The effect of mobile-app-based instruction on the physical function of female patients with knee osteoarthritis: a parallel randomized controlled trial

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Abstract

Background: Osteoarthritis is a common disease and one of the most important causes of disability in the elderly that negatively affect the quality of their life. The purpose of this study was to evaluate the effectiveness of mobile app-based-instruction in improving physical performance of female patients with knee osteoarthritis.

Methods: The present study was a randomized clinical trial. The sample included 64 female patients (40 to 70 years old) with knee osteoarthritis in Bojnurd city in 2018. They were selected from the available patients that were randomly divided into comparison and intervention groups. Before the intervention, demographic information questionnaire, Western Ontario and McMaster Universities Arthritis Index (WOMAC) questionnaire, and 36-item short-form health survey (SF-36) were employed to elicit data on demographic information, arthritis condition and health status of the participants. Intervention lasted for a period of two months for each group. Intervention group received mobile-app-based instruction coupled with routine cares, while comparison group just received the routine cares. After the intervention both groups were evaluated again in terms of arthritis condition and health status using the same scales.

Results: After the intervention, significant differences were found between the intervention and comparison groups in terms of overall WOMAC score ($p = 0.005$), pain aspect of WOMAC ($p = 0.005$), physical function aspect of WOMAC ($p = 0.005$), physical function aspect of SF-36 ($p \leq 0.05$), and vitality aspect of SF-36 ($p > 0.05$).

Conclusion: The use of mobile-app-based instruction can enhance the physical function and quality of life in patients with knee osteoarthritis.

Trial registration The research project was registered at Iranian Registry of Clinical Trials (IRCT2016120831300N2).

Keyword: Osteoarthritis, Mobile app, Patients’ training
over 240 million people worldwide are suffering from this debilitating disease [4]. OA is commonly seen in pelvic, knees, spine, and finger joints[5]. However, knee OA is the most prevalent OA (33% prevalence) and has more clinical symptoms than any other forms of OA [6]. It is one of the five causes of disability in the elderly [7, 8]. In the United States, 14 million people are affected and more than half of them are under 65 [9]. American studies show that OA is on the rise [10]. Similarly, the prevalence of osteoarthritis seems to be increasing in Iran.

In epidemiological studies, including Community Oriented Program for Control of Rheumatic Diseases (COPCORD) the worldwide prevalence of knee osteoarthritis has been estimated 7%. The prevalence of OA in Iranian population over 15 years old has been estimated to be 16.9% and that of knee OA 15.5%. Regarding the prevalence of knee OA, Iran is ranked third among the studied countries[11, 12]. Osteoarthritis reduces mobility, quality of life, and well-being [13, 14], and increases health care and economic burden [15]. Unfortunately, the growing elderly population, sedentary lifestyle and obesity can add to the complications and the prevalence of OA. The prevalence of chronic osteoarthritis is predicted to increase and become the most common chronic skeletal disease in 2040 [16]. Aside from bone and joint damages, OA appears as a result of degeneration and destruction of the articular cartilage. It is usually seen in people over 40 and has slow progression rate as a result of repeated natural or abnormal pressures [17]. Knee osteoarthritis is caused by the incorrect performance of daily activities at younger age, as well as improper lifestyle and bodily movements [18]. Women account for a higher percentage of the OA patients [19] and female sex is a risk factor that increases the likelihood of developing OA [20]. Women experience greater incidence and more severity of OA than men, so it is necessary a greater need for effective treatment and prevention of OA in women[21, 22]. In addition, women often illustrate greater pain and more substantial reduction in function than men, which can lead to sarcopenia [23]. Lower extremity muscle appears to play a greater role in the development of knee OA in women than in men[24]. Although, the prevalence of OA is high, the population mean age is growing, and OA effects on mental and physical health [20], there are currently no methods to cure or stop the cartilage destruction [25]. Available treatment options are limited and at best can be effective on some patients [16]. The person with OA lives with it for 26 years on average [26, 27] and carries the burden of the disease for a long time. Not only the medical treatments, but also systematic health care is essential for proper treatment of OA [20]. Therefore, early diagnosis and continuous monitoring of OA progress are important in establishing effective treatment [28]. OA treatment goals include relieving pain and inflammation, lowering stiffness, improving function or range of motion, and improving or maintaining the mobility, physical activity, and health-related quality of life [29]. To achieve the treatment goals Patient education is needed. This is a continuous process and an integral part of patient management. The trainer should consider different aspects of the disease and the benefits and risks of treatment options. Empowering the patients by involving them in the decision-making process and teaching them skills for positive changes in life is a lengthy process for treatment [30]. This makes the individuals tired and may cause them to forget parts of their trainings. Therefore, patient education requires consistent monitoring of the patients’ performance. Due to decreased mobility and increased disability, the patient may not be able to visit the trainers in person and receive ongoing monitoring. Some believe that the available web-based approaches are more comfortable for the patients and can help them cope with the current shortage of skilled professionals and obstacles to ongoing face to face monitoring [12]. Dallimore et al. reports that the patients who used iPad scored significantly better in terms of recovery indices and were more satisfied with their treatment than other patients [31]. It has been also found that using technology tailored to users’ needs lead to continued training in patients with OA and improve the motivational and behavioral factors [32]. A study has shown that the use of pedometer to provide feedback on walking activities of OA patients contributes to the attainment of OA treatment goals [33]. Another study found the use of smartphone app to be effective in training the OA patients and improving their condition [34].

Today, cell phones are part of everyday life, including health services. Mobile apps have the potentials to be exploited for medical purposes like instructing the patients for preventing diseases. In addition, the use of mobile apps can help for timely diagnosis and treatment, and lowering the costs of medical cares. Therefore, we decided to design a mobile app-based training program for patients with knee OA and evaluate its effectiveness on physical performance and behavioral change of these patients. Designing such apps allows for better monitoring and consistent instruction because it saves time and money, and frees the patients from the troubles of visiting their doctors in person. Proper and timely education can improve the quality of life in OA patients and reduce the incidence of knee osteoarthritis and its complications.

**Methods**

The present study is a parallel randomized controlled trial. Participants of the study were 40–70 year-old female patients with knee osteoarthritis referring to Imam Ali
Hospital in Bojnurd, affiliated to North Khorasan University of Medical Sciences. The sample size was determined through consulting previous similar studies [18, 35, 36]. Therefore, sample size was determined to consist of 28 people for each group using the G-power software with the confidence interval of 95% and the power of 80%. However, given the probability of a 10% drop in samples, 32 individuals were assigned to each group.

After determining the sample size, 64 female patients with knee osteoarthritis were selected from the referrals to Imam Ali Hospital in Bojnourd using the inclusion criteria. They were asked to sign the informed consent form before participating in the study. Patients were assigned to the intervention or comparison groups using blocked randomization method. In order to prevent information exchange between the intervention and comparison groups, patients were planned to be visited on different days. Prior to the intervention, patients were assessed in terms of demographic characteristics, OA condition and health status. To this end, demographic questionnaire, WOMAC, and SF-36 were completed for the patients in each group.

In order to observe blindness and avoid bias in data collection, the researcher who was collecting information on patients’ performance and quality of life was kept unaware to which (intervention or comparison) groups the patients were belonging. Patients in the intervention group received all the educational content only through the mobile app. They were met only once at the beginning of the study to get familiar with using the app. Patients in the comparison group attended two face to face sessions; one introductory session at the beginning of the study and another one a month later of patients’ questions and further clarifications.

During the study, both groups received routine medical care. The educational content provided to both intervention and comparison groups included learning about OA and its causes, OA risk factors, the healthy diet and nutrients, treatment modalities, and the exercises for OA patients. Two months after the intervention, both groups were assessed again in terms of OA condition and health status using OWMAC and SF-36 respectively.

One patient from the intervention group and 3 patients from comparison group were excluded from the study because of discontinuing the treatment and participation. Finally, data from 60 patients (31 patients in the intervention group and 29 patients in the comparison group) were analyzed. Over an experimentation period was completed, the patients in the comparison group were also provided with the mobile app to get benefits from the instructions.

Inclusion criteria: (1) signing the informed consent form, (2) having the symptoms of knee osteoarthritis confirmed through radiologic assessment, (3) being 40 to 70 years old, (4) having a smartphone that is always available, (5) knowing how to use the mobile apps.

Exclusion criteria: (1) needing knee surgery during the study, (2) having intra-articular injections during the study, (3) suffering from mental illnesses, (4) unwilling to continue participation, (5) lacking the post-test data.

The data collection was done by employing three questionnaires: (a) demographic questionnaire that aimed to elicit data on the history of addiction, job, education, illness, age, BMI and marital status, (b) Western Ontario and McMaster Universities Arthritis Index (WOMAC) questionnaire consisting of 24 questions in three areas of pain, stiffness, and function of joints [35, 36], (c) Short form of health survey questionnaire (SF-36) by Weir and Sherborne (1992) consisting of 36 items and 8 components of Vitality, Physical Functioning, Bodily Pain, General Health, Physical Role Functioning, Emotional Role Functioning, Social Role Functioning, and Mental Health [37].

Data were analyzed by the student’s t test, and ANOVA using SPSS 18. The ANCOVA test was also used to adjust for the effects of the WOMAC and SF-36 scores at the baseline. Adjusted scores of WOMAC and SF-36 were reported as mean (SD). Significance level to interpret the statistical results was set at \( p \leq 0.05 \).

Results
The flow diagram of participants in this clinical trial is shown in Fig. 1. Initially, 90 patients were included in the study using the inclusion criteria. However, 15 patients who were later found not eligible and 11 patients who were not willing to participate were excluded. Finally, the sample consisted of 64 female patients with knee osteoarthritis who were randomly assigned to two equal groups (intervention and comparison groups). The baseline characteristics of the participants are shown in Table 1. The results of the chi-square test showed that there was no significant difference between the two groups in terms of age, BMI, history of addiction, occupation, co-morbidity, duration of illness and education \((p < 0.05)\). Table 2 shows the means and standard deviations of the WOMAC and SF-36 questionnaires at the beginning of the study. The mean scores of intervention and comparison groups in general health were 18.67 (SD = 10.97) and 25.48 (SD = 13.17), respectively, and were significantly different before the intervention \((p = 0.035)\). There was no statistically significant difference between the two groups in other areas of WOMAC and SF-36 \((p > 0.05)\). Table 3 shows the, the means of crude d and adjusted scores (both total and sub scores) in physical performance (WOMAC) and quality of life (SF-36) after the
intervention. The adjusted $p$ values are also shown in Table 3. It was observed that after the intervention there were significant differences between the intervention and comparison groups in total, pain, and functional limitation scores of WOMAC ($p < 0.005$) except the stiffness ($p = 0.618$). Also, the results did not change after adjusting for baseline values using ANCOVA test. The comparisons of the groups after the intervention in terms of the components of quality of life (SF-36) showed that the two groups were significantly different only in physical functioning and energy/fatigue. Physical functioning and energy/fatigue scores in the intervention group were 41.45 (8.68) and 67.09 (11.74) respectively, and in the comparison group were 32.41 (7.51) and 56.72 (10.46) respectively ($p < 0.005$). After adjusting for baseline values, the difference between the two groups was also significant in the pain component ($p = 0.047$). Overall, it was concluded that the mobile app-based training program improves the physical performance of the intervention group compared to the comparison group.

**Discussion**

The purpose of this study was to evaluate the efficacy of mobile app-based-instruction in improving physical function of female patients with knee osteoarthritis. The results showed that using mobile app-based-instruction significantly reduces pain, and improves the physical function and overall condition of patients with knee osteoarthritis. It also improved some aspects of quality of life, such as fatigue/energy, physical function and pain in intervention group compared to the comparison group. These results are in line with those of Danbjørg et al. [32], Dallimore et al. [31], Skrepnik et al. [34], Semple et al. [38], Brun Thorup et al. [33]. In these studies, an application or a web-based service was used to educate and monitor the recovery process of the patients. We found no studies pointing to the ineffectiveness of mobile apps in improving the physical performance of patients with OA.

Certain explanations can be put forward on the effect of mobile app-based instruction in physical performance, pain perception and some aspects of health in patients
with knee OA. First, mobile app-based instruction provides easy access to reliable information. Efficient health care requires accurate and useful information which is difficult to obtain at times. Despite the information available in the twenty-first century, people may not be able to get access to reliable and credible information. This justifies the attempts for direct access to a specialist for proper instructions. On the other hand, visiting a doctor frequently has been time-consuming and difficult for many OA patients. The educational app, not only makes it easy to access educational services, but also provides reliable and credible information. As a result, it increases the likelihood of the use of educational content by the patients. Second, mobile apps can be used at any time and place. Smartphones enable the patients to read the instructions and use them whenever they want. Third, mobile apps make the patients more motivated to exercise and monitor their performance because mobile apps can have built-in mechanisms for allowing the patients to monitor their status and responding to their questions. Fourth, people are increasingly getting accustomed to use mobile apps. This growing habit of frequent use of mobile apps raises the effectiveness of mobile apps in instructing the patients.

**Conclusion**

Based on the results of the present study and related studies, it can be concluded that using mobile app-based instructions can significantly reduce the pain and improve some health aspects in women with knee OA. Accordingly, it is useful in medical, clinical and physiological management of knee osteoarthritis. Such benefits of mobile app-based instructions can have positive effects on the physical and mental health of people with knee OA and increase their satisfaction and quality of life. As a result, mobile app-based instruction can be used to educate patients while saving their time and money. It is suggested that the benefits of mobile app-based instruction in other diseases be further studied. Due to fact statistical significance was not found in relation to the effect of mobile app-based instruction on some aspects of quality of life (as measured by SF-39), it is recommended that efficacy of mobile app-based instruction in improving different aspects of quality of life be further studied for longer periods of life.

| Table 1 | Participant characteristics at baseline |
|---------|-------------------------------------|
| Variable | Total (n = 60) | Intervention group (n = 31) | Comparison group (n = 29) |
| Age, mean (SD) | 58.17 (7.55) | 57.84 (6.63) | 58.52 (6.33) |
| BMI, mean (SD) | 27.31 (3.98) | 27.97 (4.44) | 26.62 (3.37) |
| History of addiction, No. (%) | 32 (53.3) | 19 (61.3) | 13 (44.8) |
| Job, No. (%) | 51 (85) | 26 (83.9) | 25 (86.2) |
| Employee | 7 (11.7) | 4 (12.9) | 3 (10.3) |
| Free job | 2 (3.3) | 1 (3.2) | 1 (3.4) |
| Type of comorbidity, No. (%) | 12 (20) | 7 (22.6) | 5 (17.2) |
| No | 9 (15) | 1 (3.2) | 8 (27.6) |
| HLP | 21 (35) | 12 (38.7) | 9 (31) |
| ASTHMA | 4 (6.7) | 3 (9.7) | 1 (3.4) |
| C.P | 1 (1.7) | 1 (3.2) | – |
| Lumber pain | 13 (21.7) | 7 (22.6) | 6 (20.7) |
| Duration of catch | 1–3 years | 2 (3.3) | 2 (6.5) | – |
| 3–6 years | 7 (11.7) | 4 (12.9) | 3 (10.3) |
| 6–10 years | 49 (81.6) | 25 (80.6) | 24 (82.8) |
| 10–15 years | 2 (3.3) | – | 2 (6.9) |
| Education, No. (%) | Illiterate | 45 (75) | 22 (71) | 23 (79.3) |
| Diploma | 11 (18.3) | 6 (19.4) | 5 (17.2) |
| Associate Degree | 4 (6.7) | 3 (9.7) | 1 (3.4) |
| Married, No. (%) | 60 (100) | 31 (100) | 29 (100) |

| Table 2 | Mean scores for SF-36 and WOMACK at the baseline |
|---------|-------------------------------------|
| Domain | Average scores*, mean (SD) |
| | Intervention group (n = 31) | Comparison group (n = 29) | P value |
| WOMAC | Pain | 18.45 (5.10) | 17.17 (1.69) | 0.204 |
| Stiffness | 5.87 (1.05) | 5.58 (0.77) | 0.242 |
| Functional limitation | 48.32 (4.21) | 49.61 (5.24) | 0.333 |
| Total | 72.64 (7.15) | 72.27 (5.53) | 0.825 |
| SF-36 | Physical functioning | 27.25 (8.83) | 27.41 (7.97) | 0.943 |
| Role limitations due to physical health | 12.09 (15.64) | 13.79 (14.30) | 0.663 |
| Role limitations due to emotional problems | 27.95 (24.49) | 18.39 (22.86) | 0.124 |
| Energy/fatigue | 50.96 (13.50) | 49.82 (11.21) | 0.724 |
| Emotional well being | 60 (8.94) | 56.82 (10.33) | 0.280 |
| Social functioning | 36.69 (15.11) | 38.36 (15.24) | 0.672 |
| Pain | 40.40 (17.98) | 36.55 (17.28) | 0.402 |
| General health | 18.67 (10.97) | 25.48 (13.17) | 0.035 |

*Baseline measurement
Table 3: Comparison of the mean scores for SF-36 and WOMACK after intervention

| Domain                        | Crude scores, mean (SD) | Adjusted scores, mean (SE) |
|-------------------------------|-------------------------|---------------------------|
|                               | Intervention group (n = 31) | Control group (n = 29) | p value | Intervention group (n = 31) | Control group (n = 29) | p value |
| WOMAC                         |                         |                          |         |                         |                          |         |
| Pain                          | 11.80 (1.32)            | 13.82 (1.46)             | 0.0001  | 11.79 (0.25)            | 13.84 (0.26)             | 0.0001  |
| Stiffness                     | 4.80 (0.98)             | 4.68 (0.80)              | 0.618   | 4.73 (0.14)             | 4.76 (0.14)              | 0.895   |
| Functional limitation         | 41 (3.54)               | 45.86 (4.83)             | 0.0001  | 41.45 (0.37)            | 45.38 (0.38)             | 0.0001  |
| Total                         | 57.61 (3.87)            | 64.37 (4.85)             | 0.0001  | 57.53 (0.61)            | 64.46 (0.63)             | 0.0001  |
| SF-36                         |                         |                          |         |                         |                          |         |
| Physical functioning          | 41.45 (8.68)            | 32.41 (7.51)             | 0.0001  | 41.49 (1.19)            | 32.37 (1.23)             | 0.0001  |
| Role limitations due to physical health | 12.09 (15.50)           | 13.79 (14.33)            | 0.663   | 12.91 (0.0001)          | 12.91 (0.0001)           | 0.054   |
| Role limitations due to emotional problems | 27.95 (24.49)           | 18.39 (22.86)            | 0.124   | 29.74 (4.46)            | 16.48 (4.62)             | 0.054   |
| Energy/fatigue                | 67.09 (11.74)           | 56.72 (10.46)            | 0.001   | 67.62 (1.31)            | 57.12 (1.35)             | 0.0001  |
| Emotional well being          | 60 (8.94)               | 56.82 (10.33)            | 0.208   | 58.46 (0.0001)          | 58.46 (0.0001)           | 0.99    |
| Social functioning            | 40.32 (15.38)           | 40.51 (14.03)            | 0.095   | 40.89 (1.81)            | 39.90 (1.88)             | 0.706   |
| Pain                          | 51.61 (15.75)           | 44.13 (17.14)            | 0.084   | 50.10 (1.48)            | 45.74 (1.53)             | 0.047   |
| General health                | 26.25 (11.70)           | 31 (11.32)               | 0.117   | 29.3 (1)                | 28.04 (1.03)             | 0.504   |

Abbreviations
WOMAC: Western Ontario and McMaster Universities Arthritis Index; OA: Osteoarthritis; COPCORD: Community Oriented Program for Control of Rheumatic Diseases.

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Authors’ contributions
RG, SSAC, HRMH, and SHH conceptualized the study design. SSAC collected the data, HS performed the analysis, and RG wrote the manuscript. SSAC, HRMH, and HS were involved in experiments. SHH and HRMH was involved in drafting and editing. YJ assisted in data analysis, and reviewed the manuscript. RG supervised the project. Drafts were critically discussed and revised by all authors. All authors approved to submission. All authors read and approved the final manuscript.

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Availability of data and materials
The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
This work was approved by the Ethics Committee of North Khorasan University of Medical Sciences (ir.nkums.rec.1397.085). All the participants filled informed consent forms which were approved by the ethic committee of North Khorasan University of Medical Sciences. The research project was also registered at Iranian Registry of Clinical Trials (IRCT20161208031300N2).

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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