

# Coach2Move: Sustainable in Daily Practice?

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Muscle disorders
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON47884

### Source

ToetsingOnline

### Brief title

Coach2Move

### Condition

- Muscle disorders
- Age related factors

### Synonym

frailty, weakness

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Radboud Universitair Medisch Centrum

**Source(s) of monetary or material Support:** ZonMw doelmatigheidssubsidie

## Intervention

**Keyword:** adherence, intervention, physical activity, tailored

## Outcome measures

### Primary outcome

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 outcome

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 physiotherapists.

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

## Study description

### Background summary

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.

### Study 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.

### 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.

### Study burden and risks

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 physiotherapist 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.

## Contacts

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## Trial sites

### **Listed location countries**

Netherlands

## Eligibility criteria

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

Older adults who are community-dwelling and have mobility related to activities of daily living and have a sedentary lifestyle or are at risk of losing an active lifestyle in the near future

## Exclusion criteria

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

## Study design

### Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

**Primary purpose:** Treatment

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	06-11-2017
Enrollment:	400
Type:	Actual

## Ethics review

Approved WMO	
Date:	23-10-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	

Date:	08-11-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	17-01-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	23-07-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

#### Register

ClinicalTrials.gov

CCMO

#### ID

NCT03212859

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