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A theory of planned behavior-based intervention to improve quality of life in patients with knee/hip osteoarthritis: a randomized controlled trial

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Abstract

Osteoarthritis (OA) is a common chronic disorder among elderly people that affects joints such as the knee and hip in particular. The objective of the current study was to examine the efficacy of an intervention based on a theory of planned behavior (TPB) in improving health-related quality of life in middle-age and older adults with this condition. One hundred twenty patients diagnosed with knee/hip OA were recruited from a general hospital. Measures administered at baseline were the SF-12, EuroQol (EQ-5D), Osteoarthritis Knee and Hip Quality of Life (OAKHQoL), and TPB questionnaire. Also assessed were body mass index (BMI), Kellgren–Lawrence Scale, six-minute walk test (SMWT), muscle strength, range of motion (ROM), and joint tenderness and swelling. Participants were randomly assigned to either the intervention ($n = 60$) or the control group ($n = 60$). The intervention group received an educational program based on TPB that was administered over 1 month. The control group did not receive this treatment. Three months after the intervention, both groups were reevaluated and comparisons made. Compared to the no-treatment control group, those in the intervention group scored higher on HRQoL, both general and specific, at 3-month follow-up ($p < 0.01$). The only exception was the vitality domain. Significant differences were also found on the TPB questionnaire, the SMWT, and muscle strength in the expected direction ($p < 0.05$). While those in the intervention group improved significantly on all clinical measures from pre-test to post-test, those in the control group showed improvement only on BMI and joint tenderness. This TPB-based intervention was found to be efficacious in improving HRQoL and several clinical parameters in patients with knee/hip OA. Studies are needed to examine the effectiveness of this intervention in patients with other chronic medical conditions.

Keywords Behavior change · Osteoarthritis · Quality of life · Randomized clinical trial

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Introduction

Osteoarthritis (OA) is a common chronic joint disease in older adults. An inflammatory and degenerative process that affects articular cartilage, OA may lead to clinical complications such as pain at rest and with movement, joint stiffness, restricted range of motion, and deformity in severe cases [1]. Knee and hip joints are among the most affected [2]. Nearly, 10–15% of people between the ages of 50 and 65 years and 40% of those over age of 65 years suffer from OA [3, 4], and among those with this disease, more than 80% have significant physical limitations as a result [5]. OA has been identified as a major public health problem around the world and is not limited to a particular country or region. However, due to the increasing age of populations in developed countries, the prevalence of OA in those nations has increased in the recent decades [6]. In developing countries such as Saudi Arabia, Turkey, China, and South Korea, though, the prevalence rate of OA has been reported to be 35–55% in those age 65 years or older [7–10]. Iran is no exception in this regard, where OA (especially of the knee joint) is a common, serious, and limiting condition in the elderly [11].

Health-related quality of life (HRQoL) is a multifaceted comprehensive outcome measure that may be used to assess the overall health status among people with chronic disorders like OA. HRQoL involves physical, mental, and social dimensions of functioning and may be assessed both generally and more specifically [12]. Several studies have shown the effectiveness of both methods to identify treatment effects for patients with OA [13, 14]. However, studies of HRQoL indicate that using disease-specific measures along with general instruments creates a clearer picture of how OA affects the daily lives of those with this condition [12].

No treatment exists for OA that can stop the degeneration process and medical treatments are typically only effective in partially reducing the symptoms of this disease. However, controlling symptoms has a positive impact on adjustment and increases HRQoL [1]. Non-medical treatments as well, such as interventions that increase physical activity, weight loss, social interactions, and consumption of a healthy diet and promote lifestyle modifications, have been recommended to improve symptoms of the disease, prevent complications, and enhance HRQoL [13, 15]. Therefore, a combination of these two approaches is often utilized to improve clinical outcomes.

Although many experimental studies have examined the impact of medical or surgical interventions (i.e., medication therapy or arthroplasty) for OA patients, there are much fewer studies of non-medical interventions. As noted earlier, those interventions typically promote self-care and encourage healthy behaviors that have the potential to impact HRQoL, often not only improving symptoms but lowering the costs of treatment [16]. The development of such interventions is best guided by proven theories of behavioral change.

The theory of planned behavior (TPB) was initially developed by Ajzen and Fishbein to explain how individual intention can improve behaviors that enhance health outcomes. Behavioral intent as the key construct in this theoretical model involves attitudes, subjective norms, and perceived behavioral control. An individual's favorable or unfavorable evaluation of a given behavior refers to attitudes. Subjective norms involve the viewpoints of other important people in the person's life toward the behavior. Finally, perceived behavioral control is related to how much a behavior is easy or difficult to perform and whether the person has sufficient control over his or her ability to engage in the behavior [17]. TPB has been used in several studies to design health promotion programs for people with a range of health problems [18–20]. However, the efficacy of an intervention designed based on TPB for OA patients is unknown. The objective of the current study was to examine the impact of a TPB-based program designed to improve HRQoL among patients with knee/hip OA and to evaluate the feasibility of including such an intervention in the standard care of patients with OA.

Materials and methods

Design and sample

In this randomized controlled trial (RCT), patients being seen at a general hospital in Tehran, Iran, were screened for inclusion criteria and then randomized to either the intervention or a control group. Participants were enrolled and participated between May and September 2016. Inclusion criteria were (1) meeting American College of Rheumatology criteria for diagnosis of knee/hip osteoarthritis [21], (2) radiologic changes in the affected joint of grade 2 or higher based on Kellgren–Lawrence Scale assessed within the past month, (3) no current registration in other similar education programs, (4) fluent in Persian, and (5) age range between 45 and 75 years old. Exclusion criteria were (1) injection of corticosteroid in the affected joint within the past 6 months; (2) history of arthroplasty in the symptomatic joint; (3) receiving medications specific for OA such as chondroitin sulfate, glucosamine, and corticosteroids in the previous 6 months (those taking over-the-counter pain relievers such as acetaminophen or ibuprofen were included); and (4) physical or mental disability precluding participation in the intervention. Sample size was determined based on the formula recommended by Hulley et al. (two-tailed alpha = 0.05, beta = 0.2, effect size = 0.5) [22]. After the collection of baseline data, participants were randomized to either the educational intervention carried out over a 1-month period or a control group that received only routine treatment of OA at the hospital. People in

intervention and control groups were followed up 3 months after the completion of the intervention (Fig. 1). Participants were fully informed about the study and signed a written informed consent. The ethics committee of Baqiyatallah University of Medical Sciences approved this study.

Measures

Demographic data, two general HRQoL scales (the Short Form Health Survey [SF-12] and European Quality of Life Scale [EQ-5D]), a disease-specific HRQoL scale (i.e., Osteoarthritis Knee and Hip Quality of Life Scale [OAKHQoL], and the TPB scale were administered at baseline and follow-up. Also assessed were several clinical parameters based on examination by an orthopedist.

Demographic profile

Data on age, sex, marital status, education, employment, number of children, accommodation, and economic status were obtained. Economic status was assessed by asking participants how they evaluated their economic status (good, not good or bad, bad). Duration of OA symptoms was also inquired about.

SF-12 scale

The SF-12 asks about general health conditions and their impact on a range of functional domains, including physical functioning (PF; 2 items), role limitations because of physical problems (RP; 2 items), bodily pain (BP; 1 item), general health (GH; 1 item), vitality (VT; 1 item), social functioning (SF; 1 item), role limitations because of emotional problems (RE; 2 items), and perceived mental health (MH; 2 items). Response options range from 2 to 6 for each item based on ability to function in that domain. The raw scores of each domain are transformed to a score ranging from 0 (worst function) to 100 (best function). Two summary scores are calculated, the physical component summary (PCM) and the mental component summary (MCS), based on a standard algorithm. These two summarized scores have a mean score of 50 (standard deviation, 10) and higher scores indicate better

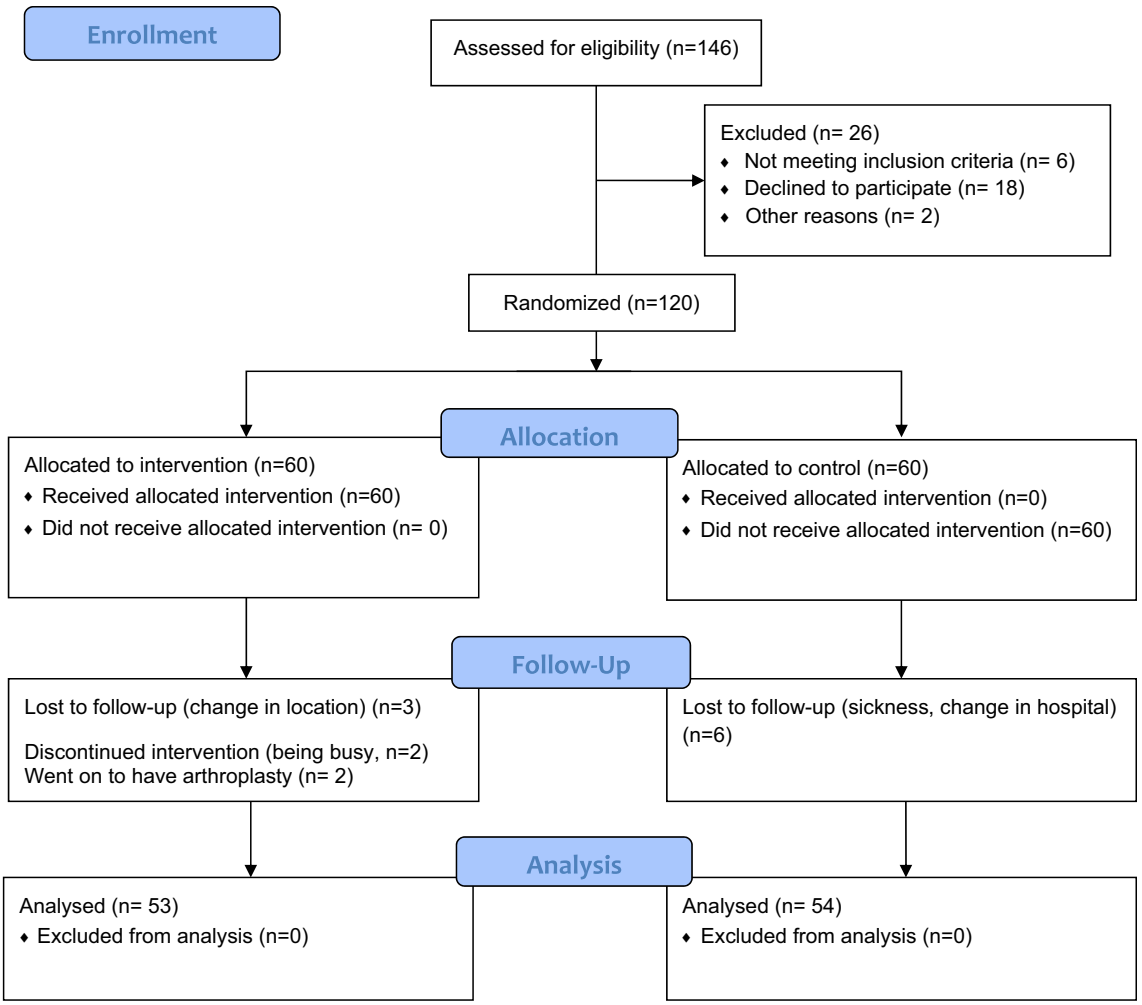

Fig. 1 CONSORT flow diagram

health. The Persian version of SF-12 has been shown to have acceptable psychometric properties [23].

EuroQoL (EQ-5D)

The EQ-5D is a generic measure of HRQoL that is widely used for many chronic disorders. This scale consists of 5 items each measuring a dimension of health status including mobility, ability to self-care, pain or discomfort, ability to perform usual activities, and anxiety or depression. The version of the EQ-5D used in this study was the EQ-5D-3L, which has three response options for each item: no problem, some or mild problem, and severe problem. Based on utility scores from UK, the total score of this scale ranges from 1 (best health) to − 0.594 (worst health). There is also a visual analogue scale (EQ-VAS) that accompanies the EQ-5D-3L and asks participants to indicate their current overall health status on a line that ranges from 0 (worst imaginable health status) to 100 (best imaginable health status). The Persian version of the EQ-5D has well-established validity and reliability.

OAKHQoL scale

This scale is a disease-specific measure of the HRQoL for patients with knee or hip OA. The OAKHQoL includes 43 items that measure five dimensions: physical activities (16 items), mental health (13 items), social support (4 items), pain (4 items), and social activities (3 items). The remaining 3 items assess sexual activity, professional activity, and relationship with spouse. Each item has a response option ranging from 0 to 10, and items on each dimension are summed based on a formula that produces a standard score ranging from 0 (worst HRQoL) to 100 (best HRQoL). Calculation of a total score is not recommended for this scale. The OAKHQoL has been previously translated and psychometrically validated for use in Iran [24].

TPB scale

A questionnaire based on the TPB model was developed to assess the primary components of attitude (7 items), subjective norm (5 items), perceived behavioral control (9 items), intention (6 items), and behavior (7 items). This scale, constructed based on the guidelines recommended by Ajzen [25], asks participants to indicate their adherence to the components of the five domains. Each item has a 7-point response option that ranges from extremely disagree (1) to extremely agree (7). Examples of items are: "I intend to restore my health by adhering to treatments or prevention measures" (intention); "Correctly adhering to preventive/curative behaviors produces a good feeling in me" (attitude); "My family members ask me to follow preventive/curative behaviors correctly" (subjective norm); "I have sufficient ability to adhere to the preventive/curative behaviors to improve my health" (perceived behavioral control); and "I adhere to the behavior such as physical exercise to improve my physical function" (behavior). Total score for every domain is calculated by summing the score of items that are belonging to that domain; higher scores indicate better adherence in that domain. The psychometric properties of the scale were assessed using content validity ratio (CVR) and content validity index (CVI), indicating acceptable validity (10 panelists, CVR = 0.75; CVI = 0.86). Cronbach's alpha for the domains ranged from 0.74 to 0.88, indicating acceptable internal consistency.

Clinical measures

(a) Kellgren–Lawrence Scale (KLS) is a classification system that can be used for knee or hip OA with five grades (0–4). Grade 0 indicates no radiographic changes of OA and grade 4 indicates large osteophytes, significant narrowing of joint space, significant deformity, and severe sclerosis. This is the most widely used system for classifying OA severity [26].

(b) Body mass index (BMI) was used to examine the effectiveness of the intervention on weight control. BMI categories were normal weight 19–24/< 25, overweight 25–30, and obese ≥ 30.

(c) The six-minute walk test (SMWT), endorsed by the American College of Rheumatology, is a performance test that can be used to measure exercise capacity in persons with OA and other chronic disorders such as respiratory disease or health failure. The SMWT is the distance a person can walk over a hard flat surface during 6 min in meters. The person is allowed to rest or self-pace as necessary [27].

(d) Range of motion (ROM) was assessed only for knee joints by a goniometer (plastic goniometers, MSD Company Ltd.) in active flexion state. Two measurements were taken with a 1-min interval and the higher score was reported.

(e) Muscle strength was measured using a digital handheld dynamometer (J-TECH Power 103 Track II Commander) for only quadriceps and hamstring muscles. Three measurements were taken with a 1-min interval and the average score was reported.

(f) Tenderness was assessed at the tibiofemoral joint line using the grading scale suggested by Cipriano involving five grades from 0 (no tenderness) to 4 (superficial palpation causes withdrawal due to pain) [28]. Absence or presence of bony swelling was examined in the tibiofemoral joint, with marginal swelling considered absent.

The intervention

The educational intervention program, designed based on TPB principles, was administered during seven group sessions

(duration between 60 to 90 min) over 1 month. Participants were also provided a CD-ROM and booklet describing preventive lifestyle procedures and the importance of treatment adherence. In the first session, the trainer described the nature of the program and its aims as well as responding to questions about the program and the schedule. At the end of this session, participants were categorized to small groups of 8 to 10. To address attitudes toward treatment adherence and preventive behaviors, the second session involved brain storming with participants regarding the outcomes of treatment adherence that could be expected. In the third session, a group discussion was conducted on the benefits and likely positive results of the adherence to recommendations and preventive lifestyle behaviors. These last two sessions sought to modify behavioral beliefs and outcome evaluations that are subcomponents of attitude. Subjective norms (i.e., subjective beliefs and motivation to compliance) were addressed in two separated sessions (no. 4 and no. 5). A role play scenario was developed for session 4 during which participants were trained to encourage people to adhere the treatments and the important role of family members' support for adherence was emphasized. In the fifth session, motivation to comply was addressed through a group discussion about important people around the individual (e.g., children, friends, and physicians) who were interested in seeing their health restored and necessity of respecting their feelings and desires. The sixth session was devoted to control beliefs, where participants were asked to list internal or external factors that might facilitate or impede their engagement in recommended preventive behaviors. The last session involved discussion of participants' perceived power and ability to adhere to healthcare recommendations and difficulties in doing so. An educational film was shown that described role models engaging in the recommended behaviors. In this video, older people with OA were displayed successfully carrying out behaviors such as physical exercises and participation in the physiotherapy treatment. In that session, the skills necessary to engage in preventive health behaviors were described in small easily comprehensible steps. Participants were asked to follow preventive and lifestyle changes as explained in the CD-ROM and booklet that had been distributed in the first session and provided with the trainer's telephone number for any questions that they might have after intervention was completed.

Statistical analyses

Analyses were conducted using SPSS software for Windows version 20 (IBM statistics). Categorical variables were described as number (percent) and quantitative variables as means and standard deviations. Intervention and control groups were compared at baseline to identify significant differences in demographic or some clinical measures. Normal distribution of data was assessed using the Kolmogorov–Smirnov test; when the normality was not confirmed ($p < 0.05$), non-parametric tests were used. For pre- to post-test within group comparisons, the McNemar test was used; for continuous variables, the dependent t test were used. For between-group comparisons of categorical data, the chi-square or Fisher's exact test was used; for comparison of continuous data, Student's t test was performed. Alpha level was set at $p < 0.05$ for all tests without correction for multiple comparisons due to the exploratory nature of these analyses.

Results

The mean age of participants was 55.8 (SD, 8.9) years and majority were female. Only 7% (eight persons) were single regarding marital status and nearly half of the subjects were illiterate or with only an elementary school education. More than 90% of participants were retired or unemployed and 93% lived in the urban centers. Two thirds evaluated their economic status as intermediate (not good, not bad) and two thirds reported they had more than two children. The average of BMI in both groups at baseline was 29.0 (SD, 4.3), with approximately 80% being overweight or obese. Only 4% (five persons) were diagnosed with hip OA and most participants had grade 2 or 3 OA based on the KLS. There were no significant differences between intervention and control groups on demographic or clinical measures at baseline (Table 1).

Table 2 presents the change in general and disease-specific measures of the HRQoL between baseline and 3-month follow-up after the intervention. All components of the SF-12 scale improved in both groups between baseline and follow-up ($p < 0.01$). However, the mental health component in the control group did not show significant improvement ($p = 0.316$). Between-group differences at follow-up were significant favoring the intervention group on all SF-12 subscales ($p < 0.01$) except the vitality subscale. Similarly, the EQ-5D-3L and EQ-VAS improved significantly within both groups from baseline to follow-up, and between-group differences were also significant at follow-up ($p < 0.01$). Within-group differences between baseline and follow-up were present for all subscales of the OAKHQoL in the intervention group, although changes were less consistent in control subjects; between-group differences at 3-month follow-up were significant for all subscales of the OAKHQoL. When only those with hip OA were assessed between baseline and follow-up, all subscales of OAKHQoL with exception of pain and social support improved significantly ($p < 0.05$). While there were no significant differences between groups on these subscales in patients with hip OA at baseline, only the mean of social support domain in the intervention group showed significant improvement compared to the control group (55.0 ± 1.3 vs. 43.3 ± 2.9). The other domains showed similar changes in both groups (not shown in the table).

Table 1 Characteristics of the sample at baseline

Variables	Total *N* (%)	Trial group *N* (%)	Control group *N* (%)	*p* value
Age				
< 50	28 (23.3)	13 (21.7)	15 (25.0)	0.666
≥ 50	92 (76.7)	47 (78.3)	45 (75.0)	
Sex				
Male	29 (24.2)	12 (20.0)	17 (28.3)	0.286
Female	91 (75.8)	48 (80.0)	43 (71.7)	
Marital status				
Single	8 (6.7)	3 (5.0)	5 (8.3)	0.717[c]
Married	112 (93.3)	57 (95.0)	55 (91.7)	
Education				
Illiterate/elementary	68 (56.7)	34 (56.7)	34 (56.7)	0.382
Secondary/high school	27 (22.5)	11 (18.3)	16 (26.7)	
University	25 (20.8)	15 (25.0)	10 (16.7)	
Employment				
Employed	10 (8.3)	3 (5.0)	7 (11.7)	0.322[c]
Not employed	110 (91.7)	57 (95.0)	53 (88.3)	
Accommodation				
Rural	9 (7.5)	4 (6.7)	5 (8.3)	1.000[c]
Urban	111 (92.5)	56 (93.3)	55 (91.7)	
Number of children				
< 3	40 (33.3)	23 (38.3)	17 (28.3)	0.245
≥ 3	80 (66.7)	37 (61.7)	43 (71.7)	
Economic status				
Good	12 (10.0)	8 (13.3)	4 (6.7)	0.112
Not good, not bad	90 (75.0)	49 (81.7)	47 (78.3)	
Bad	18 (15.0)	3 (5.0)	9 (15.0)	
Disease duration (year)[a]				
< 5	88 (73.3)	42 (70.0)	46 (76.7)	0.409
≥ 5	32 (26.7)	18 (30.0)	14 (23.3)	
BMI				
< 25	21 (17.5)	11 (18.3)	10 (16.7)	0.645
25–30	49 (40.8)	22 (36.7)	27 (45.0)	
≥ 30	50 (41.7)	27 (45.0)	23 (38.3)	
Affected joint				
Knee	115 (95.8)	58 (96.7)	57 (95.0)	1.000[c]
Hip	5 (4.2)	2 (3.3)	3 (5.0)	
Osteoarthritis grade[b]				
II	52 (43.3)	30 (50)	22 (36.7)	0.140[d]
III	64 (53.3)	29 (48.3)	35 (58.3)	
IV	4 (3.3)	1 (1.7)	3 (5.0)	

BMI, body mass index

[a] Duration of morbidity with osteoarthritis

[b] Based on Kellgren–Lawrence Scale

[c] Fisher's exact test

[d] Chi-square test was calculated after formation a 2 × 2 contingency table by integration grades III and IV

As indicated in Table 3, within-group change in the intervention group and differences between intervention and control groups indicated significant improvement in TPB components in the intervention group. There was no significant within-group change in subjective norms or perceived behavioral control in the control group ($p > 0.3$). All clinical measures also showed significant within-group improvements in the intervention group, while there was inconsistent change in the control group (only improvements on BMI and joint tenderness). Significant between-group differences were identified for meters walked on the SMWT, muscle strength, and near significant differences on joint tenderness, all favoring the intervention group.

Table 2 General and disease-specific health-related quality of life outcomes among intervention and control subjects at baseline and follow-up

Scales	Trial group		Control group		*p* value (within group)		*p* value (between groups)	
	Baseline ($n = 60$) *M* (SD)	Follow-up ($n = 53$) *M* (SD)	Baseline ($n = 60$) *M* (SD)	Follow-up ($n = 54$) *M* (SD)	Trial	Control	Baseline	Follow-up
SF-12								
Physical function (PF)	36.6 (23.2)	49.6 (12.6)	31.6 (23.8)	38.7 (25.0)	< 0.001	< 0.001	0.247	0.004
Role physical (RP)	21.6 (40.5)	92.5 (22.2)	18.3 (34.0)	45.0 (37.6)	< 0.001	< 0.001	0.628	< 0.001
Bodily pain (BP)	44.6 (19.0)	59.2 (13.8)	42.1 (19.8)	45.8 (17.3)	< 0.001	0.002	0.482	< 0.001
General health (GH)	35.4 (16.8)	48.3 (9.1)	35.8 (16.8)	40.4 (16.0)	< 0.001	0.001	0.892	0.001
Vitality (VT)	40.0 (20.5)	54.7 (15.1)	41.0 (20.1)	54.3 (18.1)	< 0.001	< 0.001	0.792	0.913
Social function (SF)	47.9 (20.7)	73.7 (21.8)	54.2 (17.3)	60.4 (16.1)	< 0.001	< 0.001	0.076	< 0.001
Role emotional (RE)	21.7 (40.5)	92.5 (24.0)	28.3 (42.5)	49.2 (40.6)	< 0.001	< 0.001	0.381	< 0.001
Mental health (MH)	54.5 (15.8)	63.5 (12.7)	53.2 (15.2)	55.8 (10.6)	< 0.001	0.316	0.639	< 0.001
PCS	34.7 (6.4)	42. 29 (3.2)	33.4 (7.2)	37.0 (6.6)	< 0.001	< 0.001	0.301	< 0.001
MCS	39.7 (8.2)	50.0 (5.2)	41.0 (7.4)	46.4 (6.0)	< 0.001	< 0.001	0.350	0.001
EuroQol								
EQ-5D-3L	0.38 (0.33)	0.66 (0.13)	0.37 (0.35)	0.53 (0.28)	< 0.001	< 0.001	0.931	0.003
EQ-VAS	49.2 (13.8)	60.7 (10.9)	49.0 (15.5)	52.2 (13.0)	< 0.001	< 0.001	0.950	< 0.001
OAKHQOL								
Physical activity	55.6 (14.1)	64.7 (9.11)	54.1 (15.4)	55.0 (13.6)	< 0.001	0.003	0.555	< 0.001
Mental health	57.9 (15.6)	66.6 (11.7)	55.0 (16.8)	55.5 (15.1)	< 0.001	0.068	0.338	< 0.001
Pain	43.3 (14.8)	54.2 (10.8)	41.3 (16.9)	42.0 (14.9)	< 0.001	0.055	0.483	< 0.001
Social support	49.1 (13.3)	59.8 (12.2)	49.0 (17.6)	50.9 (15.6)	< 0.001	< 0.001	0.988	0.001
Social functioning	40.7 (11.5)	45.3 (9.8)	39.8 (16.0)	41.6 (13.5)	< 0.001	< 0.001	0.728	0.087

SF-12, Short Form Health Survey 12; *VAS*, visual analogue scale; *MCS*, mental component summary; *PCS*, physical component summary; *OAKHQoL*, Osteoarthritis Knee and Hip Quality of Life Questionnaire

Discussion

The purpose of this study was to examine the efficacy of an educational intervention based on TPB principles on quality of life and clinical measures in a sample of middle-age and older Iranian patients with knee/hip OA. We found that the TPB-based intervention significantly improved HRQoL assessed by both general and specific measures compared to a usual care control group. Several clinical measures also improved such as BMI, SMWT, ROM, muscle strength, and joint tenderness and swelling in those who participated in the educational intervention. These objective measures, along with self-report scales, support the usefulness of this educational program in Iranian patients with OA.

There are only a few intervention studies that have applied behavioral theories to improving HRQoL in patients with OA. Dobson et al. in a systematic review examined the use of a behavior change theory to identify barriers and facilitators of exercise in patients with knee/hip OA. These investigators argued that exercise therapy is a key component to any intervention program targeting symptom management in these patients. They found the most important and prevalent barriers preventing engagement in exercise programs were related to attitude and beliefs about the consequences of exercise and the underestimation of patients' internal capabilities to overcome these barriers. In addition, reinforcement of the self-care behaviors was identified as the main facilitator of behavior change. The role of clinicians in directing patients toward active coping with these barriers and adhering to recommended treatments was also emphasized [29]. The findings from the present study confirm the results of this literature review, demonstrating that a TPB educational intervention to address change in the beliefs and attitude of patients may be helpful for the better disease management of patients with OA.

Other studies have found that interventions to modify lifestyle in the OA patients can be successful. In a program conducted in Taiwan using a multifaceted approach to promote healthy behaviors and symptom control in older patients with knee OA, researchers assessed weight reduction, pain level, and physical function of 80 participants randomized to intervention and control groups. The intervention consisted of health education, weight control, exercise training, and home visits. Two months after intervention, results indicated significant improvements on all measures in the intervention compared to the control group [30]. Similarly, in another study designed to improve health outcomes through lifestyle change, a multidimensional approach

Table 3 Theory of planned behavior (TPB) constructs and clinical outcomes in intervention and control subjects at baseline and follow-up

Scales	Trial group		Control group		*p* value (within group)		*p* value (between groups)	
	Baseline ($n = 60$) *M* (SD)	Follow-up ($n = 53$) *M* (SD)	Baseline ($n = 60$) *M* (SD)	Follow-up ($n = 54$) *M* (SD)	Trial	control	Baseline	Follow-up
TPB constructs								
Attitude	19.4 (5.3)	35.6 (6.3)	20.1 (5.6)	22.3 (5.4)	< 0.001	< 0.001	0.483	< 0.001
Subjective norms	14.9 (3.8)	18.5 (4.2)	14.2 (4.1)	14.8 (3.9)	< 0.001	0.359	0.334	< 0.001
Perceived behavioral control	21.6 (6.7)	29.6 (6.3)	20.9 (6.3)	21.2 (6.5)	< 0.001	0.478	0.556	< 0.001
Intention	18.3 (4.7)	31.2 (6.3)	17.4 (4.3)	18.5 (5.0)	< 0.001	0.025	0.276	< 0.001
Behavior	19.4 (5.5)	37.6 (6.2)	18.7 (4.9)	22.3 (5.7)	< 0.001	< 0.001	0.463	< 0.001
Clinical measures								
SMWT (m)	407(95.8)	458 (99.3)	398 (89.5)	410 (98.6)	< 0.001	0.079	0.595	< 0.013
Range of motion (flexion)[a]	113.5 (21.3)	119.3 (19.6)	115.7 (20.4)	118.6 (21.1)	0.006	0.119	0.564	0.859
Muscle strength-Q (lb)[a]	55.6 (8.4)	58.4 (8.3)	53.9 (8.2)	54.5 (7.9)	< 0.001	0.439	0.264	0.014
Muscle strength-H (lb)[a]	52.2 (7.8)	54.9 (7.7)	50.8 (7.6)	51.6 (8.1)	< 0.001	0.356	0.321	0.033
BMI (kg/m^2)	29.4 (4.6)	28.8 (4.3)	28.6 (3.9)	28.5 (3.8)	< 0.001	0.124	0.302	0.653
Tenderness grade, *n* (%)[b]								
0	26 (43.3)	34 (64.1)	28 (46.7)	29 (53.7)	< 0.001[d]	0.001[d]	0.531[c]	0.070[c]
1	20 (33.3)	14 (26.5)	15 (25.0)	13 (24.1)				
2	12 (20.0)	4 (7.5)	14 (23.3)	10 (18.5)				
3	2 (3.4)	1 (1.9)	3 (5.0)	2 (3.7)				
Joint swelling, *n* (%)								
Yes	39 (65.0)	20 (37.8)	33 (55.0)	25 (46.3)	0.028	0.518	0.263	0.369
No	21 (35.0)	33 (62.2)	27 (45.0)	29 (53.7)				

TPB, theory of planned behavior; *SMWT*, six-minute walk test; *BMI*, body mass index; *Q*, quadriceps; *H*, hamstring

[a] Only for knee joint

[b] Joint line tenderness

[c] Chi-square was calculated after integration levels 0 and 1 as well as 2 and 3 together

[d] McNemar test was calculated after integration levels 0 and 1 as well as 2 and 3 together

that included a combination of training for pain control and weight management was examined in overweight/obese OA patients. Duration of the intervention was 6 months and outcomes were BMI, pain level, physical disability, stiffness, and gait; group differences were assessed at baseline, immediately following the intervention, and 6 and 12 months later. This combined approach was also successful to enhance outcomes especially over the long term [31]. The results from these studies are consistent with the findings of the present study suggesting that multifaceted programs may be particularly effective both in the short and long terms.

Many experimental studies in OA patients have examined quality of life as the primary outcome. In their systematic review of 12 studies examining the effects of exercise therapy on HRQoL in patients with knee OA, Tanaka et al. found strong evidence that these kinds of interventions can improve both the physical and mental components of the HRQoL [14]. In a study that examined the effects of exercise-based yoga therapy on the HRQoL of the patients with knee OA, participants engaged in yoga techniques for 40 min per day for 2 weeks. Significant improvements in quality of life were found 3 months after the intervention, congruent with the findings of the present study [32]. However, most studies on the HRQoL are usually related to assessing a new pharmaceutical or surgical intervention, and unfortunately, applying psychological interventions as guided by TPB or other behavioral theory-based interventions is in the minority.

The demographic characteristics of the present sample are relatively consistent with persons more generally with OA. For example, more than 75% were age 50 years or older, as often

reported for those with OA [3]. Likewise, global prevalence of the OA is more common in women than in men, as demonstrated in the current sample [4]. The knee joint is also one of the most common locations for OA [2]. Although we invited patients with either knee or hip OA to participate in the study, only a small number of those with hip OA could be identified and included. Finally, a well-known risk factor for the development of OA is being overweight or obese [1], as in our sample where over 80% of the participants were in this category.

A surprising finding was that improvement in the vitality domain of the HRQoL did not occur, which in contrast to intervention studies similar to the present one did show improvements in this domain [14, 33]. One possible explanation may be related to the method of assessment of vitality compared to other studies. The SF-12 was used here, which is a brief version of the SF-36. In most studies reviewed, the SF-36 was used to assess general quality of life. In the SF-36, the vitality is measured using 4 items, whereas the SF-12 only uses 1 item for this domain, which may affect the sensitivity of measurement. Another reason may be due to the type of intervention used here, which was an educational program designed to encourage OA patients to adhere to treatment and comply with preventive health behaviors. There was no particular energizer or component focused on increasing vitality such as physical activity or exercise, which has been included in many similar interventions. However, the usual care program provided for OA patients by the hospital also did not change this component of quality of life in the control group.

With regard to changes in general vs. specific HRQoL measures, an interesting finding was that both mental health and pain improved in controls based on SF-12 scores; however, when using the disease-specific OAKHQoL scale, these dimensions did not improve (in contrast to significant changes in the intervention group). This may be related to the precision of measurement between the two measures. As Tangtrakulwanich et al. have suggested, disease-specific measures of quality of life have greater sensitivity to change than generic measures in OA patients [34].

Although the current RCT has a number of strengths, including sample size, randomization, a solid theory-driven intervention, and the use of both self-report and objective measures, several limitations need to be taken into account when interpreting the findings of this study. First, in spite of our intention to include patients with either knee or hip OA, the majority participants had knee OA. Thus, caution should be displayed when generalizing these results to patients with hip OA. Future intervention studies of this type should consider stratified sampling methods to increase the number of hip OA patients in the sample. Because the present study population was limited to a general hospital sample, whoever was available and willing to participate was included in the sample (and most of those were knee OA patients). Second, as noted earlier, the present intervention focused only on TPB constructs. Including other components such exercise therapy or providing nutrition consultation may increase intervention efficacy and improvement in domains such as vitality. Finally, only a single follow-up assessment was conducted at 3 months after the intervention. A longer follow-up including assessments at 6 and 12 months would be helpful in determining the long-term efficacy of the intervention.

Conclusion

In summary, a theory of planned behavior (TPB)-based intervention was shown to successfully change behavior and increase quality of life and a range of objective clinical parameters in patients with knee or hip OA (knee in particular) above that experienced by a control group of patients receiving usual care. Since this intervention specifically targeted the psychological parameters in OA patients, adding a focus on lifestyle changes (including exercise and diet) may increase its effectiveness. The cost-effectiveness of such interventions related to medical treatments or surgical procedures, along with the feasibility and acceptability of educational programs like the present one (only seven dropouts from intervention over 3 months), is a reason for implementing this intervention more widely along with other established treatments. Although no significant difference was found between treatment groups on clinical parameters such as BMI, range of motion, and tenderness/swelling, the change that did occur was in favor of the intervention group. If such changes continue over time, it is possible (though not guaranteed) that the differences would eventually reach statistical significance. Finally, testing such interventions in patients with chronic medical conditions other than OA may help to identify treatments that increase quality of life and improve clinical outcomes in those diseases as well, particularly across a range of cultural settings.

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Compliance with ethical standards

Participants were fully informed about the study and signed a written informed consent. The ethics committee of Baqiyatallah University of Medical Sciences approved this study.

Disclosures None.

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