

5th August - 2021

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**"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)

Study protocol

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

Background

Elderly and individuals with functional disabilities often face multiple personal and environmental barriers reducing their ability to engage and participate in physical and social activities [1-5]. Increasing age and level of disability correlates with lower levels of physical activity (PA), and an increased prevalence of chronic and cardiovascular diseases [6-11], which can result in premature death [12-15]. Contemporary literature indicates a dose-response relationship between PA and promotion of all health outcomes: the greatest risk reduction comes with higher intensities of PA [16], thus, PA serves as disease prevention and health maintenance [6, 17]. Moreover, the World Health Organisation encourages elderly and disabled, regardless of age or impairments, to perform any kind of PA, as 'some is better than nothing' [18]. Additionally, a recent review indicates that less PA than the recommended can enhance health outcomes among persons with a disability [19]. Moreover, a recent study has linked various alternative forms of PA and therapy to be beneficial for health promotion and rehabilitation among individuals with cerebral palsy (CP) [20]. The literature further indicates that PA can promote cognitive function among the elderly [21] and cognitively disabled [22] on top of the well-known physiological benefits of PA. Elderly and disabled persons participating in adapted sports experience an increase to mental and social health factors, e.g., decreased feelings of loneliness, increased feelings of self-efficacy [23], autonomy and well-being [24, 25] and improvements in quality of life (QoL) [25-29]. Social support is identified as a crucial facilitator of the disabled and elderly's participation in PA [30]. Prior studies, however, have mainly focused on individuals with spinal cord injuries or elderly who can participate in (elite)sport and PA by themselves, despite a disability [24, 27, 31] or physical limitations due ageing [32]. There is a lack of literature on the frailest individuals in these groups, who are unable to participate in most kinds of PA. The few studies available have low external (i.e generalisability) validity [27, 33]. Pilot studies investigating indirect PA (defined as an activity where a person unable to partake in physical activity on their own, is joined by someone who is

able, and together partake in PA) in the disabled [34] and elderly [35-40] populations exist, however, and these report promising effects of indirect PA on all health outcomes and QoL

Despite the existence of pilot studies, little is known about the physical, mental and social health benefits of participation in indirect PA in a social context. Programmes (interventions/initiatives) providing indirect PA may motivate and promote participation if (some of) the same health benefits derived from PA can be attained through indirect PA, which may in turn result in improved QoL of the elderly and disabled.

Therefore, the research project “When Movement Moves” (WMM) evaluates the pre-existing Danish programmes: Team Twin (TT) and Cycling Without Age (CWA) as both programmes make use of volunteers to assist indirect PA in disabled individuals and the elderly, respectively, using equipment designed for the purpose. The programmes ultimately share the same goal: enhancement of QoL and promotion of physical, social and mental health achieved through indirect PA in a social context [41, 42].

Aim

The overall hypothesis is that the activities delivered by Team Twin and Cycling Without Age increase the quality of life of the participants who are moved through others. The purpose of the trial is to investigate the physiological, mental, social health effect among individuals with low physical mobility participating in one of the two pre-existing initiatives: the Danish 'Team Twin' and Cycling Without Age. In these, the individuals with low physical mobility are moved by and together with normal functioning volunteers. Furthermore, we will investigate the importance of being a volunteer runner and pilot, relatives of and care staff for disabled athletes and the elderly.

Based on the above, this research project will answer the following research questions:

- 1. Does movement by others improve the quality of life (QOL) among individuals with low physical mobility*
- 2. Does movement by others improve the physiological health among individuals with low physical mobility*
- 3. Does moving individuals with low physical mobility improve health among normal functioning individuals (i.e. volunteer runners and pilots)?*
- 4. How does participation in the physical activity initiatives influence well-being, relations and attitudes among relatives (to the disabled individuals) and employees at nursing homes?*

Design and Methods

Settings

The WMM-project will be conducted in collaboration with the local departments of Team Twin (TT) and Cycling Without Age (CWA).

The Team Twin association

The TT association is the overall umbrella-organization for the sports and inclusion concept "Team Twin – We run Together". It was established in the year of 2014. Since then, the TT association have grown, and the association now has local departments established all over Denmark with the biggest local department located in Copenhagen with approximately 100 members [43]. The total amount of local department has grown to nine since the beginning and has over 400 members in varied age, disabled and non-disabled, women, men, adolescence and adults (for an overview of the organization chart of the Team Twin association see figure 1). The intensity, exercises (triathlete inspired), and duration can vary from club to club and according to time of the season. Handicap Athletes and volunteers, so called runners, are expected to participate in a minimum of 8-10 training sessions during the trial period, which is a minimum of 3 months. In the period from Oktober 2020 to January 2021, two-three new local departments are expected to be established. In close cooperation between Team Twin and Institute of Public Health , University of Southern Denmark (SDU), we will seek out to recruit the recent members of the latest established local departments of TT.

The details of times and investigations will be determined in collaboration with the local associations and with regard to planned training courses and possible participation in competitions.

Cycling Without Age

Cycling Without Age is a worldwide association started up in Denmark, whose mission is to give the elderly "the right to wind their hair". Volunteers, so-called pilots, cycle elderly people, so called passengers, with low level of mobility in rickshaws on shorter or longer trips. The primary purpose is to give senior citizens a feeling of joy and give them the opportunity to remain an active part of the community. In Denmark, there are more than 7,000 volunteer pilots across 430 locations, typically care centers, with a total of 500 rickshaws. In 2018, a total of 14,877 registered bicycle trips were made [42].

A minimum of 6-8 bicycle trips during the intervention period, which is a minimum of 3 months, is, however, assumed to be necessary in order to be able to attribute the effect to the intervention. The

details of times and examinations will be determined in collaboration with the local care centers and any planned bicycle trips.

Theoretic framework for evaluation

The programme theory illustrates the causal chain, which explains the hypothesis of how the intervention components of the Team Twin and Cycling Without Age are expected to impact the participants quality of life by participating in one of the two components (Figure 1).

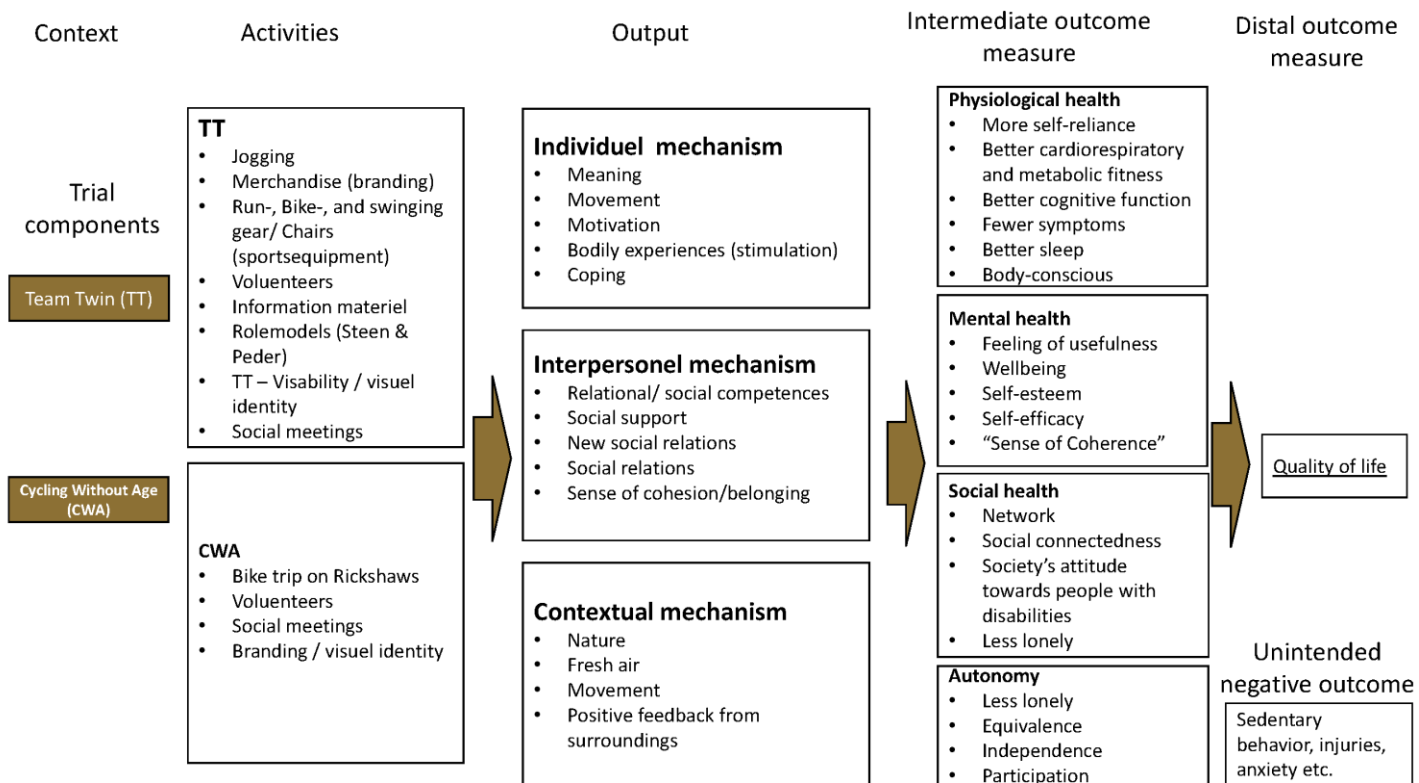


Figure 1 Overall program theory for WMM-study

Quality of life is a broad concept, and there are many different definitions, all of which include dimensions of physical, social and mental health. The World Health Organization (WHO) defines quality of life as: “..an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, personal beliefs, social relationships and their relationship to salient features of their environment.” [44] Quality of life will be elucidated from different angles and examined by different quantitative and qualitative methods such as through a) scientific methods in the form of physiological measurements and physical tests b) questionnaires and c) interviews and observations.

Study designs

The WWM-study consists of different parts and each part has its own approach, methods and measures, which will be described below. Prior to the data collection, we will pilot test our questionnaires, interview- and observation guides for the potential adjustments according to the data collection methods. Further, we will conduct a minor pilot test of the laboratory protocol with 1-2 Handiathletes affiliated in an existing local department of Team Twin. The study has been reported to the Danish National Committee on Health Research Ethics Journal-nr.: H-20010668 ().

The target groups of the WMM trial are: 1) Handiathletes (Team Twin) and Passengers (Cycling Without Age and 2) the volunteer persons called “Runners” (TT) and “pilots” (CWA), who are the persons who move the disabled, Relatives (i.e. parents and siblings of the Handiathletes and 4) Nursing Staff (e.g. NS working at a care home, disabled carer or disabled escort for elderlies). The disabilities among the Handiathletes varies but the three most common are 1) cerebral palsy, 2) muscular dystrophy and 3) non-specific inherent faulty genes. Among the elderly, it will mainly be age-related mobility decline however, also some decrease in cognitive functioning occurs among some of the participants.

Sub-study 1. Team Twin

Study design: Self-controlled before and after study. We do not consider it practically possible to carry out a study with a control group due to the relatively modest number of new members in the association.

Target group: Handiathletes (n=25) and runners (n=25). For the explorative study, interviews will be conducted with Handiathletes (n=4-6) and runners (n=4-6). Also, relatives will be included in focus group interviews (n = 4-7).

Methods: Physiological measurements and questionnaire with three measurement points. Twice before the start of the training course and once immediately after the end of the training course. This means that the individual participant acts as his or her own control. This sub study consist of two parts 1) a pre-post short-term effect evaluation; and 2) an explorative study guided by the program theory, in which examine how, why and what has an impact on mental and social health.

Study period: The baseline measure for this substudy is medio February 2021 (before the training season), and follow-up measurements will be conducted four months later in ultimo June.

Primary outcomes: Quality of Life for Handiathletes and secondarily the physiological effects.

Measurements:

Selfreported Questionnaire (Handi Athletes, Runners and relatives): Quality of Life will be measured by questionnaire. For detailed information on the questionnaire, see the measurements section below.

Weekly text-message (SMS) (Handiathletes and Runners): registration of perceived well-being and quality of life.

Movement sensors (Handiathletes and Runners): Heart rate registration (GARMIN-watch). Runners will be informed, and trained in the use of the technology. The a GARMIN-watch will be attached to the wrist of the *Handiathletes* to quantify the level of physical activity during training and races throw the trial period. Further, the Garmin-watch will monitor the quality of sleep for one week in the trial period.

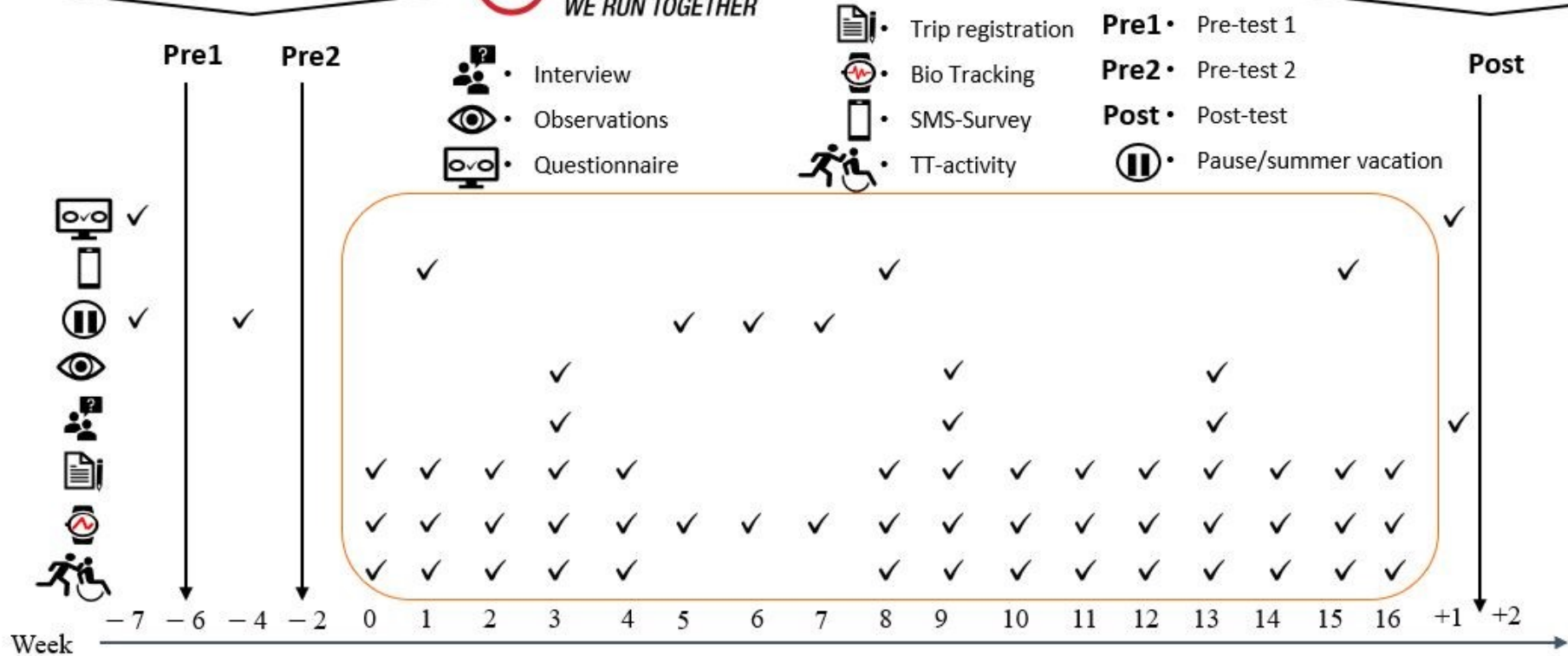
Clinical test (Handiathletes only): 1) Dual x-ray absorptiometry (DXA -scan) for measure change in body composition (body fat and lean mass), 2) Blood samples for measuring the metabolic change including; serum concentration of cholesterols, triglycerides, glucose, C-peptide, insulin and HbA1c, haematology, electrolytes, metabolites, liver- and renal status, endocrinology (including HCG if relevant) and markers of immune function/inflammatory, 3) Oral glucose tolerance test (OGTT) will be performed for screening the glucose level (metabolism inflammation: plasma- LDL, HDL, TG, TC, fasting insulin, C-peptide and glucose), 4) Blood volume (BV) status will be conducted to investigate the training effects on central underlying mechanisms of cardiorespiratory fitness, namely, total BV, plasma volume (PV) and haemoglobin mass (Hbmass).

Interviews (Focusgroup and single interviews) and observations: For detailed information on the interviews and observations, see the measurements section below.

- A medical history and examination (B1)
- Oral Glucose Tolerance Test (OGTT)
- Dual X-ray absorptiometry (DXA)
- Blood samples



- Oral Glucose Tolerance Test (OGTT)
- Dual X-ray absorptiometry (DXA)
- Blood samples



Overview of activities taking place during the TT subproject of WMM

Sub-study 2 – Cycling without age

Study design: Before and after evaluation of the Cycling Without Age activities on Quality of life using matching-adjusted indirect comparison between elderlies enrolled with the activities and elderlies not enrolled. This design is chosen, as randomization is not considered a realistic option in this real world pragmatic trial.

Target group: Passengers (Elderlies at nursing homes) (n=approx. 100 in the 'intervention group')) and pilots (n=approx. 100). In close collaboration with the association Cycling Without Age, we will recruit participants for the research project. We will strive to include older people who have not previously participated in activities with Cycling Without Age.

Methods: Selfreported questionnaire before and after the activities (at least two measurements). We will monitor whether it is possible to observe a dose-response relationship eg. Duration and distance.

Study period: The baseline measure for this substudy is spring 2021.

Primary outcomes: Quality of Life for elderlies. Secondary outcomes: mental, physical, and social health. (See program theory)

Measurements:

This section will explain the characteristics of the material and instruments used to conduct a quantitative investigation of the Cycling Without Age subproject.

Objective Functional and Cognitive Appraisal: A test battery will be conducted pre and post on-site at the participants' residence to evaluate a change in cognitive and physical function among nursing home residents. Cognitive function Brief Assessment of Impaired Cognition Questionnaire (BASIC-Q). A simple and newly invented tool for practitioners and healthcare professionals was selected to assess a possible change in the cognitive function level of the nursing home residents

Physical Function and Mobility: To evaluate physical performance and a possible change from pre to post, various physical tests were selected. Our test battery includes (1) the Short Physical Performance Battery, (2) the 4 m gait speed test and (3) the 6-min walking test (6MWT). The battery is performed on-site, where the nursing home resident lives, following recommended guidelines and standard procedures for each test [75,76]. All the tests are highly recommended in research and used among elderlies to detect functional capacity and sarcopenia symptoms. The chosen tests have shown great validity and reliability [77].

Muscle Strength; Muscle strength will be evaluated with (1) the chair and stand test (which is incorporated in SPPB) and (2) handgrip strength. The grip-strength measure is performed three times with a 1-min interval between each attempt. The attempt with the highest score (measured in kilograms) will count as the final.

Power Calculation

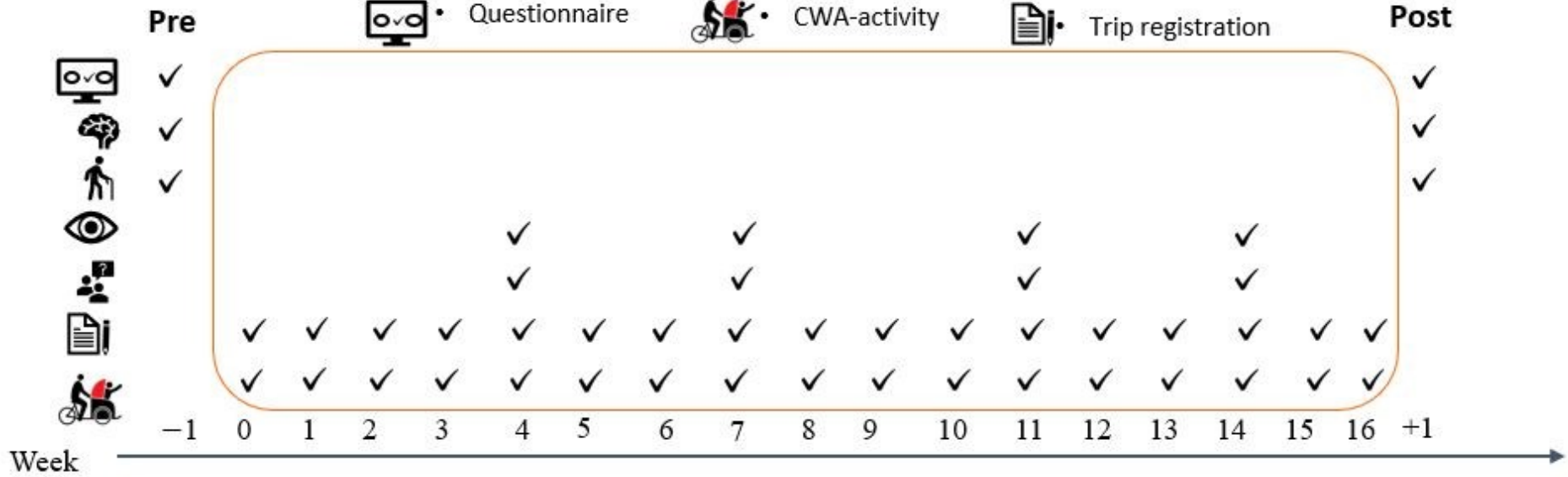
Based on a Danish Ph.D. project from 2019 [45], our study should include a minimum of 19 Handi Athletes, to detect a 10% increased effect in the main outcome (Quality of Life) (effect size 10%, absolute change 0.66, standard deviation 1.0, strength (beta): 0.8, alpha: 0.05). However, the WMM-study aim to recruit more than 19 Handiathletes to participate in the questionnaire (Sub study 2 and 3).



- Interview
- Observations
- Questionnaire

- Cognitive test
- Functional test
- CWA-activity

- Pre** • Pre-test
- Post** • Post-test
- Trip registration



Overview of activities taking place during the CWA sub-project of WMM

Data collection methods

Questionnaires

The questionnaires are mainly based on validated measures (i.a. Cantril Ladder of Life Scale WHOQOL-disability modul, WHO-5 and (S)WEMWBS), further, it will be supplemented with items from other studies including EQOL[45] and SHILD[46]. "Cantrills Ladder" is used and validated in a lot of studies as a simple way to ask people to rate their current satisfaction with life - or happiness from a scale from 0-10 (where 10 is the best and most satisfying life you can have, and 0 vice versa)[47]. Therefore, this scale is expected to a validated measure tool that can be used among many different target groups – including WMM.

New items will be developed especially related to the WMM-Study to uncover the study hypothesizes. The questionnaires will cover themes in the overall and target group specific program theory. The questionnaire will be developed among the research group, expert group and internal colleagues who have research experience with the target group.

The questionnaire for the Runners and pilots seeks to measure the volunteers Quality of life and the underlying sub-themes according to Quality of Life. The questionnaire will be developed by the research group and will seek inspiration from other studies i.e the ABC-mental health study[48]. The questionnaire will cover the following themes: QOL, life satisfaction, Identity self-assessed health, Physical activity and social cohesion, welfare, voluntariness, value & importance. Also the questionnaire to the relatives and the Nursing staff will cover the following some of the above mentioned themes.

Observations

For each of the sub study we observe 6-8 activities, where we cycle and run with the participants to get insight into how the activities proceed, the effects on mood and on how the participants interact. Insights from the participant observations are expected to feed into the subsequent interviews with the participants and give us a unique opportunity to follow up on specific elements, episodes and participant reactions in the courses. Participant observation is particularly well suited to examining social processes and concrete interactions and participant reactions in situ.

Interviews

To obtain the participants' descriptions of their experiences, qualitative interviews will be conducted with the disabled athletes (n = 4-6) and the runners (n = 4-6) (Team Twin) as well as with the passengers (n = 4-6) and pilots (n = 4-6) (Cycling Without Age). The interviews are conducted 4-5 weeks after the beginning of the activities using semi-structured, individual interviews, which are suitable for exploratory studies, where

the informants' experiences, perspectives, reasoning and ways of talking about the phenomenon under investigation are in focus.

Also, four focus group interviews will be conducted (n = 4-7) with relatives and caregivers. Focus group interviews are suitable for shedding light on different experiences and perspectives on a given research topic.

For all interviews, an interview guide is developed based on the research questions and adapted to the target group. Recruitment of the participants and sampling takes place in collaboration with Team Tvilling and Cycling Without Age associations. The empirical material (transcripts of interviews and field notes) is analyzed according to general principles of qualitative analysis.

Trial period and Organization

The project will be coordinated from 2020 to 2023 by the Center for Intervention Research at the National Institute of Public Health, SDU. The National Institute of Public Health has set up an interdisciplinary project group that has extensive experience with research into physical activity as well as mental health and quality of life, including the importance of meaningful communities. Activities will be carried out in close collaboration with the Team Twin and the Cycling Without Age associations. TrygFonden's Centre for Physical Activity Research (CFAS) is included as a project partner and will be responsible for the laboratory testing of people with physical disabilities.

Founding

The study is funded by financial support from the Bevica Foundation (2.5 mill DKK) and Helsefonden (2.5 mill DKK).

Ethics Consideration

The WMM study s will be registered in the Danish research ethics committee and data protection agency (awaiting number of registration). It will be guided and reported in accordance to the CONSORT declaration (Consolidated Standards of Reporting Trials). The trial will follow the European General Data Protection Regulation (GDPR), and the guidelines from the "Danish Council for Independent Research". Regarding the target group, the project will take their different condition in for consideration at all stages of the project.

Statistical Analysis Plan (SAP)

Changes from pre to post in mean score of QoL, measured using Cantril's Ladder [47, 49], will be the primary statistical outcome measure. Secondary outcomes will include sleep, well-being, loneliness and autonomy, as these were identified, during our design phase, to be essential factors for the target groups. In addition, changes in the objective measures (clinical examination and physical function test) will also be conducted for each target group. For descriptive statistics and to inform participant characteristics, we plan to use paired t-tests and chi-square tests. We furthermore intend to conduct regression analyses, using a mixed method approach to compare pre and post measures. Analyses will be performed as per-protocol and after the intention-to-treat principle, which, in this case, means that potential dropouts (with incomplete data) are included in the analyses. Per-protocol participants are defined as participants who have participated in a minimum of eight TT or CWA-activities in the period from pre to post measurements. The analyses will be adjusted for sociodemographic factors such as sex, age and educational level. Data is analysed using significance levels of $p=0.05$ and 95% confidence intervals. Analyses will be completed by Stata Software (StataCorp LP, College Station, Texas).

Outcomes measures and approaches

Sub-study 1. Team Twin

Outcomes and measures in the Team Twin evaluation

Measurement (outcome)	What (operational)	How (instrument)	When (timing of collection)	Who in CWA (Data source)
PRIMARY OUTCOME				
Quality of life (QoL)	Cantril Ladder of Life Scale [49]	Web- and interview-based questionnaire	Baseline, follow-up	Passengers, Pilots, Nursing staff
SECONDARY OUTCOMES				
Autonomy	The perceived feeling of being in control over ones own life	Web-based questionnaire	Baseline, follow-up	Passengers
Sleep	Sleep quality and sleep quantity	Web-based questionnaire	Baseline, follow-up	Passengers, Pilots,

Measurement (outcome)	What (operational)	How (instrument)	When (timing of collection)	Who in CWA (Data source)
Well-being	CUA: Warwick-Edinburgh Mental Well-Being Scale (S)WEMWBS [50, 51]	Web-based questionnaire	Baseline, follow-up	<i>Passengers, Pilots</i>
Loneliness	A perceived feeling of loneliness and lack of network and support [52, 53]	Web-based questionnaire	Baseline, follow-up	<i>Passengers, Pilots</i>
EXPLORATIVE OUTCOMES				
Self-perceived health	Subjectively perceived Health [54]	Web-based questionnaire	Baseline, follow-up	<i>Passengers, Pilots,</i>
Perceived pain	Mental and physical pain/discomfort [54]	Web-based questionnaire	Baseline, follow-up	<i>Passengers, pilots</i>
Self-perceived Physical performance	Subjectively perceived Physical performance [55]	Web-based questionnaire	Baseline, follow-up	<i>Passengers, pilots</i>
Self-efficacy	General self-efficacy [56, 57]	Web-based questionnaire	Baseline, follow-up	<i>Passengers, pilots</i>
Self-worth	Perceived feeling of Acceptance [45]	Web-based questionnaire	Baseline, follow-up	<i>Passengers, pilots</i>
Autonomy	The perceived feeling of being in control over ones own life	Web-based questionnaire	Baseline, follow-up	<i>Passengers, pilots</i>
Social/emotional support and network	Contact and support with friends, family and others. The perceived feeling of being valued, respected and accepted by others [54]	Web-based questionnaire	Baseline, follow-up	<i>Passengers, pilots</i>
UNINTENDED SIDE EFFECTS				
Fatigue	The perceived feeling of fatigue related to voluntariness or programme activity	Web-based questionnaire	Follow-up	<i>Passengers, pilots</i>
Anxiety	The perceived feeling of anxiety triggered by the programme activity	Web-based questionnaire	Follow-up	<i>Passengers, pilots</i>

Measurement (outcome)	What (operational)	How (instrument)	When (timing of collection)	Who in CWA (Data source)
Injuries	Amount of injuries by participation	Web-based questionnaire	Follow-up	<i>Passengers, pilots</i>
Objective functional and cognitive level (only for CWA; <i>Passengers</i>)				
Cognitive function	<i>Brief Assessment of Impaired Cognition Questionnaire (BASIC-Q) [58, 59]</i>	Interview based case-findings survey	Baseline, follow-up	<i>Passengers</i>
Physical function and mobility	Short Physical Performance Battery (SPPB) [60, 61]	Functional and physical test	Baseline, follow-up	<i>Passengers</i>
Muscle Strength	Grip Strength [62]	Physical test	Baseline, follow-up	<i>Passengers</i>
Gait endurance	6-Minute Walk Test [63, 64]	Functional test	Baseline, follow-up	<i>Passengers</i>
Trip registration for CWA				
Objective observational data from every training/trip	<ul style="list-style-type: none"> - Date (DD-MM-YYYY) - Duration (HH:MM) - Length (KM) - Participants (first name) - Environment of activity (e.g., park, forest, lake, urban) - Weather - Social activities (eat/drink) - Destination(s) - Mood - Overall satisfaction 	<p>Online trip registration</p> <p>(QR-code directing users to a short web-based questionnaire is scanned immediately after the TT or CWA- activity)</p>	<p>During the programme</p> <p>After finishing a CWA-activity.</p>	<p>Context related data completed by one person after each activity</p> <p><i>Passengers pilots</i></p>

Sub-study 2. Cycling without age

Outcome and measures in the Cycling Without Age evaluation.

Measurement (outcome)	What (operational)	How (instrument)	When (timing of collection)	Who (Data source)
PRIMARY OUTCOME				
Quality of life (QOL)	Cantril Ladder of Life Scale [49]	Web and interview-based questionnaires	Baseline, follow-up	HA, <i>Runners</i> , <i>Relatives</i>
SECONDARY OUTCOMES				
Autonomy	The perceived feeling of being in control over ones own life	Web-based questionnaire	Baseline, follow-up	HA
Sleep	Sleep quality and sleep quantity	Web-based questionnaire Bio tracking (HA) SMS-Survey (HA)	Baseline, during (HA), follow-up	HA <i>Runners</i>
Well-being	WHO-five Well-being Index [65]	Web-based questionnaire	Baseline, follow-up	HA, <i>Runners</i>
Loneliness	A perceived feeling of loneliness and lack of network and support [52, 53]	Web-based questionnaire	Baseline, follow-up	HA, <i>Runners</i>
EXPLORATIVE OUTCOMES				
Self-perceived health	Subjectively perceived Health [54]	Web-based questionnaire	Baseline, follow-up	HA, <i>Runners</i>
Perceived pain	Mental and physical pain/discomfort [54]	Web-based questionnaire	Baseline, follow-up	HA
Self-perceived Physical performance	Subjectively perceived Physical performance [55]	Web-based questionnaire	Baseline, follow-up	<i>Runners</i>
Epileptic seizures	Reduced epileptic seizures (adjusted version[66])	Paper-based questionnaire	Baseline, follow-up	HA
Self-efficacy	General self-efficacy [56, 57]	Web-based questionnaire	Baseline, follow-up	HA, <i>Runners</i>

Measurement (outcome)	What (operational)	How (instrument)	When (timing of collection)	Who (Data source)
Self-worth	Perceived feeling of acceptance [45]	Web-based questionnaire	Baseline, follow-up	HA, <i>Runners</i>
Social/emotional support and network	Contact and support with friends, family and others. The perceived feeling of being valued, respected and accepted by others [54]	Web-based questionnaire	Baseline, follow-up	HA
UNINTENDED SIDE EFFECTS				
Fatigue	The perceived feeling of fatigue related to voluntariness or programme activity	Web-based questionnaire	Follow-up	HA, <i>Runners</i>
Anxiety	The perceived feeling of anxiety triggered by the programme activity	Web-based questionnaire	Follow-up	HA, <i>Runners</i>
Injuries	Amount of injuries by participation	Web-based questionnaire	Follow-up	HA, <i>Runners</i>
Objective clinical data (only for HA:TT)				
Body anthropometrics	<ul style="list-style-type: none"> - Bodyweight - Body mass index - Whole body lean body mass - Whole body fat mass - Whole body bone mineral density 	Dual X-ray absorptiometry	B1, B2 + FU	HA
Clinical blood samples	Blood glucose control: <ul style="list-style-type: none"> - HbA1c - Fasting glucose - Fasting C-peptide and insulin 	Standard clinical procedure	B1, B2 + FU	HA
	Blood lipids: <ul style="list-style-type: none"> - Total cholesterol - Triglyceride 			
Oral Glucose Tolerance Test (OGTT)	Glucose, C-peptide, Insulin	Standard OGTT-procedure	B1, B2 + FU	HA

Measurement (outcome)	What (operational)	How (instrument)	When (timing of collection)	Who (Data source)
Fitness level	Blood volume	Estimated from haematocrit level	B1, B2 + FU	HA
Office blood pressure	Resting systolic and diastolic blood pressure (pulse)	Monitored by a standard procedure for office blood pressure	B1, B2 + FU	HA
Trip registration				
Objective observational data from every training/trip	<ul style="list-style-type: none"> - Date (DD-MM-YYYY) - Duration (HH:MM) - Length (KM) - Participants (first name) - Environment of activity (e.g. park, forest, lake, urban) - Weather - Total number of participants (<i>runners</i> and HA) - Destination(s) Overall satisfaction	Online trip registration (QR-code directing users to a short web-based questionnaire is scanned immediately after the TT or CWA-activity)	During the programmes and after finishing a programme activity.	Context related data completed by one person after each activity TT: <i>Runners</i> fulfil the online form

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