Physical Literacy-Based Intervention for Chronic Disease Management:

A Quasi-Experimental Study Protocol

02/02/2024
D: 2023/392
[NCT ID not yet assigned]

INFORMATION AND FORM CONSENT TO PARTICIPATE

Study title : Development and evaluation of a physical literacy intervention as part of the "Citizen, on the move for my health" project

Promoter of the study : University of Liège, Department of Motor Sciences

Ethics Committee : University Hospital-Faculty Ethics Committee of Liège

Local investigators: Jean-Pierre Weerts, Cédric Lehance and Alexandre Mouton, University of Liège, Department of Motor Sciences.

I. Information essential to your decision to participate

a) Introduction

Madam, Sir, you are invited to participate in an observational clinical study. This means that the physical activity program that we offered to you as part of the "Citizen, on the move for my health" project was developed in the usual way, in accordance with the conditions of good medical practice and **independently of your possible participation. to this study.**

We simply ask that you be able to use data related to your participation in this program, so that we can combine it with that of other participants who benefit from the same program and process it statistically for research purposes.

These data come from the beginning and end of cycle physical literacy assessments part of the program traditionally offered by the CHU of Liège and the University of Liège.

Before you agree to participate in this study, we invite you to understand its implications in terms of organization, benefits and possible risks, so that you can make an informed decision. This is called giving "informed consent."

Please read these few pages of information carefully and ask any questions you wish to the investigator or the person representing him or her.

This document includes 3 parts: the information essential to your decision-making, your written consent and additional information (appendices) which detail certain parts of the basic information.

If you participate in this study, you should know that:

- The treatment offered to you by the investigating physiotherapist/physical trainer in accordance with current recommendations will not be modified as a result of your participation in the study.
- This clinical study is implemented after evaluation by an ethics committee. • Your participation is voluntary and must remain free of any coercion. It requires signing a document expressing your consent. Even after signing it, you can stop participating by informing the investigator.
- The data collected on this occasion is confidential and your anonymity is guaranteed when the results are published.

• Insurance has been taken out in case you suffer damage related to your participation in this research.

• You can always contact the investigator or a member of their team if you need additional information.

Additional information on your “Clinical Study Participant Rights” is provided in Appendix II.

b) Objectives and conduct of the study

This study aims to evaluate an intervention in physical literacy (LP), a concept for promoting long-term physical activity, during adapted physical activity sessions already implemented through the “Citizen, in movement for my health »

(EMPMS).

This project, developed by the CHU and the University of Liège and supported by the AVIQ, is based on a partnership with Walloon municipalities and offers citizens the opportunity to practice physical activities free of charge supervised by trained physiotherapists and physical educators. to sport-health.

A particularity of the project is to gradually propose, through the concept of physical literacy, a motivational approach, centered on the participant, aiming to best support them towards the adoption and maintenance of physical activity throughout their life. life, for the benefit of their well-being and health.

To do this, the project will include, only in certain partner municipalities, an evaluation by assessment and monitoring of the different areas of physical literacy.

The main objective of this study is therefore to judge the impact of this physical literacy intervention on the participant's level of physical literacy and physical activity:

• Will the LP intervention, integrated into the EMPMS project in a certain municipality, have, in the short and medium term, had an impact on the dimensions of the participant's physical literacy?

• Does the LP intervention encourage the participant to (re)take, on average term, independent physical activity?

• Will the participants have obtained satisfaction and adhered to the EMPMS project and its follow-up? motivational?

Depending on the municipality in which you will participate in the EMPMS project sessions, you will benefit from an APA combined or not with an LP intervention. Participants whose APA is combined with an LP intervention will be part of the experimental group while the control group will include participants from normal APA sessions. In both cases, the sessions will be supervised by a health professional trained in adapted physical activity. After an evaluation of the initial LP for all the participants (control group and experimental group), a follow-up of both individual and collective LP will take place throughout the 3-month cycle for the participants in the experimental group. An evaluation will take place at the end of the cycle, as well as 3 months after the end of the cycle, for all participants.

c) Description of risks and benefits

As mentioned above, the program offered to you and the evaluation and monitoring tools do not differ from usual care. No additional risk of your participation in this program should be mentioned following your participation in this study.

Likewise, you should not expect any personal benefit from your participation in the study. Just know that your participation will allow us to evaluate the interest of this type of physical activity intervention and therefore, perhaps, to offer better programs in the future.

d) Collection and processing of personal data

In order to establish a report on the long-term interest and feasibility of this type of sport-health activity, particularly based on the individual characteristics of the participants, personal data concerning you will be collected and treated by members of the Musculoskeletal Medicine Department of the University Hospital of
Liège, namely:

- Identification data: name, first name, gender and date of birth;
- Data linked to a possible pathology, chronic or acute;
- Data linked to lifestyle habits linked to physical activity: sports, activities physical, hours of practice per week;
- Data linked to participation in the project: means of information and satisfaction possible relative;
- Data relating to the physical literacy assessment: specific questionnaire and physical tests.

The project managers will take all necessary measures to ensure the protection and security of your data. Prior to their recording on a secure medium, your data will be pseudonymized, which means that your identity will be replaced by a code. Access to your data will be reserved only for people involved in the project, who are subject to a duty of confidentiality. The data collected will be the subject of statistics which can be transmitted to the organizations (AVIQ) which finance these activities and used in the context of other possible scientific research, carried out by the University / CHU of Liège. Communication of research results will only include anonymized data.

e) Withdrawal of consent

Your participation is voluntary and must remain free of any constraint; it requires the signing of a document expressing your consent. Even after signing it, you can stop participating, without any justification, by informing the manager, Cédric Lehance, by email at empms@chuliege.be or by telephone at: 04 323 13 92.

Your personal data will be kept by the Musculoskeletal Medicine Department of the University Hospital of Liège, for the time necessary to achieve the objectives pursued within the framework of this project. However, if you withdraw your

consent to participate in the project, in order to guarantee the validity of the project, the data concerning you collected prior to this withdrawal may be kept and processed by the Musculoskeletal Medicine Department of the University Hospital of Liège.

You can, by providing proof of your identity, exercise a series of rights in relation to the processing of your personal data: access, rectification, deletion, limitation, erasure, withdrawal of consent, opposition and portability. To exercise these rights, you can contact the Musculoskeletal Medicine Department of Liège University Hospital, at any time, by email at the following address empms@chuliege.be or by telephone at 04/323 13 92.

For any questions relating to the processing of your personal data, you can also contact the Musculoskeletal Medicine Department of Liège University Hospital or the Data Protection Officer of Liège University Hospital at the following address: dpo@ chuliege.be.

You can also lodge a complaint with the Data Protection Authority contact@apd-gba.be.

f) Contact

If you need additional information, but also in the event of a problem or concern, you can contact the manager, Cédric Lehance, by email at empms@chuliege.be or by telephone at: 04 323 13 92

If you have questions relating to your rights as a participant in a clinical study, you can contact the patient rights mediator of your institution via the telephone number: Ms. Caroline Doppagne, Liège University Hospital, 0498/31 11 12 (between 8:30 a.m. and 4:30 p.m.).

II. Further information

a) Additional information on the organization of the study

This study will include the collection of data collected on the basis of questionnaires to be completed as well as simple physical tests forming part of the battery of exercises of the “EMPMS” project.

The questionnaire, relating to 5 of the 6 dimensions taken into account of physical literacy, was developed specifically from the literature for this project and includes more or less 20 questions (with answers in the form of a Likert scale or in open forms) for a total duration of approximately 15 minutes.

Following the questionnaire, in order to assess the physical dimension of physical literacy, you are invited to take 4 relatively simple physical tests taken from the literature and
with a total duration of approximately 15 minutes:

- Endurance test: *the 2-minute walk test.*
- Strength test: *Chair lift test (30 seconds).*
- Balance test: *Unipedal balance test*
- Flexibility test: *Chair sit and reach test.*

b) Additional information on the protection and rights of the participant in a clinical study

Ethics committee

This study was evaluated by an independent Ethics Committee, namely the Hospital-Faculty Ethics Committee, which issued a favorable opinion. Ethics Committees have the task of protecting people who participate in a clinical trial. They ensure that your rights, as a patient and as a participant in a clinical study, are respected, that in view of current knowledge, the balance between risks and benefits remains favorable to the participants, that the study is scientifically relevant and ethical. Under no circumstances should you take the favorable opinion of the Ethics Committee as an incentive to participate in this study.

Voluntary participation

Before signing, do not hesitate to ask any questions you consider useful. Take the time to talk to someone you trust about it if you wish.

Your participation in the study is voluntary and must remain free of any constraints: this means that you have the right not to participate or to withdraw without justification even if you had previously agreed to participate. Your decision will in no way change your relationship with the investigating doctor or the quality of your future therapeutic care.

If you agree to participate in this study, you will sign the informed consent form. The investigator will also sign this form and confirm that they have provided you with the necessary information about the study. You will receive the copy intended for you.

Protecting your identity

Your participation in the study means that you accept that the investigators collect data about you and that those responsible for the study use it for research purposes as well as for scientific and medical publications.

The investigator has a duty of confidentiality with regard to the data collected. This means that it not only undertakes to never reveal your name in the context of a publication or conference, but also that it will code your data (in the study, your identity will be replaced by a code identification) before sending them to the promoter.

The investigator and his team will therefore be the only ones able to establish a link between the data transmitted throughout the duration of the study and your medical records. The personal data transmitted will not include any association of elements allowing you to be identified.

To verify the quality of the study, your medical files may be examined by persons bound by medical confidentiality and designated by the ethics committee, the study sponsor or an independent audit body. In all cases, the examination of your medical files can only take place under the responsibility of the investigator and under the supervision of one of the collaborators he or she has designated.

Protection of personal data

1. *Who is the data controller? Promoter.*

   The promoter will take all necessary measures to protect the confidentiality and security of your encoded data, in accordance with current legislation1 .

2. *Who is the data protection officer ?*

   Mr Pierre-François Pirlet, dpo@uliege.be, 04/366.51.68.

3. *On what legal basis is your data collected ?*

   The collection and use of your information is based on your written consent. By agreeing to participate in the study, you agree that certain personal data may be collected and processed electronically for research purposes relating to this study.

4. *For what purposes are your data processed ?*

   Your personal data will be examined in order to produce the statistics necessary for the proper conduct of the study and its correct interpretation. They will be combined with the personal data of other participants, for the research objective of this study.

   Your personal data may also be combined with data from other studies. This makes it possible to analyze and improve the effectiveness of ABS and LP programs.

[1] These rights are guaranteed to you by the European Regulation of April 27, 2016 (GDPR) relating to the protection of personal data. personal data and the free movement of data and the Belgian law of July 30, 2018 relating to the protection of privacy with regard to the processing of personal data.

Any use of your data outside the context described in this document may only be carried out with your agreement and after approval of the ethics committee.

5. What data is collected ?

The investigating physiotherapist/physical trainer undertakes to collect only the data strictly necessary and relevant to the objectives pursued in this study, namely your name, your initials, your address, your gender, your age/date of birth, as well as data relating to your health and/or your treatment, data from questionnaires and physical tests as well as data

relating to your participation. He is the only one who can make the link between your identity and the code assigned to you.

6. How is my data collected ?

By the investigating physiotherapist/physical trainer and his team using questionnaires and physical tests.

7. Who can see my data ?

- The investigating physiotherapists/physical trainers and their team
- Promoters and their representatives
- The ethics committee having examined the study

These people are bound by an obligation of confidentiality.

8. By whom will my data be stored and secured? For how many time ?

Your data is kept by the promoter for the time required by regulations.
At the end of this period, the list of codes will be destroyed and it will therefore no longer be possible to establish a link between the coded data and yourself.

9. Will my data be transferred to other countries outside the European Union/ area European economy/ Switzerland ?

No

10. What are my rights over my data ?

You have the right to consult all the study information concerning you and to request, if necessary, its rectification.

You have the right to withdraw your consent in accordance with the “withdrawal of consent” section above.

You have additional rights to object to the way your study data is processed, to request its deletion, to limit aspects of its use, or to request that a copy of it be provided to you.

However, to ensure proper evaluation of the study results, some of these rights may only be exercised after the study has been completed. The exercise of your rights is done via the investigators.

Furthermore, if you believe that your study data is being used in violation of applicable data protection laws, you have the right to lodge a complaint at contact@apd-gba.be

c) Insurance

In an observational study, the only possible risk would be a failure in the measures taken to protect the confidentiality of your private information. The promoter assumes, even without fault, liability for damage caused to the participant (or his beneficiaries) and linked directly or indirectly to participation in this study. With this in mind, the promoter has taken out an insurance contract (Ethias SA, policy n°45.425.367, Tel: 04/220.31.11)[2].

[2] In accordance with article 29 of the Belgian law relating to experiments on humans (May 7, 2004)

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III. Informed Consent Form

Participant

I declare that I have been informed about the nature of the study, its purpose, its duration and what is expected of me. I have read the information document and the annexes to this document.

I had enough time to think about it and talk about it with a person of my choice (doctor, physiotherapist/physical trainer, family).

I had the opportunity to ask all the questions that came to mind and I received a favorable response to my questions.

I understand that data concerning me will be collected throughout my participation in this study and that the investigators and the sponsor of the study guarantee the confidentiality of this data.

I consent to the processing of my personal data according to the terms described in the section dealing with confidentiality guarantees (page 6/7). I also agree to the transfer and processing of my coded data in countries other than Belgium.

I accept/do not accept (delete where applicable) that the research data collected for the objectives of this study may be processed subsequently as long as this processing is limited to the context of this study (Development of intervention in physical literacy).

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

Name, first name, date and signature of the **participant :**

_____	_____	_____
First and last name	Date	Signature

Investigator

I, Weerts Jean-Pierre, physiotherapist and physical trainer investigator confirm having provided orally the necessary information on the study and having provided a copy of the information document to the participant.

I confirm that no pressure was placed on the patient to agree to participate in the study and that I am prepared to answer any additional questions, if necessary.

I confirm that I work in accordance with the ethical principles set out in the “Declaration of Helsinki”, in “Good Clinical Practices” and in the Belgian law of May 7, 2004, relating to experiments on humans.

Name, first name, date and signature of the **physiotherapist and physical trainer :**

_____	_____	_____
First and last name	**Date**	**Signature**