E-exercise

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22703

Source
NTR

Brief title
E-exercise

Health condition

Osteoarthritis
Knee and hip Osteoarthritis

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Faculteit der Sociale Wetenschappen
Tranzo
Source(s) of monetary or material Support: ZON-MW, The Netherlands Organization for Health Research and Development

Intervention

Outcome measures

Primary outcome

1) Phyisical activity

2) Physical functioning

Secondary outcome

1) Self-perceived effect

2) Pain

3) Fatigue

4) Self-efficacy

5) Health related quality of life

6) Volumes of care and costs

Study description

Background summary

1. BACKGROUND

Osteoarthritis (OA) is a common joint disorder. Patients with knee and/or hip OA are less physically active than the general population, while benefits of physical activity (PA) have been well documented. Provision of a PA by physical therapists is one of the treatment strategies to promote physical activity in inactive OA patients. Unfortunately, these face-to-face appointments are costly and a burden on our scarce health resources. Internet has created opportunities to support physical therapists is the treatment of OA patients. The integration of internet-based interventions within the physical therapy practice may even substitute (a part of) the face-to-face contacts with physical therapists. We therefore want to develop E-Exercise, which is an integration of a existent face-to-face physical activity intervention and an existent web-based intervention in patients with knee and hip osteoarthritis. E-exercise seems a promising tool to distribute a cost-effective PA program in patients with knee and hip OA. To date, there are no ‘blended care ‘ initiatives in the field of knee and/or hip osteoarthritis.

2.RESEARCH QUESTIONS

The following research questions will be answered:

1. What is the feasibility of E-Exercise in patients with knee and/or hip OA?

2. What is the short-term and long term effectiveness of E-Exercise in patients with knee and hip OA on the primary outcome measures physical activity and physical functioning?

3. STUDY DESIGN

For the first research question, we will perform a pilot study. At least five physical therapists will be recruited to include a total of 20 patients. All eligible individuals will receive the E-Exercise program. In total, three assessments will be performed: at baseline, 6 weeks and 12 weeks. After 12 weeks we will conduct interviews to explore the experiences with the program. Interviews will be audio-recorded and transcribed with the interviewee's permission. Results from the interviews will be used for potential content revisions of the E-exercise program.

For the second research question, we will perform a clustered randomized controlled clinical trial (RCT). Patients with osteoarthritis of hip and/or knee will be randomly assigned to either the E-Exercise intervention or the physical activity program provided by physical therapists (usual care). The study period of each patient is 12 months.

Physical therapists from the primary and secondary care settings will be recruited through The Royal Dutch Society for Physical Therapy (RDSP) organisation and network of the Tilburg University (care groups physical therapy). Another strategy is through the NIVEL Primary Care Database. A prerequisite for inclusion is that physical therapists have followed the course “PA program OA” at the Dutch Paramedical Institute. This course is about how to deliver a PA program in patients with knee and/or hip OA. Participants with knee and/or hip OA (circa 4 patients per physical therapist) will be recruited by the physical therapists themselves. Consequently, for the pilot study we need to include at least 5 physical therapists and for the RCT 50 therapists.

Study objective

N/A

Study design

Three assessments will be performed, at baseline, after 3 months and 12 months.

Intervention

Intervention condition

The intervention group will receive a web-based intervention E-Exercise and addtional face-to-face treatments from a physical therapist. E-exercise is a web-based PA program which promotes the performance of PA in the home environment of participants. E-Exercise is based on the guideline for physical therapists (Köke, 2012) and the web-based intervention Join2move (zie artroseinbeweging.nl) (Bossen, 2013). The web-based part of E-Exercise stimulates patients to increase a self-selected activity (e.g. walking, cycling or swimming) on fixed time points. The gradual increase of activities is based on the previously developed and evaluated behavioural graded activity (BGA) program for patients with knee and/or hip OA (Veenhof, 2006). An essential feature of the BGA program is the positive reinforcement of gradual PA, despite the presence of pain. Besides the gradual increase of activities, the program presents videos of exercises and information about osteoarthritis and physical activity. Every week, new weekly assignments and evaluation forms (pain and performance) will be posted on the password-secured website. If a scheduled weekly module is missed, users can choose to repeat the module, adapt the difficulty or continue with the next module. Since personal messages are updated on a weekly basis, users are encouraged to log in once a week. Automatic e-mails are generated if participants do not visit the website regularly. In addition to the web-based part, patients receive four face-to-face treatments from physical therapists. The content of these four contacts is based on the guideline RDSP-standard physical activity intervention osteoarthritis (Köke, 2012). Generally, the content includes information about OA/PA, motivation techniques to remain physically active and progress evaluation with respect to the E-exercise program. However, specific practical content considerations will be made by therapists themselves.

Control condition

Patients in the control group will receive usual care, this include a physical activity intervention provided by physical therapists. The content of the program is based on the guideline RDSP-standard physical activity intervention osteoarthritis (Köke, 2012). Practical content considerations are made by therapists themselves. This program comprises basically three elements, provision of knowledge, skills to initiate a physically active lifestyle and physical activities/exercises. The ultimate goal at the end of the treatment period (after 3 months) is to maintain a physically active lifestyle without supervision of a physical therapist.

Contacts

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Eligibility criteria

Inclusion criteria

1) Osteoarthritis of the knee and/or hip according to the clinical criteria of the AmericanCollege 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 <30minutes, crepitus, bony tenderness, bony enlargement and no palpable warmth.Diagnosis hip OA: Hip pain and hip internal rotation < 15 degree and hip flexion ¡Ü 115 degree. Or hip internal rotation ¡Ý 15 degree and pain on hip internal rotation and morning stiffness of the hip ¡Ü 60 minutes and age > 50 years

2) Not meeting the recommendations of the Dutch Norm for Health-enhancing Physical Activity (30 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 and exercise therapy and/or physical activity program in the in the last 6 months

Exclusion criteria

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). Contra-indication to perform PA without supervision will be determined by the The Physical Activity Readiness Questionnaire (PAR-Q). The PAR-Q questionnaire is designed to identify persons for who increased PA may be contraindicated.

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2013
Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL4087
NTR-old	NTR4224
Other	- : 525001007
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

Kloet et al. (2014) Effectiveness and cost-effectiveness of a blended exercise intervention for patients with hip and/or knee osteoarthritis: study protocol of a randomized controlled trial. BMC Musculoskeletal Disorders 15:269.