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Physical activity in hard-to-reach physically disabled people

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Development of an intervention to stimulate physical activity in hard-to-reach physically disabled people and design of a pilot-implementation: an Intervention Mapping approach

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Abstract

Introduction: Physically disabled people are less physically active compared with healthy people. Existing physical activity (PA) interventions are limited in reach, since they are primarily rehabilitation- or school based. The current study aims to develop a community-based intervention for stimulating PA in hard-to-reach physically disabled people.

Methods and analysis: To systematically develop a PA-stimulating intervention, intervention mapping (six steps) was applied. PA level and health-related quality of life of patients after rehabilitation was determined using questionnaires (step 1). Qualitative research was performed to study professionals' and physically disabled people's ideas about intervention objectives, determinants and design (steps 2 and 3). Since experts expressed no need for a new intervention, the existing intervention 'Activity coach' was adapted to the specific target population. The adapted intervention 'Activity coach+' composes a network of intermediate organisations that refers participants to an activity coach, who coaches participants during 1 year. After a pre intervention physical assessment by a physiotherapist, participants will be individually guided to existing organised or non-organised activities. An activity tracker will be used to monitor and stimulate PA in daily life (step 4). To support adoption and implementation, meetings between involved parties are organised (step 5). 'Activity coach+' is implemented in community in March 2017, and will be evaluated using a mixed-method analysis. Quantitative evaluation of intervention effects on PA, health and social participation takes place after 0, 2, 4, 6 and 12 months. The implementation process and experiences with the intervention will be determined using qualitative research (step 6).

Ethics and dissemination: Insights from this study will be used for dissemination and further development of the intervention. The Medical Ethical Committee of the University Medical Center Groningen confirmed that formal ethical approval was not required (METc 2016/630).

Trial registration number: NTR6858.

Strengths and limitations of this study

- 'Activity coach+' is systematically developed based on state-of-the-art evidence-based behavioural change techniques, in collaboration with professionals and the target population, to ensure cocreation.
- The implementation and effectiveness of 'Activity coach+' will be evaluated using a mixed-method analysis, which allows for an objective and in-depth understanding of the results.
- Biological, psychological and social health effects of 'Activity coach+' will be tested throughout 1 year, in order to provide an indication for sustainability of the health effects.
- The effectiveness of 'Activity coach+' will be tested using a 1-year prospective cohort study without control group, whereby it cannot be ensured that results are only caused by the intervention.
- 'Activity coach+' will be implemented and tested in a specific region in the Netherlands, what might limit the generalisability of results to other regions and countries.

Introduction

Physical activity (PA) participation benefits health and functioning in healthy people, and in physically disabled people^{23,26,111}. In physically disabled people, being physically active improves health in the biological^{108,110}, psychological^{109,145} and social¹⁴⁶ domain. Despite these health benefits, in the Netherlands physically disabled people participate less in PA compared with healthy people²⁰.

PA behaviour in physically disabled people can be described by the Physical Activity for people with a Disability (PAD) model⁴¹. The PAD model adds a behavioural component to the International Classification of Functioning, Disability and Health framework (ICF), by integrating the Attitude, Social influence and self-Efficacy (ASE) model. The PAD model explains how environmental factors (social influence and environmental barriers and facilitators) and personal factors (health condition, self-efficacy, attitude and personal barriers and facilitators) influence intention. Intention influences the level of PA functioning, whereas environmental and personal factors also directly influence the level of PA functioning⁴¹.

Compared with research on PA for healthy people, PA for disabled people is relatively understudied. Scientific interest for PA increased only the past decades^{27,147}. Within this research field, currently, science shifts from describing barriers and facilitators of participating in PA towards designing interventions, to stimulate PA participation in physically disabled people²⁹.

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Reviews on PA stimulating interventions for disabled people found more than 80 PA-stimulating interventions worldwide that were evaluated in scientific research^{33,34,40,147}. However, most interventions consist of specifically organised exercise groups aiming to improve health of people with specific diagnoses, rather than public health interventions that stimulate PA behaviour of people among people with physical disabilities in general^{33,147}. Taking in mind continuity and applicability in daily practice, stimulating PA participation in a community setting, using existing facilities is preferred^{40,148}. In the Netherlands, most PA interventions for physically disabled people approach their target populations via intermediate organisations, what limits their reach²⁰. Because an existing intervention already targets inpatient rehabilitation patients³⁵, the current study focusses on physically disabled people longer than one year post rehabilitation, or not familiar with rehabilitation.

The current study aims to describe the systematic intervention development, and design for the implementation and evaluation of a community-based PA-stimulating

intervention in long-term physically disabled adults.

Methods and analyses

The stepwise methodology of Intervention Mapping (IM) was applied for the systematic development of the PA-stimulating intervention, and the design of the implementation and evaluation plan⁴⁴. IM is a widely accepted methodology for planning theory-based and evidence-based health promotion programmes. The IM protocol consists of six steps: (1) conducting the needs assessment, (2) defining performance objectives and creating a matrix of change objectives, (3) selecting theory-based intervention methods and practical applications, (4) organising methods and applications into an intervention programme, (5) planning adoption, implementation and sustainability of the programme and (6) generating an evaluation plan⁴⁴.

Step 1: Needs assessment

Step 1 of IM aimed to assess the current PA participation of physically disabled people and its relationship with health related quality of life (HRQoL), and to indicate determinants that influence PA participation in this target population. PA participation of the target population was retrieved from a nationwide report. In the Netherlands, PA participation of people with a moderate or severe physical disability (41%) was significantly lower compared with healthy people (64%)²⁰. PA participation is indicated as the percentage of adults that participates in moderate or vigorous PA minimally 30 min/day for at least 5 days a week¹⁴⁹. We established the relationship between PA and HRQoL by questionnaire-based research, including the Dutch RAND-36⁵⁰, among former rehabilitation patients. The amount of PA was positively related to physical functioning, social functioning, physical role functioning, emotional role functioning, vitality, pain, general health and health change. No relationship was found between the amount of PA and mental health in former rehabilitation patients¹⁵⁰. Barriers and facilitators regarding sports participation in physically disabled people were described in a systematic review and a questionnaire study. Most emphasised barriers were disability, health, lack of facilities, transport and difficulties with accessibility. Fun, health, increasing physical strength and advice from rehabilitation professionals were facilitators of sports participation^{32,151}.

Step 2: Performance objectives and change objectives

Step 2 of IM aimed to describe the desired change at both the behavioural and environmental level, by creating the logic model of change (figure 1). At the level of the individual, the main outcome of the intervention is increased participation in PA, which will improve health, and thereby quality of life. At the environmental level, the main outcome is increased stimulation by peers to increase PA participation (figure 1). Depending on the personal situation of the participant, peers can be spouse, other family members, or friends. Following the IM methodology, the final outcomes were subdivided into different components. The desired change of these components was described in performance objectives. Demands on a PA-stimulating intervention for physically disabled people were investigated by qualitative research among the target population and professionals working in the field of PA for physically disabled people¹²⁵. Resulting from the qualitative research, PA participation can be subdivided into the following performance objectives: increasing participation in organised PA, non-organised PA, and activities of daily living (ADL). Performance objectives at the environmental level are increasing stimulation to participate in organised PA, non-organised PA, and PA during ADL (figure 1).

Several determinants can influence the performance objectives. Changeable determinants of PA participation at the individual level, as found in the qualitative studies, were knowledge, attitude, awareness and self-efficacy. At the environmental level, changeable determinants were social norms, physical environment and social support (figure 1)^{125,152}. Following the IM methodology, matrices of change objectives were created by crossing each performance objective with the changeable determinants (table 1). Change objectives then specify what needs to be achieved in order to accomplish the performance objectives. One of the change objectives at the individual level is, for instance, that participants know possible and suitable organised activities to participate in.

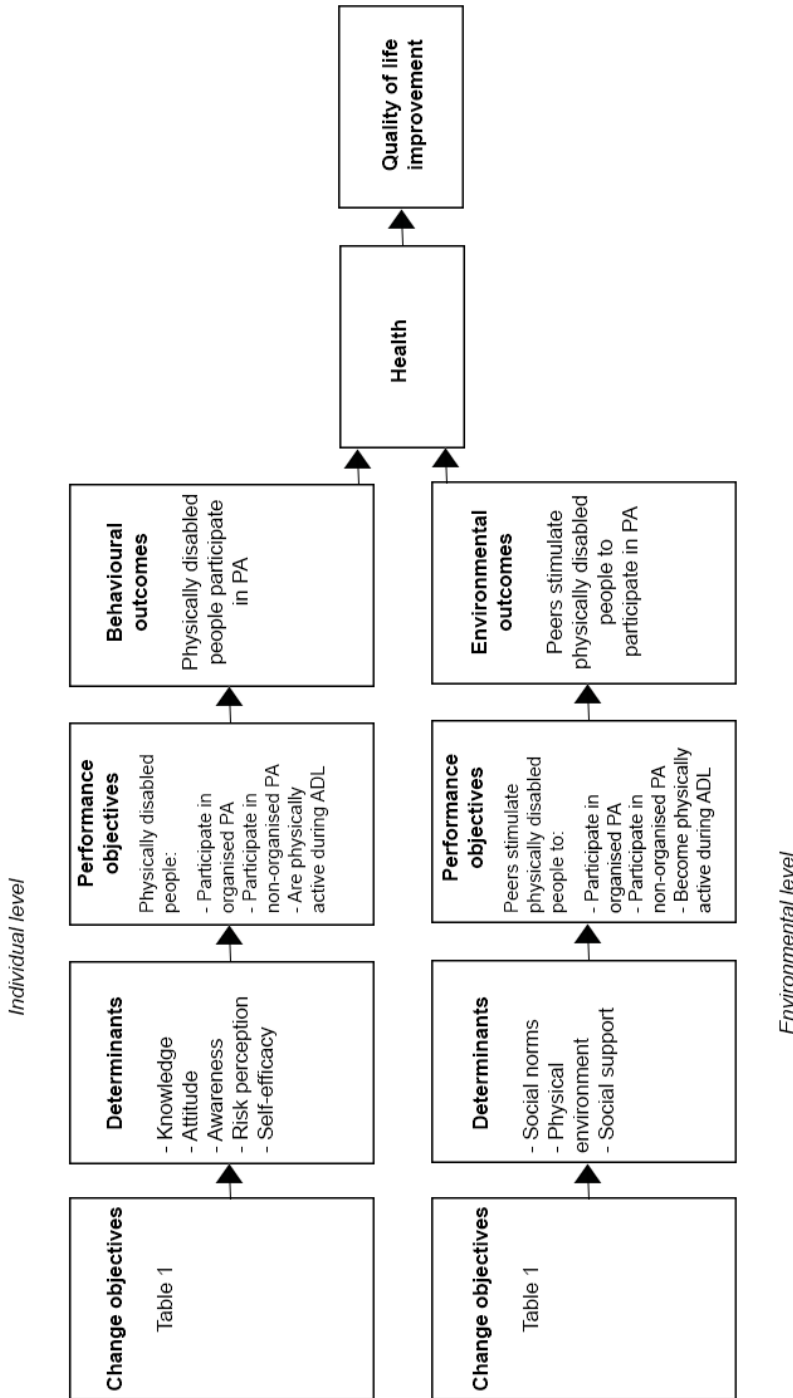


Figure 1: Logic model of change of the intervention

Table 1: Matrix of change objectives (individual level)

Performance objectives	Determinants				
Individual level	Knowledge	Attitude	Awareness	Risk perception	Self-efficacy
Physically disabled people participate in organised PA.	Physically disabled people know possible and suitable organised activities.	Physically disabled people have a positive attitude towards organised PA for disabled people.	Physically disabled people are aware of their own participation in organised PA.	Physically disabled people are aware of the risks of inactivity, and the benefits of participating in organised PA.	Physically disabled people are convinced that they can overcome barriers to participate in organised PA.
Physically disabled people participate in non-organised PA.	Physically disabled people know possible and suitable non-organised activities.	Physically disabled people have a positive attitude towards non-organised PA for disabled people.	Physically disabled people are aware of their own participation in non-organised PA.	Physically disabled people are aware of the risks of inactivity, and the benefits of participating in non-organised PA.	Physically disabled people are convinced that they can overcome barriers to participate in non-organised PA.
Physically disabled people are physically active in ADL.	Physically disabled people know which ADL are suitable.	Physically disabled people have a positive attitude towards being physically active in ADL.	Physically disabled people are aware of their own level PA level during ADL.	Physically disabled people are aware of the risks of inactivity, and the benefits of being physically active in ADL.	Physically disabled people are convinced that they can overcome barriers to become more physically active in ADL.

Table 1 (continuation): Matrix of change objectives (environmental level)

Performance objectives	Determinants		
Environmental level			
	Social norms	Physical environment	Social support
Peers and professionals stimulate physically disabled people to participate in organised PA.	Peers and professionals have a positive attitude towards organised PA for disabled people.	Peers and professionals facilitate physically disabled people to participate in organised PA.	Peers and professionals motivate physically disabled people to participate in organised PA.
Peers and professionals stimulate physically disabled people to participate in non-organised PA.	Peers and professionals have a positive attitude towards non-organised PA for disabled people.	Peers and professionals facilitate physically disabled people to participate in non-organised PA.	Peers and professionals motivate physically disabled people to participate in non-organised PA.
Peers and professionals stimulate physically disabled people to become physically active in ADL.	Peers and professionals have a positive attitude towards physically disabled people being physically active in ADL.	Peers and professionals facilitate physically disabled people to become physically active in ADL.	Peers and professionals motivate physically disabled people to become physically active in ADL.

Step 3: Theory-based intervention methods and practical applications

Step 3 of IM aimed to select theory-based intervention methods, and practical applications. The theory-based intervention methods that aimed to change the determinants of the performance objectives, were selected from the behavioural science models prescribed by the IM protocol⁴⁴. Theory-based intervention methods were translated into practical applications, adapted to the intervention population and the context of the intervention. The theory-based methods, and the practical application of the methods were selected based on the demands of physically disabled people and professionals, resulting from the qualitative studies^{125,152}. Table 2 provides an overview of the selected theoretical methods and the practical applications, separated for each determinant. Ten different intervention methods resulting from the qualitative research, are described in table 2. These different methods can be roughly subdivided into six different practical applications.

Table 2: Theory-based methods and practical applications to the intervention

Determinant	Theory-based methods	Practical applications
Individual level		
Knowledge	Tailoring ¹⁵³	Activity coaches coach participants based on their individual needs, on suitability of activities tailored to their abilities.
	Facilitation ¹⁵⁴	Overviews are made including all facilities and activities for PA, and their accessibility for people with different disabilities.
	Persuasive communication ¹⁵⁵	Activity coaches transfer their knowledge about possible activities for PA to the individual participants.
Attitude	Mass media role-modelling ^{156,157}	Role-models (physically disabled people that are physically active) tell their story, including how becoming physically active benefits them, in local newspaper articles.
Awareness	Feedback ¹⁵⁸	Participants have a pre-intervention physiotherapeutic intake, to become aware of the physical capacity and to improve self-efficacy.
	Self-monitoring of behaviour ¹⁵⁹	Participants monitor their daily physical activity (steps) using an activity tracker.
	Feedback ¹⁵⁸	Activity coaches coach participants based on their self-monitored daily physical activity (steps).
Risk perception	Persuasive communication ¹⁵⁵	Health professionals inform potential participants about the risks of inactivity.
Self-efficacy	Mass media role-modelling ^{156,157}	Role-models (physically disabled people that are physically active) tell their story, including how becoming physically active benefits them, in local newspaper articles.
	Feedback ¹⁵⁸	Participants have a pre-intervention physiotherapeutic intake, to become aware of the physical capacity and to improve self-efficacy.
	Empowerment ¹⁶⁰	Activity coaches and participants discuss barriers regarding PA and how to conquer them. The coaching strategy Motivational Interviewing will be used in this coaching.
	Goal setting ¹⁶¹	Participants are coached by the activity coach to define individual goals regarding their daily PA (steps) using an activity tracker.

Environmental level		
Social norms	Mass media role-modelling ^{156,157}	Role-models (physically disabled people that are physically active) tell their story, including how becoming physically active benefits them, in local newspaper articles.
Physical environment	Facilitation ¹⁵⁴	Overviews are made including all facilities and activities for PA, and their accessibility for people with different disabilities.
Social support	Developing new social network linkages ¹⁶²	Participants can be connected to buddies, which are people that are already participating in PA, and can motivate them and let them feel welcome.
	Persuasive communication ¹⁵⁵	Professionals from social and health care inform potential participants about the intervention.
	Mobilizing social networks ¹⁶²	Professionals from sports, health- and social care know each other, so that they can refer potential participants the appropriate person.

First, in order to improve the attitude of potential participants and to increase their self-efficacy towards PA, role-models will tell their stories in local newspaper articles. Role-models could be either professional disabled sports persons, or non-professional disabled and physically active people from the region. In their stories, role-models will focus on the benefits that they perceived after they became physically active. These role-model stories are also aimed to improve social norms from peers towards PA for physically disabled people. Second, healthcare professionals inform their patients on the risk of inactivity and inform them about the intervention to improve risk perception and to provide social support.

Third, the individual's physical capacity will be assessed by a health professional at the start of the intervention, in order to become aware of the physical capacity and to improve self-efficacy. Fourth, overviews are made including possible facilities and activities for becoming physically active, in order to increase knowledge, and to provide a stimulant physical environment. These overviews do also describe accessibility of the facilities for people with different types of disabilities. Activity coaches transfer their knowledge about possible activities for PA to the participants, and individually coach the participants on the suitability of activities, tailored to their abilities. In order to increase self-efficacy, activity coaches discuss solutions for barriers with the participants. In these discussions, the coaching technique of Motivational Interviewing

is used to induce behaviour change by revealing ambivalence, and provoking the participant to devise its own solutions for barriers. Motivational Interviewing was proven effective for stimulating PA behaviour¹⁶³.

Fifth, to increase awareness and self-efficacy, participants monitor their daily PA (number of steps) using an activity tracker. The activity coach individually coaches participants based on their daily PA, and encourages the participants to set goals for their daily PA. These goals will be individually determined. Lastly, when participants are willing to participate in organised PA, participants are connected to buddies, which are people who already participate in the activity. These people provide social support by motivating the participant and let them feel welcome at the activity.

Step 4: Intervention programme

Step 4 of IM aimed to create the intervention programme, by combining and sequencing the methods and applications resulting from step 3. Concluding from the focus groups, professionals indicated no need for a new intervention, but instead indicated need for the adaptation of an existing intervention, in order to match the demands for this specific population. The existing PA-stimulating interventions for physically disabled people in the Netherlands, were therefore compared with the demands of both the experts and the target population. The existing PA-stimulating intervention 'Activity coach' (Dutch: Beweegcoach) fulfilled most of these demands¹⁶⁴. In the adapted intervention, named 'Activity coach+', several adaptations are made, based on the demands of professionals and the target population (figure 2).

The existing intervention 'Activity coach' approaches potential participants using a network of intermediate organisations, including public healthcare, social care, physiotherapists and general practitioners. In the adapted intervention, 'Activity coach+', other health care organisations, such as domestic care, hospitals, organisations that provide medical devices (e.g. wheelchairs), and dieticians, are also included to the network. Moreover, flyers and local newspaper articles are added, compared with the existing intervention, to approach potential participants (figure 2). Flyers will be distributed via the intermediate organisations. News articles include role-model stories, and will be published approximately bimonthly in local newspapers.

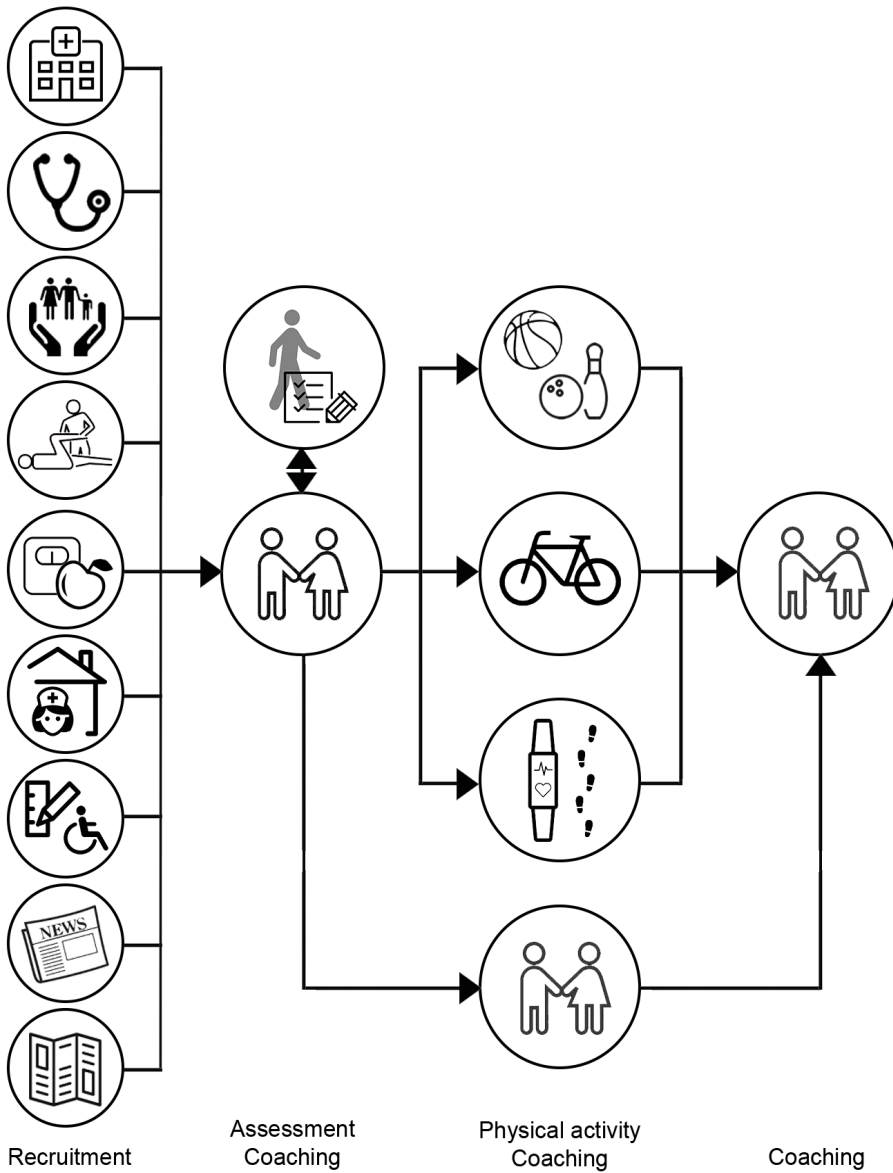


Figure 2: Schematic overview of the adapted intervention 'Activity Coach+'

Similar to the original 'Activity coach' intervention, participants will be referred to an activity coach in the adapted intervention as well. However, additional to the original intervention programme, participants will be referred to a physiotherapist for an intake (figure 2). The physiotherapeutic intake includes history taking, in which personal barriers and facilitators towards PA are discussed and physical assessment. This physiotherapeutic intake was added to the programme to guide the activity coach in deciding feasible and safe activities, and to improve awareness and self-efficacy of the participant. After the physiotherapeutic intake, the participant will be individually coached by the activity coach. The individual coaching sessions of 'Activity coach+' focus on the same topics compared with the original 'Activity coach', namely needs, barriers, facilitators and assistance from social environment. However, where the original 'Activity coach' primarily focussed on stimulating participation in organised sports or PA, 'Activity coach+' was extended by also stimulating participation in non-organised PA and PA during ADL (figure 2). Type of PA that will be stimulated (organised, non-organised or PA during ADL) will be based on the demands of the participant, as investigated during the physiotherapeutic intake and first coaching session. Participation in organised sports will be stimulated by providing overviews including activities and sports clubs in the region, including practical information such as costs, availability of facilities (e.g. an elevator), and contact information. Activity coaches help participants to explore suitable activities, and facilitate contact. Moreover, activity coaches can connect a participant to a buddy, a person who already participates in the activity. Eventually, activity coaches can assist the participant during the first visits to the activity, after which coaching will be transferred to the trainer. Participation in non-organised PA will be stimulated by assisting goal setting on, for instance, strolling and cycling. Moreover, activity coaches can connect people who can stroll or cycle together. Participation in PA during ADL will be stimulated by monitoring daily PA using a Fitbit Zip activity tracker. Activity coaches assist participants to set feasible goals for their daily number of steps.

After initial coaching, counselling sessions are planned after 2, 4, 6, and 12 months, in order to prevent relapse (figure 2). The counselling session after 2 months will be by phone, the other sessions will be face-to-face. Counselling sessions differ from the original intervention 'Activity coach', in which counselling was only provided on demand, and evaluation forms are send after 1, 4 and 12 months. A longer counselling period is applied based on the results of the qualitative studies^{125,152}.

Step 5: Adoption, implementation and sustainability

Step 5 of IM aimed to plan adoption, implementation and sustainability of the intervention. Regarding adoption, implementation and sustainability, a distinction can be made between the intermediate organisations, participants and activity coaches.

In order to improve adoption and implementation by the intermediate organisations, all intermediate organisations will be invited for an introduction meeting at the start of the intervention. This meeting will be organised in order to inform about the intervention, and the role of the intermediate organisations, and to improve collaboration between the intermediate organisations. In order to improve sustainability once the intervention is implemented, news messages will be sent to the intermediate organisations every month by email, and will include the actual number of participants and success stories.

To stimulate adoption at the level of the participant, intermediate organisations will advise participants about the intervention, and attractive flyers will be created by a graphic designer. Activity coaches will individually motivate participants during the coaching sessions, in order to improve implementation. In order to improve sustainability by the participants, activity coaches will provide individual counselling via telephone on demand. Guidelines for the execution of the intervention are provided to the activity coaches, to stimulate that they adopt the programme in the way it is designed.

Step 6: Evaluation plan

Step 6 of IM aimed to plan the evaluation of the intervention. Both the implementation process and effectiveness of the adapted intervention 'Activity coach+' will be evaluated systematically in a pilot intervention in three municipalities (Oldambt, Bellingwedde and Vlagtwedde) in the province of Groningen, The Netherlands. Research on the evaluation of 'Activity Coach+' is registered in the NTR research register (#NTR6858).

Process evaluation

The implementation process will be evaluated using qualitative research amongst involved professionals (for instance municipalities, activity coaches and intermediate organisations) and participants. Professionals will be asked on their expectations regarding the intervention and its implementation prior to the start of the intervention, and on their experiences regarding these topics approximately 8 months after the start of the intervention. Participants will be only interviewed after the start of the intervention, at least 6 months after their individual start. Participants will be asked about their experiences with the intervention, for instance about how different intervention components were adopted, and how this resulted in behavioural change. The evaluation of the implementation process will be based on the RE-AIM framework⁴⁵. Data will be analysed using thematic analysis¹¹⁵.

Effectiveness

The effectiveness of 'Activity coach+' will be evaluated using a prospective cohort study lasting 1 year. When participants agree to participate in the scientific study, the findings of the physiotherapeutic intake will be used as a baseline measurement. Follow-up measurements will take place after 2, 4, 6 and 12 months (\pm 2 weeks) at the participants home. The effectiveness of the intervention will be determined using three different outcomes. At first, participants will be asked to fill in a set of questionnaires including the RAND-36 measuring HRQoL⁵⁰, the Fatigue Severity Scale measuring fatigue¹⁶⁵, the Exercise Self-Efficacy Scale (ESES) measuring self-efficacy towards movement¹⁶⁶, the ICF Measure of Participation and ACTivities Screener (IMPACT-S) measuring social participation¹⁶⁷, and the adapted Short Questionnaire to Assess Health-enhancing physical activity (SQUASH) measuring daily PA and sedentary behaviour¹⁶⁸.

Second, physical status of participants will be investigated by a physical assessment. Body mass and length will be measured without wearing shoes, from which body mass index will be calculated. Waist circumference will be measured in the middle between the lowest rib bone and the iliac crest. The average of two measurements will be used. Blood pressure will be measured using an Omron M3 automatic blood pressure system (Omron Healthcare, Kyoto, Japan), on both the left and right arm. Hand grip strength will be measured using a dynamometer and E-link software (Biometrics Ltd, Gwent, United Kingdom) twice on both the left and right hand. Hand grip strength will be measured while standing, without elbow flexion. Total hand grip strength will be calculated as

the sum of the maximum grip strength left and right. Walking ability will be measured using the 10 m walk test, in which a distance of 10 m will be walked three times at comfortable speed, and three times as fast as possible, without running^{169,170}. Final scores for both comfortable and fast walking will be calculated as the mean walking speed (m/s) of three measurements. Exercise capacity will be measured using the 6 min walk test, in which participants walk 6 min around a set distance of 20 m^{169,171}. Covered distance during 6 min will be the outcome measure. During both walk tests, walking aids can be used when needed. When participants are wheelchair users, both walk tests can be performed in the wheelchair, resulting in the 10 m push test and the 6 min push test¹⁷². Dynamic balance will be measured using the Berg Balance Scale^{173,174}.

Lastly, daily PA will be objectively measured using the Activ8 (2M Engineers, Valkenswaard, The Netherlands)¹⁷⁵, which is a tri-axis accelerometer-based wearable and wireless device that will be attached to the thigh using Tegaderm waterproof film plaster. The Activ8 will be initialised to produce an output at an Epoch length of 15 s and worn for 7 consecutive days, except when swimming. Data will be processed using Matlab 2016b (The Mathworks Inc., Natick, MA, USA). Participants will be asked to record bedtime and wake-up time in a diary. Activity data will be only used for analyses if the device has been worn for at least 11 hours a day, for at least 4 days. Daily PA will be expressed as average counts per minute during waking hours, percentage of waking hours that are spend active (walking, running or cycling) and sedentary (sitting, lying). Moreover, number and duration of (prolonged) active and sedentary bouts will be reported. One minute intervals (sum of four 15 s intervals) will be identified as either active ($\geq 80\%$ of time spend on walking, running or cycling), sedentary ($\geq 90\%$ of time spend on sitting or lying), or neutral (time intervals that are neither active nor sedentary). Periods of active intervals, interrupted by neutral intervals of maximum 1 min, of which at least 70% of the total bout duration consist of walking, running or cycling will be defined as active bouts. Sedentary bouts will be periods of sedentary intervals, eventually interrupted by neutral intervals of maximum 1 min, of which at least 80% of the total bout duration consist of sitting or lying. Active bouts lasting at least 10 min will be identified as prolonged active bouts, whether sedentary bouts of at least 30 min will be identified as prolonged sedentary bouts.

Participants

A power calculation on outcomes of the 6 min walk test revealed that 21 participants will be needed to indicate a significant difference using a dependent samples *t*-test.

Since no earlier research was found on a heterogeneous population, as targeted in the developed intervention, the power analysis was based on earlier research in patients with chronic stroke. SD of the difference was estimated at 70¹⁷⁶, and the minimal clinically important difference for stroke patients was estimated at 45¹⁶⁹. These data together with a power of 80% and α (two-sided) of 5% resulted in a sample size of at least 21 participants. Because of the more heterogeneous target population, whereby SD is suggested to be higher, and anticipating a drop-off, 30 participants will be targeted for the effectiveness study.

Data analysis

Changes of the main outcome parameters between the first and last measurement will be analysed using dependent samples t-tests. Moreover, the longitudinal progression of outcomes over time will be analysed by multilevel modelling, SPSS 20.1 (IBM, New York, NY, USA). Multilevel models are chosen because they are robust for missing data, and can handle data which are not independent, as is the case in longitudinal data. Repeated measures within individual participants will be level 1 scores, whereas the different participants will be modelled as level 2. Months since the start of the intervention will be entered in the analysis as possible predictor for the change in outcomes, either linear, quadratic, logarithmic or a combination of these, based on the change pattern and biological plausibility. Possible confounders (e.g. age and gender) will be analysed univariately, and entered in the analysis when p -value will be $< .20$. As a first step months since the start of the intervention will be entered, secondly other confounders will be added, however, because the sample size is limited, the number of confounders will be limited as well. The model's goodness of fit will be evaluated by comparing the $-2 \times \text{Log likelihood}$ of the different models. An α of $< .05$ will be indicated as significant. Clinical relevance of individual changes will be established by comparing within participant changes (absolute or relative changes) with minimal clinically important differences from literature.

Ethics and dissemination

The study will be performed in accordance to the Declaration of Helsinki. Results of this study will be published in peer-reviewed international journals, and presented at conferences. Participants will receive a lay summary of the findings.

Discussion

The current study applied the IM procedure to systematically develop an intervention to stimulate PA in physically disabled people longer than 1 year post rehabilitation or not familiar with rehabilitation. Based on a needs assessment and qualitative research among professionals and the target population, the systematic development process resulted in the adapted intervention 'Activity Coach+' (figure 1). The implementation process of Activity coach+ will be evaluated using qualitative research, whether the effectiveness of Activity coach+ will be evaluated in a 1-year prospective cohort study, quantitatively measuring PA and biological, psychological and social health effects.

Activity Coach+ has a solid theoretical basis. The determinants of PA, as found in step 2 of IM, can be seen as environmental and personal factors of the PAD model. The relationship between these determinants and the level of PA functioning is clearly described by the PAD model. The application of IM ensures theoretical support on the stimulation of the determinants of PA (IM step 2), whereby the application of IM complements to the PAD model.

Activity Coach+ focusses on stimulating three types of PA; organised PA, non-organised PA, and PA during ADL. Activity Coach+ hereby differs from traditional interventions for physically disabled people, which primarily focus on stimulating organised PA, or a specific type of non-organised PA^{33,34,40}. By this broad focus, and the heterogeneity of the target population regarding diagnosis, Activity Coach+ is able to serve a broad population, what is desirable for a community-based intervention.

Potential participants of the intervention will be reached by intermediate organisations. This seems contrary to the assumption that existing interventions do not reach the whole target population, since they only reach the target population via specific intermediate organisations, as for instance rehabilitation centres. However, by creating a network of intermediate organisations from various background, a larger proportion of the target population is assumed to be reached. Creating a network for the distribution of the intervention was recommended by the guidelines for health-enhancing PA programmes¹⁴⁸.

Activity coach+ is primarily based on individual coaching, whereby the intervention can be individually tailored to the needs of the participant. Tailoring was found a good practice in PA interventions^{177,178}. Individually tailored interventions might be more expensive compared to non-individualised interventions, what can be a downside. One of the interventional methods is the use of an activity tracker, to provide insight

in the daily PA. The use of consumer activity trackers in PA interventions increases rapidly^{147,179}. In healthy individuals, the use of consumer activity trackers increased daily PA, but did not lead to health improvement¹⁸⁰. The effectiveness of consumer activity trackers is not yet investigated in physically disabled people.

The effectiveness of Activity Coach+ will be established in a 1-year prospective cohort study targeting around 30 participants, with no control group. The lack of a control group might limit the validity of the conclusions. However, given the heterogeneity of the target population, finding a control population that matches the participants would be practically impossible. By including the 6-month and 12-month test occasions, the design can test sustainability of the intervention effects.

One of the strengths of the current study is the use of IM, which is widely accepted and often used as a systematic framework for health intervention development. Applying IM helped subdividing the health problem into different behavioural components, and selecting theory-based methods to achieve the desired behavioural change. The use of IM also assisted describing the different components of the intervention, whereby results of the evaluation study will enable a more meaningful interpretation, what will benefit future intervention development. Implementation, testing and securing of the intervention were considered in the early stages of intervention development because of the use of IM. Moreover, the integration of both qualitative and quantitative data, and the engagement of the target population in the development process were strengths of the current study¹⁷⁷. Activity Coach+ is developed based on the Dutch healthcare system, whereby generalisation of these results to other, non-western healthcare systems might be limited.

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Conclusions

To the best of our knowledge, this is the first study describing the systematic development of a community-based intervention to stimulate PA in hard-to-reach physically disabled people. The implementation process and effectiveness of Activity Coach+ will be evaluated in future research.

