The feasibility and cost effectiveness of E-Exercise: a combination of a physical therapy treatments and a web-based intervention in patients with knee and hip osteoarthritis

Published: 20-03-2014
Last updated: 23-04-2024

The aim of this study is to investigate the cost-effectiveness of E-Exercise in comparison with usual care of a physical therapist. Research question for this RCT study is: What are the short- (3 months) and long term (12 months) (cost) effects of E...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON40161

Source
ToetsingOnline

Brief title
E-exercise

Condition

- Joint disorders

Synonym
Arthrosis, Osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: ZonMW;KNGF en Reumafonds

Intervention

Keyword: E-health, Osteoarthritis, physical activity, Physical therapy

Outcome measures

Primary outcome

Physical functioning will be assessed with the subscale *function in daily living* of the Hip Osteoarthritis Outcome Score (HOOS) and/or the Knee Injury and Osteoarthritis Outcome Score (KOOS). The HOOS and the KOOS assess 5 indicators: pain, symptoms, physical function, sport and recreation function and quality of life, in relation to patients* hip or knee complaint. Each indicator is scored on a 5-point Likert scale (0=extreme symptoms; 4=no symptoms)

Physical activity will be measured with the SQUASH. The questionnaire measures habitual physical activity during a normal week over the last few months. The total score is reproduced as minutes per week , but data can also be analysed according to whether the activity is light, moderate or intense.
Objective physical activity will be measured through ActiGraph GT3X tri-axial accelerometers. Patients will be instructed to wear the monitor on a belt around their waist for five executive days, except during sleeping, showering or swimming. In addition, participants will be requested to fill out a short activity diary. This diary contains questions about wearing time, unusual

activities and reasons for device removal. When accelerometers and diaries are returned by post, data can be downloaded, processed and subsequently analyzed. In order to determine the actual physical activity thresholds, the widely accepted thresholds by Freedson et al. will ge used: 0-99 counts for sedentary activities, 100-1951 for light PA, 1952-5724 moderate physical activity, 5725-9498 for vigorous PA and 9499- max for very vigorous activities. The total time spent in light, moderate and (very) vigorous physical activity was summed and subsequently divided by the number of days worn to compute the daily average time spent in total activity. For analysis, data were recorded at 1-minute intervals.

Secondary outcome

OA related costs made by the patients will be registered with an online cost diary. Patients will be asked to register their direct costs of OA within and outside the health care sector and on the indirect costs of productivity loss. The cost diary will cover the full 12 months of the program.

Health Related Quality Of Life will be measured with the EuroQol-5D (EQ-5D).(35) This questionnaire comprises 5 dimensions i.e., mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Patients are asked to indicate their health state on a 3-point Likert scale (1=no problems; 3=extreme problems). The questionnaire enables 245 different health states. Each health state can be ranked and transformed to a score which is defined as utility. The utility score is an expression of the quality adjusted life years (QALY*s).

Self-perceived effect will be assessed by a single question about the degree of change in physical functioning since their previous assessment. Patients can score this effect on a 7-point Likert scale (1=much worse; 7= much better).

Pain and tiredness will be measured with a numeric rating scale(NRS; 0 is no pain/not tired and 10 is worst possible pain/very tired) (NRS; 0=no problems; 10=extremely problems). Furthermore, pain will be assessed with the pain subscale of the HOOS and/or the KOOS.

Self-efficacy will be measured by the Arthritis Self-efficacy Scale (ASES).(36) Subscales for the ASES are pain, symptoms and physical functioning, the 19 statements can be scored on a 5 point-Likert scale (1=fully disagree; 5=fully agree).

Self-management skills will be measured through the Health Education Impact Questionnaire (HeiQ).(37) The questionnaire consists of 40 questions statments subdivided in 8 scales i.e., health directed behaviour, positive and active engagement in life, emotional well-being, self-monitoring and insight, constructive attitudes and approaches, skill and technique acquisition, social integration and support and health service navigation. The 40 statements can be scored on a 4 point-Likert scale (1=fully disagree; 4=fully agree).

Depression and Anxiety will be measured by the Hospital Anxiety and Depression Scale (HADS).(39) 7 items are related to depression and 7 items to anxiety. The

statements can be scored on a 4 point-Likert scale (0-3). A lower score

represents less anxiety and depression, the cut-off point for depression and

anxiety is 8 points.

Study description

Background summary

Among the elderly, osteoarthritis (OA) is worldwide one of the leading causes of pain and disability. Most common affected sites are the hip and knee (Issa, 2013). In the Netherlands, it is estimated that 312.000 persons suffer from knee OA and 238.000 from hip OA (Poos, 2009) OA is an age-related disease(Zhang, 2010) and besides pain and disability, characterized by morning stiffness, reduced range of motion, instability of the joint,(Poos, 2009) loss of health related quality of life(Salaffi,2005) and mortality (Nüesch, 2010). Due to the aging population and the increasing number of people with obesity, expected prevalence of knee and hip OA is 52% in 2040. Healthcare costs related to OA were about 715 million euro in 2007, which was 14.4% of total healthcare costs of musculoskeletal diseases in The Netherlands (Poos, 2009) .In order to regulate these costs while the population with OA is growing, there is a need for cost-effective interventions.

Because of OA related clinical symptoms people with hip and/or knee OA are less physically active than the general population (De Groot, 2008, Rosemann 2013). Where symptoms of OA results in less physical activities, in long term physical inactivity may lead to physical decline, psychological problems and eventually functional decline (Dunlop, 2006; Pisters, 2012).Since research showed that physical activity is beneficial for reducing pain and improvement of physical functioning (Dunlop2011), physical activity is widely recommended by national and international (physical therapy) guidelines (Zhang,2008)

Besides physical activity, information and self-management are recommended in order to improve physical functioning (Zhang, 2008; Peter, 2010. The inclusion of information is important since a lack of knowledge among OA patients appeared to be related to depression, anxiety and a passive coping style (Lorig. 1993). Self-management appeared to reduce disability and health related costs as in doctor visits and hospitalization (Warsi 2003;Lorig, 1993; Lorig, 1999). The ultimate goal of the physical therapy sessions for patients with OA is to increase patients* knowledge and amount of physical activity in order to improve physical functioning. Final aim is that patients maintain a physically active lifestyle without supervision of physical therapist (Köke, 2011).

With the explosion of internet accessibility, the internet has created new possibilities to support physical therapists in the treatment of OA patients. In a review of Pietrzak et al., internet interventions in patients with OA resulted in improvement of health status, access to care and communication between patients and health professionals (Pietrzak, 2013). Financially, it is likely that less face-to-face contact with a professional may result in lower costs. Besides, a cheaper intervention would make OA treatment accessible for patients without sufficient insurance (Marcus, 2009). By substitute a part of the face-to-face contacts with a physical therapist by a website, a combination of *the best of two worlds* will be generated (Van Gemert, 2013).

To date, there are no studies about the (cost) effectiveness of blended care initiatives in the field of knee and/or hip osteoarthritis. We therefore have planned to evaluate E-Exercise, which is an integration of face-to-face sessions by a physical therapist and a web-based intervention. The web-based part will be based on the online program Join2Move (Bossen, 2013), since this program showed to be effective in improvement of physical functioning and physical activity in patients with knee and/or hip OA.

Study objective

The aim of this study is to investigate the cost-effectiveness of E-Exercise in comparison with usual care of a physical therapist. Research question for this RCT study is: What are the short- (3 months) and long term (12 months) (cost) effects of E-Exercise in patients with knee and/or hip OA on physical activity and physical function in comparison with a face-to-face physical therapy intervention?

Study design

We will perform a clustered randomized controlled clinical trial will be performed. Patients with osteoarthritis of hip or knee will be randomly assigned to either the E-Exercise intervention or the physical activity program provided by physical therapists (usual care). Patients who are assigned to the usual care will be offered to participate in the E-Exercise program after the study has been finished (after 12 months without guidance of a physical therapist).The study period of each patient is 12 months. During these 12 months three assessments will be performed, at baseline, after 3 months and 12 months.

Intervention

The intervention group will receive the 12-week E-Exercise program. E-Exercise a combination of four to five face-to-face sessions with a physical therapist and a web-based intervention. The content is written according to the KNGF guideline Osteoarthritis Hip-Knee (Peter, 2010).Tailored modules are weekly

presented on the website E-Exercise. A module consists of three topics. (i) Information; various topics will be discussed (e.g. OA, physical activity, pain, medication, nutrition etc.) through texts and videos.(ii) Graded Activity; a selected activity will be increased on a weekly basis. Based on a short term goal, a tailored schedule of modules is generated on a time-contingent basis. The gradual increase of the selected activity starts slightly below the baseline value and increases incrementally towards a short term goal. This part of the intervention is derived from a previous developed and evaluated behavioral graded activity (BGA) program for patients with knee and/or hip OA (Veenhof 2006). The gradual increase in activities aims to improve physical activity levels despite the potential presence of pain. (iii) Strength and mobility exercises; each module contains specific exercises which are provided through videos.

When a patient visits, for the first time, the physical therapy practice the therapists will carry out an anamnesis, physical examination and a clinical test to confirm clinical knee and/or hip OA. Moreover, the physical therapist will also assess other in- and exclusion criteria. Eligible and interested patients will contact the research team to participate in the study. The following week after the intake is dominated by study related activities. Participates are requested to read an information letter, sign an informed consent and complete a baseline measurement. Patients start with E-Exercise after compliance with these study activities.

In the first week of the program the physical therapist will provide information about OA and the principles of E-Exercise. Together with the physical therapist, the patient chooses a central activity (e.g. walking, cycling or swimming) and four strength/mobility exercises (videos) which are presented on a website. To determine the physical load ability of the participants, patients are instructed to perform a 3-day baseline test (execution of selected activity) and 4 exercises in their home environment. Results from the baseline test (time, intensity and pain scores) will be entered on the website. Based on the performance from the baseline self-test, a range of goals will automatically be generated and presented on the website. The therapist gives instructions about the selected exercises.

In week 2, the performance of the 3-day self-test will be discussed. The results from this test have been entered into an online form on the website. Subsequently, the participant chooses, in consultation with their physical therapist, one of the proposed goals on the website. Depending on the selected goal, 12 tailored modules are generated and presented weekly on the website. The personal goal and upcoming online modules will be discussed and the four strength/mobility exercises will be again instructed by the physical therapist. The patients are encouraged the execute the first online module.

From week 3 to week 5, patients are instructed to perform three online modules. In week 6, a third face-to-face treatment will take place. During this session

patients* progress will be evaluated with respect to the online modules, the evaluation of the exercise will take place and the upcoming modules will be discussed. If necessary, the therapist can decide to schedule an additional face-to-face treatment between week 7-12. This optional session is indicated for patients who are less capable to perform unsupervised physical exercises. Indications for this additional session are made by the physical therapist themselves.

From week 7 to week 12, patients are instructed to perform another seven online modules. In week 13, the final face-to-face treatments will take place. In this final treatment the physical therapist will support and reinforce patients to maintain their active lifestyle.

Study burden and risks

Since the study has low demands on the participants and selection criteria are used to exclude participants with a contra-indication for physical activity, the risks for participation are low.

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

Patient inclusion criteria:
1) Osteoarthritis of the knee and/or hip according to the clinical criteria of the American College of Rheumatology. For knee OA: (i.e. (Altman et al, 1986).Diagnosis knee OA: knee pain and at least three of the following six: age > 50 years, morning stiffness <30 minutes, crepitus, bony tenderness, bony enlargement and no palpable warmth.Diagnosis hip OA: Hip pain and hip internal rotation < 15 degree and hip flexion * 115 degree. Or hip internal rotation * 15 degree and pain on hip internal rotation and morning stiffness of the hip * 60 minutes and age > 50 years
2) Not meeting the recommendations of the Dutch Norm for Health-enhancing Physical Activity (Thirty minutes or more of at least moderate-intensity aerobic physical activity on at least five days each week)
3) age between 40 and 80 years
4) No participation in exercise therapy and/or physical activity program in the in the last 6 months

Exclusion criteria

Exclusion criteria patients:
1) Being on a waiting list for a knee or hip replacement surgery
2) Contra-indication for physical activity without supervision (such as cardiovascular diseases)
3) No access to internet
4) Inability to understand the Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2014
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	20-03-2014
Application type:	First submission
Review commission:	METC St Elisabeth Ziekenhuis (Tilburg)
Approved WMO Date:	29-09-2014
Application type:	Amendment
Review commission:	METC St Elisabeth Ziekenhuis (Tilburg)
Approved WMO Date:	30-10-2014
Application type:	Amendment
Review commission:	METC St Elisabeth Ziekenhuis (Tilburg)

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	ID
CCMO	NL46358.008.13