The Effect of Theory-lead Intervention for Knee Osteoarthritis in Older Adults: A Cluster Randomized Trial

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Abstract

Background: Knee osteoarthritis (KOA) is a common joint disease in people over 60 years old. Exercise therapy is one of the most effective non-pharmacological treatments for KOA, but low exercise adherence needs to be improved. The present study aimed to evaluate the effect of the transtheoretical model-lead home exercise intervention (TTM-HEI) program on exercise adherence, KOA symptoms and knee function in older adults with KOA.

Methods: A two-arm, superiority, assessor-blinded, cluster randomized trial was conducted. Community-dwelling older adults with KOA were recruited from 14 community centers in Beijing, China via print and social media advertisements from April to October 2018. The intervention was a two-stage and 24-week transtheoretical model-based exercise program, and the control group underwent a same length but non-theory-based exercise program. Exercise adherence was measured by an 11-point numerical self-rating scale at weeks 4, 12, 24, 36, and 48 after the program started. KOA symptoms (pain intensity and joint stiffness) and knee function (lower limb muscle strength and balance) were measured at baseline, week 24, and week 48. Latent growth model (GLM), repeated measures ANOVA and independent t-test were the main statistical tests.

Results: A total of 189 older adults (intervention group: $n = 103$, control group: $n = 86$) were enrolled. Differences of any outcome measures at baseline were not significant between groups. The growth rate of exercise adherence in the intervention group increased 2.175 units compared with the control group (unstandardized coefficient of slope on group B2 = 2.175, $p < 0.001$), and the intervention program maintained participants' exercise adherence with 5.56 (SD = 1.00) compared with 3.16 (SD = 1.31) in the control group at week 48. In addition, TTM-HEI program showed significant effects on relieving KOA symptoms and improving knee function.

Conclusion: The TTM-HEI could improve the participants' exercise adherence, knee osteoarthritis symptoms and knee function over time.

Background

Knee osteoarthritis (KOA) is a common joint disease in adults over 60 years old, with prevalence of approximately 20–46% in China [1, 2] and 10–30% world-wide [3–6]. KOA mainly causes pain, joint stiffness, and loss of function. These physiological symptoms reduce quality of life for adults with KOA and could cause negative emotions, such as depression and anxiety [7]. Exercise therapy is viewed as one of the primary non-pharmacologic treatments for KOA and it relieves pain and knee stiffness, enhances joint function, and improves quality of life [8, 9]. Exercise therapy is recommended to people with KOA and other chronic skeletal and musculoskeletal pain by physicians or rehabilitation trainers. However, poor exercise adherence has continually been a problem, especially when evaluated long-term. The percentage of completed prescribed sessions in several previous intervention trial studies for adults with KOA ranged from 37–39% during 12-month to 18-month follow-ups, and self-rated exercise adherence on an 11-point numerical rating scale was only 3.8 to 4.4 during the same time frame [10]. Low exercise adherence for older adults with KOA during one year or longer after intervention has been reported in similar studies, with < 40% adherence rate and < 5.2 self-rated scores (11-point scales) [8, 11]. Exercise studies that integrate adherence interventions, such as health education, goal setting, behavior graded activity, booster session, exercise monitoring, etc., especially lead by theory, might improve exercise adherence in patients with KOA.

A transtheoretical model (TTM) could provide a comprehensive framework and targeted measures for patients with different exercise psychological statuses or in diverse exercise stages. In addition, essential factors that influence exercise adherence of patients, including psychological activity or behavioral strategies, are emphasized in the transtheoretical model, thereby it might be effective to increase exercise adherence and improve patient outcomes [12, 13]. The TTM contains four concepts, including 1) stages of change, 2) process of change, 3) self-efficacy, and 4) decisional balance. The 'stages of change' in the context of exercise can be described as follows: pre-contemplation (participant has no intention to start exercising within the next six months); contemplation (participant intends to start exercising within the next six months); preparation (participant plans to begin exercising within one month or is currently exercising irregularly); action (participant has been regularly exercising for < 6 months); and maintenance (participant has been regularly exercising for > 6 months [14]. The 'process of change' entails both covert and overt activities, including experiential and behavioral processes, that participants employ as they progress through the stages of the transtheoretical model [15]. In addition, this model provides important guidelines for intervention programs because the overall process consists of independent variables that individuals should adopt for progression and improvement. 'Self-efficacy' refers to an individual's confidence to change or to maintain a specific behavior throughout various situations. Self-efficacy usually increases as the individual advances throughout the 'stages of change'. 'Self-efficacy' impacts the association between the 'process of change' and the 'stages of change' [16]. 'Decisional balance' consists of the individual's perceived pros (i.e., benefits) and cons (i.e., costs) of changing their behavior over time. As an individual progress through the stages of the TTM, the perceived benefits of the behavior increase, while the perceived barriers of the behavior decrease [17].

For the older adults who don't want to exercise at all, TTM provides intervention strategies targeted for the pre-contemplation stage and contemplation stage, which could increase the possibility of older adults to enter the action stage. For those who have started exercising but have not persisted, TTM states that, according to the stage of the individual's return, targeted measures (e.g. increasing social support, setting up stimuli to remind the exercise, etc.) could promote the individual to return to the action stage[18]. Return are very common in older adults with KOA. For the older adults with osteoarthritis, three months after the end of exercise therapy is the fastest decline in compliance, and half of older adults cannot adhere to exercise for 3 months or more[19]. That means individuals in the action stage (has been regularly exercising for < 6 months) would be backward to pre-action stages (pre-contemplation, contemplation and preparation). Therefore, theoretically, the application of TTM could improve the exercise adherence of the entire older adults with KOA. However, studies using TTM for the intervention of older adults with KOA are limited, especially related to the effect of TTM on individual's exercise adherence long-term.

Therefore, the aim of the present study was to evaluate the long-term effect of TTM-based home exercise intervention (TTM-HEI) on improving exercise adherence, KOA symptoms, and knee function in community-dwelling older adults with KOA.

Methods

Design

Our study was a two-arm, superiority, assessor-blinded, cluster randomized trial. The study lasted for 48 weeks, with an intervention time of 0 to 24 weeks and a follow-up period of 24 to 48 weeks. Participant characteristics were collected at baseline only. Exercise adherence of participants was collected at 4, 12, 24, 36 and 48 weeks. Secondary outcomes (KOA symptoms and knee function) were collected at 0, 24 and 48 weeks.

To avoid contamination within a community, randomization was performed at the community level instead of at the individual level. An independent researcher used the random number function in Excel to generate the randomization sequence. Study staff opened opaque envelopes with random numbers to obtain the community allocation.

Participants signed the informed consent and were informed of their assigned group and specific exercise intervention strategies. Therefore, participants were not blinded to the allocation of groups. Moreover, study staff were unmasked to the allocation of participants after community recruitment due to the differences in the exercise intervention programs. However, the assessor and the statistician were masked to the allocation of the participants.

Sample and setting

Community-dwelling older adults with KOA were recruited from 14 community centers in Beijing via print and social media advertisements from April to October 2018. The inclusion criteria were as follows: participants were ≥60 years old, had experienced knee pain on most days within the past month, scored their average knee pain over the past week between a 3 and 7 on an 11-point numeric rating scale, and showed intact cognitive functioning, as indicated by a score of 8 to 10 on the 0 to 10 point Short Portable Mental Status Questionnaire [20]. The exclusion criteria were as follows: participants had undergone either a joint replacement or arthroscopic surgery on the affected side of the knee, had other lower-limb surgery within the past six months, showed evidence of severe deformity of the lower limbs (e.g., knee varus or valgus), exhibited other health issues that could induce adverse events during home exercise (e.g., uncontrolled high blood pressure, myocardial infarction, cerebral infarction, unstable angina, arrhythmia, severe vision problems, or neurological dysfunction), or demonstrated other regular exercise habits (at least three days a week of no less than 30 minutes of exercise per day).

Intervention

Intervention group

General stage (week 0-2)

Participants in the intervention group entered the general stage after their baseline data were collected. The goals of this period for participants were to (i) correctly learn to perform home exercise; (ii) fully understand the basic knowledge of KOA and the benefits of exercise; (iii) advance from a stage of pre-action (pre-contemplation, contemplation, and preparation) to a stage of action. Participants attended three two-hour group activities carried out by physiotherapists over two weeks. Each activity included an hour for group health education and another hour for exercise. The educational materials distributed to the participants included home exercise manuals and a printed version of the health education slides.

The exercise program was created based on literature review, clinical practice, and expert consultation. The exercise program had previously been proven to be effective to improve both symptoms and function of older adults with KOA [21]. It involved ten movements and was recommended to be practiced for 30-40 minutes per day on at least three days per week [Additional file 1].

Group health education was conducted by physiotherapists and was designed to increase participants' awareness of exercise by explaining and discussing the severity of KOA and the benefits of exercise. It involves three parts that cover the concepts of 1) clinical signs, risk factors, treatment, and nursing care for KOA; 2) the advantages and principles of exercise; and 3) final information related to routine daily care for KOA.

Stage-specific period (weeks 2-24)

In the stage-specific period, participants of each community were divided into two subgroups, including the pre-action stage subgroup and the action stage subgroup. Each subgroup had different intervention goals, and group activities were conducted separately. During this period, group activities were held every four weeks. Prior to every group activity, participants were re-assessed regarding their stage of change via phone or WeChat by research assistants and assigned to different subgroups, as necessary. Therefore, members of each subgroup were assigned/reassigned based on the participants' exercise conditions over the past four weeks, rather than being fixed into subgroups. Physiotherapists delivered TTM-based stage-matched interventions to the participants in each subgroup. A description of the core objectives, TTM-based strategies (mainly based on ten processes of change), and the recommended form of interventions at each stage are shown in [Additional file 2]. At weeks 4 and 12, physiotherapists conducted two review sessions to ensure the participants continued to do home-exercises correctly.

Control group

Participants in the control group received usual exercise guidance without any exercise adherence interventions. At weeks 0, 1, and 2, physiotherapists carried out a total of three home-exercise guidance sessions to ensure that participants were able to exercise at home correctly and safely, and to teach exercise precautions. Week 4 and week 12 of the exercise review classes and the assessments were the same as in the intervention group. The content of the exercise guidance and the prescribed exercise type and intensity were exactly the same as the intervention group.

Measures

Participant characteristics

Baseline participant characteristics were obtained using a demographics questionnaire developed specifically for this study. The questionnaire included questions on age, gender, height and weight, marital status, educational level, occupation before retirement, residence, disease duration, comorbidities, and current drug use.

Primary outcome measure

The primary outcome of the present study was exercise adherence of the participants. Participants used an 11-point numeric rating scale (0 = not at all through 10 = completely as instructed) to self-rate adherence to the prescribed home exercise program at 4, 12, 24, 36, and 48 weeks [22]. The scale's intra-class correlation coefficient was 0.77 when assessing exercise adherence among other populations with musculoskeletal disorders, which has proven to have an acceptable reliability [22].

Secondary outcome measures

The secondary outcomes of our study included KOA symptoms, including pain intensity and joint stiffness, as well as knee function (lower limb muscle strength and balance), which were collected at baseline, 24, and 48 weeks.

KOA-related pain intensity and joint stiffness were measured by the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) [23]. It includes seven items related to pain and joint stiffness rated on a 0-4 Likert scale, where higher scores indicate greater pain and stiffness. The internal reliability of the Chinese version of the WOMAC, as measured by Cronbach's α, is 0.67-0.82 across its two subscales. In addition, its test-retest reliability, based on the intra-class correlation coefficient, is 0.82-0.88 for its two subscales [24].

The adjusted total scores of pain intensity and joint stiffness ranged from 0 to 100, which were calculated from the raw ratings of the total scores as follows:

$$\text{Adjusted Score (AS)} = \frac{\text{Raw Rating (RR)}}{\text{the total scores}} \times 100$$

The muscle strength of the lower limbs was determined by the Five-Times-Sit-to-Stand Test (FTSST), which requires participants to rise from a chair and return to a seated position, with their arms folded across their chests five times as quickly as possible. Participants completed this exercise twice, with a 1 min rest period between each trial. The mean value of the two trials was used [25]. Participants' balance was measured via the Timed Up and Go Test (TUG), which measures the time it takes participants to rise from a standard height chair, walk 3 meters, turn around, return to the chair, and sit down [26].

Data collection

Community nurses recruited older adults diagnosed with KOA from 14 community centers. Doctors screened the participants according to the inclusion and exclusion criteria to determine the eligibility for participation. Next, participants signed the informed consent forms and completed the baseline assessments. Data were collected by three assessors at 0, 24, and 48 weeks, and the exercise adherence score was collected at 4, 12, 24, 36, and 48 weeks. The assessors were blinded to the group assignments.

Ethical considerations

Ethical approval was obtained from the Peking University Biomedical Ethics Committee (IRB00001052-17066) in July 2017. All participants voluntarily participated, and could withdraw at any time without negative consequences. Each participant completed written informed consent. The data collected were anonymized and kept confidential and were used exclusively for the present study.

Sample size

We used two-sample t-test power analysis to conduct the sample size calculation. The primary outcome was the difference in the exercise adherence score between the intervention group and control group at 24 weeks. Determining the mean difference (1.1) and SD (2) between the groups was based on the results of our pilot study and a relevant search on exercise interventions[27]. Power analysis was carried out with $\alpha = 0.05$, $\beta = 0.90$ and with intervention and control groups being equal size. Power Analysis and Sample Size software (PASS 2008, NCSS Corporation) calculated that 58 participants were required per group. Considering that the experimental design is a cluster randomized controlled trial (RCT), relevant factors within the community were taken into account and applied to the formula $N = [1 + (m-1)\,\rho]\,n$, where N is the sample size of the cluster RCT, n is the sample size of the individual RCT, m is the number of individuals in the predicted community and ρ is the intra-group correlation coefficient [28]. In this study, m = 15 is expected. According to the literature review [29, 30], we calculated ρ = 0.03 and N = 164. Taking into account a probable 15% loss to follow-up, the total sample size was calculated as 192 cases with 96 cases in each group.

Statistical analysis

Our study applied an intention-to-treat analysis method. Data were analyzed using SPSS version 25.0 (IBM Corporation, Armonk, NY, USA). We considered a p-value of ≤ 0.05 (two-sided) as statistically significant. Descriptive statistics (such as means and SDs, medians, interquartile ranges (IQR), frequencies and percentages) were calculated to indicate demographic and disease characteristics and outcome scores. Inferential statistics, including an independent t-test and repeated measurement ANOVA, were also used to analyze the data.

The repeated measures ANOVA was achieved by a general linear model. We used Mauchly's test of sphericity to check whether the data fit the statistical assumptions for conducting repeated measures ANOVA. When the data did not satisfy the spherical assumption (e.g. $p < 0.05$), the epsilon correction coefficient was used to correct the degree of freedom. When the results of repeated measures ANOVA showed that there was no interaction of group*time, the group main effect could be used to judge the difference between groups. If there was an interaction of group*time, it meant that the data of the two groups had different trends with time. It was not possible to judge the difference between groups by repeated measures ANOVA, so we used an independent t-test to compare the data at each time point to determine the difference between groups. In addition, we used one-way repeated measures ANOVA to test for differences among time points within the group.

In addition, for the primary outcome of exercise adherence, we used a combination of repeated measures ANOVA and latent growth model (LGM) for comprehensive analysis. Through repeated measures ANOVA, we can understand the changes and differences in the mean of exercise adherence between the two groups during intervention and follow-up; LGM can further analyze the change rate of exercise adherence over time and quantify the difference in the growth rate in exercise adherence between the two groups, while considering the interindividual variation to better elucidate longitudinal stability and change [31] and evaluating the effectiveness of the TTM-HEI. This is because effective intervention programs could not only increase the population mean, but also reduce interindividual variation. In this way, most of the participants in the intervention group can move forward in a concentrated manner according to the expected stage of behavior change, reducing the chance of regression and stagnation. The specific method is as follows:

There are two latent variables in LGM[32], which are labeled as the intercept and the slope, respectively. The intercept reflects the initial level of variables and is often restricted as an equal constant. The slope reflects the change rate of variables across time and is commonly restricted to a series of constants as linear, nonlinear, or freely estimated. In a freely estimated model, slope is restricted the first time and at the second or the last time with a value of zero and a value of one, respectively [32]. In LGM, the variation of two parameters could be analyzed by the variances or residual variances, representing the interindividual variation in the initial level and growth rate.

To better analyze the differences of exercise adherence between two groups over time, we constructed the models using two steps. First, we analyzed the effect of the groups on the initial level (intercept) and change rate (slope) by Model 1 conducting group as a covariate (0: control group, 1: intervention group). Second, we conducted multiple-group analysis to analyze the characteristics of two groups by Model 2 (control group) and Model 3 (intervention group). In the three models, the value of one was restricted to all intercepts, and the value of zero and value of one were restricted to the slope at the first time point (week 4) and the last time point (week 48), respectively, considering that the change rates of exercise adherence was unknown.

The parameters of LGM in the present study were estimated using Maximum Likelihood (ML) with 2000-replication bootstrapping to obtain stable and unbiased parameters [33]. Model fit indices were the chi-square to degree-of-freedom ratio (c^2/df; with values <3 and <5, indicating good and adequate fit, respectively), the Standardized Root Mean Square Residual (SRMR; with value below 0.08 indicating reasonable fit), and the Comparative Fit Index (CFI; with values ≥0.90 indicating acceptable level for model fit) [34]. Model fit indices in all three models were all acceptable with | c^2/df = 4.001, SRMR = 0.032, CFI = 0.966 in Model 1, |c^2/df = 5.904, SRMR = 0.070, CFI = 0.849 in Model 2, and |c^2/df = 3.074, SRMR = 0.067, CFI = 0.939 in Model 3.

Results

Participant recruitment and follow-up

Figure 1 shows the number of participants in the two groups at different time points. We recruited 280 participants from 14 community centers in Beijing, China. The patients were screened according to the inclusion criteria by the rehabilitation doctors, and 91 (32.5%) were excluded. The remaining 189 participants were randomly divided into two groups by community, and included 103 in the intervention group and 86 in the control group. After 24 weeks, there were 161 participants (89 in the intervention group and 72 in the control group) that were retained. After 48 weeks, a total of 156 participants (87 in the intervention group and 69 in the control group) completed the collection of all outcomes. The total follow-up rate was 82.5%. A total of 16 participants were lost at follow-up in the intervention group and 17 in the control group. There was no significant difference in follow-up rates between the two groups (X^2 = 0.583, P = 0.445).

Participant characteristics

The descriptive characteristics of the participants are presented in Table 1. The study involved 189 patients, including 103 patients in the intervention group, aged 46-82 years old, with a mean age of 67.38

± 7.79 years old. A total of 86 patients were in the control group, age 56-85 years old, with a mean age 68.81 ± 6.74 years old. Most participants were female (92.6%), married (82.0%), with a high-school education (38.1%), knee osteoarthritis in both knees (51.4%), and did not use a walker (94.2%). A small number of participants took analgesics (10.6%) and cartilage-protective drugs (15.3%) to relieve pain and other symptoms. The treatment groups were similar in demographics, clinical characteristics, and amount of therapy except the prevalence of diabetes (in the intervention group 17.48% of participants were diabetic versus the control group where 5.81% of participants were diabetic; $X^2 = 5.936$, $P = 0.015$).

Table 1. The demographic characteristics of the recruited participants at baseline.

Characteristic	Intervention (n=103)		Control (n=86)		p-value
	n	(%)	n	(%)	
Age - Mean (SD), y ‡	67.38	(7.79)	68.81	(6.74)	0.182
Gender †					
Male	10	(9.7)	4	(4.7)	0.266
Female	93	(90.3)	82	(95.3)	
Body mass index - Mean (SD), kg/m^2 ‡	25.12	(3.58)	24.85	(3.05)	0.578
Symptom duration - Mean (SD), y ‡	7.54	(7.83)	7.08	(7.27)	0.680
Level of education †					0.215
Primary school or less	3	(2.9)	5	(5.8)	
Junior high school	26	(25.2)	29	(33.7)	
High school	39	(37.9)	33	(38.4)	
College graduate and above	35	(34.0)	19	(22.1)	
Marital status †					0.445
Single	16	(15.5)	17	(19.8)	
Married	87	(84.5)	69	(80.2)	
Number of affected knees †					0.259
One	54	(52.4)	38	(44.2)	
Two	49	(47.6)	48	(55.8)	
Uses a walker †					0.997
Yes	6	(5.8)	5	(5.8)	
No	97	(94.2)	81	(94.2)	
Comorbid conditions †					
Hypertension					0.077
Yes	44	(42.7)	26	(30.2)	
No	59	(57.3)	60	(69.8)	
Diabetes					0.015*
Yes	18	(17.5)	5	(5.8)	
No	85	(82.5)	81	(94.2)	
Coronary heart disease					0.085
Yes	12	(11.7)	4	(4.7)	
No	91	(88.4)	82	(95.4)	
Osteoporosis					0.578
Yes	32	(31.1)	30	(34.9)	
No	71	(68.9)	56	(65.1)	
Current drug use †					
Analgesics					0.669
Yes	10	(9.7)	10	(11.6)	

Characteristic	Intervention (*n*=103)		Control (*n*=86)		*p*-value
	n	(%)	*n*	(%)	
No	93	(90.3)	76	(88.4)	
Cartilage protection drugs					0.937
Yes	16	(15.5)	13	(15.1)	
No	87	(84.5)	73	(84.9)	

SD = standard deviation

† Chi-square or Fisher's Exact tests were used.

‡ Independent samples t-test was used.

* $p < 0.05$ was considered statistically significant.

Exercise adherence

Table 2 and Figure 2 shows the exercise adherence scores in each group over 48 weeks. The scores in the intervention group and the control group are similar from weeks 4 to 12 with 7.59 (SD = 1.64) compared with 7.47 (SD = 2.24), respectively, at week 4, and 6.27 (SD = 1.86) compared with 6.19 (SD = 2.28), respectively, at week 12 (Figure 2). From 12 to 24 weeks, the exercise adherence score of the intervention group increased to 7.58 (SD = 1.29), whereas the control group continued to decline to 5.00 (SD = 1.53). Furthermore, from 24 to 48 weeks, the exercise adherence scores of the intervention group and the control group both decreased to 5.56 (SD = 1.00) and 3.16 (SD = 1.31), respectively.

Table 2. Exercise adherence score over time by group

	Intervention (n=103)	Control (n=86)		
	Mean (SD)	Mean (SD)	t †	p
Week 4	7.59±1.64	7.47±2.24	0.450	0.653
Week 12	6.27±1.86	6.19±2.28	0.254	0.800
Week 24	7.58±1.29	5.00±1.53	11.646	<0.001 #
Week 36	6.55±1.28	3.89±1.53	12.043	<0.001 #
Week 48	5.56±1.00	3.16±1.31	12.999	<0.001 #
F ‡	65.971	53.664		
p	<0.001 *	<0.001 *		

SD = standard deviation

† Independent t-test was used

‡ One-way repeated measurement ANOVA was used

* $p < 0.05$ was considered statistically significant

$p < \alpha' = 0.05/5 = 0.01$ was considered statistically significant

Repeated measures ANOVA indicated that there was a significant difference in the trend of adherence scores between the two groups from 0 to 48 weeks ($F_{time*group} = 18.400$, $p_{time*group} < 0.001$, partial $\eta^2 = 0.328$). Then, we used an independent t-test to compare the adherence scores of each time point. The results showed that scores in the intervention group were significantly better than in the control group at 24 weeks (t = 11.646, p < 0.001), 36 weeks (t = 12.043, p < 0.001) and 48 weeks (t = 12.999, p < 0.001). And there was no statistical difference in adherence scores at week 4 and week 12.

The largest absolute values of skewness and kurtosis statistics of any measurements for the total data and each group were 1.245 and 3.040, respectively, and all are within the accepted limits (absolute skewness < 2 and absolute kurtosis < 7 is acceptable)[35]. The results suggest that normality for LGM was met.

Figure 3 shows the main estimated parameters of the three LGM models. We observed no significant difference at the initial level of exercise adherence between the control and intervention groups shown by an insignificant unstandardized coefficient of intercept between the groups in Model 1 (Figure 3(a), B1 = 0.062, SE = 0.076, p > 0.05). The growth rate of exercise adherence in the intervention group was greater

(2.175 units) than that in the control group, with a positive and significant unstandardized coefficient of slope using Model 1 (Figure 3(a), $B2 = 2.175$, $SE = 0.118$, $p < 0.001$). The negative mean of the slope in Model 2 (mean = -0.002, $SE = 0.044$, $p > 0.05$) and the positive mean of the slope in Model 3 (mean = 0.024, $SE = 0.056$, $p > 0.05$) showed that exercise adherence may decline in the control group and slightly increase over time in the intervention group.

In addition, we analyzed the changes of exercise adherence over time within each group. Significant estimated slopes (Figure 3(b) and Figure 3(c)) and significant variances of slope (Model 2 variances of slope = 2.304, $SE = 0.381$, $p < 0.001$ and Model 3 variances of slope = 0.687, $SE = 0.150$, $p < 0.001$) showed the exercise adherence growth rate was observed in intraindividual variation and interindividual variation, but the interindividual variation of growth slope in the intervention group was much smaller than that in the control group. The negative correlation coefficients between the intercept and the slope (Model 2 $R = -0.734$, $SE = 0.077$, $p < 0.001$ and Model 3 $R = -1.078$, $SE = 1.282$, $p > 0.05$) showed that exercise adherence growth rate declined with the initial level growing, but such inference should be careful for intervention group because of the insignificant p-values in Model 3.

Pain intensity and joint stiffness

From week 0 to week 48, the intensity of pain in both groups decreased, but the rate of decline in the intervention group was significantly slower than that in the control group ($F_{time} = 5.051$, $p_{time} = 0.008$, partial $\eta^2 = 0.062$; $F_{time*group} = 3.301$, $p_{time*group} = 0.039$, partial $\eta^2 = 0.041$). There were no significant differences in pain intensity at baseline between the two groups. However, pain intensity in the intervention group was significantly lower than that in the control group at week 24 ($t = -2.793$, $p = 0.006$) and week 48 ($t = -2.550$, $p = 0.012$). Joint stiffness improved in both groups during the study, but the exercise in the intervention group was more effective than that in the control group ($F_{time} = 3.813$, $p_{time*group} = 0.024$, partial $\eta^2 = 0.047$; Week 24, $t = -3.376$, $p = 0.001$; Week 48, $t = -2.611$, $p = 0.010$). An intra-group comparison revealed that over three time points knee stiffness in the intervention group was significantly different over the 48 week time period compared with the control group ($F = 13.374$, $p < 0.001$, partial $\eta^2 = 0.239$). (Table 3; [Additional file3 Figure 1a and Figure 1b]).

Table 3. Secondary outcome measures over time in the control and intervention groups.

	Intervention (n=103) Mean (*SD*)	Control (n=86) Mean (*SD*)	t †	*p*
ain intensity				
Baseline	24.37±20.31	24.42±19.65	-0.017	0.986
Week 24	16.18±15.94	23.47±17.11	-2.793	0.006#
Week 48	13.62±11.28	19.64±16.83	-2.550	0.012#
F ‡	7.072	2.085		
p	0.001*	0.131		
oint stiffness				
Baseline	24.03±24.73	25.00±25.37	-0.266	0.791
Week 24	10.53±12.49	19.62±19.88	-3.376	0.001#
Week 48	9.77±14.19	17.57±21.36	-2.611	0.010#
F ‡	13.374	0.945		
p	<0.001*	0.394		
ower limb muscle trength				
Baseline	12.03±5.09	12.27±4.29	-0.350	0.727
Week 24	9.61±2.43	11.34±3.66	-3.583	<0.001#
Week 48	10.29±3.70	11.06±2.79	-1.442	0.151
F ‡	19.441	3.565		
p	<0.001*	0.034*		
alance				
Baseline	2.95±0.29	2.03±0.22	-0.775	0.439
Week 24	1.26±0.13	1.60±0.19	-4.747	<0.001#
Week 48	1.11±0.12	1.22±0.15	-2.576	0.011#
F ‡	13.847	6.687		
p	<0.001*	0.002*		

SD = standard deviation

† Independent t-test was used

‡ One-way repeated measurement ANOVA was used

* $p < 0.05$ was considered statistically significant

\# $p < \alpha' = 0.05/3 \approx 0.017$ was considered statistically significant

Lower limb muscle strength and balance

From weeks 0 to 48, the lower limb muscle strength and balance increased in the control group, but first increased and then decreased in the intervention group (Table 3). Repeated measurement ANOVA indicated that the lower limb muscle strength increased in the intervention group compared with the control group from 0 to 48 weeks (F_{time} = 16.853, p_{time} < 0.001, partial η^2 = 0.181; $F_{time*group}$ = 5.782, $p_{time*group}$ = 0.004, partial η^2 = 0.070). There were no statistical differences at baseline (t = -0.350, p = 0.727) and at 48 weeks (t = -1.442, p = 0.151) between the two groups; however, lower limb muscle strength in the intervention group was significantly higher than that in the control group at 24 weeks (t = -3.583, p < 0.001). Similarly, from weeks 0 to 48, improvements in balance in the intervention group was more significant compared with the control group (F_{time} = 12.970, p_{time} < 0.001, partial η^2 = 0.146; $F_{time*group}$ = 5.575, $p_{time*group}$ = 0.005, partial η^2 = 0.068; Week 24, t = -4.747, p < 0.010; Week 48, t = -2576, p = 0.011). (Table 3; [Additional file3 Figure 1c and Figure 1d]).

Discussion

Our study showed that TTM-HEI could significantly improve exercise adherence, KOA symptoms (both pain and joint stiffness), and physical function (muscle strength of the lower limbs and balance) long-term compared with normal exercise guidance. The rates of loss to follow-up were 15.5% and 19.8% in the intervention and control groups, respectively.

During the 48-week follow-up period, the growth rate of exercise adherence in the intervention group was greater (2.175 units) than that in the control group. In addition, from the perspective of inter-individual differences, the slope variation of the intervention group was 0.687 ± 0.150, while the control group was 2.304 ± 0.381, indicating that the inter-individual difference in the intervention group was smaller than that in the control group, and exercise adherence was more consistent and stable. Exercise adherence in the intervention group at 48 weeks was better than that in other intervention trial studies for patients with KOA [10, 11]. Possible reasons may be: i) TTM intervention program could improve the participation rate of the population. Through the use of some targeted processes of change, participants in the pre-contemplation stage and contemplation stage are fully aware of the benefits of exercise, and are willing to establish exercise behaviors, thereby transitioning to the action stage. Traditional exercise instruction cannot reach this part of the population. ii) TTM intervention program could target participants who are hindered during exercise, help them overcome obstacles, resolve conflicting emotions, and continue to exercise. Thereby TTM-HEI could reduce exercise withdrawal rate and further improve exercise adherence. iii) TTM intervention program could encourage participants who have returned to resume exercise. During the intervention, there was a certain phenomenon of regression in the intervention group. When the physiotherapists found that participants had a regression, they first assessed which stage they returned to, and then understood the reason for the return. According to the specific reasons, the physiotherapists implemented intervention strategies that match the current stage of change, and encourage returner to resume exercise.

In addition, we found that KOA symptoms (pain intensity and joint stiffness) and knee function (lower limb muscle strength and balance) improved from 0 to 48 weeks in both the intervention and control groups; however, the degree of improvement in the intervention group was significantly larger than that in the control group. We found that from 0 to 24 weeks, knee function, muscle strength, and balance in the intervention group improved rapidly, but the improvement rate slowed or decreased slightly from 24 to 48. However, the improvement in the control group was at a slower rate than that in the intervention group. Therefore, given that both groups performed the same exercise program, the changes observed between the intervention group and the control group were possibly caused by differences in exercise adherence. Our results corroborated previous studies, which showed the direct positive relationship between exercise adherence and exercise-related outcomes [36, 37]. A previous study showed that lack of exercise compliance was the main impediment to the positive expected outcomes of exercise intervention in KOA patients[38]. Therefore, improving exercise compliance is the key to the successful long-term effects of exercise intervention.

Several limitations existed in our study. First, neither participants nor physiotherapists were blinded to group allocation, possibly resulting in an overestimation of the effects of the exercise intervention. Secondly, due to limited resources, we only included participants from the Beijing urban area. It is unclear if TTM-HEI is effective for additional types of older adults with KOA, for example those from a rural location. Thirdly, since we recruited participants via print and social media, those who were already interested in being active and caring for themselves were more likely to participate. This may increase selection bias. Finally, we applied a self-rating scale to evaluate exercise adherence, and some patients may have recall bias which could decrease accuracy. Future studies may introduce objective outcomes to assess exercise adherence.

Conclusion

This assessor-blinded, cluster randomized study showed that a TTM-HEI can improve exercise adherence, KOA symptoms and physical function in older adults with KOA. The program is inexpensive, safe and easy to use and can be applied in community centers.

Abbreviations

KOA: knee osteoarthritis; TTM-HEI: transtheoretical model-lead home exercise intervention; LGM: latent growth model.

Declarations

Conflict of Interest Statement

The authors declare no conflicts of interest.

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Availability of data and materials

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Authors' contributions

LMW, HBC, HL, YLW, CYL, XD, JRC, NL, FY, QQW and SMS contributed to the study design and protocol. LMW, CHB and SMS contributed to mainly manage and conduct the intervention project. LH, YLW, XD and JRC contributed to assist to conduct the study, to assess the patients and collect the data. LMW and HBC conducted the statistical analyses and interpreted the data. SMS procured the project funding and led the co-ordination of the trial. All authors read and approved the final manuscript.

Ethics approval and consent to participate

The study was approved by the Peking University Biomedical Ethics Committee and written informed consent was obtained from all participants involved in the study.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Figures

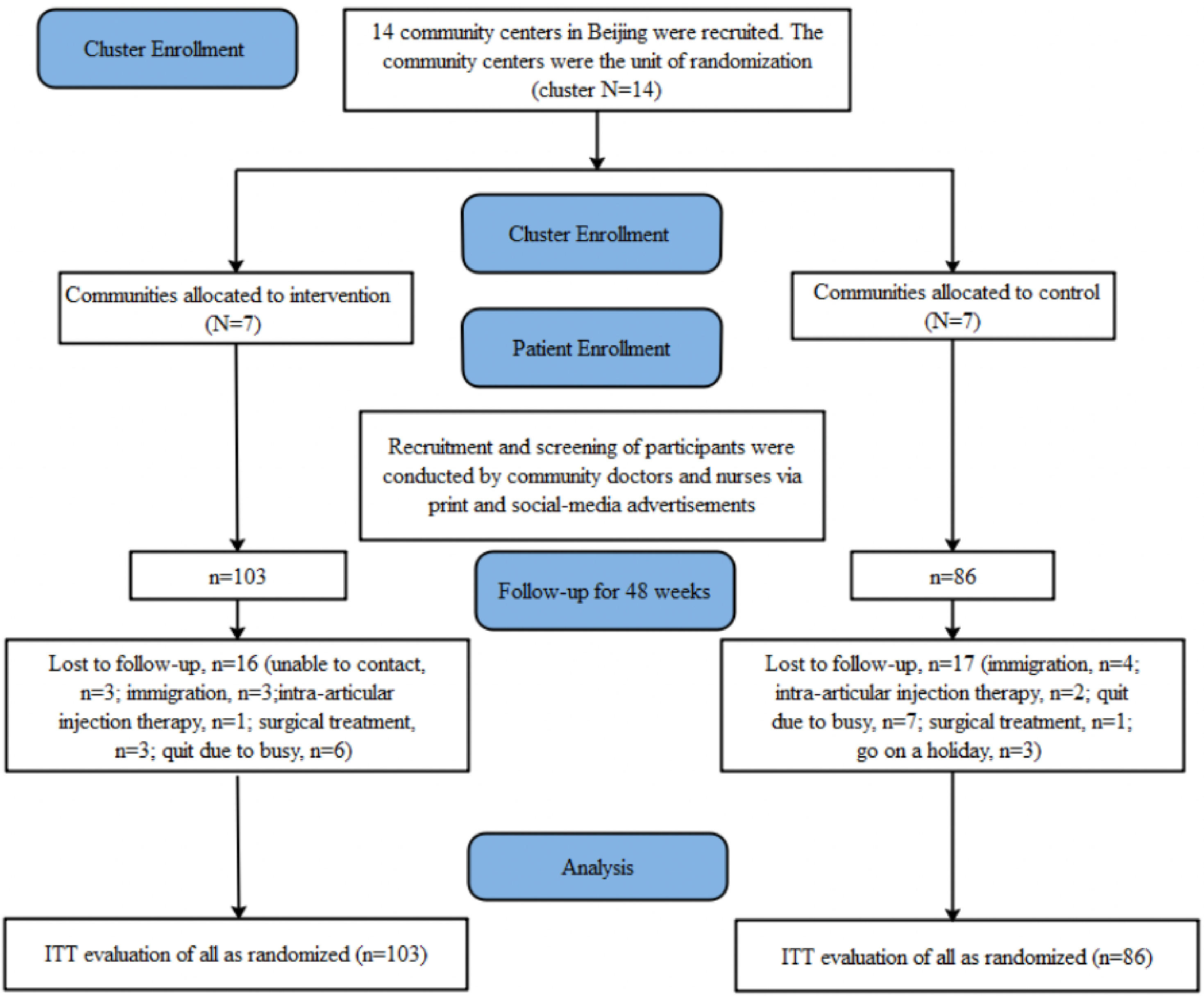

Figure 1

Flowchart of study participants.

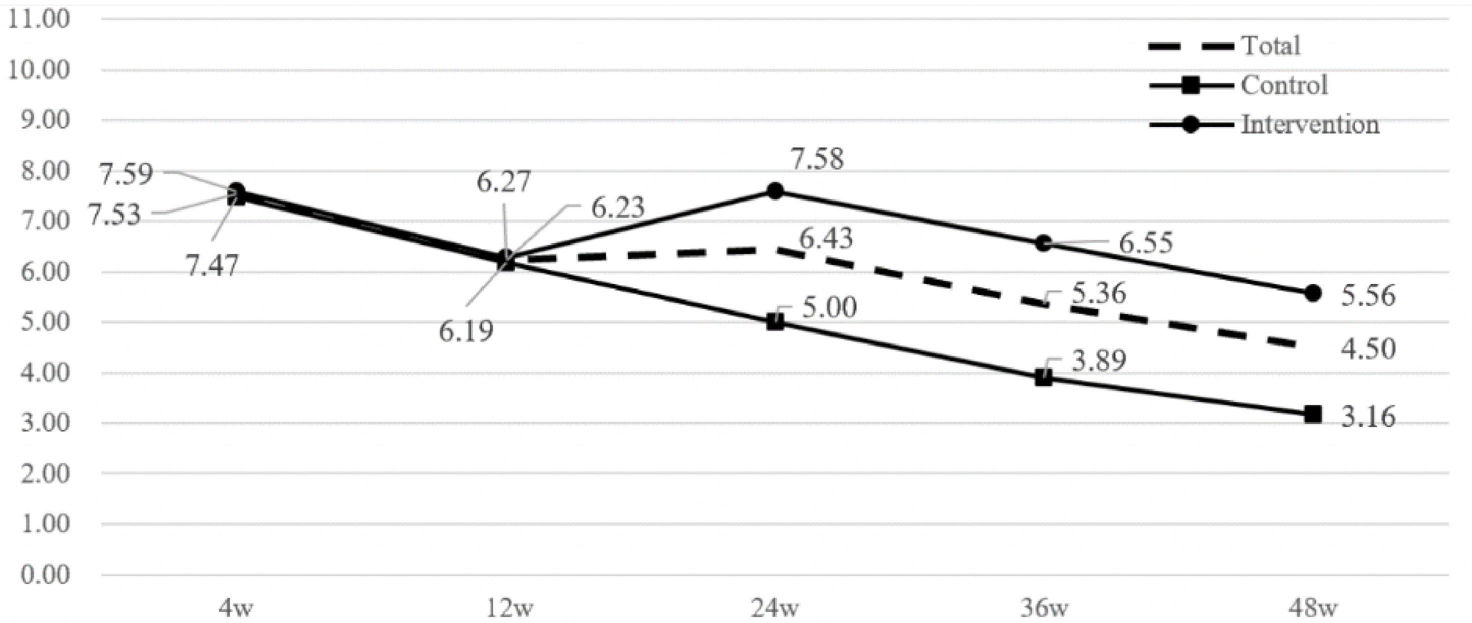

Figure 2

Exercise adherence scores in the intervention and control groups over 48 weeks.

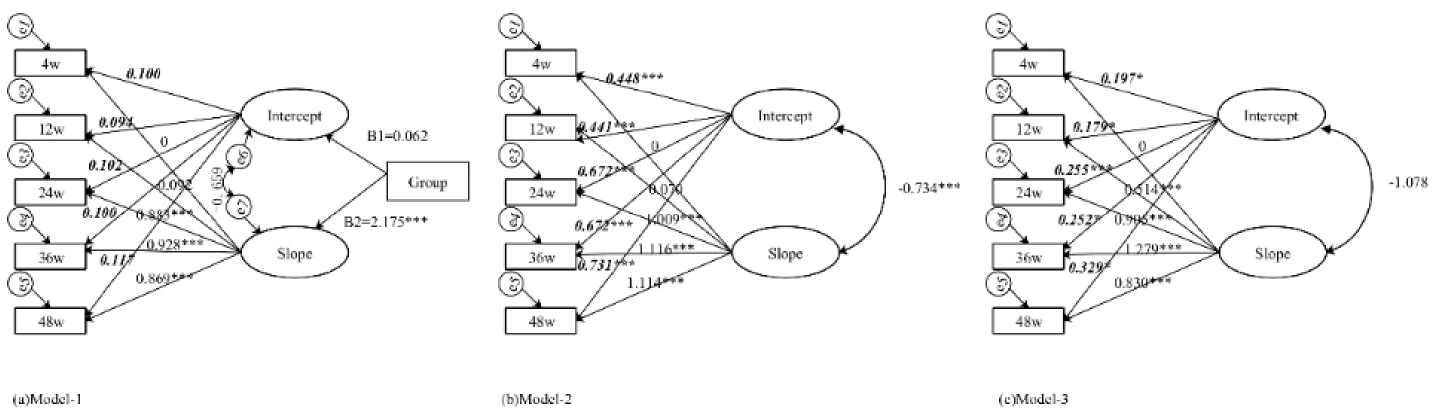

Figure 3

Main estimated parameter diagrams using the three models.

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