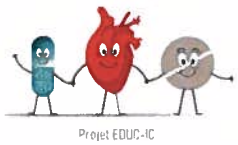


Application for participation in a medical research project :

EDUC-IC STUDY

Improving knowledge of disease and medication: a single-center randomized controlled trial in hospitalized heart failure patients

Dear Sir or Madam

We invite you to participate in our research project.

Your participation is completely free. All data collected in this project is subject to strict data protection rules.

The research project is organized by Professor Pascal BONNABRY of the Pharmacy Service of the HUG.
The main investigator is Mrs. Mégane JERMINI, hospital pharmacist and clinician at the HUG, who is leading this project as part of her doctoral thesis in pharmaceutical sciences. We will communicate the results to you if you wish.

During a meeting, we will present you the essential elements and answer your questions. To give you an overview of the project, here are the key points to remember. You will find more detailed information below.

Why are we conducting this research project?

- In the presence of heart failure, doctors introduce a treatment based on several specific drugs, in order to treat the disease. Adherence to the correct use of these drugs is not always easy and it is essential to reinforce the information about them and the disease of heart failure to optimise this adherence and the effectiveness of your treatment.
- Our research project aims to determine whether patients' knowledge of their heart failure disease and the medications that treat it can be improved by means of an educational and playful interview combined with follow-up at home with a hospital pharmacist.

What should I do if I agree to participate? - What happens to me if I participate?

- **Form of participation** :
  If you agree to participate in our project, you will be randomly assigned to either the "control" or the "intervention" group.
  If you are assigned to the "control" group, you will be asked to answer several questionnaires during your hospitalization and 1 month after your discharge by mail, e-mail, or telephone.
  If you are assigned to the second group, the "intervention" group, you will be asked to fill in the same questionnaires during your hospitalization, to follow an educational interview on heart failure with the hospital pharmacist, to see him/her again before your discharge, to accept his/her follow-up phone call the week of your return home and especially to answer several questionnaires 1 month after your hospitalization by mail, e-mail or phone call.

- **Procedure for the participants :**
  If you participate in the project and are in the "control" group, you will have to answer 4 questionnaires (n°1,2,3,4) during your hospitalization and again 3 questionnaires (n°2,3,4) at 1 month after discharge.
  1. Personal data questionnaire (5-10 minutes)
  2. Questionnaire to assess your knowledge of heart failure disease (17 questions, 20-25 minutes)
  3. Medication Belief Assessment Questionnaire (10 questions, 5 minutes)
  4. Adherence Assessment Questionnaire (3 questions, 2 minutes)

  If you participate in the project and are in the "intervention" group, you will have to answer the same 4 questionnaires as well as 1 satisfaction questionnaire during your hospitalization, follow the educational interview with the pharmacist lasting 90 minutes and answer again the knowledge evaluation questionnaire (n°2), follow the 15-20 minutes pre-discharge interview, answer his phone call in the week of your return home (15 minutes) and answer, again, 1 month after your return home, 3 of the questionnaires (n°2,3,4) as well as a last satisfaction questionnaire.
  If, and only if, you have agreed, during the pre-discharge interview with the pharmacist, to use a heart failure smartphone application (CardioMeds®) and that you use it at home, you will be asked to answer 2 other questionnaires: one on the usefulness of the digital application (5 minutes), one on self-care skills at home (10 minutes)

What are the benefits and risks of participating in the project?

Benefits

- In the best of cases, participation in this project can provide you with new knowledge about a disease you have that is tailored to your needs. It can also strengthen your follow-up between the transition from hospital to home before seeing your GP or cardiologist through follow-up by the hospital pharmacist.
- If you do not benefit from the pharmacist's intervention, because you are assigned to the "control" group, you will still receive optimal care from the hospital's medical and nursing staff.
- By participating, you are helping future patients.

Risks and constraints

There will be no risk involved in participating in the study. Your medical care will not be affected. All the data collected will be coded, which means that only Mrs Mégane JERMINI, the project investigator, will have access to these data, which she will store in a secure place in the hospital and inaccessible to others.
By signing at the end of the document, you certify that you have understood the content and freely consent to take part in the project.

Detailed information

Madam, Sir,

We invite you to participate in our research project, described in this information sheet.

1. Objectives of the study

The objectives of this project are to

- to test, with hospitalized heart failure patients, the impact of an educational and playful interview with the pharmacist on their knowledge of heart failure disease and the drugs that treat it.

- To compare the change in knowledge level between two distinct groups 1 month after hospital discharge. The first group receives the usual care provided by the hospital and the intervention of the pharmacist and the second group receives only the usual care provided by the hospital.

- to evaluate if this change in knowledge level allows to modify the patients' beliefs about their medication, to improve their therapeutic adherence to the correct use of medication as well as to decrease the risk of re-hospitalization for heart failure in the month following the hospital discharge.

2. Selection of potential study participants

Participation is open to all persons hospitalized at the HUG for the onset or worsening of their heart failure and who are taking more than two medications to treat it.

Participants must be of legal age, have full capacity of discernment, have no memory impairment and speak, read and understand French.

It is however closed to people who do not understand French or who do not have the capacity of discernment.

3. General information about the study

This is a study that takes place only at the HUG;

Participants who agree to participate in the study will be randomly assigned to one of two study groups: a "control" group that will receive only the usual care by hospital doctors and nurses without being exposed to the pharmacist's teaching, and the other group called "intervention" that will receive, in addition to the usual care, the pharmacist's teaching intervention and pharmaceutical follow-up on return from the hospital

If you are allocated to the "control" group, this project implies that you answer four questionnaires during the hospitalization, and again 3 of these same questionnaires 1 month after your return home.

If you are allocated to the "intervention" group, this project involves :

- you were actively involved in an educational and entertaining conversation with the pharmacist at your bed during hospitalization
- you agree to a second interview shortly before your discharge from hospital to prepare for your return home
- talk by phone with the pharmacist within a week of your return from hospital to review your health and medications

- you answered structured questionnaires on several occasions during your hospitalization and at 1 month after discharge:

The total duration of the study may vary from one participant to another because it is conditioned by the length of your stay in hospital. It will end 30 days after your return home as soon as we have contacted you to answer our questionnaires.

The time you will be asked to complete the various questionnaires will vary from one participant to another, but will not exceed 45 minutes. The expected number of participants for the entire study is 124. We are conducting this study in accordance with the requirements of Swiss law. In addition, we are following all internationally recognized guidelines. The competent cantonal ethics commission has reviewed and approved the study.

A description of the study can also be found on the website of the Federal Office of Public Health: www.kofam.ch.

4. Procedure for participants

Once you have agreed to participate in the study by signing this consent form, you will be asked to complete 4 questionnaires (pre-test).
It is about

- a questionnaire about your personal information (name, first name, telephone number, postal address, name of your doctor, your usual pharmacy, your comfort level with computers, smartphones and tablets) (duration 5-10 min)

- A questionnaire to evaluate your level of knowledge about heart failure and medications. (duration 20-25 minutes)

- A questionnaire to assess your beliefs and perceptions of medication (5 minutes long)

- A questionnaire to assess your adherence to proper medication use (2 minutes long)

Then the pharmacist will assign you to one of the two groups according to a predefined randomization list.

If you are assigned to the **"intervention" group**

1) The pharmacist will schedule same-day or next-day training with you.

   He or she will conduct the interview at your bedside using a variety of entertaining aids (film, games, discussion). This interview will last a maximum of 90 minutes. It can be reorganized into two shorter sessions of 45 minutes if you wish. At the end of the training you will understand what heart failure is, what its symptoms are and how you should react if these symptoms appear and also what you can watch out for. You will also know what drugs are given to treat it, their role, their most common side effects to watch out for.

2) You will be asked again to complete :
   - the knowledge assessment questionnaire on the disease and the medication to evaluate if there is a change in your knowledge level (post-test n°1) (10 min).
   - to complete a satisfaction questionnaire on the educational interview.

3) The pharmacist will meet with you a second (or third) time before your discharge from the Department of General Internal Medicine or Cardiology to review the key points of the training, answer your questions, introduce you to a smartphone application for heart failure patients developed by the HUG called CardioMeds® and discuss the medication plan at discharge.

4) In the week following your discharge from hospital, the pharmacist will contact you again by telephone or videoconference (if you prefer) to check on you, ask you a few follow-up questions about your health status and obtain a list of your current heart failure medications (call duration 20 minutes).

5) Three weeks after your discharge from hospital, we will send you by e-mail or post (if you do not have e-mail) the 4-6 questionnaires to be filled in and returned to us:

- A questionnaire to assess your level of knowledge about heart failure and medications (post-test #2) (15-25 minutes)
- A questionnaire to assess your beliefs about medications (post-test) (5 minutes)
- A questionnaire to evaluate your adherence to proper medication use (post-test) (2 minutes)
- A satisfaction questionnaire on the care provided by the pharmacist (5 minutes)
- A self-care measurement questionnaire if you use the CardioMeds smartphone application® (10 minutes)
- A usability evaluation questionnaire for the CardioMeds smartphone application® if you use it. (5 minutes)

6) One month after your discharge from the hospital, a research assistant will contact you by phone to check up on you and ask:
   - if you have answered the questionnaires and sent them back to us. If not, he will ask you the questions by phone.
   - if you have had an emergency visit to a doctor or hospital or have been re-hospitalized since your return home;
   - a list of your current medications
   - if you have installed and use the CardioMeds smartphone application®

If you are assigned to the **"control" group**

1) Three weeks after your discharge from hospital, we will ask you to complete again the 3 questionnaires that we will have sent you by e-mail or post (if you do not have an e-mail):
   - A questionnaire to assess your level of knowledge about heart failure and medications (post-test #2) (15-25 minutes)
   - A questionnaire to assess your beliefs about medications (post-test) (5 minutes)
   - A questionnaire to evaluate your adherence to proper medication use (post-test) (2 minutes)

2) One month after your discharge from the hospital, a research assistant will contact you by phone to check up on you and ask:
   - If you have had an emergency visit to a doctor or hospital or have been re-hospitalized since your return home;

- Your current medication plan and in what format (paper/electronic)
- If you have answered the questionnaires and sent them to us.
- If not, he will ask you the questions over the phone.

5. Benefits for participants

If you participate in the study, you may gain additional knowledge about heart failure and your medicines that is tailored to your needs. By knowing more about your medicines and their benefits to your heart and risks, we think you will find it easier to integrate them into your daily life and take them to treat yourself.
The results of the study could prove important in the future for people who will be affected by the same disease as you and will allow us to improve the content of this education.

6. Participants' rights

You are free to accept or refuse to participate in the project. If you choose not to participate, or if you choose to participate and change your mind during the course of the study, you will not have to justify your refusal. This will not change your usual medical care. You can ask any questions you may have about the study at any time. Please contact the person listed at the end of this information sheet.

7. Obligations of participants

As a study participant, you will be required to:

- Answer truthfully the questionnaires that we will send you during your hospitalization face to face and at home by e-mail or post;
- Follow the instruction that the pharmacist will offer you and see the pharmacist again before you are discharged from the ward where you are hospitalized if you are in the intervention group;
- Answer our phone calls (7 days and 30 days after your return home)
- Keep the investigator informed of the course of the disease and report any new hospitalizations, new disorders and changes in your condition.

8. Risks and constraints for participants

There will be no risk of participating in the study. Your medical care will not be affected by this study. All the data we collect will be coded, which means that only the investigator will have access to this data, which will be stored in a secure place in the hospital.
The constraints brought by the study will be simply time during your hospitalization (about 2 hours) and about 1 hour 30 minutes over 1 month to answer the various questionnaires and our calls once back home.

9. Other treatment options

You do not have to participate in the study. If you decide not to take part, you will be treated in exactly the same way as patients have been until now. However, you will not benefit from the training offered and the follow-up by the pharmacist until you go home.

10. Confidentiality of data and samples

For the purposes of the study, we will store your personal and medical data. Only a limited number of people may access your data in uncoded form, and only for the purpose of carrying out tasks necessary for the project. Data collected for research purposes is coded at the time of collection. Encryption means that all identifying data (e.g. name, date of birth, etc.) are replaced by a code. The code remains permanently in the hospital. People who do not know this code cannot link this data to you. In the case of publication, the aggregated data are therefore not attributable to you as a person. Your name will never appear on the Internet or in a publication. Sometimes scientific journals

require the submission of individual data (raw data). If individual data are to be submitted, they will always be coded and will therefore not identify you as an individual. All persons involved in the study in any way whatsoever are bound to confidentiality. All data protection regulations are observed and you have the right to inspect your data at any time.
During the course of the study, the study may be subject to inspections. These inspections may be carried out by the cantonal ethics commission that has initially checked and approved the study. The pharmacist-investigator may have to disclose your personal and medical data for the purpose of these inspections.

11. Withdrawal from the study

You may withdraw from the study at any time if you wish. However, the medical data collected until you withdraw will be kept and used for analysis. After analysis, your data will be "anonymized" by means of a code composed of numbers and letters. Thus, no one will know that these data are yours.

12. Participant compensation

If you participate in this study, you will not receive any compensation.

13. Compensation for damages

No damages are expected given the structure of the study. However, should this not be the case, the clinical trial and related damages are covered by the internal resources of the institution.

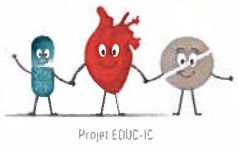
14. Funding of the study

The study is financed by the pharmacy of the University Hospitals of Geneva.

15. Contact person(s)

If you have any doubts, concerns or emergencies during or after the study, you can contact one of the following people at any time:

Mégane JERMINI
HUG Pharmacy
Rue Gabrielle Perret Gentil 4, 1205 Geneva
Tel: 079.553.01.74
E-mail: megane.jermini@hcuge.ch



Hôpitaux Universitaires Genève

ISPSO INSTITUT DES SCIENCES PHARMACEUTIQUES DE SUISSE OCCIDENTALE

UNIVERSITÉ DE GENÈVE
FACULTÉ DES SCIENCES
Section des sciences pharmaceutiques

Written consent statement for participation in a research project

Please read this form carefully. Do not hesitate to ask questions if you do not understand something or if you need clarification.

BASEC NUMBER OF THE STUDY:	Study 2022-00731
TITLE OF THE STUDY:	**EDUC-IC STUDY:** Improving knowledge of disease and medication: a single-center randomized controlled trial in hospitalized heart failure patients
RESPONSIBLE INSTITUTION :	Prof. Pascal Bonnabry HUG Pharmacy Rue Gabrielle Perret Gentil 4, 1205 Geneva HUG
PERSON RESPONSIBLE FOR THE PROJECT AT THE SITE :	Ms. Megane I rmini Pharmacist specialized in hospital and clinical pharmacy
PARTICIPANT :	
DATE OF BIRTH :	

- I declare that I have been informed orally and in writing by the undersigned pharmacist-investigator responsible for this study of the objectives and conduct of the study.
- I am participating in this study voluntarily and accept the contents of the information sheet provided to me on the above study. I have had sufficient time to make my decision.
- I have received satisfactory answers to the questions I asked in relation to my participation in the study. I will keep the information sheet and receive a copy of my written consent form.
- I agree that my treating physician may be informed of my participation in the study.
- I agree that the competent specialists of the study sponsor (investigator, trained research assistants), as well as the competent ethics committee may consult my raw data in order to carry out controls, provided that the confidentiality of these data is strictly assured.
- I am aware that my personal data may be transmitted for research purposes within the framework of this project only and in an encrypted form
- I may, at any time and without having to justify myself, revoke my consent to participate in the study, without this having any adverse repercussions on my further treatment.

- I am informed that in the event of damage, the HUG, as promoter, will take charge of the damage in accordance with the legal provisions in force.

Place, date	Geneva, the
Type	❑ Ms. ❑ Mr.
Name and surname of the participant in block letters.	
Signature of participant	

Investigator's Certification: I hereby certify that I have explained to the participant the nature, importance and scope of the study. I hereby declare that I have fulfilled all obligations in connection with this project in accordance with applicable law. Should I become aware, at any time during the course of the project, of anything that might affect the participant's consent to participate in the project, I undertake to inform him/her immediately.

Place, date	Printed name of investigator providing information to participants.
Signature of investigator	