PATIENT INFORMATION LEAFLET

The support person, family member or close friend

Article L. 1111-6 of the French Public Health Code

Remote Medicine for the Management of Behavioural and Psychological Disorders

Principal Investigator:
Doctor Maria SOTO
Department of Geriatrics
Toulouse University Hospital Centre
Tel.: 05 61 14 56 68
E-mail: soto-martin.me@chu-toulouse.fr

Research sponsor:
Toulouse University Hospital Centre,
Hôtel Dieu-St Jacques
2 rue Viguerie
31059 TOULOUSE Cedex 9.

Dear Sir/Madam,

We are inviting your relative/the person whom you support or a family member or close friend *(delete as appropriate)* to take part in a study, the primary aim of which is to demonstrate the suitability of remote medicine for managing behavioural disorders in individuals with dementia and living in residential care homes (EHPAD: Etablissement d'Hébergement pour personnes Agées Dépendantes - nursing homes).

This research is sponsored by Toulouse University Hospital Centre. The principal investigator is Dr. Maria SOTO, a hospital practitioner in the Geriatrics Department of Toulouse University Hospital. The participation of your relative/patient is entirely voluntary. Before deciding on whether he/she should take part, you must carefully read these pages which contain important information about the various aspects of research we are making available to your relative/patient. Do not hesitate to ask the study investigators any questions that you deem relevant. You can also forward this information leaflet to the doctor treating your relative/patient, if you so wish, in order to have their opinion.

Why is this research being carried out?

We want to assess remote medicine in this indication in an attempt to improve the strategy for treating Behavioural and Psychological Symptoms of Dementia (BPSD) in nursing homes. Remote medicine has been assessed in many chronic disorders with encouraging results. We want to use remote medicine in nursing homes in order to make a rapid diagnosis in the real-life context taking into account the opinions of all the stakeholders assisting you on a daily basis. This would also avoid often lengthy consultation waiting times and, if need be, schedule "elective" hospital admissions (always with the consent of the doctor treating your relative/patient) with the expert at the memory centre following up your relative/patient. Last but not least, remote medicine would also prove beneficial in providing continuous training in these disorders for nursing teams working at the establishments in question.
No study has been carried out in this specific area to date. However, before embarking on a large-scale national study, we thought it would be beneficial to focus on the practical aspect of remote medicine in nursing homes and, above all, on the option for nursing home teams to familiarise themselves with this modern method of communication.

What are the objectives of this research?

The **primary** objective is to assess the feasibility and suitability of remote expertise in the management of elderly subjects presenting cognitive disorders compounded by BPSD in nursing homes.

We want to carry out a sociological evaluation of the suitability of remote medicine for use by medical and nursing personnel in nursing homes. We also want to have some idea of the potential impact of remote medicine on certain parameters that are crucial in establishing the quality of care delivered (number of non-elective hospital admissions or consultations for BPSD, number of prescriptions for neuroleptic and psychotropic medicines in general

and the cost of your treatment for patients living in the la Midi-Pyrenees region). We will do this by comparing 2 groups of nursing homes: an "intervention" group with access to remote medicine, and a "control" group that will follow standard practices without remote medicine.

Who can take part?

The person you represent can take part in this trial if he/she meets the following criteria:

- is **less than 65 years old**,
- lives **in a nursing home,**
- has been **diagnosed with dementia** (possible or probable) by the treating physician or by a specialist, with documented evidence in the medical record,
- has **disruptive BPSD,**
- **is not taking part in any other clinical trial,**
- the **treating physician authorises** the person you represent to take part in this study,
- and you have **given your consent** for this person take part in this research. If there is no support person, a family member or, otherwise, a person with whom you maintain strong, stable ties will be appointed.
- **receives social security benefits and has no judicial protection.**

How long will the research last?

You will take part in the study for 2 months. The total duration of this study is 3018 months including an 18-month enrolment period.

If you give your consent for your relative/the patient to participate, what will be expected of him/her?

This study will be carried out in 230 establishments in the Midi-Pyrenees region, Limousin and Aquitaine. A random allocation process will be carried out prior to start-up to identify those establishments that will test out the remote medicine approach (intervention group) and those that will continue to use standard methods to treat the behavioural problems displayed by your relative/the patient (control group).

Only patients in the intervention group will benefit from remote medicine. In this case, 2 consultations will take place, 1 month apart. These will be attended by the co-ordinating physician, nursing staff from the nursing home and, if possible, the doctor treating your relative/the patient together with the nursing team and medical expert from the University Hospital Centre.

If the co-ordinating doctor deems it necessary, your relative/the patient will be able to participate in the remote medicine session (this will take the form of a remote consultation).

The consultation will last 30 to 40 minutes. The behavioural problems will be assessed during the last consultation.

Patients in the control group will receive standard treatment with no specific, study-related visit.

An opinion will be formed and advice given on how to best treat your relative/the patient. A report will be compiled and attached to the medical record which will be available to the treating physician and the persons taking care of your relative/the patient. The treating physician may or may not decide to follow the advice given for treating your relative/patient.

Regardless of the group to which your relative's/the patient's nursing home is assigned, data regarding medication and the number of non-elective hospital admissions and/or consultations for behavioural disorders will be documented.

Patients in the control group will receive standard treatment with no specific, study-related visit.

If your relative lives in a residential care home in the Midi-Pyrenees region, his/her healthcare costs will be analysed during the study (this analysis will only be carried out in the Midi-Pyrenees region).

This information will be collected by the Medical Information Department (MID) at Toulouse University Hospital Centre. To this end, the MID will identify your relative by his/her name, first name, date of birth and post code of the residential care home. This information will be exchanged via secure file transfers and encoded between CRAM (Regional Health Insurance Fund) and MID via the Toulouse University Hospital Centre server. The data collected from CRAM will be incorporated in the study database once your identity has been encoded, in order to safeguard the anonymity of your relative.

What are the potential disadvantages?

There are no additional disadvantages associated with this studyin terms of standard patient care**.** No substance will be administered to your relative/the patient during this clinical trial. No other adverse reactions are anticipated in connection with this study.

What are your relative's rights/the patient's rights?

Participation in this study is entirely voluntary.

All of the trial-related costs will be borne by the study sponsor.

The investigator who monitors your relative/the patient during this study must provide all of the necessary explanations regarding the trial. Your relative/the patient has the option to withdraw from the trial at any moment whatsoever and for any reason whatsoever, without incurring any repercussions and, in particular, with no repercussions on his/her treatment or medical follow-up.

Within the scope of this trial, your relative's/the patient's personal data will be processed electronically by the Toulouse University Hospital Centre in order to analyse the data collected in terms of research objectives, as outlined for you in this leaflet. To this end, the medical data relating to your relative/the patient will be forwarded to the trial sponsor (Toulouse University Hospital Centre) or to individuals or companies acting on its behalf, in France or abroad. All of the data relating to your relative/the patient will be used purely for medical research purposes. The data will be identified by a code (the nursing home number), your initials and a number denoting the chronological order of enrolment in the study). This information may be transmitted to French or foreign health authorities but confidentiality will be maintained at all times. All of the information will be subject to strict medical confidentiality.

In accordance with the French Data Processing and Freedom of Information Act, your relative/the patient will be available to access and correct their personal data at any time (law No. 2004-801 dated 6 August 2004 amending law No. 78-17 of 6 January 1978 relating to the Data Processing and Freedom of Information Act). They are also entitled to oppose the transmission and use of data covered by professional confidentiality and likely to be used and processed during this clinical trial. You can also access all of the medical data recorded for your relative/the patient either directly or via a doctor of your choice, in accordance with the provisions of Article L1111-7 of the French Public Health Code. These rights can be implemented by contacting the Principal Investigator of the DETECT study (Dr. Maria SOTO).

In accordance with law No. 2004-806 dated 9 August 2004, relating to the French Public Health policy, this trial was approved by the Comité de Protection des Personnes (CPP) Sud-Ouest et Outre-Mer I, (South West and Overseas Territories I Ethics Committee) on 04/09/2014 and authorised by the Agence Nationale de Sécurité des Médicaments et des produits de santé (ANSM - French National Agency for Medicines and Health Products Safety), on 20/08/2014 (Art L1121-4 of the French Public Health Code).

The study sponsor (Toulouse University Hospital Centre) has taken out a civil liability insurance policy with the GERLING Company (insurance policy No. 1006648-140018-10998)) to cover any damages potentially associated with this trial.

For patients in the Midi-Pyrenees region, in accordance with Article 57 of the law dated 6 January 1978 relating to the Data Protection and Freedom of Information Act, and decree No. 2012-1249 of 9 November 2012, we wish to inform you that, once you have signed the informed consent form, we will collect the information relating to your relative/the patient. This information will then be encoded in order to assess the clinical and medical-economic interest of the remote medicine device. Information relating to medication administered to your relative/the patient will be sent under confidential cover by the Regional Health Insurance Fund to the Medical Information Department at Toulouse University Hospital Centre which is familiar with processing such data. The final phase of the research evaluation process is to compare the costs of standard treatment and treatment via the remote medicine approach.

The DETECT project is based on remote medicine and the University Hospital Centre shall undertake to comply with current legislation (Decree No. 2010-1229 of 19 October 2010 relating to remote medicine, and Article R 6316-2 of the French Public Health Code).

If you so wish, once this trial is completed, you will be personally informed of the overall results by your doctor as soon as they become available (Art. L1122-1 of the French Public Health Code).

After you have read this information leaflet, do not hesitate to ask the investigators any further questions you may have. After an appropriate reflection period, if you agree that your relative/the patient should take part in this study, you must complete and sign an informed consent form to confirm their participation. You will receive a copy of the completed document.

Please take time to read through this document.

1 PATIENT UNABLE TO GIVE HIS/HER CONSENT, WITH NO JURIDICIAL PROTECTION IN PLACE

- *If the patient has no juridicial protection, **authorisation to take part** must be given by a support person. An information leaflet will be given to close friends/support persons/family members. If there is no support person, a family member or, otherwise, a person with whom the patient maintains strong, stable ties may be appointed.*

INFORMED CONSENT FORM

The support person, close friend or family member

Remote Medicine for the Management of Behavioural and Psychological Disorders

Research sponsor: Toulouse University Hospital Centre, Hôtel Dieu, 2 rue Viguerie TSA 80035, 31059 TOULOUSE cedex 9
Co-ordinating Investigator: Dr. Maria SOTO, Department of Geriatrics, Toulouse University Hospital Centre, Tel.: 05 61 77 64 26

I, the undersigned, (name and first name in block capitals) ……

- Relative[1]- Relationship…… ..... ……..
- Or support person[1] who is not a family member, appointed in accordance with Article L 1111-6 of the French Public Health Code, and who is able to provide written evidence of this connection,
- Or a close friend[1]

of Mr. or Mrs./Ms. ……hereby certify that I have read and understood the information leaflet presented to me.

I have had the opportunity to put questions to
Dr.……*(name, first name)*who has explained the type of research, objectives, potential risks and constraints associated with the participation in the clinical trial of the person I represent.

I realise that my relative/the patient can withdraw his/her consent to take part in this trial at any time without having to justify his/her decision. This will not impact upon subsequent medical care or follow-up.

I have been given the assurance that decisions affecting the health of my relative/the patient will be taken at any time, based on state-of-the-art medical knowledge.

I am aware of the fact that this trial was approved by the Comité de Protection des Personnes Sud-Ouest et Outre-Mer I (South West and Overseas Territories I Ethics Committee) on 04/09/2014, authorised by ANSM on 20/08/2014 and was reported to the Commission Nationale Informatique et Libertés (CNIL - French Data Protection Authority).

The trial sponsor, namely Toulouse University Hospital Centre, has taken out a civil liability insurance policy with the GERLING Company, to cover any damages(insurance policy No. 1006648-140018-10998)).

I hereby give my consent for individuals involved in this trial and only those, or those designated by the sponsor, possibly in conjunction with a representative from the Health Authorities, to access the information regarding my relative/the patient under strict confidentiality.

[1] *Delete as appropriate*

I hereby give my consent for personal data relating to my relative/the patient, recorded during this trial, to be processed electronically by the sponsor or on the sponsor's behalf.

I have noted that, in accordance with the provisions of the Data Processing and Freedom of Information Act (law No. 2004-801 of 6 August 2004 modifying law No. 78-17 of 6 January 1978 relating to the Data Protection and Freedom of Information Act), my relative/the patient is entitled to access and rectify their personal information. They are also entitled to oppose the transmission of data covered by professional confidentiality and likely to be used and processed during this clinical trial. These rights can be implemented by contacting the Principal Study Investigator (Dr. Maria SOTO).

In the case of patients living in the Midi-Pyrenees region, data generated by the Health Insurance databases will be collected confidentially in order to carry out a medical-economical evaluation of the remote medicine device, in accordance with Decree No. 2012-1249 of 9 November 2012, and with my consent. These data will be processed by the Medical Information Department at Toulouse University Hospital Centre, which is familiar with this exercise. This evaluation can be used to compare standard treatment to remote medicine treatment.

I have also noted that the procedures carried out within the scope of the DETECT protocol are remote medical procedures and are therefore subject to Article R 6316-2 of the French Public Health Code and Decree No. 2010-1229 dated 19 October 2010 relating to remote medicine.

My consent does not exempt the investigator and trial sponsor from assuming their responsibilities vis-a-vis my relative/the patient. My relative/the patient retain all of their rights guaranteed by law.

The overall clinical trial results will be communicated to them directly, if they so wish, in accordance with Article L.1122-1 of the French Public Health Code.

The patient has been informed of his/her participation in the trial and raises no objections.

He/she can ask the doctor who invited him/her to take part for further information at any time via telephone No.: …….

<u>Section concerning only nursing home residents in the Midi-Pyrenees region:</u>

☐ The support person or family member or close friend agrees to provide the name, first name, date of birth and the patient's residential post code to the Medical Information Department at Toulouse University Hospital Centre. This information will be exchanged via secure file transfers and encoded between the Regional Health Insurance Fund and MID at the Toulouse University Hospital Centre. The data collected from the Regional Health Insurance Fund will be incorporated in the study database once the patient's identity has been encoded, in order to ensure their anonymity.

☐ The support person or family member or close friend gives their consent for the patient to take part in the DETECT study but refuses to forward the person's name, first name, date of birth and residential post code to the Medical Information Department at the Toulouse University Hospital Centre.

I hereby give my consent for my relative/the patient to participate in the proposed study.

I confirm that I have no guardian/trustee.

Written in ..... Toulouse, on __/ __/20__

Signature of the support person/family member/close friend - Name and first name:

Signature of the doctor:

Produced in duplicate: one copy is given to the trial subject and the second copy is held by the Investigator.

2 PATIENT UNABLE TO GIVE HIS/HER CONSENT AND UNDER GUARDIANSHIP OR TRUSTEESHIP

-

- *If the patient has juridicial protection,* ***authorisation to take part*** *must be given by the guardian or trustee. An information leaflet is given to the guardian or trustee.*

INFORMED CONSENT FORM

The support person, close friend or family member

Remote Medicine for the Management of Behavioural and Psychological Disorders

Research sponsor: Toulouse University Hospital Centre, Hôtel Dieu, 2 rue Viguerie TSA 80035, 31059 TOULOUSE cedex 9
Co-ordinating Investigator: Dr. Maria SOTO, Department of Geriatrics, Toulouse University Hospital Centre, Tel.: 05 61 77 64 26

I, the undersigned, (name and first name in block capitals)……..

- Guardian or trustee (delete as appropriate)
- of Mr. or Mrs./Ms. ……..hereby certify that I have read and understood the information leaflet presented to me.

I have had the opportunity to put questions to
Dr……*(name, first name)*who has explained the type of research, objectives, potential risks and constraints associated with the participation in the clinical trial of the person I represent.

I realise that the patient can withdraw his/her consent to take part in this trial at any time without having to justify his/her decision. This will not impact upon subsequent medical care or follow-up.

I have been given the assurance that decisions affecting the patient's health will be taken at any time, based on state-of-the-art medical knowledge.

I am aware of the fact that this trial was approved by the Comité de Protection des Personnes Sud-Ouest et Outre-Mer I (South West and Overseas Territories I Ethics Committee) on 04/09/2014, authorised by ANSM on 20/08/2014 and was reported to the Commission Nationale Informatique et Libertés (CNIL - French Data Protection Authority).

The trial sponsor, namely Toulouse University Hospital Centre, has taken out a civil liability insurance policy with the GERLING Company, to cover any damages(insurance policy No. 1006648-140018-10998)).

I hereby give my consent for individuals involved in this trial and only those, or those designated by the sponsor, possibly in conjunction with a representative from the Health Authorities, to access the information regarding my relative/the patient under strict confidentiality.

I hereby give my consent for personal data relating to my relative/the patient, recorded during this trial, to be processed electronically by the sponsor or on the sponsor's behalf.

I have noted that, in accordance with the provisions of the Data Processing and Freedom of Information Act (law No. 2004-801 of 6 August 2004 modifying law No. 78-17 of 6 January 1978 relating to the Data Protection and Freedom of Information Act), my relative/the patient is entitled to access and rectify their personal information. They are also entitled to oppose the transmission of data covered by professional confidentiality and likely to be used and processed during this clinical trial. These rights can be implemented by contacting the Principal Study Investigator (Dr. Maria SOTO).

In the case of patients living in the Midi-Pyrenees region, data generated by the Health Insurance databases will be collected confidentially in order to carry out a medical-economical evaluation of the remote medicine device, in

accordance with Decree No. 2012-1249 of 9 November 2012, and with my consent. These data will be processed by the Medical Information Department at Toulouse University Hospital Centre, which is familiar with this exercise. This evaluation can be used to compare standard treatment to remote medicine treatment.

I have also noted that the procedures carried out within the scope of the DETECT protocol are remote medical procedures and are therefore subject to Article R 6316-2 of the French Public Health Code and Decree No. 2010-1229 dated 19 October 2010 relating to remote medicine.

My consent does not exempt the investigator and trial sponsor from assuming their responsibilities vis-a-vis my relative/the patient. My relative/the patient retain all of their rights guaranteed by law.

The overall clinical trial results will be communicated to them directly, if they so wish, in accordance with Article L.1122-1 of the French Public Health Code.

The patient has been informed of his/her participation in the trial and raises no objections.

He/she can ask the doctor who invited him/her to take part for further information at any time via telephone No.: ……

<u>Section concerning only nursing home residents in the Midi-Pyrenees region:</u>

☐ The guardian/trustee agrees to provide the name, first name, date of birth and the patient's residential post code to the Medical Information Department at Toulouse University Hospital Centre. This information will be exchanged via secure file transfers and encoded between the Regional Health Insurance Fund and MID at the Toulouse University Hospital Centre. The data collected from the Regional Health Insurance Fund will be incorporated in the study database once the patient's identity has been encoded, in order to safeguard their anonymity.

☐ The guardian/trustee gives their consent for the patient to take part in the DETECT study but refuses to forward the person's name, first name, date of birth and residential post code to the Medical Information Department at the Toulouse University Hospital Centre.

I hereby give my consent for the patient to participate in the proposed study.

Written in ..... Toulouse, on __/ __/20__

Signature of the responsible person - Name and first name:

Signature of the doctor:

Produced in duplicate: one copy is given to the trial subject and the second copy is held by the Investigator.