

## Amsterdam University of Applied Sciences

### Effectiveness of a blended physical therapist intervention in people with hip osteoarthritis, knee osteoarthritis, or both

*a cluster-randomized controlled trial*

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## Effectiveness of a Blended Physical Therapist Intervention in People With Hip Osteoarthritis, Knee Osteoarthritis, or Both: A Cluster-Randomized Controlled Trial

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**Background.** Integrating physical therapy sessions and an online application (e-Exercise) might support people with hip osteoarthritis (OA), knee OA, or both (hip/knee OA) in taking an active role in the management of their chronic condition and may reduce the number of physical therapy sessions.

**Objective.** The objective of this study was to investigate the short- and long-term effectiveness of e-Exercise compared to usual physical therapy in people with hip/knee OA.

**Design.** The design was a prospective, single-blind, multicenter, superiority, cluster-randomized controlled trial.

**Setting.** The setting included 143 primary care physical therapist practices.

**Participants.** The participants were 208 people who had hip/knee OA and were 40 to 80 years of age.

**Intervention.** e-Exercise is a 3-month intervention in which about 5 face-to-face physical therapy sessions were integrated with an online application consisting of graded activity, exercise, and information modules. Usual physical therapy was conducted according to the Dutch physical therapy guidelines on hip and knee OA.

**Measurements.** Primary outcomes, measured at baseline after 3 and 12 months, were physical functioning and free-living physical activity. Secondary outcome measures were pain, tiredness, quality of life, self-efficacy, and the number of physical therapy sessions.

**Results.** The e-Exercise group (n = 109) received, on average, 5 face-to-face sessions; the usual physical therapy group (n = 99) received 12. No significant differences in primary outcomes between the e-Exercise group and the usual physical therapy group were found. Within-group analyses for both groups showed a significant improvement in physical functioning. After 3 months, participants in the e-Exercise group reported an increase in physical activity; however, no objectively measured differences in physical activity were found. With respect to secondary outcomes, after 12 months, sedentary behavior significantly increased in the e-Exercise group compared with the usual physical therapy group. In both groups, there were significant improvements for pain, tiredness, quality of life, and self-efficacy.

**Limitations.** The response rate at 12 months was 65%.

**Conclusions.** The blended intervention, e-Exercise, was not more effective than usual physical therapy in people with hip/knee OA.

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Osteoarthritis (OA) is the most common chronic condition of the joints.<sup>1</sup> Prevalence of this rheumatic disease increases with age and mostly affects the hip and knee. Based on radiographic diagnosis, 5% to 15% of people 55 years old and older are affected with hip OA<sup>2</sup> and 10% to 30% with knee OA.<sup>3</sup> Because of the aging population and the growing number of people with obesity, the prevalence of OA is expected to increase,<sup>1</sup> with an extra demand on health services as a consequence. People with OA of the hip, OA of the knee, or both (hip/knee OA) experience pain, stiffness, crepitation, reduced range of motion, and sometimes inflammation.<sup>4</sup> Daily activities become more problematic, and these, in combination with psychological factors, put people at risk for a negative spiral of inactivity, resulting in muscle weakness and even more limitations in daily activities.<sup>5</sup>

The most recommended nonsurgical and nonpharmacological treatment for patients with OA is physical therapy.<sup>6,7</sup> Physical therapist intervention consisting of muscle strengthening exercises, aerobic exercises, and patient education has shown to be effective in reducing levels of pain and improving physical functioning.<sup>2,3</sup> One of the approaches to increase activity levels among patients with OA is graded activity.<sup>8</sup> However, the downside of face-to-face physical therapy sessions is that they are costly. With the increasing prevalence of OA, there is a need for effective and cost-effective interventions to manage hip and knee OA.

Technological developments provide new solutions for guiding patients to a physically active lifestyle. For example, internet-based interventions, which are accessible at any time and place, might be able to replace part of physical therapists' face-to-face guidance. In literature, the integration of therapeutic guidance and online care is called "blended care."<sup>9</sup> One of the main advantages of blended care is that the online part can support patients 24/7 in exercise at home. Well-designed online applications can be used as a medium for many behavior change techniques, such as goal-setting

assignments, monitoring of outcomes and behavior, instruction, and providing information.<sup>10,11</sup> Next, patients' online evaluations of home assignments can provide valuable information for physical therapists about patients' individual needs for guidance. Whereas online self-guided interventions often struggle with high rates of nonusage, the combination with therapeutic guidance is seen as highly promising in terms of usage, effectiveness, and cost-effectiveness.<sup>12,13</sup>

Given the high potential of blended interventions for people with OA, we developed the intervention e-Exercise.<sup>14</sup> In e-Exercise, physical therapy sessions are combined with an online application to improve free-living physical activity in patients with hip/knee OA. The integration of physical therapy sessions and an online application might replace part of the therapeutic guidance. In addition, we expect that the online application can support patients in taking an active role in the management of their chronic condition in daily living by providing access to a 24/7-available behavior-change application. Therefore, we hypothesize e-Exercise to be more effective than usual physical therapy. The aim of this multicenter superiority cluster-randomized controlled trial was to investigate the short- and long-term effectiveness on physical functioning and free-living physical activity of e-Exercise compared to usual physical therapy in people with hip/knee OA.

## Methods

### Design Overview

A prospective, single-blind, multicenter, superiority, cluster randomized controlled trial was conducted. From May 2014 to August 2014, 248 physical therapists working in 143 primary care physical therapist practices were recruited. Half of the physical therapists were instructed to treat people with hip/knee OA according to the e-Exercise protocol, and the other half of the physical therapists were instructed to treat people as usual. Enrollment of participants started in September 2014 and ended in March 2015. Study outcomes were assessed at baseline, 3 months, and 12 months. The study

design and protocol were approved by the Medical Ethical Committee of St Elisabeth Hospital, Tilburg, the Netherlands (Dutch Trial Register ref. no. NTR4224). Because we wanted to prevent less accurate answers or nonresponding, we deleted some secondary outcome measures (ie, motivation, locus of control, depression and anxiety, self-reported adherence, and self-management) that are listed in the trial register and executed the study as described in the study protocol.<sup>15</sup> The trial is reported according to the CONSORT Cluster Trial checklist (eAppendix 1, available at [academic.oup.com/ptj](http://academic.oup.com/ptj)).

### Setting and Randomization

Physical therapists were recruited in 2 ways. First, an invitational letter was sent to a random sample of 800 physical therapist practices in 3 provinces of the Netherlands. Second, an advertisement was placed in the online newsletter of The Royal Dutch Society for Physiotherapy. Physical therapist practices could participate with 1 or 2 physical therapists. Inclusion criteria for physical therapists were (1) practicing in primary care and (2) treating at least 6 patients with OA of the hip and/or knee per year. Physical therapists were cluster-randomized on the level of physical therapist practice using a computer-generated sequence table. To avoid contamination across physical therapists working in the same practice, randomization of the 248 eligible physical therapists took place at the level of the physical therapist practice using a 1:1 allocation ratio. By email they were informed about their allocation. Physical therapists were not masked, since they had to treat according to the randomization. The main investigator (C.J. J.K.) was masked to group assignment until completion of statistical analyses. Participants were assigned to a unique trial code. Participant information was stored separately from outcome data.

All physical therapists were invited for a half-day training. Physical therapists allocated to the e-Exercise group ( $n = 123$ ) were instructed about the study procedure and how to use the online application. Physical therapists allocated to the "usual physical therapy"

group (n = 125) were also instructed on the study procedure and received a presentation about the Dutch OA guideline.<sup>16</sup> Physical therapists who followed the training and recruited at least 2 participants received accreditation points for the Dutch physical therapy registration. Physical therapists allocated to the “usual physical therapy” group received e-Exercise log-in codes and an invitation for an instruction session after the study period.

### Participants

People who had hip/knee OA and visited a participating physical therapist were invited to participate in the study. Also, recruitment advertisements were placed in local newspapers, and information brochures were sent to general practitioners. Physical therapists verified patient eligibility for study participation. Eligibility criteria were as follows: an age of 40 to 80 years and hip/knee OA according to the clinical criteria of the American College of Rheumatology.<sup>17</sup> The 6 exclusion criteria were as follows: being on a waiting list for a hip or knee replacement surgery, contraindications for PA without supervision according to the Physical Activity Readiness Questionnaire (PAR-Q), sufficiently physically active according to the physical therapist, participation in a physical therapy and/or PA program in the past 6 months, no access to internet, and inability to understand the Dutch language. Eligible people were informed by their physical therapist about the study and received an information letter and informed consent form. Participants were masked to the study hypotheses but were not masked to the comparator intervention. After an informative phone call with the researcher (C.J.J.K.), participants were asked to return their informed consent form.

Participant characteristics (age, sex, height, weight, educational level, location of OA, duration of OA, and the presence of comorbidities) were assessed as part of the baseline questionnaire.

### Intervention: e-Exercise

The development and pilot study of e-Exercise is described elsewhere.<sup>14</sup> The overall aim of e-Exercise is to stimulate

a physically active lifestyle regardless of OA-related sensations. The intervention e-Exercise takes 12 weeks and is a combination of about 5 face-to-face sessions with a physical therapist and an online application focusing on behavioral graded activity, exercises, and information. The e-Exercise protocol is based on the Dutch OA guideline.<sup>16</sup> In a participant's first session (week 1), the therapist created an e-Exercise account and provided support in the selection of 1 type of PA—for example, walking or cycling—and 4 strength and stability exercises. The participant was informed about the first online assignment, which was a 3-day baseline test to assess physical load ability. The results were discussed during the second face-to-face session and used for the formulation of a short- and long-term goal. During the third session in week 6, participant progress was discussed using online progress reports (ie, a summary of website visits and patients' experiences with the exercises). In the last session (week 12), the maintenance of PA was discussed and supported. Although physical therapists were recommended to treat according to the e-Exercise protocol, they were free to deviate from the protocol with respect to their clinical competence.

The online part of e-Exercise consisted of 3 modules:

- Graded activity—the duration of a participant's chosen PA was gradually increased until the individual short-term goal was met.
- Strength and stability—each week the participant was asked to perform 2 video-supported exercises on 3 different days, and the number of repetitions was increased gradually every 4 weeks.
- Information—each week a new video was generated about OA etiology, pain management, weight management, motivation, medication, and social influences on pain.

Weekly automatic emails informed and reminded patients about new assignments and content, and, at the end of the week, patients were asked to evaluate the execution of their assignments. Depending on their answer to

the question “Were you able to execute the graded activity assignment, or did you do less or more?” automatic tailored feedback was generated. (The online application of e-Exercise can be seen at <https://www.e-exercise.nl> [in Dutch]; a promotional video with English subtitles is available at <https://www.youtube.com/watch?v=4l9GoQWwY58>.)

### Intervention: Usual Physical Therapy

Usual physical therapy in the current study was defined as any treatment provided by the physical therapist. Physical therapists were encouraged to practice according to the Dutch OA guideline, which recommends the same 3 elements as e-Exercise: information, physical exercise, and strength and stability exercises.<sup>16</sup> No restrictions were given with regard to the number of face-to-face sessions.

### Outcomes and Follow-up

Participants received an online questionnaire and an accelerometer at baseline, after 12 weeks, and after 12 months. The physical therapist measured physical functioning objectively at baseline and after treatment. No financial incentives were offered to complete the measurements. In case of an unfilled questionnaire, a first reminder was sent after 10 days and a second reminder or a phone call after 15 days. A detailed description of outcome measures and interpretation are given in eAppendix 2 (available at [academic.oup.com/ptj](http://academic.oup.com/ptj)).

**Primary outcome measures.** Physical functioning was assessed subjectively with the subscale “function in daily living” of the Hip OA Outcome Score (HOOS) and/or the Knee Injury and OA Outcome Score (KOOS).<sup>18,19</sup> A lower score on the sum score (0-100) indicates problems in physical functioning. Physical functioning was assessed by the physical therapists using the Timed “Up & Go” (TUG) test.<sup>20</sup>

Free-living PA was assessed subjectively with the Short Questionnaire to Assess Health-Enhancing Physical Activity (SQUASH), a questionnaire that measures habitual PA during the preceding week.<sup>21</sup> PA was objectively



assessed using ActiGraph GT3x (ActiGraph, Pensacola, Florida) triaxial accelerometers. Participants were instructed to wear the accelerometer on a belt around their waist for 5 consecutive days, except during the night or when showering or swimming. Accelerometer data were eligible if patients had worn the meter at least 3 days, for 8 hours or more.<sup>22</sup> PA thresholds of Freedson et al<sup>23</sup> were used to distinguish sedentary activity and light, moderate, and vigorous PA. Moderate activity and vigorous activity were summed and divided by the number of wearing days to calculate a PA score in minutes per day.

**Secondary outcome measures.** Other symptoms and functional limitations were assessed with the HOOS and the KOOS, using 4 other subscales: pain, symptoms, sport/recreation function, and quality of life.<sup>18,19</sup>

Self-perceived effect was assessed by a single question about the degree of change in OA symptoms. Scores ranged from 1 (much better) to 6 (much worse).

Pain and tiredness were assessed using a numeric rating scale ranging from 0 (no pain/not tired) to 10 (worst possible pain/very tired).

Self-efficacy was assessed by the Arthritis Self-efficacy Scale (ASES), using the subscale "pain and symptoms."<sup>24</sup> Scores ranged from 1 to 5; a higher score indicates greater self-efficacy.

**Other measures.** Quantitative data about website usage, stored on the backend of the website, were used to analyze adherence to the online application. Usability was assessed using the System Usability Scale (SUS).<sup>25</sup> A higher SUS score (range = 0–100) indicates better usability. For interpretation, a grading system introduced by Sauro and Lewis<sup>26</sup> was used. Physical therapists were asked to fill out a registration form about the number and content of face-to-face sessions.

## Data Analysis

Descriptive statistics were used to describe patients' general characteristics and the number and content of the

physical therapy sessions. Frequencies, *t* tests, and chi-square tests were used to explore differences in demographics between both groups. Primary analysis was performed according to the intention-to-treat principle. Per-protocol analyses were performed for participants who adhered to the e-Exercise intervention and for all participants who received usual physical therapy. They were considered to be adhering to the intervention if they completed at least 8 of 12 modules.<sup>27</sup>

Multilevel repeated measures analyses were used to determine the short-term (3-month) and long-term (12-month) effectiveness of e-Exercise compared to usual physical therapy on primary and secondary outcome measures. The 3-level hierarchy consisted of repeated measurements (level 1), nested within participants (level 2), and nested within physical therapists (level 3). Analyses were controlled for the physical therapist, baseline values, sex, body mass index, level of education, and location of OA. Between-group effect sizes were calculated according to the Cohen *d* using the pooled standard deviation. Effect sizes of 0.2, 0.5, and 0.8 or larger were considered to represent small, medium, and large effects, respectively.<sup>28</sup> According to the recommendations of Twisk et al<sup>29,30</sup> about handling missing data in longitudinal mixed-model analyses, no imputation techniques were used. In order to investigate selective attrition, a nonresponse analysis with *t* tests and chi-square tests was performed by comparing general characteristics and primary baseline variables of responders and nonresponders at 3 and 12 months. For per-protocol analyses, participants who were adherent and completed  $\geq 8$  modules were compared with participants in the usual physical therapy group. Per-protocol analyses consisted of multilevel analyses controlling for the same variables as the primary analysis.

**Sample size.** The power calculation was based on a previous multicenter cluster-randomized controlled trial among patients with hip/knee OA<sup>8</sup> and was performed for the primary outcome measure physical functioning

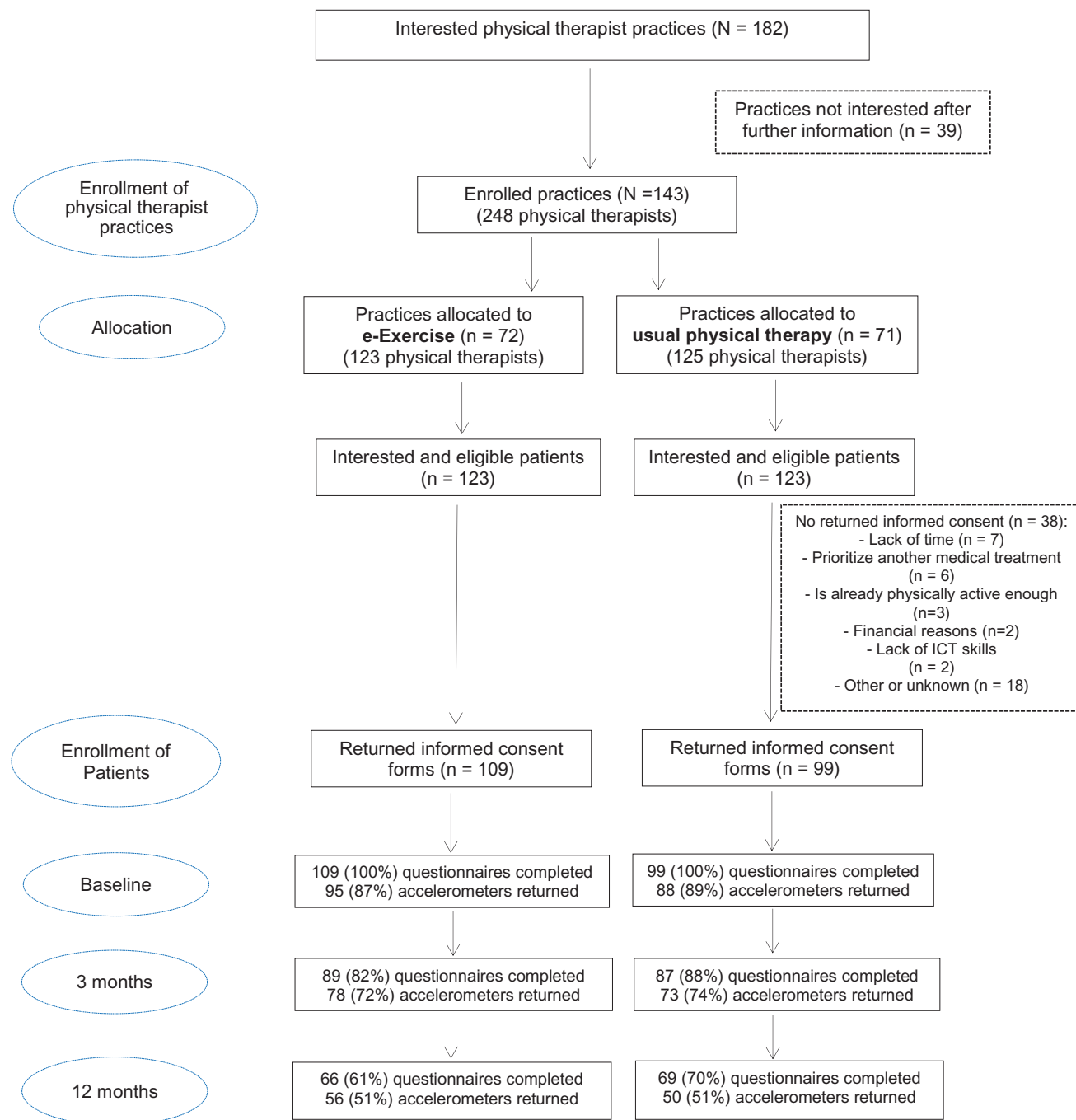
(power = 0.8; alpha = .05). A target sample size of 200 participants was chosen to detect a small to medium effect size (0.2–0.4) in physical functioning at a 2-sided significance level of .05, anticipating a maximum loss to follow-up of 20% over the study period of 12 months. Because we had 4 primary outcome measures, we applied a Bonferroni correction. A 2-tailed significance level of  $.05/4 = .0125$  was considered as statistically significant. Analyses were carried out using SPSS Statistics 23.0 (IBM SPSS, Chicago, Illinois).

## Role of the Funding Source

This study was funded by ZonMw (ZonMw Research Program Sport, ref. no. 525001007), the Dutch Rheumatoid Arthritis Foundation, and the Royal Dutch Society for Physiotherapy. The funders played no role in the conduct of this study.

## Results Participants

In total, 246 eligible people were included (Fig. 1). Thirty-eight people did not return informed consent after reading the participant information letter because of lack of time ( $n = 7$ ), priority for another medical treatment ( $n = 6$ ), a physically active lifestyle ( $n = 3$ ), financial reasons ( $n = 2$ ), a lack of information communication technology skills ( $n = 2$ ), or other/unknown reasons ( $n = 18$ ). From the physical therapist practices allocated to e-Exercise, 109 participants filled out the first questionnaire. From the physical therapist practices allocated to usual physical therapy, 99 participants completed the first questionnaire. The response rates for the follow-up questionnaire was 85% at 3 months (e-Exercise,  $n = 89$ ; usual physical therapy,  $n = 87$ ) and 65% at 12 months (e-Exercise,  $n = 66$ ; usual physical therapy,  $n = 69$ ). Eligible accelerometer data at baseline and after 3 months and 12 months were available for 88%, 73%, and 51% of the 208 participants, respectively. Demographics are shown in Table 1. The e-Exercise group consisted of more people with a low level of education (e-Exercise, 24.8%; usual physical therapy, 12.1%;  $P = .04$ ) at baseline. No other differences in demographics were seen between



**Figure 1.** Flow chart. ICT=information communication technology.

groups. After 3 months, responders differed from nonresponders in body mass index (responders, 27.4 [SD = 4.4]; nonresponders, 29.0 [4.1];  $P = .02$ ). No statistical differences were seen between participants who wore the accelerometer and those who did not.

### Content and Number of Physical Therapy Sessions

In total, 149 physical therapist registration forms were returned, 77 about participants who received usual physical therapy and 72 about participants who received e-Exercise. Figure 2 shows the

content of physical therapy sessions of usual physical therapy and e-Exercise. Overall, physical therapists who applied usual physical therapy provided active and passive mobilizations, endurance training, and functional and strength exercises more often. Participants in the

Table 1.

Demographics and Unadjusted Primary Outcome Measures for Participants at Baseline, 3 Months, and 12 Months<sup>a</sup>

Measurement	Baseline		3 mo		12 mo	
	e-Exercise	Usual Physical Therapy	e-Exercise	Usual Physical Therapy	e-Exercise	Usual Physical Therapy
No. of respondents	109	99	89	87	66	69
Sex						
Women	74 (67.9)	67 (67.7)	60 (67.4)	57 (65.5)	44 (66.7)	44 (63.8)
Men	35 (32.1)	32 (32.3)	29 (32.6)	30 (34.5)	22 (33.3)	25 (36.2)
Age, y, mean (SD)	63.8 (8.5)	62.3 (8.9)	63.6 (8.1)	62.6 (9.1)	64.1 (7.7)	61.7 (8.8)
BMI, kg/m <sup>2</sup> , mean (SD)	27.8 (4.2)	27.9 (4.9)	27.4 (4.4)	27.7 (4.8)	26.9 (4.2)	27.7 (4.9)
Location of OA						
Knee	71 (65.1)	67 (67.6)	59 (66.3)	58 (66.7)	45 (68.2)	48 (69.6)
Hip	21 (19.3)	17 (17.2)	19 (21.3)	16 (18.4)	16 (24.2)	12 (17.4)
Both	17 (15.6)	15 (15.2)	11 (12.4)	13 (14.9)	5 (7.6)	9 (13.0)
Duration of symptoms						
<1 y	21 (19.3)	20 (20.2)	14 (15.7)	19 (21.8)	11 (16.7)	14 (20.3)
1–5 y	42 (38.5)	38 (38.4)	38 (42.7)	33 (37.9)	31 (47.0)	31 (44.9)
≥5 y	46 (42.2)	41 (41.4)	37 (41.6)	35 (40.2)	24 (36.4)	24 (34.8)
Education						
Low	27 (24.8)	12 (12.1)	23 (25.8)	9 (10.3)	17 (25.8)	8 (11.6)
Middle	41 (37.6)	51 (51.5)	35 (39.3)	46 (52.9)	26 (39.4)	34 (49.3)
High	41 (37.6)	36 (36.4)	31 (34.8)	32 (36.8)	23 (34.8)	27 (39.1)
No. of comorbidities						
0	62 (56.9)	62 (62.6)	47 (52.8)	53 (60.9)	37 (56.1)	40 (58.0)
1	20 (18.3)	20 (20.2)	16 (18.0)	18 (20.7)	11 (16.7)	15 (21.7)
≥2	27 (24.8)	17 (17.2)	26 (29.2)	16 (18.4)	18 (27.3)	14 (20.3)
Physical functioning, scores of 0–100, mean (SD)	61.3 (18.3)	55.5 (21.4)	66.7 (18.2)	62.2 (20.4)	69.3 (18.7)	65.3 (22.8)
Timed “Up & Go” test, s, mean (SD)	8.4 (2.1)	8.6 (5.8)	7.3 (1.7)	7.3 (2.4)		
Physical activity, subjective, min/d, mean (SD)	98.4 (118.4)	107.0 (103.3)	120.4 (111.0)	131.4 (122.2)	105.6 (97.2)	125.8 (123.0)
Physical activity, objective, min/d, mean (SD)	25.2 (23.1)	22.5 (21.8)	25.5 (17.7)	25.5 (23.7)	23.5 (19.9)	25.3 (22.8)

<sup>a</sup>Data are reported as number (percentage) of participants unless otherwise indicated. BMI=body mass index, OA=osteoarthritis.

usual physical therapy group received 12 sessions (range = 2–29); participants in the e-Exercise group received, on average, 5 sessions (range = 2–16).

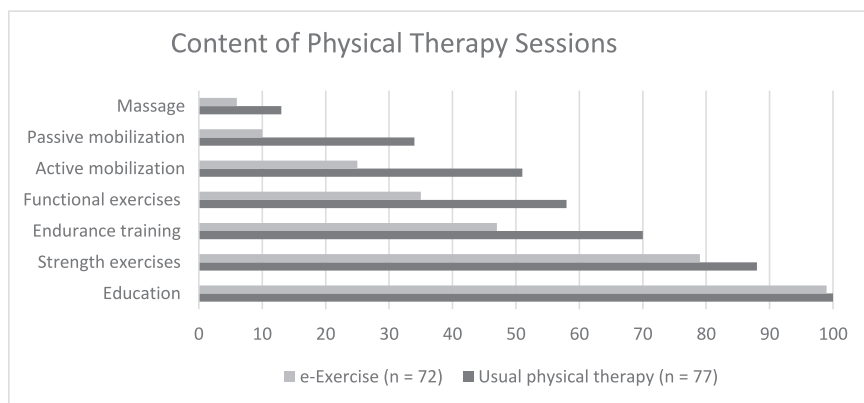
### Usability and Adherence

At 3 months, the average System Usability Score of 85 responders was 73.1 (SD = 18.6), which corresponds with a grade B usability. For 90 of 109 participants, adherence data were available. Of these participants, 73 (81.1%) completed at least 8 of 12 modules and were classified as “adherent.” A detailed overview of adherence to e-Exercise and related factors is published elsewhere.<sup>27</sup>

### Short-Term Effectiveness

After 3 months, no statistically significant differences were seen between e-Exercise and usual physical therapy for the primary outcome measures of physical functioning and physical activity (Tab. 2) and the secondary outcome measures (Tab. 3). Within the usual physical therapy group, significant improvements were seen for physical functioning, the Timed “Up & Go” Test, subscales of the HOOS and the KOOS (pain, sport, and quality of life), the Numeric Rating Scale (NRS) for pain, and self-efficacy (subscales pain and symptoms). Within the e-Exercise group, significant improvements were

seen for physical functioning, subjective PA, pain (NRS and HOOS/KOOS), tiredness, and self-efficacy (subscales pain and symptoms). The self-perceived effect of participants in the e-Exercise group was 3.1 (SD = 1.2), and that of participants in the usual physical therapy group was 3.1 (SD = 1.3); a score of 3 means “a little bit better.” The results of the per-protocol analyses showed that there were no statistically significant differences between the participants who were adherent in the e-Exercise group and those who were adherent in the usual physical therapy group (results not shown).



**Figure 2.**

Applied physical therapist interventions (percentages of participants who received the given interventions as part of their physical therapist treatment for osteoarthritis). e-Exercise=combination of physical therapist sessions with an online application.

### Long-Term Effectiveness

At the 12-month follow-up, no statistically significant differences were seen between groups for the primary outcome measures. For secondary outcome measures, a significant difference was seen on changes in sedentary behavior (usual physical therapy group,  $-29.4$  min/d; e-Exercise,  $+8.3$  min/d;  $P \leq .01$ ; effect size =  $-0.73$ ). Within the usual physical therapy group, statistical significant improvements were seen on physical functioning, subscales of the HOOS and the KOOS (pain and quality of life), NRS pain, and NRS tiredness and self-efficacy (subscales pain and quality of life). Within the e-Exercise group, statistically significant improvements were seen on physical functioning, subscales of the HOOS and the KOOS (pain, symptoms, and quality of life), NRS pain, and NRS tiredness and self-efficacy (subscales pain and quality of life). The results are shown in Tables 2 and 3. The self-perceived effect of participants in the e-Exercise group was 3.4 (SD = 1.4), and that of participants in the usual physical therapy group was 3.1 (SD = 1.6). Long-term results of the per-protocol analyses showed that there were no statistically significant differences between the participants who were adherent in the e-Exercise group and those who were adherent in the usual physical therapy group (results not shown). The intraclass correlation coefficient (ICC) ranged from 0.0% to 1.4%.

### Discussion

The aim of this multicenter superiority cluster-randomized controlled trial study was to investigate the short- and long-term effectiveness of e-Exercise compared to usual physical therapy in people with hip/knee OA. Because online applications can support people in exercise at home,<sup>13,31</sup> we expected that e-Exercise would be more effective than usual physical therapy. The results of this randomized controlled study showed that there were no significant differences between the e-Exercise group and the usual physical therapy group with respect to physical functioning and free-living PA. However, within-group differences showed that both interventions were significantly effective with respect to physical functioning and most secondary outcomes soon after treatment and after 12 months. Notably, participants in the e-Exercise group visited the physical therapist 5 times, whereas the usual physical therapy group received, on average, 12 sessions. This reduction of face-to-face sessions might lead to a reduction in health care costs, which will be investigated in a future cost-effectiveness study.

Integrating face-to-face physical therapy with online applications is an upcoming field and, to our knowledge, this is the first randomized controlled trial evaluating the effectiveness of blended care in patients with hip/knee OA compared

to usual physical therapy. The comparison of the average change in both treatment groups showed minimal differences, with small effect sizes in all primary and secondary outcome measures. To illustrate, participants improved, on average, 7.2 points for physical functioning (e-Exercise,  $+7.1$ ; usual physical therapy,  $+7.3$ ; effect size = 0.04;  $P = .95$ ) and 16.1 points for pain (e-Exercise,  $+15.5$ ; usual physical therapy,  $+17.7$ ; effect size = 0.07;  $P = .56$ ) as measured with the HOOS and the KOOS (on a 0–100 scale). If we would have used a noninferiority design, we probably would have specified a noninferiority margin of  $0.5 \times 0.3 = 0.15$ .<sup>2,3,32</sup> Because all of our between-group effect sizes were below this value, e-Exercise and usual physical therapy are likely to be equally effective. These within-group effects are comparable to those found in other studies of exercise therapy for patients with hip/knee OA<sup>2,3</sup> and underline the potential of blended care.

Although participants in the e-Exercise group reported a significant increase in PA after 3 months, in both groups, no significant improvements in objective PA were found. This result is in accordance with a recent meta-analysis that found no consistent evidence for improvement of objective PA in lower limb OA.<sup>33</sup> Next to the difficulty of measuring free-living PA,<sup>34</sup> an explanation in our trial might be participants' high level of PA at baseline. Whereas PA was set as an inclusion criterion (administered during physical therapists' anamnesis), baseline data show that participants already met the global recommendations for PA.<sup>35</sup> Physical therapists might have underestimated participants' level of PA, leading to a physically active study population with less room for improvement. In addition, a significant increase in sedentary behavior within the e-Exercise group compared to the usual physical therapy group was determined. Because sedentary behavior increases morbidity and mortality risk,<sup>36</sup> we will include an information module about this topic within a future e-Exercise intervention. Taking into account the difficulty of changing PA and sedentary behavior, we also recommend combining e-Exercise with wrist-worn activity trackers for self-monitoring. At



Table 2.

Adjusted Primary Outcome Measures: Improvements and Differences Within and Between Groups

Outcome Measure	No. of Participants	e-Exercise, Mean (95% CI)	Within-Group Difference (P) <sup>a</sup>	No. of Participants	Usual Physical Therapy, Mean (95% CI)	Within-Group Difference (P) <sup>a</sup>	Difference in Difference, Mean (95% CI) <sup>b</sup>	Between-Group Difference (P) <sup>a</sup>	Between-Group Effect Size
Physical Functioning, Scores of 0–100									
Baseline	109	52.7 (47.3 to 58.0)		99	50.7 (45.1 to 56.4)				
3 mo	87	56.8 (51.0 to 62.7)	<.01	87	56.3 (50.2 to 62.4)	<.01	–1.4 (–5.6 to 2.8)	.52	0.01
12 mo	65	59.8 (51.4 to 68.1)	<.01	69	58.0 (49.6 to 66.5)	<.01	–0.2 (–6.4 to 6.0)	.95	0.04
Timed “Up & Go” Test, s									
Baseline	72	9.6 (8.1 to 11.1)		74	9.8 (8.3 to 11.3)				
3 mo	68	8.5 (7.3 to 9.7)	.01	66	8.4 (7.1 to 9.7)	<.01	0.3 (–0.8 to 1.5)	.58	0.02
Physical Activity, <sup>c</sup> Subjective, min/d									
Baseline	109	126.7 (73.7 to 179.6)		99	129.8 (73.8 to 185.9)				
3 mo	87	154.2 (100.2 to 208.1)	<.01	87	141.7 (85.0 to 198.4)	.26	15.7 (–13.4 to 44.7)	.26	0.04
12 mo	65	193.1 (122.5 to 263.8)	.41	69	200.9 (129.5 to 272.4)	.22	4.6 (–27.9 to 37.2)	.78	–0.02
Physical Activity, <sup>c</sup> Objective, min/d									
Baseline	95	35.4 (25.3 to 45.5)		88	33.7 (23.1 to 44.3)				
3 mo	79	34.9 (24.7 to 45.1)	.78	72	35.0 (24.3 to 45.6)	.52	–1.8 (–7.2 to 3.6)	.51	0.00
12 mo	56	43.4 (30.1 to 56.8)	.28	50	44.6 (30.8 to 57.6)	.89	3.0 (–3.9 to 10.0)	.39	–0.02

<sup>a</sup>Adjusted for baseline, sex, body mass index, level of education, pain, type of osteoarthritis, and physical therapist.<sup>b</sup>Difference between baseline and 3 months in e-Exercise vs. usual physical therapy; difference between baseline and 12 months in e-Exercise vs. usual physical therapy. Baseline and 3-month data were extracted from short-term analyses; 12-month data were extracted from long-term analysis.<sup>c</sup>Moderate and vigorous intensities.

the same time, these trackers can be used for continuous measurement of intervention adherence.<sup>37,38</sup>

A remarkable difference between e-Exercise and usual physical therapy is the content of the physical therapy sessions. Physical therapists who applied e-Exercise provided, for a smaller proportion of participants, active and passive mobilizations, endurance training, and functional and strength exercises. A possible explanation is that participants in the e-Exercise group were extensively encouraged to take an active role in their treatment. A detailed description of patients' and physical therapists' experiences with e-Exercise is published elsewhere<sup>27</sup> and also is

provided in other data (C.J.J.K., D.B., H.J.d.V., D.H.d.B., et al, unpublished data, 2017).

### Strengths and Limitations

The strength of this study is that we compared e-Exercise with usual physical therapy. This design made it possible to set up conclusions about the additional value of a blended delivery mode compared to face-to-face physical therapy. Unfortunately, we had to deal with high dropout rates: 15% after 3 months and 35% after 12 months. Percentages of missing data in our accelerometer data were even higher. We might have overloaded the participants with too many measurements. Although we did not find clinically relevant differences

in baseline demographics between responders and nonresponders, results should be interpreted with caution. It is known that dropout rates in eHealth studies are accompanied with non-usage attrition.<sup>39</sup> For future studies, we recommend the use of in-person survey visits because doing so might increase response rates and would also allow the measurement of objective physical functioning by an independent researcher.<sup>40</sup> The final limitation is the discrepancy between our intended study population and the actual study population. Selection of patients was done by the physical therapists, and the clinical diagnosis of OA was not confirmed by an independent caregiver. Next, physical therapists assessed

## Blended Physical Therapy in Hip/Knee OA

**Table 3.**

Adjusted Secondary Outcome Measures: Improvements and Differences Within and Between Groups

Outcome Measure	No. of Participants	e-Exercise, Mean (95% CI)	Within-Group Difference (P) <sup>a</sup>	No. of Participants	Usual Physical Therapy, Mean (95% CI)	Within-Group Difference (P) <sup>a</sup>	Difference in Difference, Mean (95% CI) <sup>b</sup>	Between-Group Difference (P) <sup>a</sup>	Between-Group Effect Size
Pain, Scores of 0–100									
Baseline	109	50.4 (42.1 to 58.8)		99	43.9 (35.2 to 52.7)				
3 mo	87	55.8 (47.3 to 64.3)	<.01	87	48.8 (39.9 to 57.7)	<.01	0.5 (–4.1 to 5.0)	.84	0.14
12 mo	65	65.9 (54.3 to 77.5)	<.01	69	61.6 (49.9 to 73.4)	<.01	–2.0 (–8.9 to 4.8)	.56	0.07
Symptoms, Scores of 0–100									
Baseline	109	53.1 (45.9 to 60.4)		99	51.2 (43.5 to 58.8)				
3 mo	87	54.2 (46.7 to 61.7)	.50	87	54.4 (46.5 to 62.3)	.05	–2.1 (–6.6 to 2.4)	.35	0.00
12 mo	65	56.7 (46.3 to 67.1)	<.01	69	62.1 (51.6 to 72.6)	.03	–7.4 (–13.8 to –1.0)	.73	–0.10
Sport, Scores of 0–100									
Baseline	109	36.3 (39.2 to 50.8)		99	39.7 (29.8 to 49.6)				
3 mo	87	39.3 (42.7 to 55.4)	.23	87	46.6 (36.1 to 57.1)	<.01	–3.9 (–11.0 to 3.1)	.27	–0.16
12 mo	65	45.9 (32.5 to 59.3)	.05	69	49.1 (35.5 to 62.6)	.04	0 (–8.3 to 8.3)	.99	–0.05
Quality of Life, Scores from 0–100									
Baseline	109	45.0 (39.2 to 50.8)		99	44.2 (38.1 to 50.4)				
3 mo	87	49.1 (42.7 to 55.4)	.02	87	53.0 (46.3 to 59.7)	<.01	–4.7 (–9.5 to 0.2)	.06	–0.10
12 mo	65	52.5 (43.6 to 61.4)	<.01	69	56.1 (47.0 to 65.1)	<.01	–4.3 (–10.3 to 1.8)	.16	–0.08
Sedentary Behavior, Objective, min/d									
Baseline	95	495.5 (457.3 to 533.6)		88	514.0 (474.1 to 553.9)				
3 mo	79	505.8 (466.5 to 545.0)	.19	72	498.3 (457.4 to 539.3)	.05	26.0 (3.9 to 48.1)	.02	0.03
12 mo	56	521.0 (467.5 to 574.6)	.37	50	501.3 (447.0 to 555.7)	<.01	29.4 (10.3 to 48.6)	<.01	0.08
Pain, Scores of 0–10									
Baseline	109	5.4 (4.3 to 6.4)		99	6.1 (4.9 to 7.2)				
3 mo	87	4.1 (3.0 to 5.2)	<.01	87	5.3 (4.1 to 6.4)	<.01	–0.5 (–1.1 to 0.2)	.16	–0.18
12 mo	65	3.8 (2.4 to 5.2)	<.01	69	4.0 (2.6 to 5.5)	<.01	0.4 (–0.5 to 1.3)	.40	–0.03
Tiredness, Scores of 0–10									
Baseline	109	6.1 (5.1 to 7.2)		99	6.1 (5.1 to 7.2)				
3 mo	87	4.8 (3.8 to 5.8)	<.01	87	5.6 (4.5 to 6.7)	.02	–0.8 (–1.4 to –0.1)	.02	–0.13
12 mo	65	5.6 (4.2 to 7.0)	<.01	69	5.6 (4.2 to 7.1)	<.01	–0.1 (–0.9 to 0.8)	.84	0

(Continued)

Table 3.

Continued

Outcome Measure	No. of Participants	e-Exercise, Mean (95% CI)	Within-Group Difference (P) <sup>a</sup>	No. of Participants	Usual Physical Therapy, Mean (95% CI)	Within-Group Difference (P) <sup>a</sup>	Difference in Difference, Mean (95% CI) <sup>b</sup>	Between-Group Difference (P) <sup>a</sup>	Between-Group Effect Size
Self-efficacy for Pain, Scores of 1–5									
Baseline	109	3.6 (3.3 to 4.0)		99	3.5 (3.2 to 3.9)				
3 mo	87	3.9 (3.6 to 4.3)	<.01	87	4.0 (3.6 to 4.4)	<.01	–0.1 (–0.4 to 0.1)	.33	–0.05
12 mo	65	4.1 (3.6 to 4.6)	<.01	69	4.0 (3.5 to 4.5)	<.01	0 (–0.3 to 0.3)	.99	0.04
Self-efficacy for Symptoms, Scores of 1–5									
Baseline	109	3.5 (3.1 to 3.8)		99	3.4 (3.0 to 3.7)				
3 mo	87	3.7 (3.4 to 4.1)	<.01	87	3.8 (3.4 to 4.2)	<.01	–0.2 (–0.4 to 0.1)	.20	–0.05
12 mo	65	3.7 (3.2 to 4.2)	<.01	69	3.7 (3.2 to 4.3)	<.01	–0.1 (–0.4 to 0.1)	.29	0
Pain Reported by Physical Therapist, Scores of 0–10									
Baseline	72	6.4 (5.5 to 7.3)		74	6.6 (5.7 to 7.5)				
3 mo	69	4.2 (3.2 to 5.1)	<.01	73	4.5 (3.6 to 5.5)	<.01	–0.2 (–0.9 to 0.6)	.64	–0.06

<sup>a</sup>Adjusted for baseline, sex, body mass index, level of education, pain, type of osteoarthritis, and physical therapist.

<sup>b</sup>Difference between baseline and 3 months in e-Exercise vs. usual physical therapy; difference between baseline and 12 months in e-Exercise vs. usual physical therapy. Baseline and 3-month data were extracted from short-term analyses; 12-month data were extracted from long-term analysis.

participants' level of physical activity during anamneses with a single question. After analyses of the baseline data, it turned out that participants were already sufficiently physically active at baseline. On the one hand, it is a limitation that our inclusion strategy resulted in a physically active population that had less room for improvement on this outcome measurement during the intervention. On the other hand, our inclusion strategy has the advantage that it reflects physical therapists' clinical reasoning process in daily practice. In the future, physical therapists will select patients for e-Exercise in the same way.

### Clinical Implications and Future Directions

We recommend further elaboration of an instrument to determine patients' suitability for a (partly) online intervention. In line with a stepped care strategy that promotes starting with relatively simple treatment modalities,<sup>41</sup> patients could start with an unguided internet-delivered

intervention like Join2Move.<sup>12</sup> If this simple treatment modality appears to be inadequate, physical therapist guidance can be added (e-Exercise). In case of deterioration of symptoms or unsatisfying results, the frequency of face-to-face contact can be increased.<sup>41</sup> In a future study we will describe the cost-effectiveness of e-Exercise compared to usual physical therapy from a societal perspective.

### Conclusions

The blended intervention e-Exercise was not more effective than usual physical therapy in patients with hip/knee OA. Both interventions led to clinical improvements.

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### Ethics Approval

The study design and protocol were approved by the Medical Ethical Committee of the St Elisabeth Hospital Tilburg, the Netherlands (Dutch Trial Register ref no. NTR4224).

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