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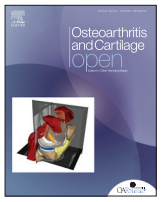

Clinical Trial

Clinical benefit of physical rehabilitation after total hip and knee arthroplasty: A pragmatic, randomized, controlled trial (The DRAW1 trial)

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ABSTRACT

Importance: Comparative effectiveness trials have not shown superiority of one type of physical rehabilitation over another following total hip (THA) and knee (TKA) arthroplasty. We therefore ask the fundamental effectiveness question: Does physical rehabilitation "work" better than no physical rehabilitation?
Objective: To compare the effectiveness of a 6-week program of physical rehabilitation (home-based tele-rehabilitation, or home-based rehabilitation) to no physical rehabilitation following THA and TKA.
Design: 3-arm,randomized, controlled, superiority trial with blinded outcome assessments. 377 patients (210 THA/167 TKA) were screened for eligibility before the targeted sample size of 168 patients was reached. Outcome measures were assessed at baseline, at the end of intervention (6 weeks), and 3 and 12 months postoperatively. The primary outcome was the Hip disability and Osteoarthritis Outcome Score (HOOS)/Knee injury and Osteoarthritis Outcome Score (KOOS)-subscale: function in daily living. Secondary outcomes included: HOOS/KOOS-subscales: pain, symptoms, and quality of life, patient global assessment, analgesics, walking aids, 30-s chair stand test, 4 × 10 m fast-paced walk test, exercise adherence, and satisfaction.
Results: Comparing physical rehabilitation (home-based telerehabilitation, and home-based rehabilitation) to no physical rehabilitation, the mean group-differences for the primary outcome were 3.3 (95%CI: −1.9 to 8.6; p = 0.10) points at 6 weeks, and 1.9 (95%CI: −3.7 to 7.6; p = 0.25) and 2.6 (95%CI: −4.4 to 9.6; p = 0.23) points at the 3- and 12-months follow-ups, respectively.
Conclusion: Physical rehabilitation was not superior to the no physical rehabilitation comparator following THA or TKA in terms of self-reported function or any of the secondary outcomes.
Trial registration: NCT03750448 (November 23, 2018), URL: https://clinicaltrials.gov/ct2/show/NCT03750448.

1. Introduction

Post-discharge physical rehabilitation following THA and TKA for severe osteoarthritis is promoted to restore function and mobility of the affected joint, and it is routine clinical practice most places [1,2]. However, the practices of post-discharge physical rehabilitation following THA and TKA vary substantially in terms of content, duration, and intensity [1–7]. This variation in clinical practice is an example of genuine uncertainty within the expert medical community about the preferred treatment, and questions the fundamental effectiveness of physical rehabilitation following THA and TKA.

Several systematic reviews and meta-analyses of RCTs have compared the effectiveness of different types of post-discharge rehabilitation delivery modes following THA and TKA [1,3,8,9]. Generally, home-based rehabilitation after initial instruction has been found to be as effective as outpatient, more closely supervised, rehabilitation in the long term measured by performance-based and self-reported outcomes [1,3,8–11].

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To inform the DRAW1 trial, we undertook systematic reviews of RCTs that assessed fundamental effectiveness by comparing physical rehabilitation after THA and TKA to a "no physical rehabilitation" comparator on patient-reported outcomes for function and pain [12,13]. Three trials were identified – none of which included telerehabilitation [14–16]. Two of the trials found their physical rehabilitation intervention superior to the comparator [15,16], and one found no superiority [14]. The identified trials were small, not prospectively registered and they lacked detailed reporting of interventions.

Therefore, there is a need for a trial that assesses the fundamental effectiveness of physical rehabilitation after THA and TKA to inform its clinical use. We ask: does physical rehabilitation "work" compared to no physical rehabilitation following THA and TKA and does delivery mode matter?

1.1. Objective

To compare the effectiveness of physical rehabilitation (home-based telerehabilitation, home-based rehabilitation combined) and no physical rehabilitation following THA and TKA in terms of self-reported function. Our hypothesis was that physical rehabilitation would be superior to no physical rehabilitation.

2. Method

This is the primary trial report for the "**D**oes **R**ehabilitation after total hip and knee **A**rthroplasty "**W**ork"? (DRAW1 trial)" [17]. It used a superiority, three-arm, parallel-group, randomized, controlled, trial (RCT) design with blinded outcome assessments at baseline (before intervention), at 6 weeks (end of intervention, primary endpoint), and follow-ups at 3 and 12 months. The trial protocol was based on the PREPARE trial guide [18] and the SPIRIT checklist [19] and published open access [17]. No protocol changes were made during the study period. The trial report adheres to the Consolidated Standards of Reporting Trials (CONSORT) [20]. The trial was pre-registered at ClinicalTrials.gov [21] (NCT03750448) November 23, 2018, and approval was obtained from the Ethics Committee of the Capital Region Denmark [22] before inclusion started January 2019 (ID: H-18056678). Trial procedures were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration [23].

2.1. Participants

To reflect current clinical practice and to increase external validity, few eligibility criteria were used.

The inclusion criteria were:

- Primary, unilateral THA or TKA due to osteoarthritis.
- Referred to receive postoperative rehabilitation at our institution (usual practice in the Capital Region of Denmark).
- Able to speak, read, and understand Danish language.
- Aged 18 years or more.

The exclusion criteria were:

- Not able to comply with exercise instructions.
- Discharged to a nursing home facility or receiving in-home rehabilitation by home care.

2.1.1. Setting

All patients were recruited using consecutive sampling at three outpatient rehabilitation trial sites on the isle of Bornholm, Denmark. All patients, who received a THA or TKA, were referred to postoperative, free-of-charge rehabilitation at our institution, reflecting the current clinical practice. Before discharge from the hospital, patients with THA or TKA had obtained independent basic mobility (transfer and walking) with an appropriate walking assistant device and experienced acceptable pain levels. Patients referred to our institution received a letter of invitation to initiate outpatient rehabilitation few days after their discharge, commencing their outpatient rehabilitation five to seven days after discharge.

Patients deemed eligible for trial inclusion were introduced to the trial individually by an experienced physiotherapist, serving as the intervention deliverer, during the first consultation. Patients were given thorough written and oral information about the nature of the trial, and if interested in participating in the trial were asked to sign informed consent. The physiotherapist attending the first consultation conducted baseline assessment immediately after the patient had provided written consent and before randomization. If written consent was not provided, the patient was offered usual care home-based rehabilitation. Randomization was carried out by an external, independent physiotherapist not otherwise involved in the trial, using a computer-generated random allocation sequence (1:1:1 allocation rate) concealed in 168 sequentially numerated, opaque, sealed envelopes with tamper-proof seal determining allocation to one of the three trial arms. Permuted block randomization was used to achieve balanced group allocations (block sizes of 9) due to a limited number of telerehabilitation units.

2.1.2. Interventions

The interventions under investigation were home-based telerehabilitation, home-based rehabilitation, and 'no physical rehabilitation' following THA and TKA. Originally, the municipality rehabilitation service wanted a trial to investigate the effectiveness of a tele-solution compared to the usual care practice of home-based rehabilitation before committing to a significant investment (the tele-solution). The question from the municipality rehabilitation service was related to a mixed population of THA and TKA because the usual care rehabilitation practice was the same after the two types of surgery. At the same time, our research department wanted to assess the fundamental effectiveness of physical rehabilitation. From the literature [1,3,8–11] it was clear that rehabilitation exercise modality and degree of supervision were not confounders, which is why we combined the two physical rehabilitation groups for the primary analysis of fundamental effectiveness. This fostered the DRAW1 trial, which consequently featured three trial arms in which the two rehabilitation arms were combined for the primary analysis to assess the fundamental effectiveness of physical rehabilitation in a mixed population of THA and TKA. The primary objective of this trial was therefore to investigate the fundamental effectiveness of physical rehabilitation to a no physical rehabilitation comparator, and secondarily to compare the individual physical rehabilitation interventions to the no physical rehabilitation comparator. The interventions were initiated during the first consultation at our outpatient facility following discharge.

2.2. Home-based telerehabilitation

Patients received interactive virtual rehabilitation using a mobile app. The home-based telerehabilitation is based on sensor technology, developed by ICURA (www.icura.dk). This technology consists of motion sensors that can measure and analyze the quantity and quality of the exercises, and a mobile application that can guide the patient with visual response. A unique feature of the ICURA trainer is that it allows the physiotherapist to remotely supervise the individual patient's exercise adherence and progress. This technology has already been implemented in several different rehabilitation facilities across Denmark, and, hence, reflects current clinical practice in these places (picture 1).

2.3. Home-based rehabilitation

Patients were instructed in identical exercises as patients allocated to home-based telerehabilitation. However, the home-based rehabilitation intervention only received a written exercise program with instructions

Picture 1. Features of home-based telerehabilitation (ICURA).

on how to perform the exercises at home (no tele solution), also considered usual practice. The home-based exercise program was created using exercise templates from Exorlive (www.exorlive.com). Using a link in the exercise program, the patients were able to see short instruction videos of the exercises (picture 2).

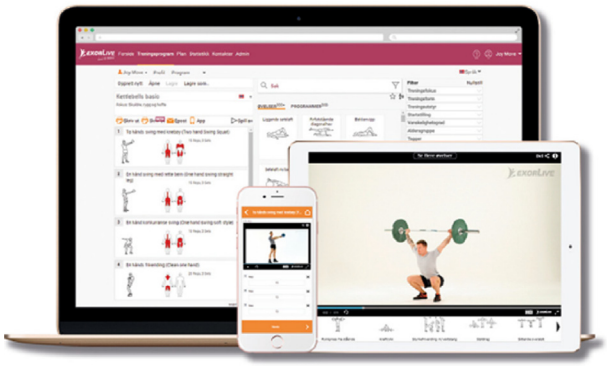
2.4. No physical rehabilitation

Patients were not prescribed any therapeutic rehabilitation exercise. They did not receive any physical activity or exercise designed and prescribed for restoring normal function. Patients were instructed to gradually return to activities of daily living such as walking, vacuuming, or other forms of pre-surgical activity when they felt ready. Justification for the content and naming of this trial arm can be found in our published trial protocol [17] in the peer review history.

Patients in all three interventions were given identical standard pamphlets with information about the surgery they had undergone, expected discomforts and possible complications as well as recommendations regarding the return to activities of daily living. Exercise instructions given to the two physical rehabilitation interventions were included as 'add-ons' to the standard. The exercise program in the two physical rehabilitation interventions consisted of four exercises for THA (seated leg extension, standing hip extension, set and get up, and walk on a step) and four exercises for TKA (seated leg extension, sitting and getting up, walking on a step, and range of motion exercises). Each exercise progressed in difficulty every other week. Each exercise was performed daily in 3 sets of 10 repetitions with an intensity of 15RM. This exercise intervention is considered usual care following THA and TKA at our institution. The pamphlets, including detailed intervention descriptions using TIDieR [24] and CERT templates [25], are available open access [26].

2.4.1. Outcomes

All outcome assessors were licensed physiotherapists and trained by the primary investigator to ensure standardization. Outcomes were collected during the first consultation after discharge (baseline), at the end of the 6-week intervention (first follow-up), at 3 months postoperatively (second follow-up), and 12 months postoperatively (third and final follow-up).



Picture 2. Home-based rehabilitation (Exorlive).

The primary outcome was the difference between groups in the mean score of Hip disability and Osteoarthritis Outcome Score (HOOS)/KOOS function in the daily living-subscale (ADL-subscale) after the 6-week intervention. The ADL subscale was chosen as the primary outcome as it is usually physical function that prescribed rehabilitation is targeted to improve [1,3]. The ADL-subscale was identified as highly relevant based on semi-structured patient interviews before the trial began. The patients found the HOOS/KOOS subscale most relevant among other presented outcomes to measure postoperative progress. As HOOS and KOOS both have the same high degree of internal consistency [27,28], we found it valid to compare the combined mean differences between groups.

The secondary outcomes included the between-group differences at all follow-ups for the three subscales of the HOOS/KOOS (i.e. pain, symptoms, and quality of life) [27,29]. The HOOS/KOOS subscale: function in sport and recreation was considered inappropriate to answer by patients following THA and TKA, and were therefore not included. To supplement the primary outcome of self-reported function, we used a patient global assessment, as recommended by OARSI [30], asking: "How would you rate your current level of function during your usual activities of daily living?" (0–100 visual rating scale) [31]. Performance-based function was measured by the 30-s chair stand and 4 × 10 m fast-paced walk tests as recommended by OARSI [32]. Furthermore, patient satisfaction [33] and exercise adherence (0–100 %, where 100 % indicates that all repetitions foreach exercise were performed every day as prescribed) were assessed at the end of the 6-week intervention. Current use of analgesics, walking assistant devices, and adverse events (e.g., hospitalizations) were also registered at each follow-up assessment. Outcome assessors documented the time usage of each consultation to investigate the total time of rehabilitation consultations given to each patient for all three rehabilitation strategies. Any additional time spent monitoring home-based telerehabilitation was also documented.

2.4.1.1. Data from medical records. All the above-mentioned outcome measurements were passed on from medical record files in collaboration with the physiotherapist who had performed the outcome assessment.

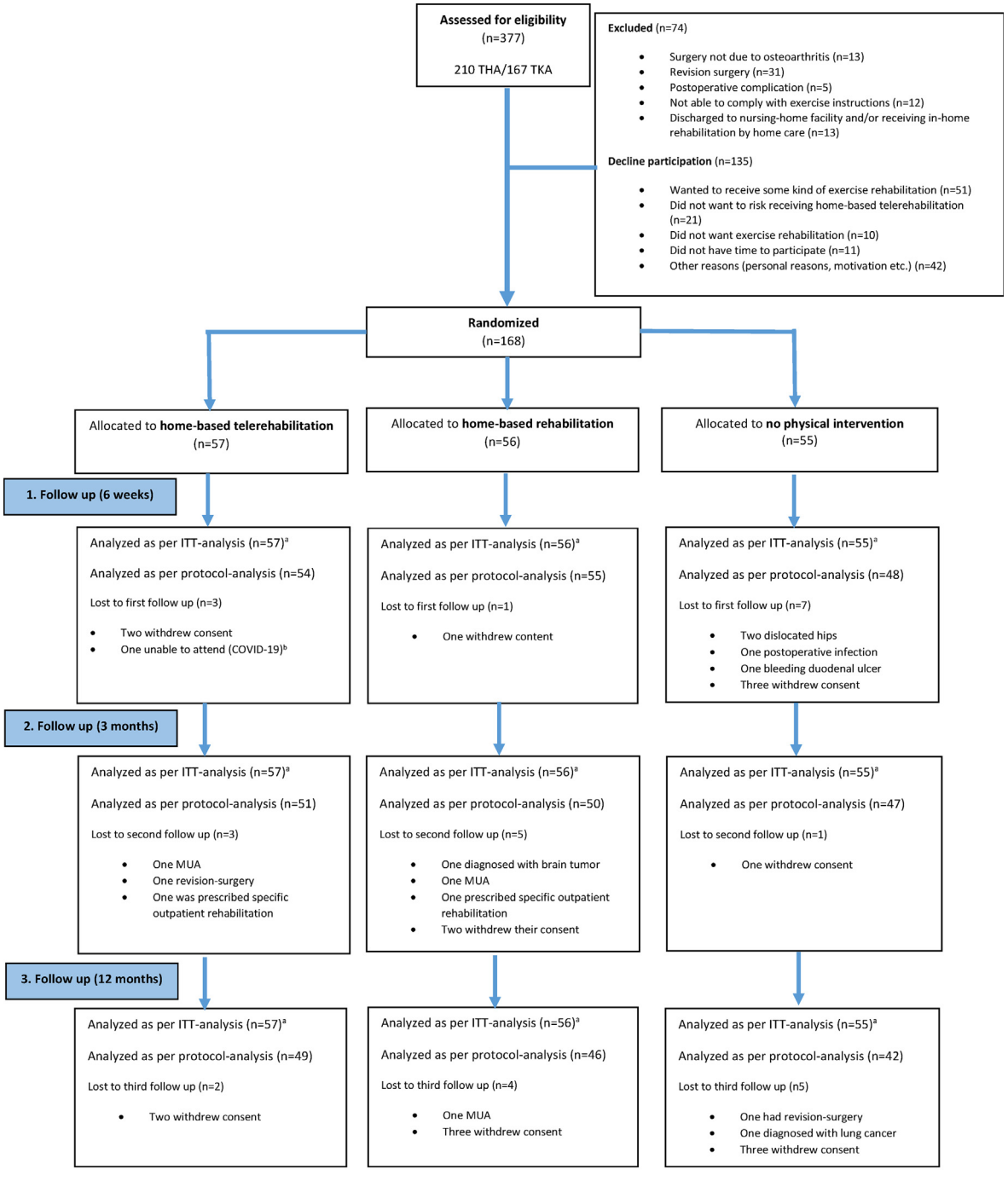
2.4.2. Blinding

Due to the nature of the trial, patients and caretakers could not be blinded to group allocation. However, they were blinded to the trial hypothesis to prevent ascertainment bias. Outcome assessors were blinded to group allocation. During the first consultation, baseline outcome measures were recorded *before* randomization and intervention allocation (the assessor had no knowledge of the allocation sequence), minimizing the risk of bias. During follow-ups, the outcome assessors were blinded to group allocation before and during outcome assessments. The patients were instructed orally and in writing not to disclose their

allocation. The outcome assessors were instructed not to ask questions about allocation, keeping the assessors unaware of the participant's assigned intervention. The principal investigator, who was the primary point of contact for the patients during the trial, was not an outcome assessor and not blinded to allocation.

2.4.3. Sample size

To compare physical rehabilitation (home-based telerehabilitation and home-based rehabilitation) to no physical rehabilitation, a clinically important difference of 10 points on the HOOS/KOOS subscale: function in daily living (ADL) [27,28] was used as the superiority margin. The sample size was estimated using a one-sided *t*-test, expected common standard deviation of 20 HOOS/KOOS points, power of 0.8, and a significance level of 0.05, resulting in a sample size of 50 patients in each group. With a sample size of 100 (patients receiving one of the two physical rehabilitation strategies, 2 × 50) and 50 (patients receiving no physical rehabilitation), same superiority margin, expected SD, and significance levels, the expected power was 0.89. To account for an expected



[a] Number of imputations in intention- to-treat analysis: 5

[b] Patient had missing data for the first follow up, but remained in the study to the second follow-up.

Fig. 1. Flowchart.

10 % loss to follow-up [34], we included 56 patients in each group, resulting in a total of 168 patients (3 × 56 = 168).

2.4.4. Statistical methods

The statistical analysis plan was published with the trial protocol [17]. The primary analysis aimed to evaluate the mean difference at 6 weeks between physical rehabilitation (home-based telerehabilitation and home-based rehabilitation) and no physical rehabilitation (primary trial objective). This was assessed by independent two-sample t-tests if normality assumptions were acceptable. If not, the Wilcoxon sum rank-test was used. The same tests were used in the secondary analysis: to compare the two physical rehabilitation interventions individually to the no physical rehabilitation intervention. Nominal outcomes were analysed by the chi-squared test or in cases with less than five expected counts for any observation, Fisher's exact test was used. Data analysis followed the intention-to-treat principle. Missing data were imputed using multiple imputations. Specific imputation models were fitted for each missing variable, models included type of surgery, gender, age, and prior assessment of the specific outcomes. Additionally, a per protocol analysis was conducted for the primary outcome in which all patients having an exercise adherence of at least 80 % were compared to patients in the 'no physical rehabilitation' intervention. The statistical analysis was conducted using the statistical software program 'R' (version 4.3.1) [35].

3. Results

Participant flow: 377 patients (210 THA/167 TKA) were referred to our outpatient rehabilitation institution between the January 25, 2019 to the January 12, 2021 and assessed for eligibility. 74 patients were not eligible, and 135 patients declined participation, leaving 168 participants to be included in the trial (inclusion rate: 55.5 %) (Fig. 1).

3.1. Lost to follow up

11 patients were lost before the first follow-up at the end of the 6-week intervention period (three from the home-based telerehabilitation intervention, one from the home-based rehabilitation intervention, and seven from the no physical rehabilitation intervention). Total loss to follow-up during the trial period was 31 participants (18 %) (eight from the home-based telerehabilitation intervention, 10 from the home-based rehabilitation intervention, and 13 from the no physical rehabilitation intervention, Fig. 1).

168 patients were randomized and allocated. Normality was found acceptable based on QQ-plots and histograms for all outcome measures, except for the 30s chair stand test and 4 × 10 m fast-paced walk test. These two outcome measures were therefore analysed using the Wilcoxon sum rank-test.

Besides a higher proportion of independent walkers (e.g., no use of a walking assistant) in the 'no physical rehabilitation' intervention compared to the two physical rehabilitation interventions at baseline, groups were found to have similar baseline characteristics (Table 1).

3.2. Primary outcome

3.2.1. Physical rehabilitation versus no physical rehabilitation

In the primary analysis, self-reported function measured by the HOOS/KOOS improved from baseline to the 6-week (A1) assessment by 21.9 (95%CI: 18.9 to 24.9) points after physical rehabilitation and by 18.5 (95%CI: 14.2 to 22.8) points after no physical rehabilitation. The difference between groups at the 6-week follow-up was not statistically significant (mean difference of self-reported function: 3.3 points (95 % CI: −1.9 to 8.6; p = 0.10)). Corresponding changes in self-reported function from baseline to the later follow-ups were: 26.3

Table 1
Baseline characteristics.

	Physical rehabilitation[a] (n = 113)	No physical rehabilitation (n = 55)	Home-based telerehabilitation (n = 57)	Home-based rehabilitation (n = 56)
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
THA/TKA	62 THA/51 TKA	31 THA/24 TKA	31 THA/26 TKA	31 THA/25 TKA
Days from surgery to baseline assessment	8.5 (2.58)	9.5 (3.48)	8.5 (2.44)	8.5 (2.74)
Side (left/right)	52/61	26/29	23/34	29/27
Men/women	50/63	26/29	25/32	25/31
Age	67.5 (8.6)	69.7 (9.5)	67.5 (8.9)	67.4 (8.2)
Height	171.1 (8.8)	172.1 (9.2)	170.3 (9.7)	172.1 (7.7)
Weight	86.9 (17.4)	85.8 (17.0)	85.9 (16.8)	87.9 (18.1)
BMI	29.6 (5.1)	28.9 (5.1)	29.5 (5.1)	29.6 (5.2)
Current use of analgesics, number of users (%)				
- Paracetamol	87 (77.0 %)	43 (78.2 %)	43 (75.4 %)	44 (78.6 %)
- NSAID	43 (38.1 %)	15 (27.3 %)	17 (29.8 %)	26 (46.4 %)
- Opioids	53 (46.9 %)	24 (43.6 %)	24 (42.1 %)	29 (51.8 %)
- Neuropathic medicine	4 (3.5 %)	0 (0 %)	1 (1.8 %)	3 (5.4 %)
Walking aid, number of users (%)				
- No walking aids	3 (2.7 %)	10 (18.2 %)	2 (3.5 %)	1 (1.8 %)
- Use one elbow stick	27 (23.9 %)	8 (14.5 %)	13 (22.8 %)	14 (25.0 %)
- Use two elbow sticks	78 (69.0 %)	33 (60.0 %)	40 (70.2 %)	38 (67.9 %)
- Use a walker	5 (4.4 %)	4 (7.3 %)	2 (3.5 %)	3 (5.4 %)
Primary outcome				
HOOS/KOOS-subscale: ADL	57.0 (18.2)	60.1 (19.1)	56.6 (17.2)	57.4 (19.3)
Secondary outcomes				
HOOS/KOOS-subscales				
- Symptoms	56.7 (20.5)	56.9 (17.9)	58.0 (17.7)	55.5 (23.1)
- Pain	56.9 (20.6)	59.2 (18.7)	56.4 (19.2)	57.3 (22.0)
- Quality of life	43.1 (22.0)	45.3 (20.3)	40.7 (19.7)	45.5 (24.1)
Global assessment	48.5 (21.1)	51.4 (19.8)	46.1 (20.3)	50.9 (21.9)
30-s Chair stand test	2.4 (4.7)	2.4 (4.8)	2.7 (4.7)	2.2 (4.7)
4 × 10 m fast-paced walk test	59.5 (34.1)	55.7 (33.7)	57.8 (28.3)	61.3 (39.3)
Physio-time (min)	113.5 (17.7)	104.3 (22.3)	120 (17.2)	106.5 (15.5)

THA: total hip arthroplasty. TKA: total knee arthroplasty. BMI: Body Mass Index. NSAID: non-steroidal anti-inflammatory drug. HOOS: Hip disability and Osteoarthritis Outcome Score. KOOS: Knee injury and Osteoarthritis Outcome Score. ADL: activities of daily living.

[a] Physical rehabilitation = home-based telerehabilitation and home-based rehabilitation combined.

Table 2
Changes from baseline to follow ups between physical rehabilitation and no physical rehabilitation.

	Follow up	Physical rehabilitation[a] (95%CI)	No physical rehabilitation (95%CI)	Mean difference (95%CI)	*P*-value
Primary outcome					
HOOS/KOOS: ADL	A1	21.9 (18.9–24.8)	18.5 (14.2–22.8)	3.3 (−1.9 to 8.6)	0.104
Secondary outcome					
HOOS/KOOS: ADL	A2	26.3 (23.1–29.5)	24.4 (19.7–29.0)	1.9 (−3.7 to 7.6)	0.250
	A3	29.4 (25.7–33.2)	26.9 (20.9–32.8)	2.59 (−4.4 to 9.6)	0.231
HOOS/KOOS: Symptoms	A1	13.3 (10.0–16.5)	14.6 (9.8–19.4)	−1.3 (−7.1 to 4.5)	0.660
	A2	18.3 (14.7–21.9)	20.7 (15.2–26.3)	−2.5 (−9.0 to 4.1)	0.458
	A3	26.4 (22.6–30.2)	28.7 (22.7–34.7)	−2.3 (−9.3 to 4.7)	0.511
HOOS/KOOS: Pain	A1	17.3 (14.3–20.3)	18.7 (14.4–23.1)	−1.4 (−6.7 to 3.9)	0.597
	A2	23.9 (20.3–27.6)	22.8 (17.1–28.5)	1.1 (−5.7 to 7.9)	0.744
	A3	30.0 (26.1–34.0)	28.6 (22.9–34.3)	1.4 (−5.5 to 8.3)	0.682
HOOS/KOOS: Quality of life	A1	19.4 (15.7–23.1)	20.5 (14.7–26.3)	−1.1 (−7.8 to 5.6)	0.745
	A2	26.3 (22.1–30.5)	29.8 (23.9–35.7)	−3.5 (−10.9 to 4.0)	0.360
	A3	33.1 (28.5–37.8)	34.5 (27.5–41.5)	−1.4 (−9.8 to 7.1)	0.752
Global assessment	A1	23.9 (19.3–28.6)	21.5 (14.2–28.8)	2.4 (−5.9 to 10.8)	0.566
	A2	29.5 (25.2–33.8)	27.3 (20.5–34.1)	2.2 (−5.7 to 10.1)	0.583
	A3	34.3 (29.6–39.0)	32.4 (25.5–39.2)	1.9 (−6.3 to 10.1)	0.643
Satisfaction	A1	81.5 (78.5–84.5)	84.2 (79.9–88.5)	−2.7 (−8.0 to 2.6)	0.319
Exercise adherence	A1	74.9 (63.5–86.4)			
30-s Chair stand test[b]	A1	9 (0.8–11)	5 (0–11)		0.189
	A2	10 (3.3–12.7)	8.9 (0.4–14)		0.946
	A3	11.1 (5.8–14)	10.6 (2.7–14.5)		0.526
4 × 10 m fast-paced walk test[b]	A1	−17.6 (−26.4 to −11.5)	−16.4 (−23.8 to −10.1)		0.318
	A2	−20.3 (−32.3 to −13.3)	−16.9 (−26.9 to −10.9)		0.195
	A3	−22.0 (−32.4 to −13.8)	−20.3 (−27.9. To −12.0)		0.301
Consultation time (minutes)	A1	80.2 (76.9–83.6)	77.6 (73.0–82.2)	2.6 (−3.4 to 8.7)	0.384
	A2	64.6 (61.7–67.4)	63.1 (58.9–67.4)	1.4 (−3.8 to 6.7)	0.594
	A3	54.7 (51.8–57.6)	53.4 (48.7–58.1)	1.3 (−4.0 to 6.6)	0.622
Usage of analgesics, numbers of users (%)[c,d]					
Paracetamol	A1	51 (45.0 %)	18 (33.3 %)		0.236
	A2	33 (29.4 %)	12 (21.3 %)		0.400
	A3	19 (16.7 %)	4 (7.1 %)		0.220
NSAID	A1	21 (18.3 %)	7 (12.5 %)		0.500
	A2	20 (17.6 %)	4 (6.4 %)		0.113
	A3	8 (7.3 %)	1 (2.4 %)		0.459
Opioids	A1	14 (12.8 %)	2 (4.2 %)		0.171
	A2	7 (5.9 %)	2 (4.3 %)		0.985
	A3	6 (5.2 %)	4 (7.1 %)		0.959
Neuropathic medicine	A1	1 (0.9 %)	0 (0 %)		1.000
	A2	6 (4.9 %)	1 (2.1 %)		0.725
	A3	2 (2.1 %)	0 (0 %)		0.866
Number of independent walkers (%)[c,d]					
	A1	88 (77.9 %)	49 (89.1 %)		0.122
	A2	107 (94.7 %)	52 (94.5 %)		1.000
	A3	111 (98.2 %)	53 (96.4 %)		0.837

Follow ups. A1: after the 6-week intervention. A2: 3 months postoperatively. A3: 12 months postoperatively.
[a] Physical rehabilitation = home-based telerehabilitation and home-based rehabilitation combined.
[b] 30s chair stand test and 4 × 10 m fast-paced walk test were analysed with Wilcoxon sum rank-test. as normality assumptions for these tests were not acceptable.
[c] *The use of analgesics and numbers of independent walkers were analysed using the Chi Squared test.*
[d] Frequencies and percentages are based on pooled estimates from the multiply imputation data sets.

(95%CI: 23.1 to 29.5) points for the physical rehabilitation interventions and 24.4 (95%CI: 19.7 to 29.0) points for the no physical rehabilitation comparator at 3 months (A2) and 29.4 (95%CI: 25.7 to 33.2) points for the physical rehabilitation interventions and 26.9 (95%CI: 20.9 to 32.8) points for the no physical rehabilitation comparator at 12 months (A3). The between-group differences were not statistically significant at 3 months (1.9 points: 95%CI: −3.7 to 7.6, p = 0.25) or 12 months (2.6 points: 95%CI: −4.4 to 9.6, p = 0.23). No statistically significant differences were found for any of the secondary outcomes (Table 2).

3.2.2. Stratified analysis

The two physical rehabilitation interventions (home-based telerehabilitation and home-based rehabilitation) were compared individually to no physical rehabilitation (Table 3). The self-reported function improved from baseline to 6-week follow-up (A1) by 22.9 (95%CI: 18.7 to 27.1) points for the home-based telerehabilitation intervention and 20.8 (95%CI: 16.7 to 24.9) points for the home-based rehabilitation intervention. Comparing home-based telerehabilitation to no physical rehabilitation, the between-group difference at 6 weeks (A1) was 4.4 (95%CI: −1.6 to 10.4; p = 0.08) points, while the between-group difference between the home-based rehabilitation intervention and the no physical rehabilitation comparator was 2.3 (95%CI: −3.7 to 8.2; p = 0.23) points at the same time point. Corresponding changes in self-reported function from baseline to the later follow-ups were: 25.5 (95%CI: 21.7 to 29.3) points for the home-based telerehabilitation intervention and 27.1 (95%CI: 23.3 to 30.1) points for the home-based rehabilitation intervention at 3 months (A2). At 12 months (A3) the

Table 3
Linear regression analysis by stratifying physical rehabilitation into home-based telerehabilitation and home-based rehabilitation.

Outcomes		Mean difference (95%CI)	*P*-value	Mean difference (95%CI)	*P*-value
Primary outcome		No physical rehabilitation vs. home-based telerehabilitation		No physical rehabilitation vs. home-based rehabilitation	
HOOS/KOOS-ADL	A1	4.4 (−1.6 to 10.4)	0.076	2.3 (−3.7 to 8.2)	0.226
Secondary outcome					
HOOS/KOOS-ADL	A2	1.1 (−5.4 to 7.7)	0.368	2.8 (−3.8 to 9.3)	0.204
	A3	3.5 (−4.4 to 11.5)	0.189	1.6 (−6.4 to 9.7)	0.345
Symptoms	A1	−2.5 (−9.1 to 4.0)	0.449	−0.1 (−6.9 to 6.8)	0.988
	A2	−4.3 (−11.6 to 3.0)	0.247	−0.6 (−8.3 to 7.1)	0.881
	A3	−3.6 (−11.7 to 4.6)	0.384	−1.1 (−9.2 to 7.1)	0.799
Pain	A1	−0.8 (−6.8 to 5.3)	0.807	−2.1 (−8.1 to 4.0)	0.499
	A2	0.6 (−7.3 to 8.4)	0.888	1.7 (−6.0 to 9.4)	0.662
	A3	2.0 (−5.9 to 10.0)	0.617	0.8 (-7.1 to 8.8)	0.835
Quality of life	A1	2.0 (−5.6 to 9.5)	0.609	−4.2 (−12.0 to 3.6)	0.284
	A2	−1.0 (−9.2 to 7.3)	0.821	−6.0 (−14.9 to 2.9)	0.185
	A3	0.8 (−9.1 to 10.6)	0.880	−3.5 (−13.1 to 6.1)	0.471
Global assessment	A1	5.3 (−4.0 to 14.7)	0.261	−0.5 (−10.0 to 9.0)	0.910
	A2	3.3 (−5.7 to 12.2)	0.469	1.1 (−8.0 to 10.2)	0.809
	A3	2.7 (−6.7 to 12.0)	0.572	1.2 (−8.6 to 10.9)	0.814
Satisfaction	A1	−2.4 (-8.5 to 3.6)	0.430	−2.9 (−9.0 to 3.2)	0.346
30-s Chair stand test[a]	A1	5 (0–11) vs 8.6 (2–11)	0.273	5 (0–11) vs 9 (0–11)	0.240
	A2	8.9 (0.4–14) vs 10.5 (4–12.2)	1.000	8.9 (0.4–14) vs 9 (1.8–13)	0.952
	A3	10.6 (2.7–14.5) vs 11 (5.1–12.8)	0.762	10.6 (2.7–14.5) vs 11.4 (6.2–14.3)	0.291
4 × 10 m fast-paced walk test[a]	A1	−16.4 (−23.8 to −10.1) vs −18.2 (−24.8 to −13.5)	0.158	−16.4 (−23.8 to −10.1) vs −15.9 (−27.5 to −10.0)	0.764
	A2	−16.9 (−26.9 to −10.9) vs −20.6 (−32.5 to −14.0)	0.160	−16.9 (−26.9 to −10.9) vs −19.6 (−29.0 to −12.2)	0.401
	A3	−20.3 (−27.9 to −12.0) vs −22.2 (−31.7 to −13.9)	0.326	−20.3 (−27.9 to −12.0) vs −21.2 (−32.4 to −12.6)	0.424
Consultation time (min)	A1	3.5 (−3.3 to 10.3)	0.306	1.8 (−5.1 to 8.6)	0.611
	A2	1.8 (−4.6 to 7.8)	0.562	1.1 (−4.9 to 7.0)	0.726
	A3	0.3 (−5.8 to 6.4)	0.921	2.3 (−3.67 to 8.3)	0.442
Number of users of analgesics (%)[b,c]					
Paracetamol	A1	18 (33.3 %) vs 25 (44.4 %)	0.345	18 (33.3 %) vs 25 (45.5 %)	0.293
	A2	12 (21.3 %) vs 12 (21.2 %)	1.000	12 (21.3 %) vs 21 (38.0 %)	0.115
	A3	4 (7.1 %) vs 7 (12.0 %)	0.668	4 (7.1 %) vs 12 (21.7 %)	0.104
NSAID	A1	7 (12.5 %) vs 12 (20.4 %)	0.425	7 (12.5 %) vs 9 (16.4 %)	0.784
	A2	3 (6.4 %) vs 7 (11.5 %)	0.589	4 (6.4 %) vs 13 (24.0 %)	0.034
	A3	1 (2.4 %) vs 1 (2.0 %)	1.000	1 (2.4 %) vs 7 (13.0 %)	0.147
Opioids	A1	2 (4.2 %) vs 6 (11.1 %)	0.351	2 (4.2 %) vs 8 (14.5 %)	0.150
	A2	2 (4.3 %) vs 3 (5.8 %)	1.000	2 (4.3 %) vs 3 (6.0 %)	1.000
	A3	4 (7.1 %) vs 1 (2.0 %)	0.489	4 (7.1 %) vs 5 (8.7 %)	1.000
Neuropathic medicine	A1	0 (0 %) vs 1 (1.9 %)	1.000	0 (0.0 %) vs 0 (0.0 %)	!
	A2	1 (2.1 %) vs 4 (7.7 %)	0.422	1 (2.1 %) vs 1 (2.0 %)	1.000
	A3	0 (0 %) vs 1 (2.0 %)	1.000	0 (0 %) vs 1 (2.2 %)	1.000
No use of walking aid (%)[b,c]					
	A1	49 (89.1 %) vs 48 (84.2 %)	0.631	49 (89.1 %) vs 40 (71.4 %)	0.036
	A2	52 (94.5 %) vs 53 (93.0 %)	1.000	52 (94.5 %) vs 54 (96.4 %)	0.984
	A3	53 (96.4 %) vs 55 (96.5 %)	1.000	53 (96.4 %) vs 56 (100 %)	0.468

Follow ups. A1: after the 6-week intervention. A2: 3 months postoperatively. A3: 12 months postoperatively.

[a] 30s chair stand test and 4 × 10 m fast-paced walk test were analysed with Wilcoxon sum rank-test and reported as median (IQR). as normality assumptions for these tests were not acceptable. ! = unable to calculate p-value due to lack of observation.

[b] The use of analgesics and use of walking aid were analysed using the Chi Squared test.

[c] Frequencies and percentages are based on pooled estimates from the multiply imputation data sets.

Table 4
Adverse events.

Adverse events	Home-based telerehabilitation	Home-based rehabilitation	No physical rehabilitation
Before first follow up (6 weeks)	N = 0	N = 0	N = 4 Two had dislocated hips One experienced postoperative infection One was diagnosed with a bleeding duodenal ulcer
Before second follow up (3 months)	N = 3 One had MUA One had revision surgery One was prescribed supervised, outpatient rehabilitation	N = 3 One diagnosed with brain tumor One had MUA One was prescribed supervised, outpatient rehabilitation	N = 0
Before third follow up (12 months)	N = 0	N = 1 One had MUA	N = 2 One had revision surgery One was diagnosed with lung cancer
Total	**N = 3**	**N = 4**	**N = 6**

MUA: manipulation under anesthesia.

improvement was 30.4 (95%CI: 26.0 to 34.8) points for home-based telerehabilitation intervention and 28.5 (95%CI: 23.8 to 33.2) points for the home-based rehabilitation intervention. Comparing home-based telerehabilitation and no physical rehabilitation, the between-group difference was 1.1 (95%CI: −5.4 to 7.7; p = 0.37) points at 3 months (A2) and 3.5 (95%CI: −4.4 to 11.5; p = 0.19) points at 12 months (A3). The between-group difference between home-based rehabilitation intervention and the no physical rehabilitation comparator was 2.8 (95% CI: −3.8 to 9.3; p = 0.20) points at 3 months (A2) and 1.6 (95%CI: −6.4 to 9.7; p = 0.35) points at 12 months (A3). No statistically significant differences were found for any of the secondary outcomes by comparing the two physical rehabilitation interventions individually to the no physical rehabilitation intervention (Table 3). Comparing one of the investigated physical interventions with no intervention does however hold less power than our primary analysis (both physical rehabilitation interventions combined), and should be therefore be considered as explorative comparisons.

3.3. Ancillary analyses

A per protocol analysis was performed for all patients in the physical rehabilitation intervention who had an exercise adherence of at least 80 %. By comparing this subgroup of patients to the no physical rehabilitation comparator, the mean difference was 4.2 (95% CI: −1.3 to 9.7; p = 0.07) points at the primary endpoint. At the 3- and 12-months follow-ups, the corresponding mean differences were 4.1 (95%CI: −1.8 to 10.1; p = 0.09) and 4.7 (95%CI: −2.5 to 12.0; p = 0.10) points, respectively. Regression analysis on exercise adherence between the two physical rehabilitation interventions and subgroup analysis for age can be found in the Supplements (please see Supplements).

3.3.1. Harms

Thirteen adverse events occurred in 13 participants (Table 4).

4. Discussion

In this first trial of fundamental effectiveness of physical rehabilitation following a mixed cohort of THA and TKA, we found that two different physical rehabilitation interventions considered usual practice was not superior to no physical rehabilitation in terms of self-reported function or any of the secondary outcomes at any time point.

We hypothesized that physical rehabilitation would be superior to no physical rehabilitation following THA and TKA, based on the systematic reviews we used to inform this trial [12,13]. Several reasons may help explain why this was not the case.

A physiologic response is triggered by the surgical trauma (the surgical stress response) which includes both hormonal and metabolic changes [36]. Perhaps the surgical stress response and spontaneous recovery are what mainly determine the trajectory of recovery. The effect size of spontaneous recovery may be so large that physical rehabilitation (with a much smaller effect size) does not add anything of clinical relevance we can measure. Perhaps the response to exercise that we normally expect is blunted by the stress response. Indeed, arthrogenic muscle inhibition, or activation failure of the muscle, is commonly observed after TKA [37], while some evidence indicates that it also exist following hip surgery [38]. It is generally accepted that arthrogenic muscle inhibition is caused by a change in the discharge of sensory receptors from the damaged joint that ultimately limit activation of the quadriceps muscle [39,40], which in turn may impede physical rehabilitation interventions. The finding of non-superiority may be caused by under-dosage of physical rehabilitation in the intervention groups; however, we believe the physiological response to surgery to be the most likely explanation for the finding. Some support for this notion exists. High-intensity rehabilitation exercises targeting muscles with pronounced strength losses after THA and TKA have not been shown to be superior to comparators using lower exercise dosages/intensities for strength and function outcomes. For example, Jakobsen and colleagues (2014) found that 7 weeks of progressive strength training was not superior compared to physical rehabilitation without progressive strength training following discharge from TKA [41]. Both groups experienced similar changes in knee extension strength after the 7-week intervention. The main finding was subsequently replicated by Bade et al., in 2017 [42] using a sample size twice as large. Similar results were found in THA when comparing supervised, progressive resistance training to unsupervised home-based exercises after THA [43]. Moreover, a recently published prospective cohort study examined the dose-response relationship between the extent of objectively quantified exercise dosage performed and the alteration in performance-based function measured by gait speed following THA, and found no indication of an exercise dose-outcome response relationship [44]. Our results, both in terms of self-reported outcome measures, as well as performance-based outcome measures, support these findings. For example, patients receiving physical rehabilitation improved by 9 (95% CI: 0.8 to 11) and −17.6 (95%CI: −26.5 to −11.5) in terms of 30-s chair stand test and 4 × 10 m. fast-paced walk test, respectively. While the no intervention improved by 5 (95%CI: 0 to 11) in the 30-s chair stand test and −16.4 (95%CI: −23.8 to −10.1) in the 4 × 10 m. fast-paced walk test, these between-group differences were non-significant (please see Table 2), supporting the finding of non-superiority.

In support of the notion that spontaneous recovery mainly determines the recovery trajectory – and that different rehabilitation interventions cannot easily modify the trajectory – we found no differences between the three applied rehabilitation interventions across outcomes and time points. The patients expressed that they were overall satisfied with the operation and postoperative care (between 81.3 % and 84.2 % satisfaction across the three trial arms), while the self-reported exercise adherence between the two physical rehabilitation interventions were similar (74.8 % and 75.0 %). For telerehabilitation specifically, one of the most

compelling arguments in favor of home-based telerehabilitation is that it motivates patients to exercise more than other modalities of physical rehabilitation [45]. If true, this should have been reflected in superior outcomes in this trial, which it was not.

This randomized controlled trial has several strengths including pre-registration, 55 % recruitment rate, random allocation, no protocol deviations, blinded outcome assessors, and 1-year follow-up. The trial also has limitations. Investigating a mixed cohort of both THA and TKA patients does not allow stratification of the results to either type of surgery alone.

In this randomized, controlled trial, physical rehabilitation was not found to be superior to no physical rehabilitation following a mixed cohort of THA or TKA in terms of self-reported function any of the secondary outcomes. Similarly, neither home-based telerehabilitation nor home-based rehabilitation individually demonstrated superiority to no physical rehabilitation. These findings can inform discussions about the clinical use of physical rehabilitation after THA and TKA.

Author contribution

All authors meet the International Committee of Medical Journal Editors criteria for authorship. All authors take responsibility for the integrity of the work as a whole, from inception to finished article. Specific, primary contribution to the following points were as follows: Conception and design (TMC, TB, KT), Analysis and interpretation of the data (TMC, TB, KT, TK), Drafting of the article (TMC, TB, KT, TK), Critical revision of the article for important intellectual content (TMC, TB, KT, TK), Final approval of the article (TMC, TB, KT, TK), Provision of the study patients (TMC), Statistical expertise (TK), Obtaining of funding (TMC, TB), Collection and assembly of data (TMC, TK).

Data sharing statement

The authors commit to making the relevant anonymized patient-level data available on reasonable request.

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This abstract adheres to the CONSORT extension for abstract checklist.

Declaration of competing interest

The authors declare no competing interest.

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Appendix A. Supplementary data

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