2022-A01460-43 Version 2 of 30/03/2023

Patient information guide

Comparison of the effectiveness of an adapted physical activity programme in a structure with a self-programme in patients in the chronic phase of a stroke : StrokAPA

Sponsor: AP-HM (Assistance Publique Hôpitaux de Marseille)
Direction de la Recherche Santé et Maladies Rares - 80 rue Brochier - 13 354 Marseille Cedex 5 - France

Coordinating investigator: Dr COTINAT - Pr VITON's PRM Department - Address: Hôpital Sainte Marguerite, 270 Boulevard Sainte Marguerite, MARSEILLE, 13009 Tel: 04 91 74 42 48

Dear Sir/Madam

Dr / P r _____ has asked you to take part in a study entitled **"Comparison of the effectiveness of an adapted physical activity programme in a dedicated structure with a self-programme in patients in the chronic phase of a stroke".**
Assistance Publique des Hôpitaux de Marseille is the promoter of this research and will ensure that it runs smoothly.

In accordance with Law 2012-300 of 5 March 2012 on research involving the human person (known as the Jardé Law) / Public Health Code; Title II of Book 1 on research involving the human person, we ask you to read this information leaflet carefully, which is intended to answer any questions you may have, before deciding whether or not to take part in this research.
Don't hesitate to ask questions if anything is unclear or if you would like further information.

Context

Stroke is the leading cause of acquired motor disability in adults. Physical activity is a cardiovascular protective factor and reduces the risk of stroke recurrence. However, daily physical activity levels in patients with stroke sequelae are well below international recommendations. The creation of adapted physical activity programmes is an interesting option for these patients, with the aim of increasing their daily physical activity. Some programmes are carried out in a facility, others independently. We propose to compare the effectiveness of these two methods.

Aims of the study

The aim of this study is to compare the practice of an adapted physical activity programme in a dedicated facility with a self-programme carried out at home. The secondary objectives will be to study patients' walking ability, endurance, balance, quality of life and motivation to engage in physical activity.

This could increase the interest in adapted physical activity, which is still underdeveloped in France. One of the main advantages of our programme is that it requires only a medical examination to ensure that there are no contraindications, and can be carried out in association with adapted physical activity teachers. This study could have several effects: for you and your family, it would reinforce the practical feasibility and interest of this type of programme, by enabling you to make gains in walking in everyday life. From the point of view of the healthcare system, the results of our pilot study could constitute a further step towards optimising the care of people suffering the after-effects of a stroke.

Satger E, *et al*. *BMJ Open* 2024; 14:e084688. doi: 10.1136/bmjopen-2024-084688

Conduct of the study

Your participation in the study consists of :
Participation in an adapted physical activity programme in a dedicated facility and in an independent programme, as well as wearing a pedometer (Stepwatch) on the ankle of the non-affected limb for the duration of your participation in the study. The order of these programmes will depend on the group to which you belong. The group will be allocated to you by chance.

Your participation will begin with an inclusion medical visit to ensure that there are no contraindications to your taking part in the adapted physical activity programmes.
After this visit, you will be assigned to a group according to a random allocation.
Group 1 will take part in the study for 26 weeks. They will start with the structured programme for 12 weeks, then after a 1-week break, they will begin the independent physical activity programme for 12 weeks.
Group 2 will take part in the study for 13 weeks. It will start with the programme of physical activity in autonomy for 12 weeks, then after a 1-week break, it will start the programme in a dedicated structure, outside the study, in a compensatory manner. This programme in a dedicated structure, taking place outside the study, will not be covered by the research insurance but by the institution's insurance.

The supervised programme is carried out at the Institut Universitaire de Réadaptation de Valmante Sud, with 3 sessions a week of adapted physical activity.
The self-programme includes consultations with an adapted physical activity teacher every 3 weeks at Hôpital Sainte Marguerite to keep you motivated and answer any questions you may have.

The pedometer ™ data is collected every 3 weeks, during the consultations scheduled in the 2 programmes.
Walking ability, endurance, balance, perceived quality of life and motivation to engage in physical activity were assessed at the inclusion visit and at a visit at 13 weeks in both groups. ème A final consultation is scheduled in group 1 at 26 weeks for a final assessment.

Benefits, risks and constraints associated with taking part in this research

Expected benefits

- For you: The aim of your participation is to enable you to increase your daily physical activity and improve your walking, endurance and balance, as well as increasing your motivation to engage in physical activity. The long-term aim is to improve your quality of life.
  Regular physical activity also reduces the risk of a stroke recurring.
- For the company: The results of our pilot study could be a further step towards optimising care for people suffering after-effects of an accident.
  the feasibility and effectiveness of a programme of physical activity for the treatment of stroke.
  The only requirements are a medical consultation to ensure that there are no contraindications and follow-up by an adapted physical activity teacher.

Foreseeable risks and constraints
The risks associated with this study are not significant:

- Your participation will require your personal time to take part in adapted physical activity programmes,
- During tests and adapted physical activity, the risks of falls and injuries remain,
- As the aim of this study is to increase your physical activity, it is possible that participation in this study may result in fatigue after the adapted physical activity sessions.
- Your participation means that you will have to wear the Stepwatch pedometer every day, around the ankle of your non-affected lower limb, without any additional risk.

Compensation - payment of study costs

- At the end of your participation in the study, you will receive an allowance of *€100.* to compensate for the constraints suffered.

- In accordance with current regulations, you are hereby informed that the maximum amount of compensation received over a 12-month period by a person participating in biomedical research is set at €4,500.

Reflection period

You have between 1 and 7 days to decide whether or not to take part.

Legal and ethical aspects

You may refuse to give your authorisation. This refusal will have no impact on the quality of care you receive.

This project falls within the scope of research involving the human person involving minimal risks and constraints (category 2), within the meaning of article L.1121-1 paragraph 1, of the Public Health Code.

It is subject to the regulations that apply to research "involving the human person".
"These include Law no. 2012-300 of 5 March 2012 on research involving the human person (known as the Jardé Law), as amended by Order no. 2016-800 of 16 June 2016, and its implementing decrees.

This study received a favourable opinion from the Est IV Committee for the Protection of Individuals on 02/05/2023.

This research is conducted in accordance with the reference methodology MR 001 approved by the Commission Nationale de l'Informatique et des Libertés (CNIL) on 13 July 2018 and with which Assistance Publique - Hôpitaux de Marseille has undertaken to comply (Récépissé n°2205999 v 0 of 30 August 2018).

In accordance with the law, the APHM, the promoter of this research, has taken out insurance with SHAM (18 rue Edouard Rochet 69372 LYON Cedex 08 - +33 (0)4 72 75 50 25) under the number policy number 166 005.

As part of this study, your personal data will be processed to enable the results of the research to be analysed in the light of the objective presented to you.

This data processing is based on the performance of a task in the public interest entrusted to the data controller (article 6.1.e of the RGPD) and the exemption to process health data for scientific research purposes (art.9 RGPD).

All personal information collected throughout the study will be treated as confidential. All study data concerning you will be pseudonymised. You will be given a code number. This will be used to identify you and any personal information without having to use your name, medical record number or other common identifiers. Your data will remain strictly confidential and may only be consulted by the medical team, persons duly authorised by the sponsor and, if necessary, by representatives of the Competent Authorities.

The demographic data (sex and age) and clinical data (weight, height and previous and current treatments) concerning you, required for this research, will be processed electronically by the research organisers.

This computerised processing is under the responsibility of the data controller: Assistance Publique Hôpitaux de Marseille (80 rue Brochier, 13354 Marseille Cedex 5 - Tel: 04 91 38 00 00), represented by its legal representative in office.

It will be carried out in accordance with the provisions of law no. 78-17 of 6 January 1978 on data processing, data files and individual liberties.

Data collected as part of this research will not be transferred to countries outside the European Economic Area (EEA).

Further studies :

The data collected during this research will be used for research purposes. At the end of the study, unless you object, we would like to keep the data so that it can be re-used for other studies on adapted physical activity programmes for patients in the chronic phase of a stroke, for a period of 15 years.

You will be informed of these new studies via the APHM website: http://fr.ap-hm.fr. Your

personal data will be kept for 15 years after the end of the research.

Pursuant to Act no. 78-17 of 6 January 1978, amended on 12 December 2018, on Data Processing, Data Files and Individual Liberties (Title II "Processing covered by the personal data protection regime provided for by Regulation (EU) 2016/679 of 27 April 2016"; Chapter II "Rights of the data subject") you have :

- a right of access, rectification and deletion of your data collected in the context of this study and likely to be processed, and a right to limit their processing,
- the right to object to the collection, processing and transmission of your data covered by professional secrecy,
- a right to portability: you can ask for your personal data to be returned to you or transferred to a third party where possible.

You may withdraw your consent to the collection and processing of your personal data at any time.

You can exercise these rights by contacting the investigating doctor treating you or the study coordinator, Dr Maeva COTINAT.

If you have any questions or complaints about the processing of your data during this study, you should first contact the doctor treating you in the study, who will be able to direct your request.

In the event of any difficulties in connection with the management of the data collected, you may submit a complaint to the Data Protection Officer at Assistance Publique Hôpitaux de Marseille, by e-mail to dpo@ap-hm.fr.

You may also submit a complaint concerning the way in which your data is processed to the supervisory authority responsible for applying data protection law in France, the Commission Nationale de l'Informatique et des Libertés (CNIL), online via the link: https://www.cnil.fr/fr/webform/adresser-une-plainte or by post to the following address: Commission Nationale de l'Informatique et des Libertés, 3 Place de Fontenoy, TSA 80715, 75334 PARIS CEDEX 07.

The presentation of this data will not allow you to be identified, either directly or indirectly.

These data may be used for scientific publications, but your name or any other element that might identify your participation will not appear.

In accordance with the law (art L1122-1 of the Public Health Code), you may, if you wish, be informed orally of the overall results of this research by contacting the investigating doctor in charge of the study.

The study data and the results of the treatment will be kept for a period of 15 years after the end of the study, on paper or electronically.

Your doctor will keep you informed of any new information or changes concerning the study that may affect your health or your willingness to continue the study.

If you wish, on request, the study doctor will be able to inform you of the overall results of the study, approximately one year after the last patient has completed participation in the study.

Your authorisation does not relieve the sponsor and the investigator of their respective responsibilities.

For further information, to request access to your data, or to obtain the overall results of the study, please contact Dr COTINAT on 04 91 74 42 48 or by e-mail: maeva.cotinat@ap-hm.fr

Thank you for taking the time to read this information letter. If you agree to take part in this research, please date and sign the attached consent form.

To take part in this study, you will need to sign the form below entitled "Consent form".

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INFORMED CONSENT FOR PATIENT PARTICIPATION

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Coordinating investigator: Dr COTINAT - Pr VITON's PRM Department - Address: Hôpital Sainte Marguerite, 270 Boulevard Sainte Marguerite, MARSEILLE, 13009 Tel: 04 91 74 42 48

I, the undersigned, ...*(name, first name)*, who is due to receive treatment for my illness, declares :

1. Having freely agreed to take part in the study entitled **"Comparison of the effectiveness of an adapted physical activity programme in a dedicated structure with a self-programme in patients in the chronic phase of a cerebrovascular accident: StrokAPA",** without this releasing the organisers of the research from their responsibilities,
2. Have understood that if I agree to take part in this research, I must sign this document,
3. Have understood that signing the consent form does not relieve the sponsor and the investigator of their respective responsibilities.
4. I certify that I am over 18 and that I am not under any legal protection (guardianship, curatorship, safeguard of justice),
5. I understand that I have a period of reflection between the time I receive the information and the time I sign this document,
6. I have been informed that I may withdraw my agreement to participate at any time, without justification and without any prejudice to me,
7. I have been informed that I retain all my rights guaranteed by Law 2012-300 of 5 March 2012 on research involving the human person (known as the Jardé Law) / Public Health Code, Title II of Book 1 on research involving the human person,
8. Have been informed that this research has received a favourable opinion from the Comité de Protection des Personnes Est IV dated 02/05/2023.
9. Have been informed of the purpose, progress, advantages and disadvantages of this research, and that it will be carried out in accordance with Good Clinical Practice as defined in the Official Bulletin published by the Ministry of Social Affairs and Employment,
10. To have been able to ask all the questions I wanted and to have received appropriate answers that I clearly understood, and to have noted that I could add to this information throughout the study by contacting Dr COTINAT, coordinating investigator (**04 91 74 42 48**),

11. Have been informed that the Promoter of this study is the APHM and that, in accordance with the law, the APHM has taken out insurance with SHAM under number 166.005,
12. I have been informed of the use of pseudonymised data concerning me, collected as part of this research by computer processing. The presentation of the results of the study will not enable me to be identified, either directly or indirectly (Act no. 78-17 of 6 January 1978, as amended, relating to information technology, files and civil liberties),
13. Have been informed that this data may only be consulted by the study investigators and the sponsor or by persons authorised by the sponsor and bound by professional secrecy, or by persons authorised by the administrative, health and legal authorities,
14. I have been informed that I may, if I wish, access this data, check it and request changes if necessary, in accordance with the law in force (Law no. 78-17 of 6 January 1978, as amended, relating to information technology, files and civil liberties),
15. Have noted that any new information arising during the course of the study, which could affect my participation, will be communicated to me as soon as possible,
16. Have understood that the sponsor, or the coordinating investigator, may decide to stop the study at any time,
17. I have been informed that the overall results of the study may be communicated to me in accordance with Article L1122-1 of the French Public Health Code,
18. Be affiliated to a social security scheme, or be a beneficiary of such a scheme,

I agree to take part in this study under the conditions specified above.

☐ YES N O ☐

I agree that the data collected in the course of this research may be re-used for other studies on adapted physical activity programmes for patients in the chronic phase of a stroke for a period of 15 years.

☐ YES N O ☐

Done at ..... Le .....

Name and signature of subject Name and signature of investigating doctor

If required :

If the patient cannot read or write independently, a third person, completely independent of the investigator and the sponsor, must certify that he/she has read this document to the patient and has obtained his/her agreement to sign on his/her behalf:

Last name : _____First name :

_____

Relationship with the

patient :_____

Signature :