

## Information and Consent Form

**Project Title:**

**Persistence - A disease management program to optimize the use of antidepressants: Impact on improving symptoms and work productivity**

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Funding agency : Canadian Institutes for Health Research

Sponsors : Eli Lilly, Lundbeck, sanofi-aventis, Merck, Pfizer, AstraZeneca

## **Introduction**

We are requesting your participation in this research project because you have recently started an antidepressant for depression or generalized anxiety.

However, before accepting to participate in this study and signing the informed consent form, please take the time to read, understand, and carefully consider the following information.

This document explains the objectives, procedures, advantages, risks and inconveniences of this study. If you feel that some information is not clear please ask the principal investigator or any other member of the research team answer your questions.

## **Goals and objectives of the study**

The program is a disease management program designed to inform and support patients taking an antidepressant for depression or generalized anxiety. The goal is to improve the use of these medications especially regarding the duration of treatment. Antidepressants should be taken for a period of at least six months in order to improve mood and other symptoms. In reality, treatments are often stopped before the six months and this often compromises their effectiveness and increases the risk of relapse.

The program consists of three elements:

- Telephone questionnaires completed with a research nurse will deal with your opinions on depression and anxiety and the medications, possible problems related to the treatment, possible side effects, work-related productivity issues, as well as your symptoms. These telephone interviews will take place at enrollment as well as 1, 3, and 6 months at times that will have been preset with the nurse. Each interview will last 30 to 40 minutes.
- Your physician will receive, by mail, a summary of your answers to the questionnaires, which will enable him/her to discuss these issues further with you.
- Two information modules, one on depression and anxiety and the other on psychotherapy, have been designed to improve your knowledge about the illnesses and enable you to actively participate in your treatment. The first will be mailed to you shortly after enrollment the other 1 month after.

This study's goal is to optimize treatment with antidepressants with regards to persistence with treatment, improving symptoms of depression or anxiety, effects on productivity at work (absenteeism, presenteeism, disability), and cost/benefits of this program.

## **Study participation**

You may have received an invitation to participate either by your pharmacist or have seen posters or announcements in your place of work or pharmacy. When you begin an antidepressant treatment for depression or anxiety, you are eligible to participate in the study if you meet the following inclusion criteria:

- You are between 18 years old and 64 years old
- You speak French or English (in order to understand the questions)
- You had not taken antidepressants 3 months prior to your present treatment

- You have begun an new antidepressant treatment in the last 6 months for depression or anxiety
- Please note that this study does not involve persons receiving an antidepressant for another indication other than depression or generalized anxiety (not for social phobia, obsessive compulsive disorders, bipolar disorder, panic disorder, agoraphobia, post-traumatic stress disorder)

If you meet the criteria and you agree to participate, you must sign this consent form and sending it to the PERSISTANCE program by fax or scan at the number you will find in the "Resource Person" section. It is also possible that you have already filled out the form with your pharmacist. Be sure that you can change your mind and no longer wanted to participate. If this happens, just let the person who will contact you to conduct an interview.

Since this is an evaluation study, participants will be randomly assigned to one of the two following groups:

1. The disease management program as described above
2. Usual care (no support program nor feedback letters to your doctor)

At your enrollment, the nurse will randomly assign you to your group. You have a 1 in 2 chances of being part of group 1.

### **Participants in Group 1:**

Your participation in the study involves completing questionnaires over the phone with a research nurse. After your enrollment, the nurse will contact you again 3 more times over 6 months according to a schedule you will have decided on together.

There will be a total of 4 phone calls.

The first being at your registration, then the nurse will contact you at 1, 3 and 6 months.

### **Participants in Group 2:**

You will simply complete the questionnaires at enrollment and 6 months later on your health and your experience with the treatment, quality of life, and work productivity. This will in no way affect the care you usually get from your physician and we will send you the information modules on depression and anxiety by mail at 6 months.

### **All Participants (the following points 1 and 2 are mandatory, only point 3 is optional)**

1. We will also ask your authorization to use for your private medical insurance number for information about any services/treatments that are not covered by the Quebec provincial health plan (RAMQ) for a period of 12 months before and 12 months after beginning your antidepressant.

The reason for reviewing data for 12 months prior to your enrollment is to obtain information on your medications, hospitalizations, use of services, for example, from a psychologist, acupuncturist, massage therapist or other alternative care during that period; the reason for reviewing data for the 12 months after your enrollment is to monitor your persistence with your antidepressant treatment as well as your use of medical or other services.

2. We will also ask your authorization to obtain and use your Medicare number in order to consult, and if applicable, obtain information from the files at the Régie d'assurance-

maladie du Québec (RAMQ) on your medical visits and medications taken a period of 12 months before and 12 months.

3. We will also ask for your physician's name and address in order for us to let him/her know that you are enrolled in the program as well as to send him/her a feedback letter telling him/her about how you are doing with regards to your treatment and your symptoms. These feedback letters will be sent only with your approval. There is no obligation on his/her part to take the feedback letter into consideration with regards to your follow-up care.

### **Advantages and benefits**

You may benefit directly from your participation in this study but we cannot guarantee it. If you are part of Group 1 'disease management program', you may benefit from support with your antidepressant treatment. If you are part of Group 2 'usual care' you will however receive documentation on depression after 6 months. At the very least, results obtained may contribute to the advancement of knowledge in the field.

### **Risks and Inconveniences**

There are no risks directly attributable to this program or the study. There is the inconvenience in the time required to complete the questionnaires.

### **Voluntary participation in the study and withdrawal or exclusion**

Your participation in this project is voluntary. You are free to accept or refuse to participate and can withdraw from the project at any time without justification and this will in no way affect the treatment you are entitled to nor will it interfere with the relationship you have with your physician. Should you wish to withdraw from the study you simply have to inform the research team at the number supplied in the **Resource Persons** section of this form.

Participation in this study can be interrupted by the principal investigator of the research project, the Ethics committee of the CHUM, the sponsors, funding agency, can end your participation without your consent, notably if new discoveries or information indicates that your participation in the project is no longer in your best interest, if you do not abide by the study rules or if there are administrative reasons for stopping the project.

Participants will be advised by letter and by telephone of any new information that may likely make them reconsider their participation in the study.

### **Confidentiality**

With your authorization, your doctor will be informed of your participation in this study.

During your participation in this project, the principal investigator and her personnel will collect data and keep it in your research file. Only the data required to answer the scientific objectives of this study will be collected.

This data may be comprised of your age, gender, education and your answers to the questionnaires. During the study analysis data will be coded, no names will be used. The database will be stored in a computer that is not connected to any network and in a location that is accessible to the study researchers only.

The data collected will be kept strictly confidential within the limits of the law. In order to conceal your identity and preserve the confidentiality of the data, you will be identified only by a number. The key that will link your name to the number will be kept by the principal investigator only. **Your employer will not be informed of your participation in this program nor will the answers you supply to us be divulged to them.** The data obtained by your private insurance company and the RAMQ will remain strictly confidential and will be revealed to no one.

The principal investigator will use the data for study purposes in order to meet the study's scientific objectives described in the consent form. The data will be kept for a maximum of 7 years after the study termination in order to make it possible to improve the program if necessary by the principal investigator.

The study results may be published in scientific journals or be part of scientific discussion, but it will never be possible to identify you.

For control purposes, your research file may be reviewed by a person mandated by the CHUM Research Ethics committee or by a person mandated by the study sponsor or funding agency. All these individuals and organizations adhere to a confidentiality rules.

For safety reasons, especially if we need to contact you quickly, your name and family name, your address and phone numbers and the date of your enrollment and end of study participation date will be kept for 1 year after the end of the project in a separate file by the principal investigator.

You are allowed to consult your research file in order to check the data collected and rectify if necessary, and this as long as the principal investigator and/or centre has this data. However, in order to preserve the scientific integrity of the study, you could have access to some of the data only once your participation in the study is complete.

### **Communication of general results**

You may be made aware of the general results of this study if you make a request to the principal investigator at the end of the study. The results will be mailed to you.

### **Funding of the research project**

The principal investigator has received financial support from the funding agency and the sponsors in order to carry out this study.

### **Payment**

You will not receive any financial compensation for your participation in this study. However, a lump sum of \$50.00 will be given to you as a token of our thanks for your participation in this study as well as for your time.

### **Compensation in case of prejudice and rights of study subjects**

Should you suffer any prejudice due to your participation in this study, you will receive all services and care that your health status requires without any fees on your part.

By accepting to participate in this research project, you do not give up any of your rights nor do you free the researchers from their civil or professional responsibilities.

## Contact Persons

For any questions regarding this program and this study (before, during and after your participation), you may contact :

the project coordinator at 514-890-8000 ext 14872 or

fax 514 284-4884

the principal investigator:

Professor Yola Moride

Centre de Recherche CHUM

Faculty of Pharmacy, Université de Montréal

Tel: (514) 890-8000 (ext.14356)

For any urgent questions, you may call: the study call centre at **514-284-4884** or toll free at **1-888-984-4884**. This centre will put you in contact with a nurse that will be able to help you (or she may refer you to Info-Santé, or suicide prevention, or 911.)

For any questions with regards to your rights as a participant in this study or if you have a complaint or comments, you may contact the Commissaire locale adjointe à la qualité des services at the Hôpital Hotel-Dieu du CHUM at 514- 890-8000 ext 12761.

## Ethics

The Research Ethics Committee of the CHUM has approved this research study and insures the follow up. In addition, it will be responsible for approving any modifications or revisions made to this consent form or to the study protocol that are requested.

