMED CONSENT FORM

RESEARCH PROJECT TITLE: FAMILY CONFERENCES IN THE APPROACH OF DEPENDENT PATIENTS WITH DISCHARGE CLINICAL COMPLEXITY: FROM FAMILY HEALTH TEAMS TO PALLIATIVE CARE

PROMOTER: Faculty of Medicine of Coimbra

COORDINATING INVESTIGATOR/SUPERVISOR: HUGO ALEXANDRE DA CRUZ RIBEIRO

CLINICAL STUDY CENTER: Center for the Study of Palliative Care

INVESTIGATOR: Ana Catarina Andrade Nascimento

ADDRESS: USF COIMBRA CENTRO

TELEPHONE CONTACT: (+351) 936735437

PARTICIPANT NAME: _____

You are invited to voluntarily participate in this study because you are a patient or a family member of a patient with a need for palliative care from the CPCT Gaia or high dependence on the FHUCC.

The following information is intended to clarify the nature, scope, consequences, and risks of the study, so that, once informed, you can decide whether or not to participate in this study.

If you have no questions about it, you should decide whether or not to participate. If you do not wish to participate, you will not suffer any kind of penalty. If you wish to participate, you will be asked to sign and date this form.

After your signature and that of the Investigator, you will be given a copy, which you should keep.

1. GENERAL INFORMATION AND STUDY OBJECTIVES

This study will take place at CPCT Gaia and FHU Coimbra Centro and aims to: Evaluate how family conferences are important for the knowledge and attitudes/skills of caregivers and even patients. Study the impact of family conferences on patients in palliative care and their families. Evaluate family members' perception of the quality of care provided to the patient. Evaluate the knowledge and expectations of patients and

their families regarding the disease trajectory and care, through the application of a questionnaire before and after a family conference. Evaluate how family conferences are structured in a palliative care team vs. a family health team.

This is an observational, analytical, cross-sectional study with two assessment points.

This study was approved by the Ethics Committee of the Faculty of Medicine of the University of Coimbra (FMUC) in order to guarantee the protection of the rights, safety and well-being of all participants included and to ensure public proof of this protection.

2. STUDY PLAN AND METHODOLOGY

Inclusion criteria (the user will have to verify all criteria):

- Follow-up in palliative care at ECSCP Gaia for more than 1 week;
- Patients dependent on the USF Coimbra Centro who have a caregiver or family member responsible for care 24/7

Sample recruitment: Recruited users will be asked about their willingness to voluntarily answer a questionnaire before and after the Family Conferences. In the case of patients with considerable cognitive impairment, the legal guardian will be invited to participate in this study.

If, at any time, it is found that the user is not eligible to participate in the project and/or the user does not wish to participate, all usual health care will be provided. Intervention and evaluation: Application of the FPCS questionnaire before and after the family conferences, using printed or digital questionnaires. FPCS is attached (appendix 1).

Informed consent: Informed consent will be given in person by signing a specific form provided.

3. PROTECTION OF PARTICIPANT DATA

3.1. Responsible for data

Ana Catarina Andrade Nascimento

3.2. Data collection

Ana Catarina Andrade Nascimento

Hugo Alexandre da Cruz Ribeiro

4. RISKS AND POTENTIAL INCONVENIENCES FOR THE PARTICIPANT

AVAILABILITY OF TIME

5. POTENTIAL BENEFITS

Improved quality of communication and care provided.

6. NEW INFORMATION

Not applicable.

7. PARTICIPATION / WITHDRAWAL OF CONSENT

You are entirely free to accept or refuse to participate in this study. You may withdraw your consent at any time by notifying the investigator, without any consequence, without having to explain the reasons, without any penalty or loss of benefits, and without compromising your relationship with the investigator who is proposing your participation in this study.

Consent that has been withdrawn does not cover data collected and processed up to that date.

The study investigator may decide to terminate your participation in this study if they believe it is not in your best interest to continue. Your participation may also end if the study plan is not being followed. The investigator will notify you if either of these circumstances arises.

8. CONFIDENTIALITY

Respect for the participant's right to privacy and the protection of their personal data will be guaranteed; it must also be ensured that the duty of secrecy and confidentiality to which they are bound will be fulfilled, as provided for in Article 29 of Law No. 58/2019, of 08/08.

9. RIGHT OF ACCESS AND RECTIFICATION

You may exercise the right of access, rectification and opposition to the processing of your data. However, this right may be subject to limitations, in accordance with the Law.

10. CONTACTS

If you have any questions about this study, please contact:

Researcher ANA CATARINA ANDRADE NASCIMENTO

Address USF COIMBRA CENTRO

Telephone 936735437

Email CATARINA.21@LIVE.COM.PT

If you have any questions regarding your rights as a participant in this study, you may contact:

Presidente da Comissão de Ética da FMUC

Universidade de Coimbra • Faculdade de Medicina

Pólo das Ciências da Saúde • Unidade Central Azinhaga de Santa Comba, Celas

3000-354 COIMBRA • PORTUGAL

Tel.: +351 239 857 708 (Ext. 542708) | Fax: +351 239 823 236

E-mail: comissaoetica@fmed.uc.pt | www.fmed.uc.pt

DO NOT SIGN THE INFORMED CONSENT FORM UNLESS YOU HAVE HAD THE OPPORTUNITY TO ASK AND RECEIVE SATISFACTORY ANSWERS TO ALL YOUR QUESTIONS.

INFORMED CONSENT

Research Project Title: FAMILY CONFERENCES IN THE APPROACH OF DEPENDENT PATIENTS WITH DISCHARGE CLINICAL COMPLEXITY: FROM FAMILY HEALTH TEAMS TO PALLIATIVE CARE

Participant's Name: _____

ID/Passport Number: _____

Contact Information: _____

Investigator's Name: _____

Within the scope of carrying out the aforementioned Research Project, I declare that I have read:

- a. the information attached to this form and voluntarily agree to participate in this study;
- b. the nature, scope, consequences, potential risks and expected duration of the study, as well as what is expected of me as a participant;
- c. I understand the information and explanations given to me. I know that at any time I may ask new questions to the researcher responsible for the study;
- d. that the researcher undertakes to provide any relevant information that arises during the study and that may alter my willingness to continue participating;
- e. and I agree to comply with the protocol of this study. I also undertake to inform the researcher of any changes in my health status that may occur (when applicable);
- f. and I authorize the use and disclosure of the study results for exclusively scientific purposes and permit the disclosure of these results to the competent authorities;
- g. that I can exercise my right of rectification and/or opposition, within the limits of the Law;
- h. that I am free to withdraw from the study at any time, without having to justify my decision and without suffering any penalty. I also know that the data collected and processed up to that date will be maintained;

i. that the investigator has the right to decide on my possible premature withdrawal from the study and undertakes to inform me of the respective reason;

j. that the study may be interrupted by decision of the investigator, the sponsor or the regulatory authorities.

Location and date: _____

Signatures Participant: _____

Legal representative: _____

Legal representative: _____

Investigator (*): _____

(*) I confirm that I explained to the aforementioned participant the nature, scope, and potential risks of the aforementioned study.