Pedaling-Based Protocol Superior to a 10-Exercise, Non-Pedaling Protocol for Postoperative Rehabilitation After Total Knee Replacement A Randomized Controlled Trial

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A Pedaling-Based Protocol was Superior to a Ten Exercise Non-Pedaling Protocol for Post-Operative Rehabilitation after Total Knee Replacement in a Randomized Controlled Trial

Abstract

Background: Despite Total Knee Replacement (TKR) patients routinely receiving physical therapy in the immediate and early post-operative phase, there is a paucity of research into the optimal exercise protocols in both the acute inpatient setting and early period after discharge. The acute period after TKR has become increasingly important for post-operative rehabilitation as average length of stay (LOS) rates decline worldwide. Pedaling has often been recommended by clinicians after TKR for rehabilitation, but to our knowledge, there has been no investigation into its utility in the acute post-operative setting. Therefore, we performed a randomized controlled trial evaluating the efficacy of pedaling in the acute postoperative period.

Methods: Sixty TKR patients were randomized into either a three exercise pedaling (Pedaling-based) or ten exercise non-pedaling (Multi-exercise) physical therapy post-operative protocol. Outcomes were assessed at 2 days, 2 weeks and 4 months, and included physical tests of function, patient reported outcomes, and other perioperative measures.

Results: The primary outcome, the Six Minute Walk Test (6MWT), was significantly greater in the Pedaling-based group than the Multi-exercise group at 2 days post-operatively (mean difference 66 meters, p = .001). Other functional tests, the 10-meter walk speed (10MWT) and the Timed Up and Go (TUG) test, were both significantly superior in the three exercise pedaling group at 2 days (10MWT p = .016; TUG p = .020) as was the patient reported Oxford Knee Score (OKS) (p = .034). The OKS, continued to be superior at 2 weeks (p = .007), and the VAS score was significantly better for the Pedaling-based group at all timepoints assessed. Length of stay was also significantly shorter by a half day, for the

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Pedaling-based group at 2.5 days, compared with the Multi-exercise at 3.0 days (p = .024).

The Multi-exercise protocol was not superior for any outcome measure at any timepoint.

Conclusions: A Pedaling-based protocol in the immediate post-operative period after TKR was superior to a standard Multi-exercise protocol in both functional and patient reported outcomes, with these benefits decreased over time.

Level of evidence: Therapeutic Level I

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Introduction

Rates of primary total knee replacement (TKR) for end stage knee osteoarthritis (OA) are increasing from 5 to 17% per year, on a background of increasing musculoskeletal disease expenditure[1]. As this knee OA healthcare cost burden will increase due to aging populations and rising obesity rates, it is vital to optimize all aspect of perioperative TKR management[2]. While TKR patients typically receive some form of physical therapy post-operatively, variations between institutions exist as to what type of therapy is prescribed on a background of paucity of evidence-based best practice, which can result in suboptimal outcomes at a greater cost[3]. While there is literature evaluating physical therapy following TKR, especially examining continuous passive motion, none we are aware of have had a focus on entire exercise protocols in the post-operative inpatient setting[4,5], making the formulation of clinical guidelines problematic[6].

Pedaling is often prescribed after TKR, with the circular motion being theorized to improve flexion range and actively recruit the quadriceps while generating low tibiofemoral forces that are less than half that of walking[7]. A poll of members of the American Association for Hip and Knee Surgeons revealed 96.4% consider pedaling to be an appropriate exercise for "unlimited activity"[8]. However, despite being frequently recommended, widely available, patient-driven and low-cost[9], to our knowledge there has been no investigation into pedaling's utility in the acute post-operative setting[10].

The purpose of this trial was to compare a three-exercise floor pedaling (Pedaling-based) protocol with a ten-exercise non-pedaling (Multi-exercise) protocol, both commenced within 24 hours of TKR and continuing as self-directed home programs for 2 weeks post-discharge. We hypothesized there would be no difference for any outcome measure between the two protocols.

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Materials and Methods

Trial Design

The study was a randomized controlled trial (RCT), designed and reported according to the CONSORT guidelines. Institutional review board approval was obtained, and the trial was prospectively registered at ANZCTR.org.au (12617000647336)[11].

Study Participants

Patients over the age of 18 years scheduled to undergo unilateral TKR for a primary diagnosis of OA were eligible for inclusion. Patients were excluded if they: a) pre-operatively planned to discharge to an inpatient rehabilitation/hostel facility such that the home exercise program could not be completed independently, b) declined to participate or c) were scheduled for a contralateral TKR within 4 months of the initial procedure. Patients were enrolled from June to December 2017, and randomly assigned to the Pedaling-based (intervention) protocol or to the Multi-exercise (control) protocol. Demographic data were collected including age, gender and body mass index (BMI), as well as pre-operative baseline scores for the Oxford Knee Score, maximum knee flexion, and ASA Physical Status Classification.

Randomization

Randomization with a 1:1 allocation ratio was performed using a computer-based random number generator, Research Randomizer (Version 4.0)12. Group allocation was concealed from both the allocator and the patient by opaque sealed envelopes. Individuals completed the random allocation sequence, patient enrollment, and outcome assessment. The patient, operating surgeon and assessing therapist were blinded to allocation. Participants were also blinded to group allocation and were not aware of the exercises each group performed.

Therapy sessions were undertaken one to one with the physical therapist independent of any

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other patient. During post-operative surgical rounds, the surgeon was blinded to the patient's

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group allocation. Exercise apparatus were removed from the patient's room and the surgeon was instructed not to discuss the patient's rehabilitation protocol. The chief investigator and treating physical therapist were required to be informed of the patient's group allocation, however, the assessing therapist was independent to the trial design and blinded to the patient's group allocation when carrying out testing protocols.

Surgical Procedure

A high-volume orthopedic surgeon with 16 years post arthroplasty fellowship performed all the procedures at Pindara Private Hospital in Queensland, Australia with a standardized perioperative protocol. Under tourniquet, a medial parapatellar approach was performed and all patients received computer navigated, cemented, fixed bearing, cruciate retaining Next Gen Total Knee Replacements (Zimmer, Warsaw, IN.) with patella resurfacing and cross-linked polyethylene. Pre-operatively patients received a low dose spinal anesthesia with 3ml 0.25% Bupivacaine and an ultrasound guided single-shot adductor canal block using 20ml of 0.75% Ropivacaine 1 hour prior to surgery. A posterior capsular and periarticular block was performed prior to component implantation with 20ml of 0.75% Ropivacaine diluted into 100ml saline. Surgical drains and indwelling urinary catheters were not used. A Buprenorphine 5mg (5ug/hr) patch was applied for 7 days, and as-required oral narcotics (oxycodone 5 – 10mg 4-6 hourly) were administered for breakthrough pain and after discharge. A stratified thromboembolism prevention protocol was undertaken with low-risk patients receiving Aspirin 100mg daily for 3 weeks and high-risk patients receiving Low Molecular Weight Heparin for 10 days then Aspirin for two weeks. All patients were prescribed intermittent foot pumps while inpatients and 45 degrees knee flexion over pillows while supine for the first 24 hours. All patients received Tranexamic acid intraoperatively, 1g Intravenously and 1g topically. All wounds were closed in flexion with subcuticular Monocryl (Ethicon, Cornelia, GA, USA) covered with adherent water-resistant dressings.

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Physical Therapy Interventions

Patients were first mobilized on the day of surgery and received 20 minutes of physical therapy, twice daily, until discharge. The Pedaling-based group's primary exercise was stationary pedaling on a set of floor pedals while seated, the height of the chair was adjusted for patient comfort. Patients were encouraged to commence with forwards/backwards half rotations until full revolutions could be achieved. Self-directed pedaling outside of the prescribed physical therapy periods was encouraged. Gait retraining and a knee extension stretch were also included in the pedaling protocol (Appendix Figure 1).

The Multi-exercise group received the hospital's existing 10-exercise program which was considered the standard of post-operative physical therapy care. This included seated knee bends, inner range quadriceps strengthening exercises and functional exercises such as supported mini squats and calf raises. The Multi-exercise group also received gait retraining and knee extension stretches (Appendix Figure 2). The patients were assisted by the therapist to perform exercises until they could be completed independently.

On discharge, both groups received a brochure detailing their allotted program and instructed to continue with their exercises, as a self-directed home program, twice daily for 20 minutes until the two week post-operative surgeon review. Patients were instructed to keep a record of their daily therapy regime in a diary to monitor compliance. The intervention phase of the trial ended at the 2 week assessment for both groups. Participants from both groups could then self-determine their rehabilitation until the final 4 month assessment.

Outcome Measures

Study outcomes were pre-specified at registration and prior to commencement of the trial. Performance-based physical function outcomes were measured at 2 days (T1), 2 weeks (T2) and 4 months (T3) post-surgery. The primary outcome of performance-based physical function was the TKR validated 6-minute walk test (6MWT)[12-15]. Secondary outcomes of

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performance-based physical function were the Timed Up and Go test (TUG), Timed 10-meter walk test (10MWT) and maximum knee flexion range of motion (KROM) measured in sitting. Other secondary outcomes measured were patient reported outcome measures (PROM) and pain scales including the Oxford Knee Score and the EQ-5D questionnaire incorporating a VAS quality of life scale[16-19]. Further perioperative outcomes included length of stay (LOS) post-surgery and the patient's "safe for discharge" status based on therapist-assessed standardized pre-defined criteria. Self-rated pain threshold (5-point Likert scale) and breakthrough analgesia consumption were recorded day 2 post-operatively, and self-rated satisfaction with the exercise protocol (5-point Likert scale) were recorded 2 days and 2 weeks post-operatively.

Sample Size

Based on previous published literature which used the 6MWT as a primary outcome measure in a TKR population, a sample size of 60 patients was required to detect a clinically meaningful change of 50 meters between groups, given 80% power and type 1 error rate of 5% (2-tailed analysis) and a within subject SD of 70m[20].

Statistical Analysis

Data were analyzed using the Statistical Package for Social Sciences (SPSS version 24)[21]. Descriptive statistics for continuous data are expressed as mean values with standard deviations (SD) and statistical significance considered as P values <.05. The chi-square test was used to analyze differences in baseline variables between groups with respect to categorical data. Categorical data are presented as counts and percentages. Normally distributed continuous data were analyzed using an independent samples t-test, with associated 95% confidence intervals. A non-parametric test, the Mann-Whitney U, was used when data was not normally distributed, and results presented as median and range.

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Stationary Floor Pedals (10) were purchased by the hospital at a fixed cost of $35.00 USD each, trial participants in the intervention group were loaned the Pedals and were asked to return the Pedals to the hospital on completion of the exercise period for future use (Figure 1).

This trial is registered: ANZCTR.org.au (12617000647336)

Results

Participant flow

Seventy eight patients were assessed for eligibility, of those, 17 did not meet the inclusion criteria and 1 refused participation. In total, 60 patients were consented and randomized to either the Pedaling-based protocol (n = 30) or the Multi-exercise protocol (n = 30) (Figure 2). No adverse events during the treatment period were incurred by participants.

Baseline characteristics

The two groups had similar clinical and demographic baseline characteristics and comparable levels of reported preoperative function and pain as assessed by the Oxford Knee and Lysholm Scores. (Table 1).

Numbers analyzed

All 60 participants received the intervention/control protocol they were assigned and were assessed for all primary and secondary outcome measures at 2 days (T1) and 14 days (T2) post-operatively. A final assessment was conducted at 4 months (T3), at this time 4 patients, 2 from each group, did not attend testing and were not included in the 4-month analysis.

Effect of Intervention

The primary and secondary outcome scores for all time points are shown in Tables 2 and 3.

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The primary outcome, the Six Minute Walk Test (6MWT), was significantly greater in the Pedaling-based group at 2 days (T1) post-operatively (mean difference 66 meters, p = .001). The Pedaling-based group had non-significant increases in distance over the Multi-exercise group at 2 weeks (mean difference 2 weeks = 42 meters, p = .073) and at 4 months (mean difference 4 months = 26 meters, p = .259).

In regard to secondary outcomes, the 10-meter walk speed (10MWT) and Timed Up and Go (TUG), were both significantly greater in the Pedaling-based group at 2 days (10MWT p = .016; TUG p = .020), but not significantly different at 2 weeks or 4 months. KROM was not significantly different at any timepoint. The OKS was significantly better for the pedaling group at 2 days (mean difference 4.5, p = .034) and 2 weeks (mean difference 5.6, p = .007); as was the EQ5D Score at 2 weeks (mean difference 1.3, p = .037). The VAS component of the EQ5D was significantly better for the pedaling group at all assessment time-points (p = .031 (T1); p = .050 (T2); p = .044 (T3)). At 4 months there was no significant difference in average mean OKS scores for both groups (Multi-exercise score = 37.6, Pedaling-based score = 39.3; p = .263).

Length of stay was shorter for the Pedaling-based group by a half day (p = .024). Analgesia consumption, home exercise program compliance, self-reported pain threshold or satisfaction with exercise protocols were similar.

Discussion

In this RCT, a Pedaling-based physical therapy protocol following TKR, in the acute post-operative period, commencing within 24 hours and continuing for 14 days, was superior to a Multi-exercise protocol in respect of both the primary outcome measure, the 6 Minute Walk Test, and a number of other clinically important secondary outcome measures examining pain

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and function. The Multi-exercise protocol was not superior for any outcome measure at any timepoint.

Optimal rehabilitation after joint replacement is lacking in robust clinical evidence, despite its significant health cost and described central role in patients' functional outcomes. Improving walking distance is a function that is "important to a great extent" early after surgery to patients, and as such the primary outcome measure of this study, the 6 Minute Walk Test, was a clinically appropriate functional primary outcome measure[22]. The Pedaling-based group walked 66m further in 6-min than the Multi-exercise group at day 2, notable given a small meaningful increase in 6-min walk distance has been defined as 20m, while a 50m increase or greater is substantial[23]. These differences are also consistent with other studies describing 6MWT distance improvements of between 36 – 61m as representing a meaningful clinical change[13,24].

The pedaling group also had better patient reported outcome measures, including the Oxford Knee Score, which measures knee pain and function from the patient's perspective, and the EQ5D, which includes a patient's self-rated health on a vertical visual analogue scale[17,18]. At both 2 days and 14 days, the pedaling group reported less pain and greater function with both the OKS and EQ5D, with the >4.5 points difference between the group's OKS being considered clinically meaningful[25]. In regard to perioperative measures, Length of Stay and Readiness for Discharge, the Pedaling-based group were significantly better for both, however a shorter time to discharge would be expected given this group were walking faster and further with less pain and greater function. A half-day LOS reduction would have a significant financial benefit to the private healthcare sector in Australia, equating to an approximate $400 **(Australian dollars, 2016)** saving per hospital stay for a TKR patient[26].

Other outcomes showed no difference. For uncertain reasons both groups had similar opiate consumption, despite the lower pain reported by the pedaling group. Moreover, the lower

reported pain and described benefits of pedaling for improving maximum knee flexion did not actually translate into improved flexion. Importantly, both protocols were similarly tolerated with respect to reported satisfaction, and all patients were able to complete their prescribed protocols without any untoward events.

The most profound differences between the two groups were at the earliest assessment at 2 days, with the benefits of the pedaling then decreasing over time. Hospital length of stay (LOS) rates after TKR are declining, with the mean inpatient period decreasing from 4.06 to 2.97 days in the United States from 2002 to 20132, and as a result the inpatient physical therapy undertaken in the immediate post-operative phase is of increasing importance. It was for this reason that our initial outcomes assessment was undertaken at day 2, prior to discharge, rather than later. At 2-weeks, the Pedaling-based group's PROMs remained superior, while the VAS scores were significantly better at all timepoints, including the 4-months final assessment. At 4-months, both groups had improved from baseline, but without any functional differences.

It should be emphasized that while the benefits of pedaling was the focus of this study, the pedaling group also underwent gait retraining and knee extension stretches as part of a complete rehabilitation protocol. Pedaling as a post TKR exercise in isolation could be potentially problematic as it doesn't retrain the patient's gait nor achieve full extension.

Another important difference between the two protocols is that while both had similar satisfaction, and due to ethical constraints mandating equal allocated therapist time, the simpler Pedaling-based protocol was more amenable to being self-directed compared to the more complicated Multi-exercise protocol.

A limitation of this study is its generalizability to other patients at other institutions. All TKR were performed by an experienced surgeon at a single high-volume institution, using cruciate-retaining prostheses, on patients planning discharge to home who received an

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anesthetic regime designed to allow day of surgery mobilization. Therefore, these results may not be generalizable when different anesthetic regimes are used or in patients who plan to discharge to an inpatient rehabilitation facility. Participant characteristics were similar to the overall primary TKR population, except both groups had a higher proportion of males.

In conclusion, a Pedaling-based physical therapy protocol after TKR was superior to a standard Multi-exercise protocol in the acute post-operative period. The Pedaling-based protocol was superior in both functional outcomes (6MWT, TUG, 10MWT) and PROMs (OKS, EQ5D, VAS) at day 2, and superior in PROMS at days 14 (OKS, EQ5D, VAS) and at 4 months (VAS). A Multi-exercise protocol was not superior for any outcome measure at any timepoint.

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Figure Legends

Figure 1. Stationary Floor Pedaling device, $35.00 USD

Figure 2. CONSORT (Consolidated Standards of Reporting Trials) diagram showing the flow of patients through the trial

Appendix Figure 1. Pedaling-Based Exercise Protocol

Appendix Figure 2. Multi-Exercise Protocol (2 pages)

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Table 1. Baseline preoperative characteristics of participants (*N* = 60).

Characteristic	**Standard Multi-Exercise Protocol (*n* = 30)**	**Bike Pedalling Protocol (*n* = 30)**
Age (yrs)	66.0 (8.7)	66.8 (6.7)
Gender, *n* (%)		
male	18 (60)	22 (77)
female	12 (40)	8 (23)
BMI (kg/m^2)	29.4 (4.4)	29.3 (4.3)
Oxford knee score	22.2 (5.4)	25.8 (6.7)
Lysholm knee score	45.4 (13.9)	50.6 (18.8)
Knee flexion (degrees), *median (range)*	110.0 (90.0-110.0)	110.0 (85.0-120)
ASA Physical Status Classification, *n* (%)		
I	2 (7)	2 (7)
II	19 (63)	21 (70)
III	9 (3)	7 (3)

All values are expressed as mean (SD) unless otherwise indicated.
BMI: body mass index.

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Table 2. Results of functional outcome measures (physical & patient reported) at all timepoints

	Multi-Exercise Protocol		Pedaling-Based Protocol			
Outcome	***n***	**Mean (SD)**	***n***	**Mean (SD)**	**Mean difference (95% CI)**	***p*-value**
6 Min Walk test (Meters)**						
2 days	30	187.0 (67.0)	30	252.9 (73.5)	65.8 (29.4 to 102.2)	0.001*
14 days	30	348.6 (81.8)	30	390.2 (94.2)	41.6 (4.0 to 87.2)	0.073
4 months	28	488.3 (89.7)	28	514. 0 (78.5)	25.7 (19.5 to 70.9)	0.259
10m walk speed (Meters/Second)						
2 days+	30	0.60 (0.20 to 1.10)	30	0.70 (0.50 to 1.50)		0.016*
14 days+	30	1.05 (0.70 to 1.70)	30	1.15 (0.70 to 2.30)		0.199
4 months	28	1.50 (0.25)	28	1.54 (0.24)	0.04 (0.01 to 0.12)	0.592
TUG walk test (Seconds)						
2 days+	30	23.9 (12.6 to 54.3)	30	19.3 (9.4 to 40.2)		0.020*
14 days+	30	10.7 (6.4 to 24.4)	30	10.0 (5.7 to 18.5)		0.662
4 months	28	7.1 (1.3)	28	6.9 (1.3)	-0.2 (-0.5 to -0.9)	0.578
Knee Flexion (Degrees)						
2 days	30	90 (50 to 110)	30	90 (80 to 115)		
14 days	30	93 (70 to 150)	30	95 (80 to 125)		
4 months+	28	110.4 (9.1)	28	113.0 (10.4)	2.7 (2.6 to 7.9)	0.310
Oxford Knee Score						
2 days	30	20.2 (7.4)	30	24.7 (8.5)	4.5 (0.34 to 8.6)	0.034*
14 days	30	23.1 (7.9)	30	28.8 (7.6)	5.6 (1.6 to 9.7)	0.007*
4 months	28	37.6 (4.8)	28	39.3 (6.1)	1.7 (1.3 to 4.6)	0.259
EQ-5D-5L Score						
2 days	30	12.1 (3.1)	30	11.1 (3.5)	1.0 (-0.7 to 2.7)	0.244
14 days	30	10.4 (2.6)	30	9.0 (2.2)	1.3 (0.1 to 2.6)	0.037*
4 months+	28	7.0 (5.0 to 11.0)	28	6.0 (5.0 to 11.0)		0.263
EQ-5D-5L VAS						
2 days+	30	60 (10 to 95)	30	80 (25 to 100)		0.031*
14 days+	30	75 (50 to 97)	30	88 (40 to 100)		0.050*
4 months+	28	88 (50 to 100)	28	90 (75 to 100)		0.044*

* Statistically significant difference (P value < 0.05)
** Primary Outcome Measure
+ Values reported as Median (Range)

Table 3. Results of perioperative measures, pain and satisfaction scales at indicated timepoints

	Multi-Exercise Protocol		Pedaling-Based Protocol		
Outcome	***n***	**Median (Range)**	***n***	**Median (Range)**	***p*-value**
LOS (Days)	30	3.0 (2.0 to 6.0)	30	2.5 (2.0 to 5.0)	0.024*
Readiness for DC (Days)[+]	30	2.0 (1.0 to 4.0)	30	2.0 (1.0 to 4.0)	0.002*
PRN Analgesia (Mg Endone)					
2 days	30	10.0 (0.0 to 40.0)	30	5.0 (0 to 60.0)	0.350
Pain Threshold^					
2 days	30	2.0 (1.0 to 4.0)	30	2.0 (1.0 to 5.0)	0.557
Protocol Satisfaction^^					
2 days	30	1.0 (1.0 to 2.0)	30	1.0 (1.0 to 3.0)	0.115
14 days	30	1.0 (1.0 to 2.0)	30	1.0 (1.0 to 3.0)	0.687
HEP Compliance					
14 days	30	100 (55 to 100)	30	100 (50 to 100)	0.314

* Statistically significant difference (P value < 0.05)
[+] Difference indicated by Mean Ranks: Pedaling Protocol (24.1) was better than Standard Protocol (36.9); $U = 257.00$
^ Likert Scale: High Pain threshold 1 (strongly agree) to 5 (strongly disagree)
^^ Likert Scale: Protocol Satisfaction 1 (very satisfied) to 5 (very dissatisfied)

Figure 1

Figure 2

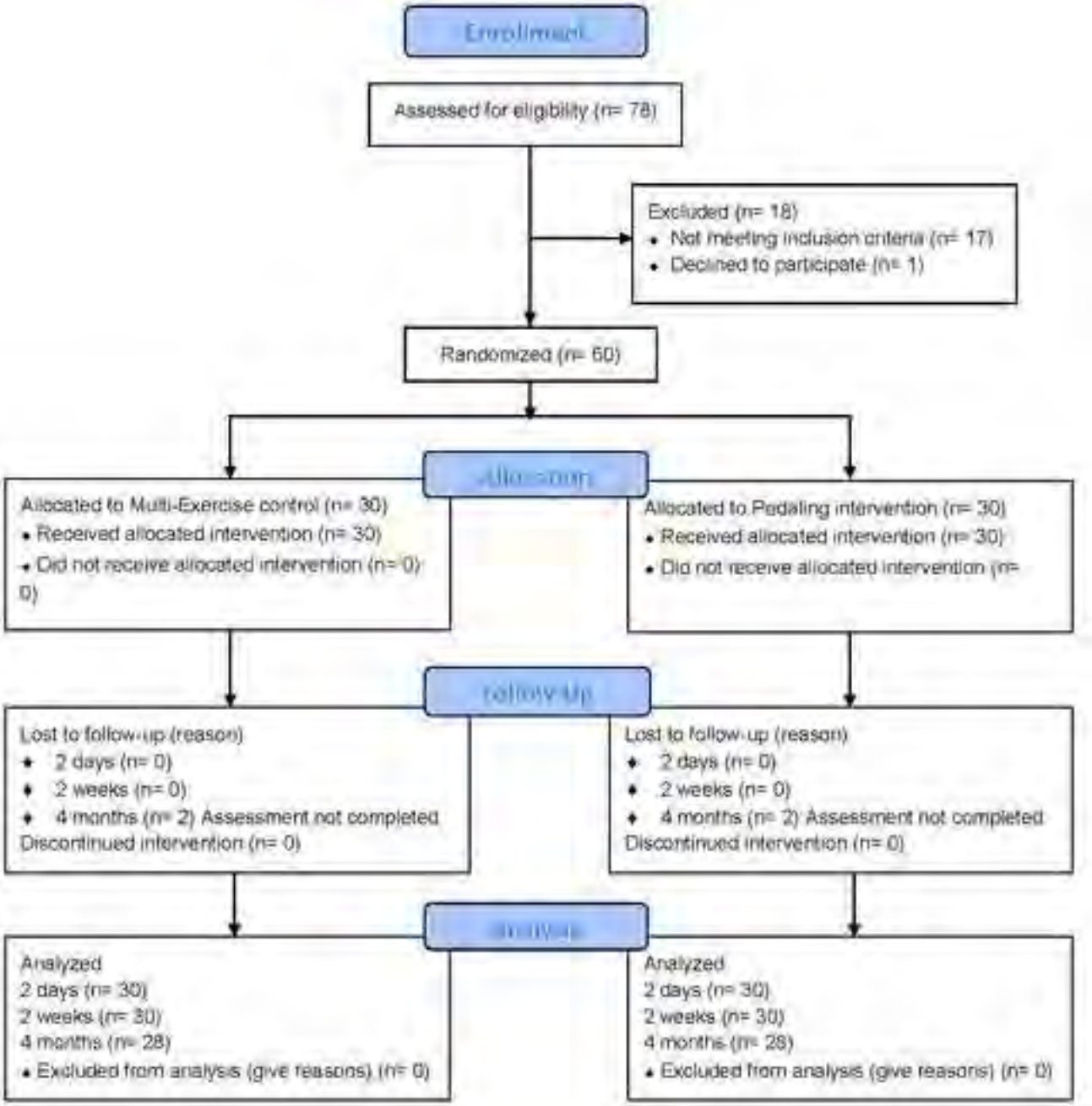


Fig. 2
CONSORT (Consolidated Standards of Reporting Trials) diagram showing the flow of patients through the trial

Appendix Figure 1

Heel - Toe Walking

Take a step and land with heel on floor.

Stretching: Hamstring/Calf – Theraband

While lying safely in bed.
With knee straight, loop theraband around foot.
Gently pull on theraband until stretch is felt in hamstring/calf.
Hold __30__ seconds.

Repeat 5 times per set.
Do 2 sessions per day.

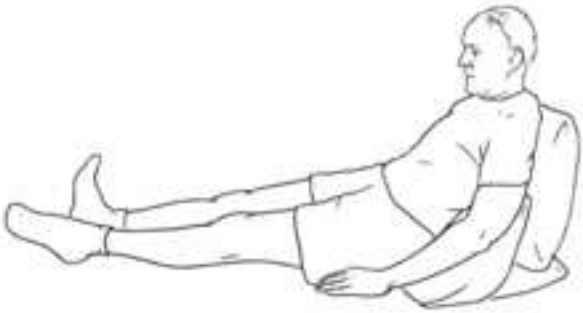
Bike Pedaling

Place hands on seat or arms of chair for support and turn pedals backwards and forwards until able to comfortably achieve a full rotation.

Repeat 30 revolutions.
Do 2 sessions per day.

Appendix Figure 2

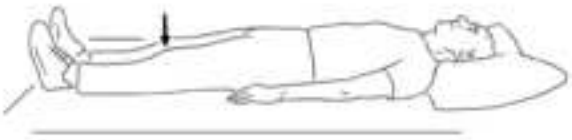
ANKLE PUMPS



Bend ankles up and down, alternating feet.

Repeat __10__ times. Do __2__ sessions per day.

THIGH MUSCLE CONTRACTION



With leg out straight tighten quadriceps by pushing back of knee into surface. Hold 3-5 seconds.
10 reps per set, 2 sets per day

HEEL RAISE WITH TOWEL ROLL UNDER KNEE

Lying on back with rolled towel (about 6 inches wide) under knee, slowly straighten knee to fully extended (straight) position. Hold 3-5 seconds, then relax. Repeat with other knee.

Repeat __10__ times. Do __2__ sessions per day.

STRAIGHT LEG RAISE

Keep operated leg as straight as possible and tighten muscles on top of thigh. Slowly lift straight leg off the bed and hold 3-5 seconds. Lower it, keeping muscles tight. Relax.

Repeat __10__ times. Do __2__ sessions per day.

KNEE/CALF STRETCH

Sit with knee straight and theraband or towel looped around foot. Gently pull on towel and push knee down into bed until stretch is felt behind knee.

Hold 30 seconds.

Repeat 5 times
Do 2 sessions per day.

HEEL SLIDE KNEE BENDS

Bend knee and pull heel toward buttocks.

Repeat __10__ times. Do __2__ sessions per day.