

**“Coach2Move: Sustainable in Current
Practice?”
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TABLE OF CONTENTS

1. SUMMARY	4
2. INTRODUCTION AND RATIONALE	6
3. OBJECTIVES	8
4. STUDY DESIGN	8
6. STUDY POPULATION	11
a. Population (base).....	11
b. Inclusion criteria.....	11
c. Exclusion criteria.....	11
d. Sample size calculation	11
7. INVESTIGATIONAL PRODUCTS	13
a. Coach2Move	13
b. Implementation	14
c. Comparative arm:	15
8. METHODS	15
a. Study parameters/endpoints	16
a.I Main study parameter/endpoint	16
a.II Secondary study parameters/endpoints.....	17
a.III Other study parameters	18
b. Randomisation, blinding and treatment allocation	18
c. Study procedures.....	19
d. Withdrawal of individual subjects	20
9. STATISTICAL ANALYSIS	20
a. Primary study parameter(s).....	20
b. Secondary study parameter(s).....	21
c. Other study parameters	21
10. ETHICAL CONSIDERATIONS.....	22
a. Regulation statement.....	22
b. Recruitment and consent	22
c. Objection by minors or incapacitated subjects	23
d. Benefits and risks assessment, group relatedness	23
11. REFERENCES	23

1. SUMMARY

Rationale: Physical activity is beneficial to older adults to improve health conditions and decrease risk on frailty. Coach2Move is a physiotherapeutic intervention aimed at maintaining or improving mobility among older adults who visit physiotherapists using a personalized tailored approach based on an in-depth hypothesis oriented behavioural, physical and environmental diagnostic exploration with a primary focus on a long-lasting increase of physical activity in daily living and enhancing self-efficacy and self-management using the social context combined with a physical training.

Our hypothesis is that implementing Coach2Move in physiotherapeutic practice leads to better physical outcomes and lower costs than usual care.

Objective: The main objective of this study is to research whether implementation of a focused personalized problem-oriented coaching intervention (Coach2Move strategy) is more effective to improve physical activity, mobility and health status in community-dwelling older adults than usual care physiotherapy. In addition, cost-effectiveness will be determined.

Study design: stepped wedge cluster randomised trial and mixed methods process analysis. Due to the design, control- and intervention period range from 3 to 15 months. The period of wash-out and implementation lasts 3 months.

Study population: Elderly people ≥ 70 years old referred to the physiotherapist because of a decrease in physical functioning/ mobility and/or at risk of physically inactive lifestyle.

Implementation: The Coach2Move approach is stepwise introduced in the participating practices. At a predefined randomised time point during the study, an implementation and wash-out period takes place in which the practices switch from control to intervention. This is preceded by an online e-learning in which two patient cases are being discussed. The implementation is conducted by a course consisting of two day parts in which the PT(G)'s are being educated in the aspects of Coach2Move. During the implementation and wash-out period, no measurements take place in the practices so the PT(G)'s have the time and opportunity to fully explore and experiment with the implementation of the Coach2Move strategy among their own clients. In addition to the course, three peer assessment meetings are being planned in which the PT(G)'s reflect and evaluate on their own use of Coach2Move and to those of others.

Intervention: The Coach2Move approach is stepwise implemented in 16 physiotherapy practices. On each site, at least one physiotherapist in geriatrics and one physiotherapist will receive a two-day training in the Coach2Move approach, which makes use of elements of the Hypothesis Oriented Approach for Clinicians (HOAC-II) and the International Classification of Functioning and Health (ICF). Participants receive physiotherapy according to the Coach2Move approach instead of the usual care physiotherapy.

Main study parameters/endpoints: In this study, each participant is measured four times. The first, being the baseline measurement (T0) is prior to physiotherapeutic treatment, while the second is directly after ending the treatment (T1). The following two are respectively six- (T2) and twelve months (T3) after the moment the participant started the treatment.

The primary outcome measures are the cost per quality-adjusted life year (QALY) gained, mobility measured by the modified Timed up and Go (TUG) and the level of moderate physical activity (LAPAQ). Secondary outcomes include: quality of life (EQ-5D), the degree of frailty (Evaluative Frailty Index for Physical activity), perceived effect (Global Perceived Effect and Patient Specific Complaints) and health care utilization costs.

In addition, qualitative data of experiences in implementation of Coach2Move will be gathered from interviews with patients and focus groups with PTG's and PTs.

The quantitative analysis will be based on quality indicators of medical records of patients for each physiotherapist scored by the researcher. The files in the control period are compared with those after implementation of Coach2Move.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The physiotherapeutic process according to the Coach2Move strategy does not have more risk compared to usual care physiotherapy. The additional load related to the study participants are being exposed to consists of the three measurement moments in which questionnaires are being conducted. These moments each will take the patients approximately 60 minutes.

Since we believe that all older adults could benefit from the Coach2Move approach, we have composed broad in- and exclusion criteria so we would include a realistic sample of the Dutch older adults who are seeing a PT(G) for mobility problems. This includes older adults suffering from dementia, since we hypothesize we could involve informal caregivers or other health authorities in the treatment to help achieve the set goals.

2. INTRODUCTION AND RATIONALE

The population of older adults in the Netherlands is increasing. An increase of 1.4 million older adults is estimated between 2012 and 2041 [1]. Not only the number of older adults is increasing, the life expectancy is rising as well. Along with an increasing age, the need for healthcare is rising as well. Older adults are more vulnerable for adverse health outcomes such as functional dependency, hospitalisation and death [1].

A recent systematic review has shown that physical activity is beneficial for older adults to prevent or even reduce frailty and improve quality of life [2]. However, increasing physical activity is known to be very challenging; especially if an individual is coping with health disorders, ageing and unhealthy lifestyle [3]. Older adults with limited mobility reported poor health, fear of falling, negative experiences, lack of company and an unsuitable environment as barriers to exercise [4]. However, a sedentary lifestyle leads to more adverse outcomes [5]. Physicians and physiotherapists play a key and pivotal role in promoting exercise behaviour among older adults. Especially in the elderly population, the lack of knowledge and understanding of the relationship between moderate exercise activity and health is an relevant barrier, as many lived through a time period when exercise was not valued or deemed necessary. In addition, many elderly feel they already receive enough exercise in their activities of daily living [6].

A new and promising approach to help frail older adults to increase their levels of physical activity is Coach2Move. This strategy, based on clinical reasoning conform the Hypothesis Oriented Algorithm for Clinicians (HOAC-II) and the International Classification of Health (ICF), provides guidance in the diagnostic and therapeutic process to physiotherapists [7-9]. This is complemented with behavioural changing techniques such as motivational interviewing and shared decision-making, which are a valuable addition to usual physiotherapy[10]. By effectively using the context of the patient and focusing on strengths and the potential to adapt instead of the disease and the weaknesses, a high level of adherence to physical activity is expected to maintain. In a previous trial (CMO registration number: 2012/233), we demonstrated that the Coach2Move approach is superior to regular physiotherapy in terms of increasing physical activity, reducing frailty, improving quality of life and reducing healthcare costs [11]. In short, in less physiotherapeutic sessions, better outcomes were realized. It is therefore that the RIVM (Rijksinstituut voor Volksgezondheid en Milieu) has appraised the Coach2Move approach as good evidence for effectiveness. Despite these promising findings, we still have questions regarding the generalisability of these findings. Our reservations towards the generalisability of the approach are caused by the following:

1. We included a modest (n=130), yet somewhat selective study sample: nearly half of the eligible individuals declined randomisation and thereby participation. We need to understand how this group of eligible non volunteers respond to Coach2Move. Therefore, we will use a study design that avoids randomisation at the patient level.
 2. The Coach2Move approach significantly increased the level of moderate physical activity among the treatment group and reduced levels of frailty significantly after 6 months, but the clinical importance of these findings is still unclear. Thus, we need a replication of the effects in the light of physical functioning, a larger more variable study population and a longer follow-up.
- In addition, the results from the earlier carried out RCT concerning the cost-effectiveness of Coach2Move have to be replicated on a larger scale.

For the reasons mentioned above, it is important to further implement Coach2Move and study its effect, costs, and feasibility in current practice. A stepped wedge cluster randomised trial design is chosen because we believe that the implementation strategy will do more good than harm (making a parallel design, in which certain practices do not receive the intervention or to withdraw the intervention as would occur in a cross-over design, is unethical) and it furthermore minimizes contamination.

To further improve the implementation of Coach2Move, process evaluation will be carried out by having several meetings in which both participants and PT(G)'s will be interviewed on their experiences and their opinions on Coach2Move. Data received by process evaluation will be analysed both quantitatively and qualitatively.

The objective of this study is to assess the cost-effectiveness of the implementation of a patient and context focused tailored coaching intervention (Coach2Move) in the daily physiotherapy practice for older adults with mobility problems compared to usual physiotherapy. Our hypothesis is that Coach2Move leads to better physical outcomes and lower costs than usual care.

3. OBJECTIVES

Primary Objective:

The aim of this study is to investigate the (cost)effectiveness of the implementation of Coach2Move physiotherapy of the management of community-dwelling older adults (≥ 70 years) with mobility problems and/or physically inactive lifestyles in a pragmatic real-world setting.

Our main research question is:

Can we improve cost-effectiveness of physiotherapy care for older adults with mobility limitations? In other words, does the implementation of the Coach2Move strategy lead to better outcomes and lower costs than usual care physiotherapy?

Secondary Objective(s):

By use of a process evaluation [12], we also aim to investigate the processes through which the Coach2Move intervention operates on outcomes and how the implementation of the program is achieved in the context of potential organisational and other differences between places and therapists.

Our secondary research questions are:

1. Which factors in the delivery procedures influence the reach of the intervention?
2. Which factors in the fidelity of the intervention influence the outcomes?
3. What are the patient experiences concerning effectiveness, pros and con's of the Coach2Move intervention?
4. What are the experiences of Physical Therapists (PT's) and Physical Therapists in Geriatrics (PTG's) concerning effectiveness and feasibility and which barriers and facilitators for implementation are perceived?
5. What are the experiences of relevant stakeholders in the multidisciplinary network concerning effectiveness and practicability of Coach2Move?

4. STUDY DESIGN

To assess the cost-effectiveness of Coach2Move compared to usual physiotherapy care, we will use a stepped wedge cluster randomised trial design. A stepped wedge study has several advantages over RCTs: it allows evaluating as well as implementing a new promising intervention (Coach2Move) versus regular care in real-life setting and minimizes nonparticipation and contamination.

In this study 16 physiotherapy practices will be included. The 16 practices will be divided into 4 clusters (4-4-4-4). Each practice will include at least 25 patient during the entire duration of the study, which means a minimum number of 400 (16x25) patients will be included. Per cluster four months are planned for implementation of Coach2Move, from which one month is incorporated to serve as a wash-out period between the control and implementation phase (thus resulting in 15 months of data in all practices) (please see Figure 1 for a visual depiction). During the wash-out and implementation period in a cluster, included patients will not be measured. In total, this should generate approximately 200 participants in the control group and 200 participants in the intervention group.

Control group is defined as all patients who meet the inclusion criteria and signed informed consent, who were treated in the indicated practices by participating therapists prior to the Coach2Move education of those therapists, whereas the intervention group is defined as all eligible patients who were treated after the Coach2Move education of the therapists. In other words, the control group receives regular physiotherapy, whereas the intervention group receives physiotherapy conform Coach2Move strategy.

For patients included during these 15 months, we will collect data at baseline, directly after the end of the program and 6 and 12 months after the start of intervention. In this stepped wedge study, we have set our measurement periods at time intervals of three months, resulting in a total inclusion duration of 15 months, an implementation period of 3 months and a follow-up of 12 months (thus clinical study duration 30 months in total). At the start of the study, all clusters start together in the control group, where none of the practices work according to the Coach2Move strategy and provide usual care. At different time points the clusters will cross-over to the intervention condition. The time points at which the different practices transition to Coach2Move are determined at random. By the end of the trial, all practices will have implemented Coach2Move.

The Implementation and Wash-out period consists of 3 months in which the therapists retrieve a 2-day education in Coach2Move and in which 3 peer assessment meetings take place. During this period, no measurements are carried out to give the therapists the opportunity to gain experience with Coach2Move before the measurements commence in the intervention period. This has no direct consequences for the participants.

All data will be collected by researchers from Radboudumc. Data sampled at baseline relevant for clinical decision-making will be communicated to the PT(G), to avoid load on the patient.

Figure 1. Depiction of proposed stepped wedge, cluster randomised design.

	3 months	6 months	9 months	12 months	15 months	18 months
Group 1 (Practices 1,2,3,4)	Control	Imp + WO	Intervention	Intervention	Intervention	Intervention
Group 2 (Practices 5,6,7,8)	Control	Control	Imp + WO	Intervention	Intervention	Intervention
Group 3 (Practices 9,10,11,12)	Control	Control	Control	Imp+ WO	Intervention	Intervention
Group 4 (Practices 13,14,15,16)	Control	Control	Control	Control	Imp+ WO	Intervention

Abbreviations: Imp +WO = Implementation and wash-out period.

A mixed methods process evaluation is designed to investigate the processes through which the Coach2Move intervention operates on outcomes and how the implementation of the program is achieved in the context of potential organisational and other differences between regions and practices.

Quantitative data will be collected and qualitative analyses (open interviews, focus groups and surveys) will be held with the participating PT(G)'s, relevant stakeholders and patients. Hindering and facilitating factors found during analysis will be used to fine-tune the implementation of the intervention strategy.

To test fidelity quality indicators are scored by reviewing patient files of physiotherapists.

This will be done by two independent blinded persons. Random sampling of patient files of different time periods after implementation will be compared with files from the control period. Subject to review is the change in scores between and after implementation of Coach2Move.

Time schedule:

July 2017 – October 2017	Development of implementation tools: educational materials, ICT optimization per practice, preparation measurement economic evaluation, development of measurement instruments for process evaluation, and randomisation of start points, meeting with the patient advising group to reflect on educational material and measurements. Publication of the trial protocol and the process analysis protocol.
November 2017 – March 2019	Gathering of data and measurements of actual usual care and care based on the Coach2Move approach and experiences with the implementation by professionals and patients.
November 2017 – March 2020	Control- and intervention measurements over 4 clusters: inclusion of patients, quality indicator measurement (clinical reasoning, patient-centeredness and monitoring by measurements), measurement of primary and secondary outcomes on pre-post and at 6- and 12 months follow-up.
March 2020 – December 2020	Finalizing analyses and publications.

6. STUDY POPULATION

a. Population (base)

Sixteen PT practices will participate. All practices comprise at least two physiotherapists of whom at least one is specialized in geriatrics, as evidenced by a professional degree. During the study, data will be collected from community-dwelling older adults (≥ 70 years) who visit the PT practice due to mobility problems related to activities of daily living. In addition, potential participants must have a sedentary lifestyle or must be at risk of losing an active lifestyle in the near future (as rated by the participant, relatives, or a referring physician).

b. Inclusion criteria

All older adults from 70 years or older who are referred to the physiotherapist are included in this study. However, not all older adults will be followed for the full duration of the study. Only those who are community-dwelling, have mobility related problems or problems related to activities of daily living and have a sedentary lifestyle or are at risk of losing an active lifestyle in the near future are eligible for follow-up. Only clinical data is obtained from the participants who are not eligible for follow-up to control for selection bias.

Eligible for separate analysis:

- Patients with problems understanding advises and/or communicating with the professional due to Dutch language problems and/or mild dementia are not excluded, because we think that the Coach2Move approach will be adequate because of the focus on contextual resources.

c. Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Patients who are not ambulatory after treatment and/or are in palliative phase.
- Patients who are indicated to become institutionalised in the near future.

d. Sample size calculation

Primary endpoints are TUG and LAPAQ at 6 months, and the combined objective of this trial is to show that one of these improves while the other does not deteriorates [13]. With the Stepped Wedge design as below (4 groups of 4 practices with 5 patients in each of 5 measurement periods and none in the implementation period, so 400 patients in total), a simulation study shows that the SE (standard error) is $0.21 \times \text{SD}$ for each endpoint when the ICC = 0.10 (regardless of the size of the effect due to the linearity of the analysis model).

Figure 1. Depiction of proposed stepped-wedge, cluster randomized design.

	3 months	6 months	9 months	12 months	15 months	18 months
Group 1 (Practices 1,2,3,4)	Control	Imp + WO	Intervention	Intervention	Intervention	Intervention
Group 2 (Practices 5,6,7)	Control	Control	Imp + WO	Intervention	Intervention	Intervention
Group 3 (Practices 8, 9,10)	Control	Control	Control	Imp+ WO	Intervention	Intervention
Group 4 (Practices 11,12,13)	Control	Control	Control	Control	Imp+ WO	Intervention

Abbreviations: Imp +WO = Implementation and wash-out period.

Then applying the method as described by Donkers et al. with the following design parameters [13]:

- TUG: relevant effect: 1.4 seconds; SD=2.0 seconds; non-inferiority margin= 0.4 seconds, so $SE=0.21 \times 2=0.42$; [14]
- LAPAQ: relevant effect: 15 minutes; SD=30 minutes; non-inferiority margin=5 minutes, so $SE=0.21 \times 30=6.3$; [15]
- Correlation between TUG and LAPAQ is low (correlation of -0.4 etc found, so we assume correlations of the stepped wedge estimates of no more than +0.3; [16] yields that the power for the combined objective is >80% (actually 86%).

7. INVESTIGATIONAL PRODUCTS

a. Coach2Move

The intervention consists of geriatric physiotherapy conform the Coach2Move approach. Coach2Move is a personalized coaching strategy for physiotherapists to elicit physical activity in elderly patients who visit their physiotherapist for mobility problems. This approach helps the PT(G) in clinical reasoning by providing an extensive, pre-structured and systematically organised diagnostic protocol based on the HOAC-II and ICF [7-9]. The diagnostic phase requires more time (60 minutes) than the conventional physiotherapy intake (30 minutes), during which not only impairments and disabilities, but wishes, barriers and facilitators both intrinsic as well as in the context considering physical functioning are profoundly examined. Motivational interviewing is used to find and deal with barriers for becoming physically active and shared decision-making in goal setting.

Physiotherapy conform the Coach2Move strategy is patient focused (tailor made) and goal-oriented. The PT(G) coaches the patient and the environment in reaching and maintaining his/her own goals (self-management).

Another key element of Coach2Move is the knowledge of result among patients. By repeating the measurements conducted at baseline on regular basis (every 6 weeks) and give feedback on the outcomes, patients are aware of the consequences a physical active lifestyle has on their health status. A positive change over time is most likely to increase the adherence of staying physically active.

Based on the extensive intake and in consultation with the patient, a stratified intervention is chosen by picking the best fitting option out of the three patient-tailored intervention profiles with a predefined number of intervention sessions. These profiles have been drawn up to guide the progress throughout the treatment.

These three patient-tailored intervention profiles are defined as follows:

1. Intervention Profile 1 (maximum of five sessions).

Population: Physically inactive older adults with minimal not hindering physical constraints to become (more) physically active.

Intervention: Coaching on self-management and the environment to increase physical activities.

2. Intervention Profile 2 (maximum of eleven sessions).

Population: Older adults with minor or acute mobility problems who can train safe at their own, recovery expected within 2 months.

Intervention:

- (1) Temporary physical therapy intervention to overcome barriers to become (more) physically active (e.g. training of strength, endurance, flexibility or balance, fear reduction, involving social environment, adaptation to personal factors, advising walking aids, etc.).
- (2) Coaching on self-management to become and stay more physically active.

3. Intervention Profile 3 (maximum of eighteen sessions).

Population: Older adults with moderate-to-severe mobility problems and specific problems in activities and participation.

Intervention:

- (1) Supervised physical therapy intervention aimed at decreasing mobility problems and problems in activity and participation and risk on falling.
- (2) Temporary physical therapy intervention to overcome barriers to become (more) physically active (e.g. training of strength, endurance or balance, fear reduction, involving social environment, advising walking aids, etc.).
- (3) Coaching on self-management to become more physically active.

Similarities with usual care physiotherapy: use of physical therapy modalities (such as training of strength, endurance, balance, flexibility, functional training, etc.).

Contrast with usual care physiotherapy: using an extensive intake based on a decision algorithm (clinical reasoning) with an analysis of disabilities and abilities, using motivational interviewing, shared decision-making in setting meaningful goals on increasing (adherence for) physical activity, enhancing self-efficacy and self-management, regular measurements and giving feedback on progress, using personal and environmental factors, using intervention profiles with a predefined number of consults (based on expected recovery), and intervention given by a PT(G) with additional education in Coach2Move.

A process analysis has shown that the Coach2Move strategy differed from usual care physiotherapy in almost all physiotherapeutic phases, but the main contrast was defined by a more patient-centered problem analysis and the use of inspiring goals based on shared decision-making, leading to greater adherence and self-management [17]. In a recent international study it was also recognized that patient-centeredness of guidelines should be increased, which resulted in 14 recommendations including patient-centered intervention goals, use of the ICF terminology in problem analysis, adopting a shared decision-making method, and incorporating patient-reported health outcome measures, elements present in the Coach2Move strategy [18]. These key elements are part of the shift from a biomedical to a biopsychosocial perspective on health: defining health as the ability to self-manage and adapt, with not only a focus on illness and interventions, taking into account strengths rather than weaknesses [19]. Although appreciated, this concept requires substantial personal input, of which not everyone is capable of. Although patients are focused on a broad concept of health (especially the elderly), physicians (including PTs) assess health from a more narrow and biomedical standpoint [20]. So the transfer from a biomedical to a biopsychosocial approach seems to be challenging but necessary for successful treatment results [21].

For participants suffering from (mild) dementia, a social chart will be composed consisting of relevant persons and institutions, so participants are able to receive contextual support instead of intrinsic motivations and personal responsibility in the achievement of set goals.

b. Implementation

Initially, all participating practices of physiotherapy treat the subjects by usual care. At some point in time (selected at random) during the Implementation and wash-out period, Coach2Move is introduced through a two-day education program and two peer assessment meetings. In the control period, physiotherapeutic care will take place as usual. To make sure there is no interference in the treatment due to the study, eligible patients are visited by the researcher within 1 week of registration. In that visit, tests and questionnaires are performed which are not included in usual care. During the implementation period, the extensive intake will be carried out under supervision by a researcher of Radboudumc. This is to ensure all necessary tests are performed.

Furthermore, it is focussed to guarantee objectivity. Lastly, the PT(G) can be coached and receive feedback to optimize the intake. After the implementation phase, the PT(G) is expected to perform the extensive intake on his or her own without the presence of a researcher. The follow-up measurements are being conducted by the researchers of Radboudumc.

The PT(G) is educated in the Coach2Move strategy in a baseline training of 2 days. The education consists of one physical meeting and a web-based e-learning. This education will focus on:

- Setting priorities in physiotherapy treatment by using an algorithm that emphasizes clinical reasoning.
- Making shared decisions on meaningful treatment goals focused on dissolving barriers exercises, and increasing physical activity.
- Making SMARTI focused goals.
- Focusing on coaching and self- management among patients to increase long-term results.
- Working patient-centered.
- Improving motivational interviewing skills.
- Gaining skills for adequate coordination with other involved formal and informal caregivers.
- Using appropriate measurement instruments in the diagnostic phase but also in the evaluation of the intervention and as feedback instrument for the patient and therapist.

In addition to the e-learning, three meetings will be planned in which peer assessment among participating physiotherapists takes place. Peer assessment is an effective way to improve adherence to new guidelines and approaches. Personal feedback and awareness of professional performance are known to be effective in improving the implementation of new strategies [22]. Moreover, insight into the electronic medical record (EPD) will be provided to researchers to support the clinical reasoning and patient involvement and monitoring process and to stimulate communication with the local care network if available.

c. Comparative arm:

In this study, all participating PT practices will serve as their own control. Initially, all 16 practices will provide their usual PT care. No instructions will be given on treatment content, frequency and/or duration of the treatment episode.

8. METHODS

The most of the outcomes in our study are based on questionnaires combined with an easy to perform physical diagnostic test. To avoid an extensive load on participants in the study, we have consulted a target group of older adults (<http://www.netwerk100.nl/>) to evaluate our questionnaires on time consumption, user-friendliness and feasibility. In accordance with Network 100, the most appropriate questionnaires have been chosen to measure the parameters used in this study.

a. Study parameters/endpoints

a.I Main study parameter/endpoint

The primary outcomes of the effectiveness of Coach2Move on health status is based on the level of physical activity of participants as measured by the LAPAQ questionnaire, subscale moderate activity and a physical test, the TUG [23, 24].

Success of the trial will be declared if at least one of these parameters improves while the other does not deteriorate [13].

The subscale of the LAPAQ is a comprehensive questionnaire in diverse (physical) activities of daily living with moderate intensity including walking, riding a bicycle, gardening, heavy household chores and sports activities. The questionnaire is specifically designed to assess habitual physical activity among older adults. In this study we use a modified version, which is less time consuming for both the therapist and the patient. Outcome of the test is the amount of time spent being moderately physical active. A questionnaire was chosen due to difficulties activity monitors have shown measuring active minutes and/or step count in a population of older adults. Objective activity monitors perform well at moderate or higher walking speeds, but tend to lose accuracy at decreased gait speeds [25]. Since the LAPAQ has proven to be a valid, reliable and responsive instrument for classifying physical activity in older adults, this questionnaire has been chosen as a suitable outcome [23].

The TUG is a measurement for functional mobility. The TUG is a test commonly used in PT(G) care and allows international comparison. During the test, the patient is instructed to rise out of a chair, walk 4 meters, turn, walk back and sit down on the chair. This procedure is timed. The average time in seconds this takes is the score on this test. Due to limitations of place in housing of patients, the test we use is slightly modified: patients are required to walk 3 meter instead of the usual 4. Outcome is the amount of time in seconds it takes to complete this test. Gait speed has shown to be a reliable proxy indicator for the physical condition of older adults [26].

Another aspect of this study is the investigation of the potential efficiency of the Coach2Move strategy compared to usual care physiotherapy in frail elderly patients referred to physiotherapy by a physician or patients that enter the physiotherapy practice by direct access. The study perspective is societal. The informal caregiver is included in this economic evaluation. The economic evaluation is based on the general principles of a cost-utility analysis.

Primary outcome measures for the economic evaluation, considering the 12 months follow-up period are costs and direct and indirect and QALYs (EQ-5D, derived from the EuroQoL). The incremental cost-effectiveness ratio (ICER) "cost per QALY gained" will be computed and uncertainty surrounding this ICER will be determined using a non parametric bootstrap method. A cost-effectiveness acceptability curve will be derived that is able to evaluate efficiency by using different thresholds (Willingness to Pay) for a QALY gained. The impact of uncertainty surrounding deterministic parameters on the ICER will be explored using one-way sensitivity analyses on the range of extremes.

The cost analysis measures on patient level, volumes of care (consisting of the production factors: personnel, materials and capacity in a prospective way using patient/caregiver based diaries and therapist scoring sheets [CRFs]). Per arm full cost prices will be determined using

real costs of participating practices. If not available, standard cost prices according to the Dutch guidelines for costing research will be used.

Certain procedures standard cost prices are not available real cost prices will be determined using activity based costing. This approach applies to the health care production part of the economic evaluation.

During the follow-up period costs of informal caregivers will be estimated using a caregiver-based diary (adapted version of van den Berg et al., 2006) [27] and a questionnaire on 3 months recall basis in line with the follow-up pattern of the clinical trial [28]. The friction cost-method will be applied following the Dutch guidelines for costing research [29].

Also medical costs and travel time to health care providers and related costs that patients and caregivers make will be considered (also on the basis of a diary combined with 3 months recall). Utilities from the EQ-5D will be transformed in QALY's using the trapezium method.

a.II Secondary study parameters/endpoints

To measure the level of frailty and participation the Evaluative Frailty Index (EFIP) is used. The Frailty Index is a 50-item questionnaire on deficits in health (signs, symptoms and disabilities) in multiple domains (physical, psychological, social and general health status). This Frailty Index is based on the literature and refined in Delphi rounds. It was sensitive to change in both the pilot- and the trial study. The content validity is good, psychometric properties were tested alongside the earlier study [30]. The score on this questionnaire is expressed as the ratio of deficits present to the total number of deficits considered.

The Global Perceived Satisfaction and Effect (GPE) score is used to measure patients' satisfaction about the intervention and the perceived effect on a 7-point Likert scale ranging from very unsatisfied to very much satisfied and very much deterioration to very much improvement, respectively [31].

The Patient Specific Complaints Scale (PSC) is commonly used in PT(G) and measures the functional status of a patient. The patient selects up to three most important mobility problems in daily life, which are the most important goals to improve. The degree of hinder is scored by the patient on a 10 point numeric scale [32]. A higher score indicates a higher level of difficulty experienced in the activity mentioned.

The quality of life is tested by usage of EQ-5D questionnaire [33]. This questionnaire consists of six questions comprising 5 domains: mobility, self care, daily activities, pain and emotions. The EQ-5D is recommended where a more concise assessment is required, particularly where a substantial change in health is expected [34].

At baseline comorbidities are registered using the Cumulative Illness Rating Scale-Geriatrics (CIRS-G) [35].

The CIRS-G in combination with registration of the physiotherapy intervention during each session and registration of health care utilization will be used to explore whether a PT intervention is adjusted because of the presence of comorbidity, if the presence of comorbidity influences the effect of an intervention, and if comorbidity require other interventions than PT.

a.III Other study parameters

From the physiotherapy patient files information on demographics, medical diagnosis, cultural background and living situation (alone or with partner) are extracted. Furthermore, the number of therapeutic sessions, number of adverse events and healthcare consumption are recorded.

Information on the process of implementation of Coach2Move will be collected by usage of various methods.

The reach of the intervention is tested based on the characteristics of patients included in relation to the total group patients treated in the same practice during the study period and related to the population in the region.

Furthermore, interviews in each practice with two patients will be carried out to get insight in patient experiences in pros and con's of the intervention, the experienced effectiveness and advises to improve the intervention. Over practices, we will guarantee a representative sample of participating patients and possibly context. Moreover, group interviews with PT's and PTG's within each practice will inform us about views and experiences of facilitators and barriers in delivering the Coach2Move interventions and views on which elements on the Coach2Move were effective and which were not, and if the education, peer assessment, EPD, and measurement procedures were viewed as helpful or unhelpful in supporting them to realize behavioural change strategies including needs assessment, problem analysis, shared decisions on SMARTI goals, and monitoring feedback.

Moreover, we will interview two patients in each practice after a period of 12 months after baseline to get insight in patient experiences of maintaining (or not) any lifestyle changes in physical activity made as a result of the intervention and their views of which aspects on the program were helpful and which were less.

Another aspect of the study is to evaluate the fidelity of the PT(G)'s to Coach2Move. This is done by the scoring of quality indication scores of patient files. PT(G)'s are asked to assess patients conform the Coach2Move approach. This asks for an extensive and thorough intake to require optimal clinical reasoning during the therapeutic process.

By scoring the files on integrality of data, it can give insight in the diagnostic therapeutic process before and during the implementation of Coach2Move. Scoring will be independently carried out by two researchers. Of every participating therapist, 10 files will be scored: 5 during the control period and 5 during the implementation period.

b. Randomisation, blinding and treatment allocation

Coach2Move is rolled-out sequentially to 4 groups; each comprising 4 physiotherapy practices. The time points at which the different practices receive Coach2Move are determined at random.

Randomisation will be carried out by a random number generator operated by an external independent researcher. By the end of the trial, all practices will have implemented Coach2Move (Figure 1).

Blinding takes place at patient level. Although patients receive an information letter prior to participation, the exact goal of the study is not specified to make sure the expectations are not biased by placement in control- or intervention group. It is stated that the study focuses

on gaining a better understanding in physiotherapeutic treatment among older adults and therefore monitors health before- and after the treatment.

Since the Coach2Move strategy relies heavily on a more extensive and thorough intake including the usage of several questionnaires which otherwise would not be used with regular physiotherapy, it is therefore complicated to blind both the participants as well as the researchers since this study uses outcomes otherwise not obtained.

c. Study procedures

Participating subjects are tested on four occasions: prior to the intervention, after 3, 6 and 12 months after commencement of the intervention.

Subjects are exposed to several questionnaires on the four moments of testing. One physical test is carried out on each of these four moments.

Procedure of patients in the study:

1. Registration at physiotherapy practice
2. Information on study
3. Informed consent
4. First assessment at the start of the intervention (t0) in which a number of measures will be performed. Questionnaires: LAPAQ, EQ-5D, EFIP, PSC and CIRS-G. In addition, the modified TUG is carried out. This assessment will take approximately 60 minutes and is carried out by one of the researchers during the control period or by one of the participating PT(G)'s during the intervention period.
5. Physiotherapy treatment. In either the experimental or the control group, the physiotherapist determines the number of physiotherapy consults that are needed. This is common in physiotherapy. During the intervention period, the patient and the PT(G) will choose the best fitting intervention profile together.
6. The second assessment (t1) at three months after the start of the intervention: questionnaires: LAPAQ, EQ-5D, EFIP, PSC, GPE and healthcare utilization. Again, the modified TUG is carried out. This assessment will take approximately 45 minutes.
7. The third assessment (t2) at six months after the start of the intervention. Questionnaires: LAPAQ, EQ-5D, EFIP, PSC, GPE, healthcare utilization and adherence. The modified TUG is performed. This assessment will also take approximately 45 minutes and is carried out by the researcher.
8. The fourth assessment (t3) at twelve months after the start of the intervention. Questionnaires: LAPAQ, EQ-5D, EFIP, PSC, GPE, healthcare utilization and adherence. The modified TUG is carried out once again. This assessment will also take approximately 45 minutes and is carried out by the researcher.

A randomised selection of participants is asked to join in focus group meetings to share experiences on Coach2Move. Participation is voluntarily.

All participants will be debriefed after the study by sending an information brochure concerning the most important outcomes and conclusions of the study. In addition, the participating practices for physiotherapy will be sent the same information in flyer format, which they can hang in a visible spot in their practice. Dutch magazines and newspapers will be approached to publish the research outcomes, as has happened during the previous trial of Coach2Move.

Procedure of enrolled therapists in the study:

1. Start with physiotherapeutic care as usual.
2. Electronic medical record (EPD) will be provided to support clinical reasoning and monitoring the process.
3. Intake is performed by the PT(G), alongside of an extensive intake carried out researcher of Radboudumc during the control period. During the intervention period, the PT(G) is charged with the extensive intake.
4. Web-based e-learning on Coach2Move
5. Coach2Move introduction through a two-day education program
6. Extensive physiotherapeutic intake under supervision of a researcher
7. Peer assessment meetings
8. Physiotherapeutic treatment conform Coach2Move approach
9. Physiotherapeutic intake takes place without presence of a researcher.
10. Focus groups on process evaluation of implementation

d. Withdrawal of individual subjects

Participating patients can leave the study at any time for any reason if they wish to do so without any consequences. Treatment will be continued accordingly. This means that during the control period physiotherapeutic treatment will be continued corresponding regular care, whereas during the intervention period treatment will be continued conform Coach2Move strategy, since Coach2Move will be provided to all patients. The investigator can decide to withdraw a subject from the study for urgent medical reasons. Their collected data however, will still be analysed.

Participants suffering from dementia will be treated according to the Code of conduct: incapacitated elderly. In consultation with their informal caregiver, the choice could be made to withdraw from the study.

9. STATISTICAL ANALYSIS

Descriptive statistics (mean, SD, proportions) will be used to report patient and PT(G) characteristics. Results on pre-structured questions on the interviews will be analysed using descriptive statistics (mean, SD, proportions).

The scores on the quality indicators of the patient files will be summarized using descriptive statistics. Descriptive summaries and charts will be produced presenting the quantitative results of the process analysis to help identify patterns of potential incomplete delivery.

a. Primary study parameter(s)

Cost-Effectiveness Analysis (CEA):

The Incremental cost-effectiveness ratio (ICER) “cost per Quality-Adjusted Life Year (QALY) gained” based on EQ-5D utilities will be computed and uncertainty will be determined using an appropriate method such as: the bootstrap method, Taylor expansion or the Fieller confidence interval method. A cost-effectiveness acceptability curve will be derived that is able to evaluate efficiency by using different thresholds (Willingness to Pay) for a QALY.

The cost analysis exists of two main parts. The direct costs of the regular physiotherapy and Coach2Move intervention will be determined on a per patient basis. Further, on patient level, volumes of care will be measured prospectively using medical records and cost questionnaires. Also travel time to the therapeutic sessions and related costs patients make will be considered.

The second part of the cost analysis consists of determining the cost prices for each volume of consumption in order to use these for multiplying the volumes registered for each participating patient. The Dutch manual for costing in evaluation analyses will be used [29]. For units of care/resources where no guideline or standard prices are available real cost prices will be determined. Research has shown that QALY's can be determined by applying a scoring method, such as developed by Versteegh and colleagues, on a meaningful health state classification measure, such as the EQ-5D. By means of the Dutch tariff, valuations can be determined for all possible health states as measured by the EQ-5D [27].

b. Secondary study parameter(s)

Quantitative Data Analysis

Data analysis to determine the overall effectiveness strategy subsequently involves comparison of the data points in the control section of the wedge with those in the intervention section. Because of the hierarchical design (patients nested within practices or within therapists), multilevel linear and logistic regression analysis will be used to compare the outcomes between treatment groups, with age, sex, comorbidity, frailty level and physical functioning at baseline at the patient level as covariates[13]. Time will be included as a fixed effect according to Donkers et al. [13]. In addition, subgroup analyses will be performed between PT and PTG levels.

c. Other study parameters

Qualitative Data Analysis

Interviews and focus group discussions will be elaborated verbatim (every word captured exactly, each final anonymised transcript will be added to the analysis). A structured thematic approach will be used to analyse the qualitative data.

The analysis will consist of five steps: 1) familiarization and initial coding line by line by two researchers; 2) developing a consolidated codebook; 3) coding and indexing all transcripts against the consolidated codebook, and discussion in the research group to focus on key findings for each study objective; 4) charting overall findings and look at any differences in patients, practices and context in dialogue with the project group and patient panel; 5) synthesis and drawing conclusions. In the analysis phase, descriptive summaries of interview data will be produced presenting the data per practice to help identify patterns.

Synthesizing quantitative and qualitative results:

An overall synthesis of the findings of the process evaluation study will take place to describe the context, the implementation of the intervention and the mechanisms of impact, with the aim of explicating the main trial findings and interrogating the intervention theory. Where data is available, we will test hypotheses based on qualitative analysis quantitatively. We will also, where appropriate, conduct the reverse operation and use quantitative data to focus qualitative analyses. Where data from different sources provide competing narratives or findings, we will make these explicit when reporting and provide a justification of our interpretation in such differences.

Budget Impact Analysis (BIA):

BIA will be performed according to the guidelines. Its purpose is to estimate the financial consequences of adoption and diffusion of standard use of the Coach2Move in the Netherlands. Several scenarios will be evaluated.

The aim is to assess these consequences in the medium-long term from the various budget holders' perspectives 1) wider societal perspective; 2) the more narrow perspective of the public purse; 3) the perspective of the health insurers; 4) the perspective of the health care provider.

Considering the budget impact of the new treatment mix, we will take into account market dynamics such as estimates of uptake of the Coach2Move induced treatment mix and substitution rates of usual care. For the BIA perspectives most of the cost are collected in the CEA and complemented with resources consumed not included in the CEA (like implementation costs). Both annual resource use (in terms of volumes consumed) and cost (volumes multiplied by prices) will be presented. With regard to prices and depending on the perspectives, several scenarios will be explored: charges, passenger rates (passanten tarieven), negotiated prices (if available) and real prices (CEA) based.

Effectiveness of the ultimate treatment mix will be accounted for as potential short-term savings in health care costs. The BIA will be assessed through modelling and analysed in a probabilistic way.

Deterministic uncertainty concerning BIA input such as the perspective, pricing parameters, time horizon, uptake, etc. will be dealt with by generating the budget impact as a series of scenario analyses covering a relevant range of costs.

10. ETHICAL CONSIDERATIONS

a. Regulation statement

This study will be conducted according to the principles of the Declaration of Helsinki (version 64, Fortaleza, 2013) and in accordance with the Medical Research Involving Human Subjects Act (WMO).

b. Recruitment and consent

Patients will be recruited in sixteen physiotherapy practices within a 12 month time period. All patients are consecutive patients that meet the inclusion criteria of this study, either referred to physiotherapy by a physician or contacting a physiotherapist by direct access because of mobility problems. Initial information on the study will be given by the secretary of the physiotherapy practice. The secretary will also give an information letter to the potential participants. The investigator of this study and an independent contact person can be approached for questions. The potential participant will get the time he/she needs to think about participation with a maximum of one week. However, it is recommended to commence as soon as possible considering the perceived need for treatment. The researcher will subsequently make an appointment with the participant for the first assessment and will also deal with informed consent. The data of the repeated measurements of the tests on the four assessments (0-, 3-, 6- and 12 months) will be used. Not all patients in this study are

followed for the full duration of this study. From those older adults not eligible based on the in- and exclusion criteria, only clinical data is analysed.

c. Objection by minors or incapacitated subjects

Older adults suffering from mild dementia are eligible to be included in the study as well. Guardians and/or (family) care givers are asked to sign a modified informed consent with strict arrangements when to withdraw the participant. These arrangements are conform Code of Conduct: Incapacitated Elderly.

d. Benefits and risks assessment, group relatedness

The risk of participating can be considered negligible and in the earlier studies it appeared clear that older adults like to participate and that the burden is minimal. Included patients are referred to physiotherapy and they receive physiotherapy. Physiotherapy is no invasive therapy and the risk of adverse events can be considered very small. The choice to include older adults suffering from mild dementia as well, was made to ensure a representative sample of current physiotherapeutic practice in the Netherlands. Dementia will not be diagnosed as part of the study, but when it is present (i.e., as diagnosed by a specialist during the regular treatment trajectory separate from the study) these patients will not be excluded. After all, community-dwelling, older adults with dementia are referred to primary care physiotherapy regularly. To study the effect of Coach2Move in this group, separate subgroup analyses will be carried out.

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