Implementation of a Cost-Effective Physical Therapy Approach (Coach2Move) to Improve Physical Activity in Community-Dwelling Older Adults With Mobility Problems: Protocol for a Cluster-Randomized, Stepped Wedge Trial

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Background. Coach2Move is a personalized treatment strategy by physical therapists to elicit physical activity in community-dwelling older adults with mobility problems.

Objective. The primary objective of this study is to assess the effectiveness and cost-effectiveness of the implementation of Coach2Move compared with regular care physical therapy in daily clinical practice.

Design, Setting, Participants, and Intervention. A multicenter cluster-randomized stepped wedge trial is being implemented in 16 physical therapist practices (4 clusters of 4 practices in 4 steps) in the Netherlands. The study aims to include 400 older adults (≥70 years) living independently with mobility problems and/or physically inactive lifestyles. The intervention group receives physical therapy conforming to the Coach2Move strategy; the usual care group receives typical physical therapist care.

Measurements. Measurements are taken at baseline and 3, 6, and 12 months after the start of treatment. The primary outcomes for effectiveness are the amount of physical activity (LASA Physical Activity Questionnaire) and functional mobility (Timed Up and Go test). Trial success can be declared if at least 1 parameter improves while another does not deteriorate. Secondary outcomes are level of frailty (Evaluative Frailty Index for Physical Activity), perceived effect (Global Perceived Effect and Patient Specific Complaints questionnaire), quality of life (EQ-5D-5 L), and health care expenditures. Multilevel linear regression analyses are used to compare the outcomes between treatment groups according to an intention-to-treat approach. Alongside the trial, a mixed-methods process evaluation is performed to understand the outcomes, evaluate therapist fidelity to the strategy, and detect barriers and facilitators in implementation.

Limitations. An important limitation of the study design is the inability to blind treating therapists to study allocation.

Discussion. The trial provides insight into the effectiveness and cost-effectiveness of the Coach2Move strategy compared with usual care. The process evaluation provides insight into influencing factors related to outcomes and implementation.
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Physical activity has beneficial effects for older adults in the prevention and reduction of frailty and improvement of quality of life. However, increasing physical activity is known to be very challenging, especially if an individual is coping with health disorders, ageing, and an unhealthy lifestyle. Older adults with limited mobility reported poor health, fear of falling, negative experiences, lack of company, and an unsuitable environment as barriers to exercise and to be physically active. Physicians and physical therapists play a pivotal role in promoting exercise and physically active behavior among older adults.

Coach2Move is a personalized coaching strategy for physical therapists to elicit physical activity and empower elderly patients who visit their physical therapist for mobility problems. This strategy supports clinical reasoning by providing an extensive, prestructured, and systematically organized diagnostic protocol based on the Hypothesis Oriented Algorithm for Clinicians II and the International Classification of Functioning, Disability and Health. The therapeutic intake requires more time (60 minutes + 30 minutes of registration time) than a usual care physical therapist intake (30 minutes), during which not only are impairments and disabilities evaluated but—in particular—abilities, needs, and wishes. In addition, barriers and facilitators—both intrinsic and context related—in relation to physical functioning are thoroughly examined. Based on the information gathered during the anamnesis and physical examination, physical therapists are trained to explicitly make shared decisions with the patients and, if adequate, their caregivers regarding treatment goals and the therapeutic strategy to increase physical abilities and activity. Moreover, therapists are stimulated to assign patients to 1 of the intervention profiles based on expected recovery trajectory. The number of expected consultations is determined together with patients to empower self-management ability. Key elements of the Coach2Move strategy are shown in Figure 1 and have been described in more detail in previous publications.

In a previous randomized clinical trial (RCT), Coach2Move delivered by physical therapists specialized in geriatrics was shown to be cost-effective compared with regular physical therapy among older adults with mobility problems. Because the number of elderly with mobility problems will increase, more physical therapist involvement will be necessary in the future. Therefore, it is necessary to implement Coach2Move in day-to-day physical therapist practices among physical therapists working together with those specialized in geriatrics without any coaching of the research team.

The present article describes the design of the implementation study. The primary aim of this trial is to assess the effectiveness of the implementation of the Coach2Move physical therapy strategy for community-dwelling older adults with mobility problems and/or physically inactive lifestyles in a pragmatic real-world setting (effect evaluation). The secondary aim is to assess the cost-effectiveness of Coach2Move (economic evaluation). And the third and final aim is to gain insight into factors that modify the outcomes and which factors at the organizational, professional, and patient levels influence the implementation of the program (process evaluation).

Methods

Study Design

Using a cluster-randomized stepped wedge trial design, we will compare a group of patients receiving usual care physical therapy with a patient group receiving Coach2Move physical therapy. Each patient is measured at baseline (T0) and 3 (T1), 6 (T2), and 12 (T3) months after inclusion in either usual care or a Coach2Move period. Within the stepped wedge design, Coach2Move is implemented in all 4 clusters (each containing 4 physical therapist practices) at standardized different points in time. This enables comparison between clusters but also comparison of time periods within clusters. Cluster randomization was chosen to avoid randomization at patient and physical therapist levels and to minimize contamination between therapists working in the same practice. By randomizing the order of implementation of Coach2Move, we aim to include a more clinically relevant population as opposed to the previously conducted RCT, where nearly one-half of the eligible individuals declined randomization and, thereby, participation.

The total study duration is 18 months (6 periods of 3 months) in which 16 practices, divided into 4 clusters of 4 practices, are participating (please see Fig. 2 for a visual depiction). Because 1 period has been scheduled as a washout period (without including patients) between the usual care and Coach2Move periods, patients are included in 5 periods, resulting in 15 months of data. Each practice aims to include 5 patients per time period. This is intended to lead to an accumulated number of 400 participants: approximately 200 participants during the usual care periods and approximately 200 other participants during the Coach2Move periods. Each participant is measured at baseline (T0), and 3 (T1), 6 (T2), and 12 (T3) months after inclusion in either usual care or Coach2Move period. This means that the study will be completed in 30 months. Patient recruitment started in November 2017 and ended in May 2019. The stepped wedge design implements Coach2Move in all clusters at different points in time, and therefore enables comparison between clusters but also within clusters between time periods: before and after implementation. The stepped wedge design has been chosen because the cost-effectiveness of this intervention was already established, and choosing this design guarantees that all clusters will have implemented Coach2Move by the end of the study. At the time of first submission of this manuscript, 193 patients (48% of expected total) were enrolled in the study.
### Key Elements of the Coach2Move Strategy

1. **Use of motivational interviewing**: exploring questions for help and identifying perceived barriers and facilitators in relation to physical activity.

2. **Use of an algorithm (based on Hypothesis Oriented Algorithm for Clinicians II)*** that emphasizes an extensive intake and supports clinical reasoning to obtain insight into abilities and disabilities, and set priorities.

3. **Shared decision-making about meaningful treatment goals** (Specific, Measurable, Acceptable, Realistic, Time-bound, and Inspiring [SMART]) formulated to increase physical activity, including signing a treatment agreement.

4. **Coaching about self-management** to improve long-term results.

5. **Focusing on meaningful activities at home** with help from family, friends, or professionals.

6. **Systematically monitoring, evaluating, and sharing feedback** on progress by usage of questionnaires and physical performance tests.

7. **Working according to 3 patient-tailored intervention profiles** with a predefined number of consultations based on expected recovery.

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**Figure 1.**

Key elements of the Coach2Move strategy.

**Figure 2.**

Depiction of proposed cluster-randomized stepped wedge design. Pts = patients; Impl = implementation; WO = washout period.

| Cluster 1 (Practices 1-4) | 3 Months | 6 Months | 9 Months | 12 Months | 15 Months | 18 Months |
|--------------------------|----------|----------|----------|-----------|-----------|-----------|
| Usual care 20 pts        | Imp + WO 0 pts   | Coach2Move 20 pts | Coach2Move 20 pts | Coach2Move 20 pts | Coach2Move 20 pts |

| Cluster 2 (Practices 5-8) | 3 Months | 6 Months | 9 Months | 12 Months | 15 Months | 18 Months |
|--------------------------|----------|----------|----------|-----------|-----------|-----------|
| Usual care 20 pts        | Usual care 20 pts | Imp + WO 0 pts   | Coach2Move 20 pts | Coach2Move 20 pts | Coach2Move 20 pts |

| Cluster 3 (Practices 9-12) | 3 Months | 6 Months | 9 Months | 12 Months | 15 Months | 18 Months |
|---------------------------|----------|----------|----------|-----------|-----------|-----------|
| Usual care 20 pts         | Usual care 20 pts | Coach2Move 20 pts | Coach2Move 20 pts | Coach2Move 20 pts |

| Cluster 4 (Practices 13-16) | 3 Months | 6 Months | 9 Months | 12 Months | 15 Months | 18 Months |
|-----------------------------|----------|----------|----------|-----------|-----------|-----------|
| Usual care 20 pts           | Usual care 20 pts | Coach2Move 20 pts | Coach2Move 20 pts |Coach2Move 20 pts |Coach2Move 20 pts |

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### Setting and Participants

Sixteen physical therapist practices were recruited by placing an advertisement in the magazine and website of the professional association calling for physical therapists in geriatrics. Practices in the Netherlands were eligible if they (1) performed primary care physical therapist treatment; (2) comprised at least 1 general physical therapist with experience in working with the elderly and 1 physical therapist specialized in geriatrics, as evidenced by a professional master's degree; and (3) agreed to participate in education and peer-assessment rounds.

To ensure there were enough eligible patients for the study, practices had to have at least 75 newly registered older adults for physical therapy in the year prior to the study.

Inclusion criteria for patients are as follows:

1. Older adults of ≥70 years living independently.
2. Limitations in independent, purposeful physical movement of the body or of 1 or more extremities and/or a physically inactive lifestyle (<30 min/d of moderate vigorously physical activity) or at risk of losing a physically active lifestyle soon.
3. Referred for physical therapy by a physician or decided to attend physical therapy by themselves.

Exclusion criteria are as follows:

1. Patients who are not ambulatory, even after physical therapist treatment and/or are in palliative phase.
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2. Patients indicated as likely to be institutionalized soon.
3. In an advanced stage of a severe degenerative neurological disease.
4. Contraindication for being physically active or exercising.
5. Ongoing physical therapeutic treatment.

Patients with problems understanding advice and/or communicating with the professional due to Dutch language problems and/or mild dementia have not been excluded and are eligible for subgroup analysis. For this group, we hypothesize that we could involve informal caregivers or other health authorities in their treatment to help achieve therapeutic goals.

Study Procedures
In this study, all 16 participating practices serve as their own control (see Fig. 2). Thus, initially, all practices provide care as usual. No instructions are provided on treatment content, frequency, and/or duration of treatment episode. To make sure there is no interference in the usual care treatment period due to the study, eligible patients are visited by researchers within 1 week after registration for the baseline measurements, including tests and questionnaires not necessarily included in usual care. At some time point, based on cluster randomization, the implementation and washout period commences. During this period, physical therapists are educated in Coach2Move and can implement questionnaires and elements of the Coach2Move strategy with patients who are not included in this study. So, in this period, physical therapists can build up a routine. After the implementation period, the tests and questionnaires included in the Coach2Move strategy and can serve as baseline measurements carried out without the presence of researchers. All follow-up measurements in both the usual care and Coach2Move patients are being conducted by independent researchers. Because most measurements on a patient take place in either the usual care or Coach2Move period of the corresponding practice, no contamination between Coach2Move and usual care conditions is expected. A full depiction of the patient flow is found in Figure 3.

Randomization, Blinding, and Treatment Allocation
Coach2Move is rolled-out sequentially every 3 months to each cluster in a preassigned random order. Firstly, for each cluster, 4 practices were combined based on geographical location (to ensure feasibility of the measurements) and stratified according to practice characteristics (stand-alone practice vs health care centers). Randomization took place on a cluster level by using a random number generator operated by an external independent researcher not involved in the study.

Because the Coach2Move strategy relies heavily on a different method of history-taking and testing, leading to a more time-consuming and extensive intake, it is therefore impossible to blind physical therapists to the process. However, measurements during the usual care period are conducted by the researchers, so physical therapists are blinded for these outcomes. Baseline measurements during the Coach2Move period are performed by the physical therapists as part of the Coach2Move strategy, although follow-up measurements are conducted by the researchers. Researchers are not blinded because of the stepped wedge design. Nonetheless, each measurement is performed without information about the earlier measurements or information from the therapist. However, blinding takes place at the patient level. Patients receive an informative letter prior to participation in which the goal of the study (comparing usual care vs Coach2Move) is not specified to make sure expectations are not biased by knowing group allocations. Patients included during the usual care period receive usual care physical therapy, while patients included during the Coach2Move period receive physical therapy conforming to the Coach2Move strategy; thus, individual patients are not aware of the changing approach in the practice.

Implementation of Coach2Move
An implementation and washout period of 3 months is scheduled to give the physical therapists the opportunity to gain experience with Coach2Move in daily practice prior to the Coach2Move period.

To implement Coach2Move, participating physical therapists follow a 2-day educational course and attend 3 peer-assessment meetings. Before enrolling in the 2-day course, physical therapists complete an e-assessment that measures their baseline clinical reasoning according to Coach2Move and motivational interviewing skills in 2 patient cases. Based on answers of experts in both skills, differentiations between “appropriate” and “less appropriate” answers are made, which are converted to a script concordance test (Maas MJ et al; unpublished data). Participating therapists are invited to complete this e-assessment prior to implementation, and, based on their outcomes in the e-assessment, the 2-day predesigned education program is tailored to already existing competencies. Completion of the e-assessment is mandatory prior to participating in the Coach2Move course. Moreover, the e-assessment is repeated 12 months later to test the effect of the educational trajectory.

The course consists of 2 days, of which the first is dedicated to motivational interviewing, whereas the second day involves education in other key elements of Coach2Move. The education is accredited by the Royal Dutch Association of Physical Therapy and is complemented by 3 peer-assessment meetings in which
physical therapists review their own skills and those of their colleagues. Each peer-assessment meeting has its own topic: the first focuses on motivational interviewing, the second on administering questionnaires and SMARTI-goal setting, and the third on how to incorporate Coach2Move efficiently into the extensive intake. Peer assessment is effective in improving adherence to new guidelines and strategies. Personal feedback and awareness of professional performance are known to be effective in improving the implementation of new strategies. In addition, electronic medical records (EPD) will be adjusted to the Coach2Move flow to support clinical reasoning, patient involvement, and monitoring process and to stimulate communication with local care networks if available. Physical therapists are financially compensated for additional time spent during the extensive intake. After the implementation period, physical therapists are expected to give treatment conforming to Coach2Move.

**Outcomes for Effectiveness and Costs**

The primary outcomes for the effectiveness of Coach2Move on health status are based on the physical activity level of patients as measured by the LASA Physical Activity Questionnaire, subscale moderate activity, and a physical test measuring functional mobility, the Timed Up

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**Figure 3.**

Patient flow. CIRS-G = cumulative illness rating scale for geriatrics; EFIP = evaluative frailty index for physical activity; EQ-5D = EuroQoL 5 dimensions; GPE = global perceived effect; LAPAQ = LASA physical activity questionnaire; PSC = patient-specific complaints; TUG = timed up and go test.
and Go. A physically active lifestyle has shown to lead to decreased health care utilization and thus lesser costs. Secondary outcomes include level of frailty (Evaluative Frailty Index for Physical Activity), perceived effect (Global Perceived Effect and Patient Specific Complaints questionnaire), and quality of life (EQ-5D-5 L). The outcomes of this research relate to the change between baseline and 6 months at the patient level.

Information on demographics, medical diagnosis, cultural background, and living situation (alone or with partner) is extracted from physical therapy patient files together with information on adverse events and volumes of care. At the patient level, costs were sampled using cost questionnaires in which the patients and/or their family reported usage of health care utilities and travel costs of the past 3 months. Serious adverse events are recorded in line listings including date of events and a brief description of what happened; these are reported to the medical ethical committee. For a more comprehensive description and rationale of the chosen parameters, see Supplementary Appendix I (available at https://academic.oup.com/ptj).

**Study Parameters for Process Analysis**

Conforming to the MRC framework, a process evaluation is used to study how the implementation of Coach2Move has been established. This evaluation will take place on different levels: context, implementation, and mechanisms of impact. In each practice, interviews with a sample of patients are carried out after a period of 12 months after baseline to gain insight into patient responses, interactions, and advice to improve the intervention. In addition, group interviews with physical therapists within each cluster inform us about experiences of facilitators and barriers to implementing and delivering Coach2Move. Moreover, discussions are encouraged about the elements that were effective and whether the education, peer assessment, EPD, and measurement procedures were helpful in supporting them to realize behavioral change strategies. Interviews with both patients and physical therapists are conducted until, respectively, data saturation and consensus are achieved. Furthermore, fidelity of the physical therapists to Coach2Move is evaluated by scoring patient files using quality indicators developed for the process evaluation of the original RCT. Scoring is independently carried out by 2 researchers. In every practice, 10 files are scored: 5 from the usual care period and 5 from the Coach2Move period. Scores on fidelity to the Coach2Move strategy will be analyzed on an individual therapist level with time point of education, specialization, and clinical setting as covariates. In addition, group analyses between general and specialized physical therapists will be conducted to identify differences between groups in implementation of the strategy in daily practice.

**Sample Size Calculation**

Primary endpoints are Timed Up and Go and LASA Physical Activity Questionnaire at 6 months, and effectiveness has been defined as at least 1 of these outcomes improving while the other does not deteriorate. The power of the combined objective for 400 patients is 86%. For a more detailed explanation regarding the sample size calculation, please refer to Supplementary Appendix II (available at https://academic.oup.com/ptj).

**Data Analysis Plan**

Data collected in this study are analyzed on 3 levels: an effect evaluation where physical outcomes are compared between patients in the Coach2Move and the regular care group, an economic evaluation where health care usage is compared between patients in the Coach2Move and the regular care group, and the process analysis where barriers and facilitators of implementation are analyzed. We will use the lme4 package in RStudio version 1.2 statistical software for statistical analyses.

**Effect evaluation.** Data analysis to determine overall effectiveness involves comparison of the data points in the usual care section of the wedge with those in the Coach2Move section. In other words, patients included in a practice during a 3-month period represent the data points of that practice in that time. The outcomes of those patients are determined as the change from baseline to 6 months. Because of the hierarchical design (patients nested within clusters, practices and therapists), multilevel linear analysis (ie, generalized linear mixed models) is used to compare outcomes between treatment groups, with age, sex, comorbidity, frailty level, and physical functioning at baseline at patient level as covariates. Time is included as a fixed effect. In addition, subgroup analyses are performed between physical therapists and specialized physical therapists in geriatrics. Analyses are carried out following the intention-to-treat approach.

**Economic evaluation.** The economic evaluation will be performed from a health care perspective. The incremental cost-effectiveness ratio “cost per Quality-Adjusted Life Year (QALY) gained” based on EQ-5D-5 L utilities is computed, and uncertainty relating to clustering and design 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 is derived that can evaluate efficacy by using different thresholds (willingness to pay) for a QALY. The impact of uncertainty surrounding deterministic parameters (eg, prices) on the incremental cost-effectiveness ratio will be explored using one-way sensitivity analyses on the range of extremes.

All registered costs are calculated over a period of 12 months summarizing the outcomes sampled at each 3-month measurement point. The cost analysis consists of 2 parts. First, the direct number of usual care physical therapy and Coach2Move sessions is determined on a per
patient basis. Moreover, volume of health care use and additional support and the number of health care-associated products are calculated per patient. These include, among others, visits to health care professionals and hospitals, use of medication, and use of domestic or nursing care.

The second part of the cost analysis consists of determining cost prices for each volume of consumption. To use these for multiplying the volumes registered for each participating patient, the Dutch manual for costing in evaluation analyses is used. For resources where no guidelines or standard prices are available, real cost prices are determined. Research has shown QALYs can be determined by applying a scoring method on a meaningful health state classification measure, such as the EQ-5D-5 L. By means of the Dutch tariff, valuations can be determined for all possible health states as measured by the EQ-5D-5 L. This study compares all relevant health care costs between control and Coach2Move groups during the evaluation period of 12 months; therefore, discounting will not be applied to conform with the Dutch guideline for conducting economic evaluations in health care.

Process evaluation. An overall synthesis of the findings of the process evaluation is conducted to describe context, implementation of the intervention, and mechanisms of impact aimed at explicating the main trial findings and examining intervention theory. When appropriate, hypotheses are tested quantitatively based on qualitative data analysis and vice versa. Where data from different sources provide competing narratives or findings, we make these explicit when reporting and provide justification of our interpretation in such differences. Mixed-methods analyses are carried out to gain insight into the implementation process. Quality indicators of EPD files are analyzed quantitatively and compared between time periods before and after education within EPD files are analyzed quantitatively and compared into the implementation process. Quality indicators of Mixed-methods analyses are carried out to gain insight sources provide competing narratives or findings, we data analysis and vice versa. Where data from different practices.

Ethics
All eligible patients are informed about the study by their physical therapist or administration of the physical therapist practice and given the time they need to consider participation. Both primary researchers and an independent clinician who is informed about this study can be contacted for additional questions. Patients willing to participate sign an informed consent form.

This study is approved by the Committee of Research Involving Human Subjects of the Radboud University Medical Center, Nijmegen (registration number: NL60554.091.17) and is registered in the National Clinical Trials database (registration number: NCT03212859).

Role of The Funding Source
The funder, ZonMw, Dutch Organization for Health Research and Development (project no. 843002703), played no role in the design, conduct, or reporting of this study.

Discussion
This study describes the design of the implementation study of Coach2Move in daily clinical practice with an embedded mixed-methods process evaluation. The process evaluation is designed to study how implementation of the strategy is established in 16 practices and provides a comprehensive understanding of how outcomes are achieved. By publishing the protocol for this study, our methodological choices are made explicit and transparent and therefore enable future readers to compare what was originally intended with what has been done.

In most research concerning physical therapist interventions, the effect of standardized exercise programs is evaluated, whereas clinical practice treatment is usually personalized, especially for elderly people with multimorbidity. Larger effects could be expected from tailored interventions in relation to standardized exercise programs. Coach2Move has demonstrated to be subsequently different from usual care physical therapy for the following quality indicators: patient centeredness, focus on self-management, individual empowerment, and adherence to treatment goals. Coach2Move focuses on increasing moderate-intensity physical activity because this is a known variable that decreases the risk of many adverse health conditions and increases life expectancy. It is expected that older adults can be more self-efficacious in developing and maintaining a physically more active lifestyle by exploring and focusing on the ability to adapt instead of disabilities. By including a sample of older adults with multiple morbidities, the effects of Coach2Move can be studied in a diverse, clinically more representative sample of Dutch clinical practices.

Adoption and incorporation into daily practice of new treatment strategies, such as Coach2Move, is challenging. Successful implementation is dependent on various determinants such as the behavioral, organizational, and socio-political contexts. These determinants consist of interacting components, such as characteristics of physical therapists, physical therapist practices, and health insurance companies, which can positively or negatively influence implementation. At the physical therapist level, we try to achieve successful implementation by tailoring the education based on results of the e-assessment.
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During peer-assessment meetings, we can further focus on individual progress of physical therapists learning the Coach2Move strategy. At a practice level, we optimize EPDs for the Coach2Move strategy and guarantee no loss of income due to additional time spent on the prolonged intake. By including health insurance companies in the implementation, we hope to warrant the future embedding of Coach2Move in daily practice. When the trial has ended, success of implementation will be evaluated based on process analysis and quality indicators. If efficacious, Coach2Move holds promise for physical therapist treatment in older adults. We expect our results to inform future research into older adults with a broad spectrum of disorders.

We are utilizing a randomized cluster stepped wedge trial. This design matches well with our research question but has a number of disadvantages compared with an RCT: (1) it takes more time because of the extended time to roll out the intervention to each cluster, and (2) analysis of the design is complex due to the time effect and its interaction with therapists, practices, and clusters.30 When a change in clinical care occurs within a short timeframe, the comparison between usual care and Coach2Move groups could be influenced by factors irrelevant to the treatment given, such as organizational or personal factors. In addition, physical therapists in clusters that cross over from regular care to Coach2Move in an earlier time period gain more experience in its application in daily clinical practice than clusters that cross over in a later time period; this could therefore increase the likelihood of a more successful intervention.31 Therefore, we scheduled an implementation period in which no patients are included in order to give physical therapists the opportunity to practice with Coach2Move in daily practice.

Findings of the trial will be disseminated through peer-reviewed journals as well as national and international conferences. Upon trial completion, a summary of findings will be communicated to patients and families.

Author Contributions and Acknowledgments

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Ethics Approval

This study has been approved by the Committee of Research involving Human Subjects of the Radboud University Medical Center, Nijmegen (reg. no. NL60554.091.17). Written informed consent is obtained from all patients or their informal caregivers.

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Clinical Trial Registration

This study is registered at Clinicaltrials.gov (NCT03212859).

Disclosures

The authors completed the ICMJE Form for Disclosure of Potential Conflicts of Interest and reported no conflicts of interest. There are no financial or nonfinancial competing interests to declare in relation to this manuscript by any of the authors. The datasets generated during and/or analyzed during the current study will be available from the corresponding author on reasonable request on the completion of the study.

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