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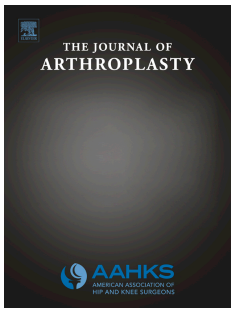

Stratification of Outpatient Physical Therapy Following Total Knee Arthroplasty: Knee Arthroplasty Physical Therapy Pathways (KAPPA) Non-Randomized Controlled Trial

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Stratification of Outpatient Physical Therapy Following Total Knee Arthroplasty: Knee Arthroplasty Physical Therapy Pathways (KAPPA) Non-Randomized Controlled Trial

Abstract

Background

Outpatient physical therapy following total knee arthroplasty (TKA) is often considered crucial for an effective recovery. However, recent evidence suggests that a self-directed pathway may yield similar benefits to supervised care. Despite this, there appear to be no established criteria to determine who can successfully self-direct their rehabilitation versus those who would benefit from outpatient physical therapy. This study aimed to determine if early postoperative criteria can stratify TKA patients into a self-directed or supervised physical therapy pathway without compromising outcomes.

Methods

Overall, sixty TKA patients were initially allocated to a self-directed, unsupervised protocol for their postoperative rehabilitation. Baseline demographics, along with functional and self-reported outcomes, were assessed preoperatively and at two weeks, six weeks, and four months following surgery. Patients were referred to supervised outpatient physical therapy if they met any of the following KAPPA criteria: 1) knee flexion range of motion (ROM) <90 degrees; 2) knee extension ROM lacking > 10 degrees; or 3) dissatisfaction with the progress of their rehabilitation.

Results

At two weeks post-TKA, 28 participants met the KAPPA criteria for supervised physical therapy for reasons of knee flexion < 90 degrees (61%), a lack of knee extension > 10 degrees (36%), or not being satisfied with the progress of their recovery (3%). The remaining 32 participants continued with a self-directed rehabilitation pathway. All outcomes assessed favored the self-directed group at two weeks, however, after an average of four supervised physical therapy sessions at four months there were no longer any differences between the two groups.

Conclusions

Over half of the included participants in this study could successfully self-direct their rehabilitation following TKA without supervised physical therapy while also maintaining excellent clinical and self-reported outcomes. For those who met the KAPPA criteria at two weeks post-TKA, four supervised physical therapy sessions appeared to be beneficial when outcomes were reassessed at four months.

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Keywords: knee arthroplasty, physical therapy, physiotherapy, rehabilitation, sustainable healthcare, postoperative care

Introduction

The global burden of knee osteoarthritis and subsequent total knee arthroplasty (TKA) surgeries is expected to increase due to a growing aging population, rising obesity rates, and sports-related knee injuries, resulting in increased healthcare costs. [1, 2]. Given the existing and predicted future financial burden associated with TKA procedures, it is crucial to critically evaluate the efficacy and economic efficiency of perioperative care, including physical therapy, which features in most TKA rehabilitation protocols [3, 4]. Recently, surgical advancements along with the adoption of Enhanced Recovery After Surgery (ERAS) arthroplasty pathways have led to progress in pain management, faster functional recovery, and earlier discharge from the hospital, resulting in significant economic benefits [5]. The improvements in clinical outcomes and shorter hospital lengths of stay for patients undergoing TKA bring into question the role of continued outpatient physical therapy post-discharge and whether there is an opportunity for further cost savings [6-8].

A systematic review reporting on the global utilization of outpatient physical therapy following TKA found Australia had the highest rate (85%) of supervised physical therapy post-discharge from the acute inpatient hospital setting, and a similar proportion (79%) was reported in the United Kingdom [3]. However, this widespread use of supervised physical therapy post-TKA contrasts with evidence suggesting non-inferior outcomes for the majority of those who undergo unsupervised or self-directed rehabilitation, while also offering greater convenience for patients and potential savings for service providers [8-14]. Despite the evidence supporting self-directed rehabilitation for individuals post-TKA, there appears to be no established criteria to assist clinicians and policymakers in determining who would be more likely to have improved outcomes with supervised physical therapy [8, 12]. Given that a proportion of patients, reportedly up to 20% [1, 15-18], experience dissatisfaction following TKA, supervised physical therapy intervention is likely to still be essential to maximizing functional outcomes and satisfaction in some individuals [18-21].

Past studies that have compared a self-directed rehabilitation pathway to supervised physical therapy post-TKA have mostly done so by utilizing randomized methodology [11, 13, 14, 22].

However, there are some key limitations to a randomized study design in this population, such as inclusion criteria favoring healthier individuals and a selection bias for participants willing to be randomized to unsupervised care. Therefore, the aim of the Knee Arthroplasty Physical Therapy Pathways (KAPPA) trial was to determine if early postoperative criteria can be established to stratify TKA patients into a self-directed rehabilitation or supervised physical therapy pathway without compromising clinical outcomes or patient satisfaction.

Material and Methods

This study received Institutional Review Board approval from the Bond University Human Research Ethics Committee (BUHREC LS00163) and was prospectively registered with the Australian New Zealand Clinical Trials Registry (Identifier ACTRN12621000974808). The study was designed and reported in accordance with the Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) statement guidelines [23].

Study Participants

Patients ≥ 18 years of age who were scheduled to undergo unilateral TKA for a primary diagnosis of osteoarthritis were eligible for inclusion and were enrolled from January 31st, 2022, to January 20th, 2023. Patients were excluded if they (1) preoperatively planned to be discharged to an inpatient rehabilitation/hostel facility, (2) were scheduled for a contralateral TKA within 4 months of the initial procedure, or (3) declined to participate.

Sample size, Recruitment, and Consent

A sample size of 60 participants was calculated based on a minimum clinically important difference (MCID) of 50 meters for the primary outcome, the six-minute walk test (6MWT), which has previously been used in TKA populations [24-26]. Participants were recruited from a single site within a private healthcare setting by a nurse practitioner independent of the study who provided patients with the participant information form and gained consent from those who wished to participate in the study. An initial 72 participants were eligible for inclusion in the study, with 9 declining due to travel reasons and 3 excluded for planned contralateral TKA within the four-month follow-up period, leaving 60 individuals consenting to participate (Figure 1).

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Surgical Techniques and Perioperative Protocols

All patients received a cemented cruciate-retaining total knee arthroplasty with patella resurfacing through an anterolateral incision and medial parapatellar approach. The anesthetic protocol included spinal anesthesia, an adductor canal nerve block, and a periarticular block of local anesthetic to the operative limb, along with tranexamic acid administered intravenously and applied topically to the joint before closure. Postoperatively, patients underwent an enhanced recovery pathway that included day-of-surgery mobilization with a physical therapist and a 3-exercise pedaling-based protocol until discharge [26]. The criteria for home discharge were independent transfers and mobility with the walking aid to be used at home, safe stair climbing assessment, and a knee flexion range of motion of 90 degrees achieved during the inpatient stay.

Allocation Procedure

The KAPPA criteria for referral to supervised physical therapy post-TKA were developed based on clinically important outcomes, including knee range of motion (ROM) and self-reported patient satisfaction. Knee ROM has been found to positively correlate with knee function and other clinical outcomes following TKA. Conversely, suboptimal knee ROM may be associated with restrictions on activities of daily living and, thus a lower quality of life [27-31]. Moreover, although the exact reasoning remains uncertain, patient dissatisfaction following TKA is often reported as up to 20% [1, 15-18]. Therefore, the KAPPA criteria for referral for supervised physical therapy were based on knee ROM and self-reported patient satisfaction outcomes when assessed at both two weeks and six weeks following TKA.

KAPPA criteria for referral for supervised outpatient physical therapy:

- Knee flexion ROM < 90 degrees
- Knee extension ROM lacking in > 10 degrees
- Dissatisfaction with the progress of recovery since surgery

Patients in the study who did not meet any of the KAPPA criteria for referral to supervised physical therapy at two weeks or six weeks following their TKA continued with self-directed rehabilitation at home. Due to the nature of the study, both participants and the physical therapists delivering the intervention could not be blinded to their group assignment.

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Interventions

All participants in the study initially commenced the self-directed rehabilitation protocol [26] at home following discharge from the inpatient hospital setting until two weeks post-surgery, when they were reviewed by a physical therapist. The self-directed protocol consisted of three exercises: seated pedaling, a knee extension stretch, and heel-toe walking practice, which was recommended to be performed three times a day or more if the patient felt comfortable doing so. Participants who met any of the KAPPA criteria were referred for individually supervised physical therapy at an outpatient clinic. Supervised physical therapy was patient-centered, and the intervention type, duration, and frequency of sessions were determined by the treating physical therapist.

Outcomes

Except for postoperative satisfaction, all outcomes were assessed one week before surgery, as well as postoperatively at two weeks, six weeks, and four months following TKA surgery. The primary outcome was the 6MWT, with secondary outcomes being knee ROM flexion and extension (measured with a long-arm goniometer), Oxford Knee Score (OKS), EuroQol EQ5D-5L instrument, which comprises five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression and the EuroQol EQ5D-VAS measuring self-rated health, as well as patient-reported satisfaction on a 5-point Likert scale.

Data Analyses

Data were analyzed using the Statistical Package for Social Sciences (IBM SPSS version 29, Armonk, New York, USA). Descriptive statistics for continuous data are expressed as mean (standard deviation) or median (range) depending on the data distribution, and statistical significance is considered as P values < 0.05. Categorical variables were summarized using counts and percentages. Normally distributed continuous data were analyzed using independent samples t-tests, with associated 95% confidence intervals (CIs). The non-parametric tests (Mann-Whitney U test) were used when data were not normally distributed, with results presented as the medians and ranges.

Results

Participant Flow

157 At two weeks post-TKA, 28 out of the 60 trial participants (47%) met the KAPPA assessment criteria
158 for referral for supervised physical therapy for reasons of knee flexion < 90 degrees (n = 17; 61%), a
159 lack of knee extension > 10 degrees (n = 10; 36%), or not being satisfied with the progress of their
160 recovery (n = 1; 3%). The remaining 32 participants (53%) continued with a self-directed
161 rehabilitation pathway. At six weeks post-TKA, after an average of four supervised physical therapy
162 sessions, 22 of the 28 participants no longer met the KAPPA criteria, were discharged from physical
163 therapy, and progressed to self-directed rehabilitation, leaving six individuals receiving supervised
164 care. At four months post-TKA, a further five participants were discharged from physical therapy,
165 leaving one participant continuing with supervised care based on the KAPPA criteria. Although across
166 the four-month duration of the study, 27 of the 28 patients were discharged from supervised physical
167 therapy, the data analyses of the groups at each assessment timepoint continued to include the
168 participants from the original two-week KAPPA criteria allocation to either self-directed (n = 32) or
169 supervised physical therapy (n = 28). Participant flow throughout the study is reported in full in
170 Figure 1.
171

172 *Baseline Participant Characteristics and Function*

173 Both the self-directed and supervised physical therapy groups had similar clinical and demographic
174 baseline preoperative characteristics and comparable outcomes of self-reported function, quality of
175 life, and pain as assessed by the Oxford Knee Score and the EQ5D, along with the EQ5D-VAS. For
176 measures of physical function, preoperative knee flexion and extension ROM were similar, however,
177 the mean distance walked for the 6MWT for the self-directed group was 51 meters further compared
178 to the physical therapy group (MD 50.5 meters, 95% CI 0.7 to 100.3; *P* = 0.047). Values for all baseline
179 preoperative characteristics and outcomes are reported in Table 1.
180

181 *Physical Function*

182 The primary outcome, the 6MWT, along with secondary outcomes, knee flexion and extension ROM,
183 were utilized to assess physical function at all post-surgery timepoints (two weeks, six weeks, and
184 four months) for both groups. Both the 6MWT and knee flexion and extension ROM were
185 significantly different between the two groups at two weeks and six weeks, with the greatest
186 difference favoring the self-directed group at the two-week assessment for the 6MWT and knee
187 flexion ROM (6MWT MD 112 meters, 95% CI 70.0 to 155.5; *P* = < 0.001; Knee flexion ROM MD 19.4

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degrees, 95% CI 13.9 to 24.8; *P* = < 0.001). However, at four months post-surgery, no significant differences in any physical function outcome measures were seen between the two groups (Table 2).

Patient-Reported Outcome Measures

Similar to the results observed for physical function, patient-reported outcome measures (PROMs) significantly favored the self-directed group at two- and six weeks post-surgery for the OKS, EQ5D, and satisfaction scale, except for the EQ5D-VAS, which was only different between the groups at the two-week assessment timepoint. In accordance with all other outcomes assessed, no significant differences in PROMs between groups remained four months post-surgery (Table 2).

Discussion

The results of the KAPPA trial support the feasibility of self-directed rehabilitation and have established potential early postoperative criteria to indicate who may benefit from referral to supervised physical therapy at two weeks post-surgery. The analysis of preoperative characteristics and outcomes for both groups showed similarity across all measures, except for the 6MWT, for which the difference was 50.5 meters (*P* = 0.047). However, although this finding was statistically significant, the clinical impact may be doubted, as this difference in walk distance is only bordering on meaningful importance to TKA patients [24-26]. Concerning postoperative outcomes, the largest differences favoring the self-directed group, which were also clinically meaningful [24-26, 32, 33], were seen at the earliest postoperative assessment (two weeks), with those differences decreasing over time (six weeks) and no longer any differences observed at four months post-surgery.

Given the growing focus on value-based care, it becomes crucial to evaluate the clinical effectiveness and economic efficiency of routine measures like postoperative supervised physical therapy, particularly in light of the existing evidence for the non-superiority of supervised physical therapy compared with unsupervised care for TKA patients [11, 13, 14, 22]. Although this existing literature provides support for self-directed pathways in select populations, guidelines call for additional research, including studies that identify patient characteristics that make an individual better suited to more supervision for their rehabilitation after discharge [34-36]. A strength in the design of the KAPPA study is that the criteria for self-directed or supervised physical therapy referral can be

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broadly applied to TKA patients who have a planned home discharge following surgery, thus potentially assisting in closing the knowledge gap on which individuals are better suited to self-directed or supervised outpatient physical therapy care.

The KAPPA trial demonstrated that approximately half of the included TKA patients could successfully self-rehabilitate and achieve excellent physical and self-reported outcomes. The group that self-directed their rehabilitation at four months post-TKA had an average 6MWT distance of 458 meters, which was 38 meters further than pre-surgery and 34 meters further than the supervised physical therapy group at four months post-surgery. For knee ROM at four months, the self-directed group had regained their preoperative flexion (118 degrees), had an OKS of 42, and their EQ5D mean was 6.3, which both exceed the patient acceptable symptom state thresholds for patients who have undergone total knee arthroplasty [37, 38]. This indicates that when the criteria established by the KAPPA trial are applied to TKA patients, these individuals can self-direct their rehabilitation, and successful outcomes can be achieved.

Knee ROM was the only physical criteria used to stratify patients in the KAPPA cohort; thus, a significant difference between the two groups was expected. However, interestingly, all other outcomes assessed at two weeks were also largely different between those stratified into self-directed or supervised physical therapy groups. This supports previous literature that suggests that knee ROM corresponds to other clinical and self-reported outcomes [27-31]. There are positive clinical implications for this finding in that the assessment of knee ROM using a long-armed goniometer can easily be performed by an orthopaedic specialist or physical therapist, is widely accessible, quick to measure, inexpensive, and has good intra- and inter-rater reliability, and the results appear to correspond to other more time-consuming assessments [39].

There are several potential strengths and limitations to this study that should be noted. Although randomized controlled trials are usually considered the gold standard in experimental research, this study used a non-randomized methodology to determine if novel criteria could stratify patients into self-directed and supervised physical therapy groups without compromising clinical outcomes. The stratification of patients into different rehabilitation pathways more closely matches clinical practice, and this study has provided a tool that has the potential to assist surgeons and physicians in that decision-making process. The non-randomized design also has the potential to reduce the selection

bias for patients willing to receive no intervention, as the groups are allocated based on clinical criteria rather than via random assignment. However, a limitation of this study was that for those who were identified to be most suited for supervised physical therapy through the KAPPA criteria, there was not an equivalent non-intervention group. Thus, it is likely that the passage of time was a confounding variable that also contributed to the improvements seen in the supervised physical therapy group.

Identifying slow-to-recover patients and offering no intervention may present some ethical considerations, however, future research could explore a delayed intervention group where referral to supervised physical therapy occurred at the six-week assessment time point. This may lead to a better understanding of which slow-to-recover patients identified at two weeks continue to improve without supervised physical therapy when reassessed at six weeks, thus further improving the efficiency of care. Another potential limitation of this study is that the longest follow-up assessment time point was four months, whereas outcomes are commonly recorded for a minimum of one year in TKA study populations. However, outpatient supervised physical therapy is most often performed for up to a maximum of two to three months following TKA, including for those with a slower than normally expected recovery [3, 34, 35, 40]. Further, given there were no longer any significant differences between the results of the two groups at four months, extending the follow-up period may not contribute substantially to the research findings. Also, there may be a limitation to the generalizability of the results of this study to patients in different settings, as all surgeries were performed by a fellowship-trained knee arthroplasty surgeon at a single high-volume institution.

The KAPPA criteria in this study demonstrated that participants with less than 90 degrees of knee flexion ROM or more than 10 degrees lacking in knee extension ROM also have inferior scores for PROMs, including the OKS and EQ5D, and walk a lesser distance at two weeks after surgery. Evaluating the generalizability of the KAPPA criteria should now be applied in future studies with more diverse patient populations to determine if it still provides a valid way to stratify TKA patients for self-directed rehabilitation. This study did not find a strong preoperative predictor for which patients were most likely to meet the KAPPA criteria for referral to supervised physical therapy when assessed postoperatively. A correlation between preoperative variables and postoperative outcomes may be more likely to be seen in a population with more diverse baseline patient characteristics.

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Conclusions

The results of the KAPPA trial demonstrated that just over half of the included participants could successfully self-direct their rehabilitation following TKA without supervised physical therapy while also maintaining excellent clinical and self-reported outcomes. Despite knee ROM being the only physical assessment used within the KAPPA criteria to stratify patients for either self-directed rehabilitation or supervised physical therapy, it corresponded to all other outcomes when assessed at two weeks post-TKA.

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Table 1. Baseline preoperative characteristics of participants

	Self-directed (*n* = 32)	**Supervised Physical Therapy** (*n* = 28)	***P*-value**
Age (years)	69.0 (6.9)	68.3 (8.3)	*NS*
Sex, *n* (%)			
Men	17 (53)	15 (54)	*NS*
Women	15 (47)	13 (46)	
Body Mass Index	29.2 (3.3)	29.6 (3.6)	*NS*
ASA Physical Status, *n* (%)			
I	3 (8)	2 (7)	*NS*
II	20 (62)	18 (65)	*NS*
III	10 (30)	8 (28)	*NS*
Oxford Knee Score	25.1 (7.3)	25.1 (8.9)	*NS*
EQ-5D-5L Score	11.2 (2.2)	11.4 (3.9)	*NS*
EQ-5D-5L-VAS	75.2 (13.1)	73.6 (16.8)	*NS*
Knee Range of Motion (degrees)			
Extension lack, median (range)	5.0 (0.0-20.0)	7.5 (0.0-30.0)	*NS*
Flexion, median (range)	120.0 (75.0-135.0)	117.5 (80.0-135.0)	*NS*
*Six-minute Walk Test (meters)	420.5 (96.8)	370.0 (95.3)	0.047

All values are expressed as mean (SD) unless otherwise indicated.
*Statistically significance (*P* = < 0.05); *NS* = non-significant; *n* = number; ASA = American Society of Anesthesiologists

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Table 2. Results of physical function and patient-reported outcome measures

Outcome Measure	Self-Directed (*n* = 32)	Supervised Physical Therapy (*n* = 28)	Mean difference (95% CI)	*P*-value
		Mean (SD)		
6 Minute Walk test (Meters)				
Pre-surgery*	420.5 (96.8)	370.0 (95.3)	50.5 (0.7 to 100.3)	**0.047**
2 weeks*	335.9 (84.2)	223.2 (78.6)	112.7 (70.0 to 155.5)	**<0.001**
6 weeks*	427.8 (87.7)	344.5 (104.3)	83.3 (33.7 to 133.0)	**<0.001**
4 months	458.0 (102.8)	424.0 (84.4)	34.0 (-14.0 to 84.0)	0.081
Knee Extension (Lack of Degrees)				
Pre-surgery^	5.0 (0.0-20.0)	7.5 (0.0-30.0)		0.139
2 weeks^*	10.0 (0.0-10.0)	15 (0.0-25.0)		**<0.001**
6 weeks^*	5.0 (0.0-10.0)	10 (0.0-20.0)		**0.041**
4 months^	0.0 (0.0-10.0)	5.0 (0.0-20.0)		0.163
Knee Flexion (Degrees)				
Pre-surgery	117.3 (14.0)	114.8 (13.1)	2.5 (-4.5 to 9.6)	0.238
2 weeks*	100.8 (9.1)	81.4 (11.9)	19.4 (13.9 to 24.8)	**<0.001**
6 weeks*	110.9 (8.8)	101.8 (12.6)	9.1 (3.6 to 14.7)	**<0.001**
4 months	117.9 (8.4)	115.0 (5.1)	2.9 (-.8 to 6.6)	0.060
EuroQol EQ-5D-5L Score				
Pre-surgery	11.2 (2.2)	11.4 (3.9)	0.2 (-1.8 to 1.4)	0.384
2 weeks*	10.3 (2.6)	12.7 (2.5)	2.4 (1.1 to 3.8)	**<0.001**
6 weeks*	7.9 (1.6)	9.3 (2.3)	1.4 (0.3 to 2.4)	**0.012**
4 months	6.3 (1.1)	6.8 (1.3)	0.5 (-.1 to 1.4)	0.062
EuroQol EQ-5D-5L Visual Analogue Scale				
Pre-surgery	75.2 (13.1)	73.6 (16.8)	1.6 (-6.1 to 9.3)	0.343
2 weeks*	75.3 (12.8)	66.7 (16.6)	8.6 (1.2 to 16.1)	**0.012**
6 weeks	84.2 (9.5)	80.9 (8.6)	3.3 (-1.4 to 8.0)	0.173
4 months	89.3 (6.9)	86.3 (8.5)	3.0 (-1.1 to 7.0)	0.072
Oxford Knee Score				
Pre-surgery	25.1 (7.3)	25.1 (8.9)	0.0 (-4.2 to 4.2)	0.497
2 weeks*	26.7 (8.9)	20.2 (8.8)	6.5 (2.0 to 11.1)	**0.003**
6 weeks*	35.3 (5.4)	31.1 (7.9)	4.2 (0.6 to 7.6)	**0.011**
4 months	42.2 (3.7)	40.6 (5.4)	1.6 (-1.2 to 5.1)	0.211
Satisfaction				
2 weeks^*	5.0 (3.0-5.0)	4.0 (1.0-5.0)		**0.002**
6 weeks^*	5.0 (3.0-5.0)	4.0 (3.0-5.0)		**0.003**
4 months^	5.0 (3.0-5.0)	5.0 (3.0-5.0)		0.575

* Statistically significant (P value < 0.05)
^ Values reported as Median (Range)
SD = Standard Deviation; CI = Confidence Interval

Figure 1. Participant flow

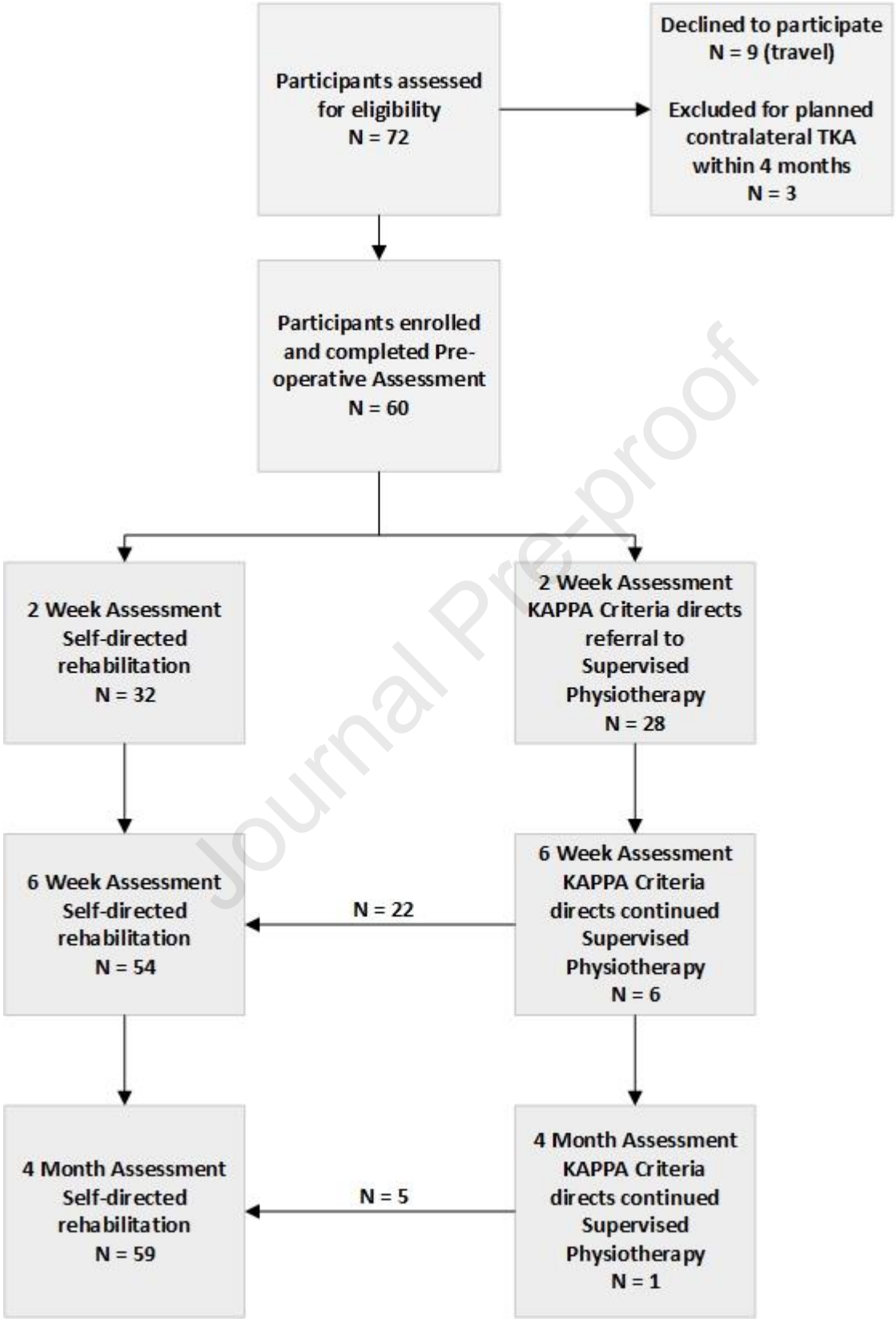

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Figure Legend

Figure 1. Participant flow

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