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## Accepted Manuscript

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## **EFFECT OF TOTAL KNEE REPLACEMENT SURGERY AND POSTOPERATIVE 12 MONTH HOME EXERCISE PROGRAM ON GAIT PARAMETERS**

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**Highlights**

- -Long term exercise after total knee arthroplasty improve maximal gait velocity
- -Higher knee extension and flexion strength is associated with maximal gait velocity
- -Decrease in knee pain during loading is associated with higher gait velocity

**Abstract**

**Objective:** To evaluate the effects of surgery and a postoperative progressive home exercise program on gait parameters among individuals operated with total knee arthroplasty.

**Design:** Single blinded randomized controlled trial.

**Subjects:** 108 patients (84 females, 24 males, mean age 69 years).

**Interventions:** Patients were equally randomized into an exercise group (EG) and control group (CG). The 12-months progressive home exercise program starting two months postoperatively was compared to usual care.

**Methods:** Gait analysis was performed using the Gaitrite electronic walkway system. In addition, knee extension and flexion strength were measured by a dynamometer preoperatively, and pain on visual analog scale (VAS) at two months and 14 months postoperatively.

**Results:** At the 12-month follow-up, maximal gait velocity ( $p= 0.006$ ), cadence ( $p= 0.003$ ) and stance time ( $p=0.039$ ) showed a greater increase among EG than CG. All the other gait parameters improved among both groups, but with not statistically discernible difference between groups. Weak correlations were found between changes in maximal gait velocity and the knee extension ( $r= -.31$ ,  $p= 0.002$ ), flexion strength ( $r=.28$ ,  $p= 0.004$ ) and pain during loading ( $r= -.27$ ,  $p= 0.005$ ) values.

**Conclusion:** The intervention produced statistically significant changes in maximal gait velocity, cadence and stance times in the exercise group compared to controls. Although the average change was small it is of importance that biggest changes occurred in those with low performance.

**Keywords:** osteoarthritis, total knee arthroplasty, gait parameters, home exercise program

The study has been registered in ClinicalTrials.gov (NCT00605124).

## **Introduction**

Total knee arthroplasty (TKA) is an effective treatment to reduce pain and subjective disability in patients with osteoarthritis of the knee, but several studies have shown that muscle strength deficiency [1-3] and functional limitations may persist for several years after the operation [4-6].

The radiological degree of severity of knee arthrosis has an influence on gait and compensatory mechanisms during walking [7,8]. Gait velocity among individuals with knee arthrosis has been established to be slower than among healthy controls at same age [8,9-12]. Among individuals with knee arthrosis average gait velocity is 23 %, cadence 33 % lower and step length 13 % shorter than among healthy controls [13]. Furthermore, despite having the same gait velocity, the duration of the support phase of the gait cycle becomes slightly longer among knee OA individuals than healthy controls [12,14,15]

Previous investigations have explored TKA and its influence on gait. Kramers-de Quervain et al. [16] stated that gait velocity and cadence were significantly improved two years after TKA surgery. Thewlis et al. [17] found that the detected gait asymmetries before the TKA, were no longer identified at six months postoperatively. Rehabilitation protocols for patients after TKA are often institution specific and no universally accepted protocol exists [18]. In a systematic review by Pozzi et al. [18], it was concluded that optimal physical therapy protocols after TKA should include progressive strengthening and intensive functional exercises either through land-based or aquatic programs. Studies included in the review used intervention durations from 4 to 12 weeks and to our knowledge studies investigating the long-term training effects on gait parameters in patients after TKA do not exist.

The primary aim of this study was to examine the effect of a one year progressive postoperative home exercise program on gait parameters among individuals with TKA starting 2 months postoperatively. In addition, the associations between the maximal gait velocity and the changes in knee muscle strength and pain were studied. Another purpose was to examine changes in gait velocity and cadence in the early postoperative phase.

## **Subjects, evaluation and intervention**

The study was carried out in the Central Finland Central Hospital. The subjects were recruited from patients selected for TKA during a preoperative orientation visit to the clinic. The inclusion criteria were 1) diagnosed knee OA, 2) primary arthroplasty of the knee in question, and 3) age over 18 years. The exclusion criteria were 1) other surgery for lower limbs planned to be carried out within 12 months, 2) dementia, 3) other serious comorbidities preventing active training, and 4) difficulty in visiting a physiotherapist due to long travelling distance. Conventional medial parapatellar approach was used in all operations in this study. Tourniquet was used routinely in all TKA operations. No mini-invasive, subvastus, midvastus, lateral (Keplish) or any kind of mini-invasive approaches were used. Of the total of 301 patients, 191 were excluded (Figure 1) and 108 volunteer patients were randomized into either the exercise group (EG, n=53) or control group (CG, n=55), using a computer-generated randomization list. The mean age (range) of the participants was 69.3 years (58 to 78) (Table 1).

The gait analysis and clinical measurements were performed before the TKA, two months after the operation at the time when the exercise intervention started, and at 12 months thereafter. All the assessments were performed by two physiotherapists blinded to the treatment group assignment. The patients filled in a questionnaire concerning their demographic and clinical characteristics at the same time points. The study plan was approved by the ethics committee of the Central Finland Health Care District and the patients gave their written consent prior to participation in the study.

Gait analysis was performed using Gaitrite electronic walkway system v3.8 (GAITrite Gold, CIR system, PA, USA), which has been stated to be a valid and reliable tool for measuring selected spatial and temporal parameters of gait [19-21]. The overall dimensions of the walkway were 12 m x 90 cm with the active sensor area of 366 cm x 61 cm containing 13824 sensors activated by mechanical pressure. The sample rate of the Gaitrite was 80 Hz. The data were collected from self-selected normal and fast gait velocities; gait velocity, cadence, step time, cycle time, swing time, stance, single support, double support, step length, stride length, base of support and toe in/out (Figure 2 and 3).

The isometric knee flexion and extension strength levels were measured using a fixed dynamometer (Ds Europe, mod. 546QTD strain gauge, Milan, Italy) [22]. During the measurements, the participants were seated with the knee and hip joints at 70° flexion, and a security strap was placed over the pelvis. After three submaximal repetitions for warm-up,

three maximal muscle contractions were performed with a one-minute rest period following each effort. If the third performance improved by more than 5 % from the best result, an additional trial was performed. The best result of each measurement was used in the final analysis.

Knee pain was measured with the visual analog pain scale (VAS). For pain intensity, the scale is anchored by “no pain” (score of 0 mm) and “worst possible pain” (score of 100 mm) [23].

## MEASURES OF PATHOLOGY AND SYMPTOM

### **Early rehabilitation**

The postoperative hospital stay was about one week. On discharge from the hospital, all patients received advice concerning the application of cold packs and a written exercise program which included active and passive knee range of motion exercises, knee flexor and extensor exercises and hip abductor and extensor exercises in the standing position using the weight of the extremity as a resistance. These exercises were instructed to be performed with 10-15 repetitions, 1-2 times per day. The patients were also recommended to be active and gradually increase their walking distance over time. In accordance with the usual care, the control group did not receive any additional guidance after discharge from hospital.

### **Intervention group**

The patients in the exercise group had individual guidance at two months after TKA, and at one and four months thereafter by the same physiotherapist. At each visit they received written information about the exercises.

From the baseline up to six weeks, the program consisted of isometric strengthening exercises for the quadriceps and hamstring muscles at multiple knee joint angles performed in a sitting position. In the functional exercises, the participant`s body weight was used as a resistance: rising on the toes, first on both legs and then on one leg, and in the step exercises, a step height of 20 cm, which is the standard step height of stairs, was used. The physiotherapist phoned the patients after the first two training weeks to ensure that there were no adverse events or any problems with the program.

At the one-month check-up- visit, the patients were given new home exercises. The new exercise program included squats, hack squats with the back held against the wall and step exercise with a 30-cm-high gym bench. In both of the squat exercises a 60° knee angle in the down position was used. The patients were advised to buy dumbbells (1-2 kg) or use other weights found at home, such as filled plastic bottles in a backpack.

At the check-up visit after four months of training the progression of the previously used exercises was increased. In the squat and hack squat exercises, the patients were instructed to increase the knee angle from 60° to 90°. In the squat exercise, the patients were instructed to increase the load on the operated side by shifting their body weight more on the operated leg by putting a book under the opposite leg. The flexibility exercises consisted of hamstring and triceps surae stretches in a standing position and quadriceps and hip flexor stretches in a supine position to be done after strength training (table 2).

The patients were given postage paid envelopes for the monthly return of the exercise diaries. They also had possibility to call or visit the physiotherapist if they needed more advice.

### **Data analysis**

The data are presented as means with standard deviations (SD) and totals with percentages. Ninety-five per cent confidence intervals (95 % CIs) are reported for the most important outcomes. The normality of the variables was tested by using the Shapiro-Wilk W-test. Comparisons between the groups were performed using the t-test or the Chi-squared test, and correlation coefficients calculated by the Spearman method. Significance of change over time was assessed using a repeated measures design. Statistical significance was set at  $p \leq .05$ . Statistical analyses were carried out with IBM SPSS Statistics 22.0 (IBM Corp., Armonk, NY, USA).

### **Results**

At baseline the only statistically significant difference between the groups appeared in duration of knee pain ( $p = 0.01$ ).

During the first six months, 72 % of the patients in the exercise group had performed the planned home-based training sessions at least twice a week. Based on the questionnaire, 49 % of the exercise group and 34 % of the control group had done the exercises at least once a week during the last month. However, 38 % of the patients in the control group and 17 % of the exercise group had received advice for gravitated exercises from another physiotherapy service (between groups  $p= 0.008$ ). The patients in the exercise group had engaged in leisure time physical activity on the average 4.7 times and in the control group 4.0 times a week ( $p = 0.55$ ).

In the exercise group, five patients discontinued training due to pain during the exercises: two participants complained of knee pain on the operated side, one of pain on the contralateral side, one of back pain and one of hip pain. Moreover, five patients discontinued training because they were satisfied with their painless knee and were not motivated to continue exercising. One patient was re-operated.

During the 12 months postoperative exercise intervention, gait velocity ( $p= 0.006$ ) and cadence ( $p= 0.003$ ) in maximal gait velocity increased statistically significantly in the exercise group compared to control group. A statistically significant difference was also found between the groups in knee flexion strength ( $p = 0.017$ ). (table 3)

In addition leg stance time of the operated leg during maximal gait velocity decreased in the exercise group by 0.06 sec and in the control group by 0.02 sec (between-group difference  $p=0.039$ ). In the whole study group, the changes in maximal gait velocity walking time correlated with the changes in the knee extension ( $r = -.31$ ,  $p= 0.002$ ) and flexion ( $r = .28$ ,  $p = 0.004$ ) strength and change in pain during loading ( $r= -.27$ ,  $p= 0.005$ ) during the 12 months intervention period.

There were no statistically significant changes in gait velocity, cadence, knee strength or pain in loading during the first two months after the operation.

## DISCUSSION

The primary aim of the present study was to examine the effect of a progressive home exercise program on gait parameters after TKA. During the 12 months intervention, starting from 2 months postoperatively, the velocity and cadence of maximal gait increased statistically significantly more in the exercise group than control group. In addition, stance time on the operated side during maximal gait velocity decreased statistically significantly more in the exercise group compared to control group. In the whole study group, the changes in maximal gait velocity walking time correlated weakly with the changes in the knee extension and flexion strength and change in pain during loading during the 12 months intervention period.

Self-selected gait velocity has been suggested to be a general indicator of lower-limb function in orthopedic patients [24]. In this study, we found no statistical significant changes in habitual gait velocity or cadence during first two months after the operation. The reason for the absence of change may be due the factors deriving from the operation itself, such as knee pain and lowered muscle strength. Also, the exercises that were performed during the first two months were light and included only a small number of repetitions thus possibly not enhancing physical performance.

Both groups improved in almost all the gait parameters during the intervention. Statistically significant differences between the groups were seen in maximal gait velocity, cadence and stance time. Walking speed among patients with knee osteoarthritis has been reported to be 0.16 m/s below that of healthy peers [25]. In this study maximal gait velocity in the exercise group increased from 1.35 m/s to 1.67 m/s during the intervention. For self-selected normal gait velocity, the change was 0.22 m/s in the exercise group and 0.18 m/s in the control group. These results resemble those reported previous studies. In their meta-analysis, Abbasi-Bafghi et al. [26] found an improvement in gait velocity of 0.20 – 0.22 m/s during the first 6 – 12 months after TKA. This is a consequential observation since walking is a basic human function and limitations in walking increase the risk for disability [27] and dependency [28].

In the present study the improvement in maximal gait velocity and cadence could be explained by long-term home exercise intervention including progression in exercise load. The exercise group gained greater lower limb muscle strength which is important for the stability of the knee joint. In addition, it is possible that diminished knee pain during loading enabled increased weight bearing on the operated leg and normalized the gait.

Other studies have also reported significantly weakened muscle strength of the knee extensors and flexors after TKA [2,29,30]. In their clinical study, Stevens-Lapsley et al. [31] reported that quadriceps strength decreased by 52 % and hamstring strength by 48 % at one month after TKA. In the present sample, at two months after surgery, knee extension strength showed a decrease from preoperative values of 49 % in the exercise group and 55 % in the control group. Knee flexion strength in the exercise group decreased by 17 % and in control group by 9 % during the early postoperative phase. Mizner et al. [32] reported that by 30 days after surgery both the knee extensors and knee flexors are at the lowest point of their force production. In this study, the first postoperative measurement time was two months after the operation, whereas previously published studies have often measured strength levels earlier in the postoperative phase. Knee extension strength increased statistically significantly in both groups during the intervention period. However, the exercise group acquired greater knee flexion strength than controls. Increase of knee flexion strength in the exercise group was 31 % and in control group 20 %. Quadriceps muscle strength has been stated to be an important factor in softening the heel contact during the gait cycle [33]. Furthermore, quadriceps strength deficits before TKA are greatly compounded early after the operation and slowly recover to levels only slightly better than the preoperative values [34]. In addition, isometric quadriceps strength has been stated to improve 10 % to 20 % from preoperative levels during at least the first two years following TKA with ordinary living without any exercise intervention (85-95 Nm) [1,35].

Only a few studies have investigated the association between pain, muscle strength and gait velocity. Kroll et al. [36] stated that improvements in velocity and stride length from five to thirteen months after TKA were not dependent on a decrease in pain. Tali & Maaros [37] found that knee pain during walking had an influence on gait velocity before TKA but not three months after the operation. Furthermore, previous studies have stated that patients having TKA report significant improvement in pain and physical function three months after surgery [38,39]. Bascuas et al. [40] found a significant increase in gait velocity and decrease in pain one year after TKA. In this study, knee pain during loading decreased markedly in both groups already during the first two months, and continued to decrease until the end of the study. However, the correlation between the change in knee pain and change in maximal gait velocity remained rather weak during the intervention period.

The strength of the present study is the long training period compared with the 3 to 26 weeks interventions used in earlier intervention studies [41-45]. The study also had only a few drop-outs. One of the limitations of this study is that it was not possible to control the load of the home exercises with any great precision. According to the 12-month questionnaire responses, exercise compliance decreased considerably during the last month. Thus, an additional limitation of the study was poor exercise compliance. A home-based exercise program seems to require a larger number of booster contacts to promote better exercise adherence and progression.

## **CONCLUSION**

The results of this randomized controlled trial showed that a 12-month progressive home exercise program after TKA produced statistically significant changes in maximal gait velocity, cadence and stance time among the exercise group as compared to usual care.

Dr. Heikkilä has nothing to disclose.

Dr. Sevander-Kreus has nothing to disclose.

Dr. Häkkinen has nothing to disclose.

Dr. Vuorenmaa has nothing to disclose.

Dr. Salo has nothing to disclose.

Dr. Pamilo has nothing to disclose.

Dr. Ylinen has nothing to disclose.

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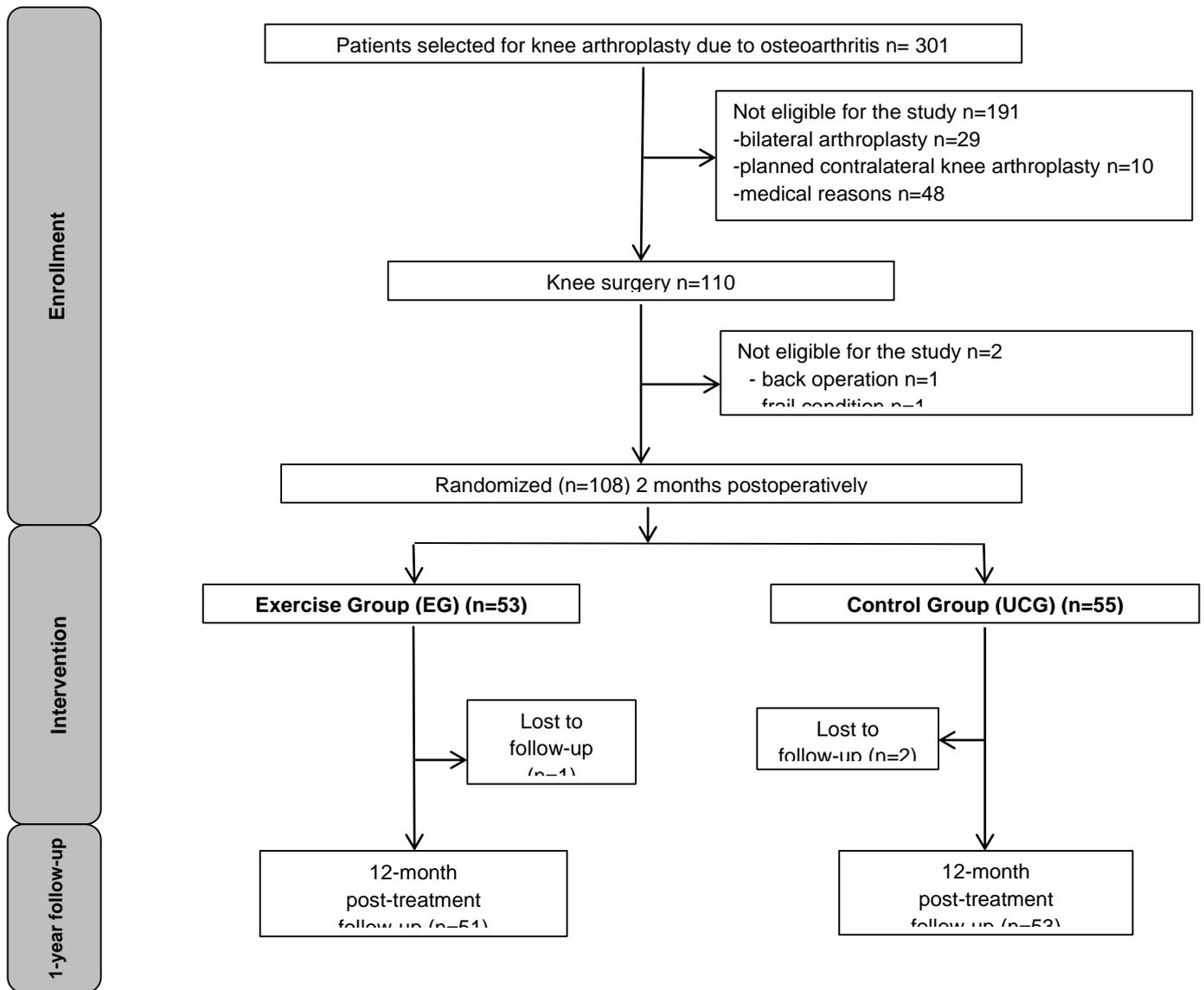


FIGURE 1. Knee arthroplasty study flowchart.

TABLE 1. Sociodemographic and clinical characteristics of the participants.

Variable	All participants N=108	Exercise group N=53	Control group N=55	p-value between the groups
<b>Sociodemographic characteristics</b>				
Females, n (%)	84 (61)	30 (57)	36 (65)	0.35
Age, years, mean (SD)	69 (9)	69 (8)	69 (9)	0.93
Body mass index, kg/m <sup>2</sup> : mean (SD)	31 (6)	31 (5)	31 (6)	0.88
Employed, n (%)	21 (15)	9 (17)	9 (16)	0.80
Education years, mean (SD)	9 (3)	9 (4)	9 (3)	0.66
<b>Clinical characteristics</b>				
Operated knee, n (%)				
Arthroscopy	60 (44)	27 (51)	23 (42)	0.35
Osteotomy	11 (8)	6 (11)	3 (5)	0.28
Contralateral knee, n (%)				
Arthroscopy	25 (23)	14 (26)	11 (20)	0.45
Osteotomy	8 (7)	2 (4)	6 (11)	0.15
Knee arthroplasty	33 (24)	15 (28)	17 (31)	0.88
Duration of knee pain, months, mean (SD)	84 (86)	66 (61)	109 (104)	0.01
Co-morbidities, n (%)				
Cardiovascular disease	29 (21)	12 (23)	12 (22)	0.92
Diabetes	19 (14)	11 (21)	8 (15)	0.40
Neurologic disease	5 (4)	2 (4)	1 (2)	0.54
Pulmonary disease	13 (9)	7 (13)	5 (9)	0.50
Other chronic disease	13 (9)	6 (11)	5 (9)	0.71

TABLE 2. The 12-month home exercise program after total knee arthroplasty (exercise group).

<b>Strength training</b>				
<b>0-3 weeks</b>	Dynamic quadriceps contraction		10-15 repetitions x 1/ day	
	Hamstring stretching		5 seconds x 1/ day	
	Lower limb raise up		10-15 repetitions x 1/ day	
	Knee flexion in sitting position		10-15 repetitions x 1/ day	
	Squatting		10-15 repetitions x 1/ day	
<b>3 weeks-2 months</b>	Previous exercises performed twice a day			
<b>2 -3 months</b>	Cycle-ergometer without resistance		5-10 min	
	Standing up from a chair		10-15 repetitions x2/ 3x week	
	Stepping up to 20 cm high platform		10-15 repetitions x2/ 3x week	
	Static quadriceps contraction in sitting position		10-15 repetitions x2/ 3x week	
	Static hamstring contraction in sitting position		10-15 repetitions x2/ 3x week	
	Transfer body weight from leg to another		10-15 repetitions x2/ 3x week	
	Squatting while back against the wall (knee 45°)		10-15 repetitions x2/ 3x week	
	Raising on toes		10-15 repetitions x2/ 3x week	
Participants were instructed to add 1 repetition at every single exercise session until 20 repetitions were reached.				
Thereafter, participants were instructed to perform 3 exercise series starting from 15 repetitions.				
<b>3-6 months</b>	Standing up from a chair		15 repetitions x 2/ 3 x week	
	Stepping up to 30 cm high platform		15 repetitions x 2/ 3 x week	
	Squatting while back against the wall (knee 60-70°)		15 repetitions x 2/ 3 x week	
Participants were instructed to add 1-2 repetitions in a week until 20 repetitions were reached.				
Thereafter, participants were instructed to use 1-2 kg dumbbells and start exercises from 15 repetitions.				
<b>6-12 months</b>	Sitting down on chair and standing up		15 repetitions x 3/ 3 x week	
	Standing up from a chair with a book placed under the healthy lower limb		15 repetitions x 3/ 3 x week	
	Stepping up to 30 cm high platform		15 repetitions x 3/ 3 x week	
	Squatting while back against the wall (knee 70-80°)		15 repetitions x 3/ 3 x week	
Participants were instructed to use self-selected dumbbells by which they could perform a serie of 15 repetitions.				
In addition the participants were instructed to add 1-2 repetitions in a week until 20 repetitions were reached.				
Thereafter, participants were instructed to add 1-2 kg dumbbells and start exercises beginning from 15 repetitions.				
<b>Stretching</b>				
<b>2 -12 months</b>	Passive hamstring stretch		30 sec x 5	
	Active hamstring stretch in supine position		5 sec x 5	
	Active stretch of calf muscles		30 sec x 5	
	Passive stretch of hip flexors in supine position		30 sec x 3	
Participants were instructed to perform stretches after every strength exercise session.				

TABLE 3. Gait parameters, muscle strength and pain preoperatively, two months postoperatively and after one year intervention in patients with total knee arthroplasty.

Variables	Preoperative		2 months*		p-value Between groups	14 months**		p-value Between groups 2 to 14 months
	Exercise Mean (SD) N=53	Control Mean (SD) N=55	Exercise Mean (SD) N=53	Control Mean (SD) N=55		Exercise Mean (SD) N=50	Control Mean (SD) N=52	
Velocity (m/sec)								
Normal	1.01 (0.31)	0.97 (0.28)	1.02 (0.27)	1.00 (0.28)	.651	1.24 (0.37)	1.18 (0.28)	.297
Maximal	1.41 (0.44)	1.38 (0.36)	1.35 (0.38)	1.34 (0.37)	.770	1.67 (0.40)	1.52 (0.41)	.006
Cadence (steps/min)								
Normal	104.8 (19.4)	106.6 (15.1)	107.8 (14.5)	108.7 (16.2)	.879	120.9 (21.4)	116.8 (11.2)	.181
Maximal	132.6 (23.6)	130.0 (17.1)	127.7 (16.9)	129.1 (17.4)	.367	141.4 (16.5)	133.7 (14.9)	.003
Muscle Strength (N)								
Knee extension	270 (150)	220 (120)	190 (90)	140 (70)	.585	350 (130)	280 (150)	.281
Knee flexion	120 (50)	110 (50)	100 (50)	100 (50)	.342	150 (50)	120 (50)	.017
Knee pain during loading (0-100 mm)								
Operated leg	55 (21)	52 (23)	22 (20)	27 (22)	.151	12 (21)	15 (20)	.695

\*2 months after total knee arthroplasty, beginning of the intervention

\*\*after one year intervention