Title of the study: Questionnaire designed to assess the behavioural factors involved in the willingness and/or behaviour of elderly people to reduce or stop medication taking.

Sponsor of the study: Université Catholique de Louvain, IRSS 30 Clos Chapelle-aux-Champs, Bte B1.30.13 ESP Building 1200 Bruxelles

Medical Ethics Committee: *Comité d'éthique hospitalo-facultaire des cliniques universitaires de Saint-Luc*

Local investigators: *Van den Broucke Stephan, IPSY 10 Place Cardinal Mercier, Bureau D215 1348 Louvain-la-Neuve*

Alves Jorge Sara, IRSS 30 Clos Chapelle-aux-Champs, Bte B1.30.13 ESP Building 3ème étage, bureau A332 1200 Bruxelles

I Information vital to your decision to take part

Introduction

You are invited to take part in a study designed to better understand the factors that explain the willingness and behavior of older people and informal caregivers to reduce or stop taking a medication that is no longer adequate.
We simply ask you to complete the questionnaire according to your point of view for each of the proposed statements. Apart from the questionnaire we will ask you to complete, no additional diagnostic or monitoring procedures will be proposed to you.

Before you agree to take part in this study, we invite you to take note of its implications in terms of organisation, possible risks and benefits, to allow you to make a decision with full awareness of the implications. This is known as giving "informed consent".

Please read these few pages of information carefully and ask any questions you want to the investigator or his/her representative.

There are 3 parts to this document: the information essential to your decision, your written consent and supplementary information (appendices) detailing certain aspects of the basic information.

If you take part in this study, you should be aware that:

- The treatment offered to you by the investigator in accordance with current recommendations will not be altered if you take part in the study.
- This clinical study is being conducted after having been reviewed by one or more ethics committees.
- Your participation is voluntary and must remain free from any coercion. It requires the signature of a document expressing your consent. Even after having signed this document, you can stop taking part by informing the investigator.
- The data collected on this occasion are confidential and your anonymity is guaranteed during publication of the results.
- Insurance has been taken out in case you should suffer any damage in connection with your participation in this clinical study.
- You may contact the investigator or a member of his/her team at any time should you need any additional information.

Further information about your "Rights as a participant in a clinical study" can be found in appendix III.

Objectives and course of the study

This study is being organised as part of the Université Catholique de Louvain's Concerted Research Action (CRA) project, called Di-Prescribe. This project focuses on reducing the use of medication in the elderly, with the aim of improving health and quality of life. on reducing the use of medication in the elderly, with the aim of improving health and quality of life.

The aim of this study is to develop and validate a new questionnaire that seeks to gain a better understanding of the factors that may be involved in the intention to reduce or stop certain medicines that older people take regularly.

We are asking you to take part in this study because we are looking for people aged over 60 who regularly take several medications and for informal caregivers of older adults who are losing their independence or who are dependent on others.

The study should include 345 people aged over 60 and 345 family carers in Belgium.

To be able to take part in this study you must :

For older adults:

- 60 or over ;
- take at least 5 medicines a day;
- have a prescription for at least one medicine that your doctor has been prescribing for a long time (1 year or more);
- not have any psychiatric problems, or a past or present dependence on drugs or alcohol;
- not be in the terminal phase of an illness;
- be able to express yourself and complete a written questionnaire in French.

For informal caregivers:

- Identify as an informal caregiver- defined as having some role in managing the health and/or medication of a family member or friend, without receiving remuneration for that role;
- Be over 18 years of age;
- Be an informal caregiver for a person aged 60 or over, who takes at least 5 medicines a day and has one or more long-term prescriptions;
- The care recipient living in the community (at home with or without the carer) or in a nursing home;
- Be capable of giving consent, expressing themselves and completing a written questionnaire in French.

Your participation in the study will last as long as it takes to complete the questionnaire (approximately 40 minutes), which will ask you questions about your demographic data, your use of medication, your assessment of your state of health and whether you have reduced or stopped taking medication.

In this study, you will also be asked to complete 2 further questionnaires. The first will assess your level of health literacy, in other words the motivation and skills of people to access, understand, evaluate and use information to make decisions about their health. The second questionnaire concerns locus of control, i.e. a person's belief about what determines their success in a given activity, events in a given context or, more generally, the course of their life.

Completing these questionnaires will take you around 20 minutes.

All your answers will be anonymised and stored for 20 years in a secure room at UCLouvain.

Description of risks and benefits

Your participation in this study does not alter your treatment or your usual care by your doctor. No risk, in terms of health, can be linked to your participation in this study.

Similarly, you should not expect any personal benefit from taking part in the study. You should know only that your participation will enable us to better understand the factors that may influence your willingness to reduce or stop one or more of the medicines you take regularly, and thus to advance research and improve the quality of patient care.

Withdrawal of consent

Your participation is voluntary and you are entitled to withdraw your consent to take part in the study for any reason, without having to justify your decision.

If you withdraw your consent to take part in the study, to guarantee the validity of the research, the data encoded up to the point at which you withdraw will be retained. No new data may be sent to the sponsor.

The sponsor/party responsible for the study may also decide to stop the study because the data collected provide a faster response than originally expected.

If you take part in this study, we ask you:

Be as honest as possible in your answers. Please note that all answers are anonymous.

Contact

If you need further information, but also if you have problems or concerns, you can contact the investigatin team l'équipe de recherche, UCLouvain, Alves Jorge, Sara (sara.alvesjorge@uclouvain.be) et Prof. Van den Broucke, Stephan (stephan.vandenbroucke@uclouvain.be).

If you have any questions relating to your rights as a participant in a clinical study, you can contact the hospital-faculty ethics committee of the Cliniques universitaires Saint Luc-UCLouvain by email at commission.ethique-saintluc@uclouvain.be.

Title of the study: Questionnaire visant à évaluer les facteurs comportementaux impliqués dans la volonté et ou le comportement de diminution ou d'arrêter des médicaments chez la personne âgée.

II Informed consent

Participant

I declare that I have been informed of the nature of the study, its purpose, its duration, the possible side effects and what is expected of me. I have taken note of the information document and the appendices to this document.

I have had sufficient time to think about it and discuss it with a person of my choice (GP, relative).

I have had the opportunity to ask any questions that came to mind and have obtained a favourable response to my questions.

I understand that data about me will be collected throughout my participation in this study and that the investigator and the sponsor of the study will guarantee the confidentiality of these data in accordance with applicable European and Belgian legislation.

I agree to my personal data being processed as described in the section dealing with confidentiality guarantees (page 5/7). I also consent to these data being transferred to and processed in countries other than Belgium.

I agree/do not agree (delete as appropriate) to the research data collected for the purposes of this study being processed at a later date provided this processing is limited to the context of the present study (better understanding of the disease and its treatment).

I have received a copy of the information to the participant and the informed consent form.

Surname, first name, date and signature of the volunteer.

Investigator

I, the undersigned, Alves Jorge Sara, co-investigator, confirm that I have verbally provided the necessary information about the study and have given the participant a copy of the information document.

I confirm that no pressure was applied to persuade the patient to agree to take part in the study and that I am willing to answer any additional questions if required.

I confirm that I operate in accordance with the ethical principles set out in the latest version of the "Helsinki Declaration", the "Good Clinical Practices" and the Belgian Law of 7 May 2004 related to experiments on humans.

Surname, first name, date and signature of the investigator's representative

Surname, first name, date and signature of the investigator

Title of the study: Questionnaire visant à évaluer les facteurs comportementaux impliqués dans la volonté et ou le comportement de diminution ou d'arrêter des médicaments chez la personne âgée.

III Supplementary information

1: Supplementary information on the protection and rights of the participant in a clinical study

Ethics Committee

This study has been reviewed by an independent Ethics Committee, namely the Ethics Committee of the Cliniques universitaires Saint Luc-UCLouvain, Brussels, which issued a favourable opinion.It is the task of the Ethics Committees to protect people who take part in a clinical trial. They make sure that your rights as a patient and as a participant in a clinical study are respected, that based on current knowledge, the study is scientifically relevant and ethical.
You should not under any circumstances take the favourable opinion of the Ethics Committee as an incentive to take part in this study.

Voluntary participation

Before signing, do not hesitate to ask any questions you feel are appropriate. Take the time to discuss matters with a trusted person if you so wish.

Your participation in the study is voluntary and must remain free of any coercion: this means that you have the right not to take part in the study or to withdraw without giving a reason, even if you previously agreed to take part. Your decision will not affect your relationship with the investigator or the quality of your future therapeutic care.

If you agree to take part in this study, you will sign the informed consent form. The investigator will also sign this form to confirm that he/she has provided you with the necessary information about the study. You will receive a copy of the form.

Costs associated with your participation

You will not receive any compensation for your participation in this study. Nor will you incur any additional costs.

Guarantee of confidentiality

Your participation in the study means that you agree to the investigator collecting data about you and to the study sponsor using these data for research purposes and in connection with scientific and medical publications.

Your data will be processed in accordance with the European General Data Protection Regulation (GDPR) and with the Belgian legislation on the protection of natural persons with regards to the processing of personal data. Professor Stephan Van den Brouck shall act as data controller for your data.

You are entitled to ask the investigator what data are being collected about you and what is their use in connection with the study. This data concerns your current clinical situation but also some of your background, the results of examinations carried out within the context of care of your health in accordance with current standards. You have the right to inspect these data and correct them if they are incorrect[1].

The investigator has a duty of confidentiality vis-à-vis the data collected.

[1] These rights are guaranteed by the European Data Protection Regulation (GDPR), by the Belgian legislation of 30 July 2018 on the protection of privacy with regards to the processing of personal data and by the Law of 22 August 2002 on patient rights.

This means that he undertakes not only never to reveal your name in the context of a publication or conference but also that he will encode your data before sending them to the manager of the database of collected data (IPSY, Professeur Van den Broucke Stephan, UCLouvain).

The investigator and his team will therefore be the only ones to be able to establish a link between the data transmitted throughout the study and your medical records[2].

The personal data transmitted will not contain any combination of elements that might despite everything allow you to be identified[3].

For the study data manager designated by the sponsor, the data transmitted will not allow you to be identified. The latter is responsible for collecting the data gathered by all investigators taking part in the study, processing them and protecting them in accordance with the requirements of the Belgian law on the protection of privacy.

To verify the quality of the study, it is possible that your medical records will be examined by third parties (ethics committee, representatives of the study sponsor, external auditors). In any event, this may only take place under the responsibility of the investigator or of one of his/her colleagues and by persons subject to the obligation of professional secrecy.

These (encoded) data will be able to be sent to Belgian or other regulatory authorities, to the relevant ethics committees, to other doctors and/or to organisations working in collaboration with the sponsor.

They will also be able to be sent to other sites of the sponsor in Belgium and in other countries where the standards in terms of the protection of personal data may be different or less stringent[4].

Your consent to take part in this study therefore also implies your consent to the use of your encoded medical data for the purposes described in this information form and to their transmission to the aforementioned people and authorities.

The sponsor undertakes only to use the data collected within the context of the study in which you are taking part.

If you withdraw your consent to take part in the study, to guarantee the validity of the research, the data encoded up to the point at which you withdraw will be retained. No new data may be sent to the sponsor.

If you have any questions relating to how your data are being processed, you may contact the investigator. The data protection officer in your hospital can be contacted as well, at following address : privacy@uclouvain.be

Finally, if you have a complaint concerning the processing of your data, you can contact the Belgian supervisory authority who ensures that privacy is respected when personal data are processed.

The Belgian supervisory authority is called:
Data Protection Authority (DPA)
Rue de la presse 35,
1000 Brussels
Tel. +32 2 274 48 00
e-mail: contact@apd-gba.be
Website: https://www.dataprotectionauthority.be

[2] For clinical studies, the law requires this link with your records to be retained for 20 years.

[3] The database containing the results of the study will therefore not contain any combination of elements such as your initials, your gender and your full date of birth (dd/mm/yyyy).

[4] The sponsor then undertakes to respect the constraints of the European General Data Protection Regulation (GDPR) and the Belgian legislation on the protection of privacy with regards to the processing of personal data.

Insurance

In an observational study, the only possible risk would be a flaw in the measures taken to protect the confidentiality of the private information about you. Even without fault, the sponsor accepts responsibility for damage caused to the participant (or his/her dependants) and linked directly or indirectly to participation in this study. In this context, the sponsor has taken out an insurance contract (name of the insurance: MS AMLIN, Boulevard Roi Albert II, 37 à 1030 Bruxelles; police number LXX111372)[5].

[5] In accordance with Article 29 of the Belgian Law related to experiments on humans (7 May 2004)