13 October 2020

ClinicalTrials.gov PRS
Protocol Registration and Results System

"When Movement Moves" - The Health Benefits Among Individuals With Low Physical Mobility Moved by Others (WMM)

ClinicalTrials.gov ID: NCT04536779

The Ethics Committee of the Capital Region of Denmark (Human subjects protection review board)

Journal-number.: H-20010668 (Date: 13th October 2020)

Participant information about participation in a scientific project.

1 Project title

When movement moves – Team Twin and cycling without age

2 Participation in the project

You are invited to participate in a research project by the National Institute of Public Health, University of Southern Denmark.

Before you decide whether to participate in *When Motion* Moves, you need to understand the project fully and why we are implementing the project. We would therefore ask you to read this participant information carefully.

You will be invited to a conversation about *When Movement Moves*, where this participant information will be elaborated and where you can ask your questions about the project. You can bring a family member, friend or acquaintance to the interview.

If you decide to participate in the project, we will ask you to sign a consent form. Remember that you have the right to a reflection period before deciding whether to sign the consent form.

Participation in the project is voluntary. You can withdraw your consent at any time and without giving a reason.

3 Purpose of the project

The primary purpose of this research project is to investigate what it means physiologically, mentally, and socially for people who cannot move themselves to be moved through others. Knowledge about this will form the basis for developing, implementing and anchoring initiatives to increase the quality of life of people with movement problems.

The secondary purpose is to study the quality of life and physiological health of people who move people with impaired movement function. Furthermore, among relatives, it is desired to measure the quality of life, relationships, community, the experience of fear of touch, the taboo towards people with disabilities, job satisfaction & well-being, unity, and social relations. In addtion among, caregivers, to measure quality of life, relationships, community, job satisfaction & well-being, unity and social relations

We will examine this in two sub-projects based on two existing initiatives that have the common purpose of creating quality of life, community and joy for people who are moved by others. These are: Team Twin and Cycling Without Age, where you are part of and/or have ties in one way or another.

4 Approach substudy 1 – Team Twin

4.1 Handiatlthes

As an active *handiathlete* and member in one of the local Team Gemini associations, it will be the planned training sessions and possibly competitions that you must participate in during the project. Training is handled in the local Team Gemini associations. The training location and time will be stated on the website of your local Team Gemini association.

In order for us to measure whether there are any effects, you must participate in a minimum of 8-10 training sessions in your respective Team Gemini association. These training sessions are within the spring/summer 2021 project period. In total, the project will include approx. 25 handiathletes, from different associations in the clinical tests, while we aim to invite everyone who is a member of the associations during the project period to answer a questionnaire.

Before you start training and competitions during the spring/summer, we would like to test you twice before the betting period and once after the stake period. You will be invited to test days, which take place at Rigshospitalet in Copenhagen, from 9 a.m. to 4 p.m. Clinical tests will be carried out by doctors, nurses and clinical research professionals.
The first two test days, before the intervention period, will take place about one month apart in the two months leading up to the start of training, i.e., the test days will be divided into two days from January-March. After the 3-month intervention period, you will be invited to one follow-up test day. This will be immediately after the intervention period.

We would like to measure you:

4.1.1 Questionnaire and interviews

In order to investigate the sociological and psychological effects, we ask you to answer a questionnaire on, among other things, quality of life, health, well-being and well-being. Some handiathletes will also be invited to interviews where we cover the same topics.

4.1.2 Clinical tests

We also want to conduct clinical tests on you. We do this to find out what effect movement through others has on your physical. The clinical tests will consist of; 1) DXA scan for body composition (muscle and fat mass), 2) We calculate blood volume from changes in the participant's haematocrit value as an indirect measure of fitness level, 3) Oral Glucose Tolerance Test (OGTT) to measure glucose metabolism and 4) blood tests to measure stress hormones and inflammation, including cytokines and CRP. Risks that may be associated with individual clinical tests are described in section 6.

4.1.2.1 How are the clinical tests carried out

The testing is carried out with other persons participating in *When Movement Moves study*. Therefore, a full day (9 am-4 pm) will be set aside for each test day. In order for us to measure special lipids, hormones, enzymes, and substances in your blood, you must show up fasting (i.e. you have *not* drunk or eaten *8 hours* before). You will receive detailed information about the clinical tests prior to and on the day of the test. You have the right to have an assistant with you for the testing.

You can expect a little waiting time between tests, as several of you must go through on the same day. Of course, we will make sure that you will get food and drinks during the day. Please let us know if you have any allergies before you show up for the test days. The procejt will also cover the expenses you incur concerning transport to and from Rigshospitalet, Copenhagen, according to the current state tariff.

4.1.2.2 Biobank and blood tests - what do we do with your collected blood?

According to the Personal Data Act, surplus biological material from the project must generally be destroyed at the end of the project. However, we will apply for the Danish Data Protection Agency's permission to establish a new research biobank with the surplus material (10 ml) for use in future research, if you consent to this. Your blood will be stored in a Data Protection Agency-registered research biobank at the Centre for Active Health (CFAS) for a maximum of 20 years and will subsequently be destroyed.
Any new research project will be notified to the Scientific Ethics Committee. When granting permission for new research, new consent must generally be obtained from you for the research. However, the Committee may authorize new research without obtaining consent if there is no risk or strain on the subject of the new research

In total we collect up to 170 ml of blood from you on the day of the test – a total amount of blood that is so small that it does not matter to you. Any excess biological material that has not been collected for future research will be destroyed.

4.1.3 Bio-tracking

During your training sessions and any competitions, you will be equipped with either an accelerometer or a watch that can monitor movement and possibly heart rate and sleep.

4.2 Runner:

As an active member as a *runner*, in one of the local Team Gemini associations, it will be the planned training sessions and any competitions that you must participate in during the project. Training sessions are carried out in the local Team Twin associations, and are typically of one to two hours duration. The training location and time will be stated on the website of your local Team Gemini association.

In order for us to measure whether there are any effects, you must participate in a minimum of 8-10 training sessions in your respective Team Twin association. These training sessions are within the spring/summer 2021 project period. Approx. 25 runners from different associations will be included in the objective measurements, while we aim to invite everyone who is a member of the associations during the project period to answer a questionnaire. We will strive to ensure that the runners have a relationship with the participating handiathletes, as the qualitative sub-project will investigate the relationship between runner and handiathlete.

We would like to measure you:

4.2.1 Questionnaire and interview

In order to investigate the effects of being a runner in a Team Gemini association, we will ask you to answer a questionnaire and possibly participate in a focus group interview, which will include social, health and psykologiske med fokus på livskvalitet, relationer, fællesskab, identitet, sundhed, trivsel, velvære og bevægelsesglæde.

4.2.2 Bio tracking

Physiological health is also relevant for us to shed light on you as a runner. Therefore, we will equip you with a heart rate monitor/accelerometer during training sessions and competitions.

4.3 Relatives:

4.3.1 We would like to measure you:

4.3.2 Questionnaire and interview:

Among relatives related to a handiathlete, we want to measure quality of life, relationships, community, the experience of touch anxiety and taboo towards people with disabilities. This is done by answering a questionnaire and possibly participating in an interview.

5 Approche substudy 2 – Cycling without age

5.1 Passengers

As a user of Cycling Without Age's initiatives, it will be the planned bike rides that you will participate in during the project. The bike rides are carried out by the volunteer pilots in the places where Cycling Without Age is offered. Bike tour times will be listed at local tender locations and may vary from location to location and duration.

In order for us to measure whether there are any effects, you must participate in a minimum of 6-8 bike tours of minimum 3 months duration with the provider where you normally participate in Cycling Without Age's activities. The bike tours are within the project period in spring/summer 2021.

We would like to measure you:

5.1.1 Questionnaire and interviews

In order to investigate the sociological and psychological effects, we ask you to answer a questionnaire on, among other things, quality of life, health, well-being and well-being. Some passages will also be invited to a focus group interview, where we uncover the very same topics.

5.1.2 Bio-tracking

During your bike rides, you will be equipped with either an accelerometer or a Pulse that can monitor movement and possibly heart rate and sleep.

5.1.3 Functional level

Immediately before and after you have participated for a minimum of 3 months and 6-8 bike rides, we will perform standardized measures for balance and coordination, so-called measurements of your functional level.

5.2 Pilot

As a volunteer *pilot* associated with Cycling Without Age, it will be the planned bike rides that you will participate in during the project. The bike tours are handled by the local Cycling Without Age providers, and are more durable in relation to the bikes. Duration and length. The time of the bike tours will vary from place to place, but will be stated at the local locations.

In order for us to measure whether there are any effects, you must participate in a minimum of 6-8 bike rides. The bike tours are within the spring/summer 2021 project period. Approximately 25 pilots from different Cycling Without Age locations will be included for the objective measurements, while we aim to invite everyone associated with the Cycling Without Age project period to answer a questionnaire. We will strive to ensure that the pilots have a relationship with the participating passengers, as the qualitative subproject will examine the relationship between pilot and passenger.

We would like to measure you:

5.2.1 Questionnaire and interview

In order to investigate the effects of being a pilot in one at Cycling Without Age, we will ask you to answer a questionnaire and possibly participate in a focus group interview, which will deal with social, health and psychological with a focus on quality of life, relationships, community, identity, health, well-being, well-being and joy of movement.

5.2.2 Bio tracking

Physiological health is also relevant for us to elucidate on you as a pilot. Therefore, we will equip you with a heart rate monitor/accelerometer during the bike rides.

5.3 Caregivers

We would like to measure you:

5.3.1 Questionnaire and interview:

Among caregivers related to one or more passengers, we want to investigate job satisfaction and well-being, unity and social relations. Knowledge about this is gathered through a questionnaire and focus group interviews with the actors involved

6 Benefits of the project

We will place great emphasis on sharing experiences and results with relevant stakeholders and decision-makers who can help anchor the results in the long term in relation to changed practices in residential homes, nursing homes, etc. essential stakeholders are the National Association of Local Authorities (KL), the Danish Parliament's Health and Elderly Committee, the National Board of Social Services and the National Board of Health, as well as municipalities and regions in the country. The project group will give

presentations at national conferences and collaborate with other health and care actors on activities promoting national dissemination. These include the Healthy City Network's physical activity theme group and mental health theme group. Furthermore, the project group will regularly inform KL's health and social care departments. Finally, a closing conference is planned, where relevant stakeholders are invited.

The overall goal is that the measures, if they prove effective, are incorporated into national guidelines as well as municipal and local action plans, which enable changes in current practice in, for example, residential homes and senior care centers; both organizationally and among staff.

1. Are there side effects, risks, complications and disadvantages?

We do not consider that there are particular side effects and disadvantages to participating in *When Movement Moves*. However, it cannot be ruled out that the physical training may lead to injuries – if, for example, A participant twists his foot, however, this is not a specific risk as a result of participating in the research project. Team Twin and Cycling without age associations handle the training and cycling programs and the activities are adapted to these specific target groups. In this way, the risk of injury and nuisance is considered minimal.

There may be minor complications associated with the clinical tests for handiatlthes:

- *Blood samples and OGTT:* Slight discomfort should be expected in connection with blood sampling and OGTT. The amount of blood taken is so small (up to about 166 ml) that it is not expected to affect the subject. However, bruising and infection may occur at the injection site, which is quite common in blood sampling.

- *Measuring body composition in DXA scanner:* No discomfort is expected. The X-ray radiation dose is equivalent to flying an ordinary airplane for 11-12 hours. That is, the radiation dose is so small (0.0004mSv) that it is not considered to pose any significant risk to subjects. (read more at SST. DK – radiation guide)

There may be risks involved in participating in the project that we do not yet know. We, therefore, ask you to tell us if you experience problems with your health while the project is ongoing. If we discover side effects that we have not already told you about, you will be informed immediately and have to decide whether you want to continue in the project.

1. Project exclusion and interruption

Exclusion from the project among handiathletes can occur if the person sustains an injury or is affected by a long-term illness and is thus prevented from participating actively in Team Twins or Cycling without age activities.
The same applies to the runners and pilots who participate in the project. If runners or pilots become ill or injured and thus cannot participate actively over a more extended period in the project, it will also cause an interruption in their participation, despite their desire to continue.
All participation is, of course, also voluntary, and all participants can therefore withdraw their commitment to participation at any time.

7 Timetable

7.1 for subproject 1

Subproject 1, Team Twin, will take place in 2020 and 2021.
The time after the end of the project will be used to analyse and interpret the research results until the end of 2023.

7.2 for subproject 2

Subproject 2, Cycling Without Age, will take place in 2021.
The time after the end of the project will be used to analyse and interpret the research results until the end of 2023.

8 Remuneration in connection with test days at Rigshospitalet

In connection with test days, where the participants themselves must arrange transport to and from Rigshospitalet, travel allowances will be paid according to current state tariffs. Furthermore, there will be catering for the participants and possibly the assessor/relatives.

9 Scientific ethics review and ethical considerations:

The design is guided by the Consolidated Standards of Reporting Trials (CONSORT) statement and will comply with EU data protection regulations – GDPR. The project is carried out in accordance with the Danish Council for Independent Research's ethical guidelines, and the project will be approved by the Danish Data Protection Agency and the Scientific Ethics Committees before start-up. The condition of persons with reduced mobility will be taken into account at all stages of the project.

10 Access to trial results

The results from *When Motion Moves* will be published after the completion of the project in 2023. Where subproject 1 and subproject 2 are completed.

11 In closing

We hope that with this information you have gained sufficient insight into what it means to participate in *When Movement Moves*, and that you feel equipped to make the decision about your possible participation. We also ask you to read the enclosed material "The subject's rights in a health science research project".

12 Contact information and further questions

If you want to know more about the trial, you are very welcome to contact a research associate on the project:

- Project Manager, Associate Professor, PhD Christina Bjørk Petersen, chrb@sdu.dk, 65507746
- Project employee, research assistant, cand. Scient.: Andreas Jørgensen, ajor@sdu.dk, 65557718

Sincerely,

Participant information to the Scientific Ethics Committee, Copenhagen

Christina Bjørk Petersen
Project Manager, Associate Professor, PhD
National Institute of Public Health, SDU

Review Number 72374, Version 2, 01/09-2020

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Journal-nr.: H-20010668

Date: 13-10-2020

Translation of decision by the Science Ethics Committee

H-20010668 - When Movement Moves - Team Twin and cycling without age

The Ethics Committee of the Capital Region of Denmark has processed the matter at its meeting on 6 October 2020 and has taken the following decision:

The project is approved under Law No 593 of 14 June 2011 on the scientific ethics treatment of health science research projects with subsequent changes (consolidated in Decree-Law No 1083 of 15/09/2017).

The authorisation is valid until 31 March 2023 and includes the following documents:

The protocol received 1 October 2020

- Participant Information Team Gemini of 1 September 2020, version 2
- Participant Information Cycling without age, version 2, of 1 September 2020
- Consent declaration (clinical test) received 1 October 2020
- Consent declaration (without clinical tests), received 1 October 2020
- Advert text, Team Twin and Cycling without age, received 1 October 2020

The approval applies to the notified test sites and the notified responsible investigator in Denmark.

The committee is not the jurisdiction of the data protection framework. The committee assumes that the project is carried out in accordance with the Data Protection Regulation and the Data Protection Act.

Implementation of the project in violation of the approval is punishable by a fine or imprisonment, cf § 41 of the Committee Act.

Amendment;

Where substantial changes are made to the minutes during the implementation of the project, they shall be notified to the committee in the form of additional protocols. The amendments may only be implemented after approval by the committee, cf. § 27(1) of the Committee Act.

Additional protocols must be notified electronically on www.drvk.dk with the notification number and password already assigned.

Significant changes include changes that may affect the safety of the subjects, interpretation of the scientific

documentation on which the project is based and the implementation or management of the project.These include changes in in and exclusion criteria, study design, number of subjects, experimental procedures, duration of treatment, effect parameters, changes in subjects or test sites, and substantive changes in the written information material for the study subjects.

Where new information means that the researcher is considering changing the procedure or stopping the trial, the committee should be informed about it.

Harms and adverse events

Ongoing reporting

The committee shall be informed immediately if the project has suspected serious, unexpected side effects or serious adverse events, cf. § 30(1) of the Committee Act.

Only side effects and adverse events occurring in Denmark need to be reported. Notification shall be made within 7 days of the knowledge of the case by the sponsor or the responsible investigator.

When reporting, a template form can be used, which can be found on www.nvk.dk. The form may be submitted electronically using a digital signature.

Annual report

Once a year throughout the study period, a list of all serious (anticipated and unexpected) adverse side effects and serious adverse events, together with a report on the safety of subjects, shall be sent to the committee, in accordance with Section § 30(2) of the Committee Act.

The material must be in Danish or English.

When reporting, a form shall be used, which is available on the www.nvk.dk. The form togehter with the appendix may be submitted electronically using a digital signature.

End:

The responsible investigator and any sponsor must inform the committee within 90 days of the end of the project, cf. Section 31(1) of the Committee Act.
The project is regarded as completed when the last subject is terminated.

If the project is interrupted earlier than planned, a justification for this must be sent to the committee no later than 15 days after the decision has been made, cf. section §31 (2) of the Committee Act.
If the project does not start, this and the reasons for it shall be communicated to the Committee.
The Committee asks for a copy of the final research report or publication, cf. section §28 (2) of the Comi- te Act.
In this connection, we must point out that there is a duty to publish negative, positive and inconclusive test results, cf. the Committee Act
§ 20(1), no. 8.
The obligation to report final trials and reports is the responsibility of the trial manager and any sponsor jointly.
Supervision
The committee supervises that the project is carried out in accordance with the approval, cf. § 28 and 29 of the Committee Act.

Signature on the consent form

The Committee points out that the person responsible for the study may delegate his duty to sign the consent form to the person giving the oral information talk. In this case, there must be a written delegation to this effect on the experimental site.

The following committee members have been involved in the assessment of the project:

René Mathiasen, Klaus Müller, Tiit Illimar Mathiesen, Lotte Risom, Stig E Bojesen, Leila Lindén, Annie Hagel, Jette Jul Stenbæk Jensen, Ove Thuen

Sincerely,

René Mathiasen Chairman of Committee C

Copy sent to:
Mathias Ried-Larsen