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Designing an Exergame and Clinical Evaluation of its Effect on Pain Sensation and Muscle Strength in People with Cervical Osteoarthritis: An Introductory Randomized Clinical Trial

Reihaneh Atashkar[1], Javad Rasti[2], Ebrahim Sadeghi-Demneh[3]

Original Article

Abstract

Introduction: Cervical osteoarthritis is a disease resulting from degeneration of facet joints in cervical vertebra, and is more prevalent among the elderly. It may be associated with paresthesia, muscle weakness in limbs, severe pain in neck, shoulder, and back, spinal cord dysfunction, and myelopathy.. The present study aims to design an exergame and clinically evaluate its effect on pain sensation and muscle strength in people with cervical osteoarthritis.

Materials and Methods: This was a randomized clinical trial study conducted on 23 patients referred to the Physiotherapy Clinic of Shariati Hospital in Isfahan, Iran, by an orthopedic specialist. The subjects were randomly assigned to two groups of the exergame (n = 12) and normal (n = 11). The exergame group received routine physiotherapy treatment along with performing isometric neck exercises with the exergame and the normal group received routine physiotherapy treatment with isometric exercises in a video game. Both groups were treated for 4 weeks as 3 sessions per week. The Neck Disability Index (NDI), Visual Analogue Scale (VAS), and Hand-Held Dynamo-meter (HHD) were respectively used to measure the neck functional disability, pain severity, and isometric strength of the neck muscles in three steps (baseline, post-treatment assessment, and follow-up at 1 month).

Results: The results of this study showed that in both groups, mean neck muscle strength increased, followed by a decrease in the mean pain intensity and mean level of functional disability. In the exergame group, the pain intensity was significantly lower than the normal group ($P \leq 0.048$).

Conclusion: One of the main challenges in designing an exergame for neck rehabilitationis to perform isometric exercises with specific repetition, intensity, duration, standard training protocol. Playing a game seems to gradually improve neck pain and functional level in patients with cervical osteoarthritis.

Keywords: Cervical osteoarthritis, Exergame, Neck muscle strength

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Introduction

Cervical spine dysfunction is widespread and accounts for a large portion of occupational therapists works, in both the public and private sectors; Thus, patients with chronic neck pain use health services twice as much as normal people, and these costs have a negative impact on the economies of countries (1,2). Additionally, this process leads to a decrease in natural movements and efficiency of various organs of the body, especially the musculoskeletal system (3). As a result of this decrease in mobility, over time, the person experiences a decrease in flexibility, and muscle strength and endurance, which together cause the onset of pain and discomfort in different parts of the body, especially the neck (1,4).

Cervical osteoarthritis is one of the functional disorders of the cervical spine that is widely observed in adults. This disease is associated with degenerative changes in the cervical vertebrae and is almost seen in all individuals over the age of 50. The degenerative

1-Department of Biomedical Engineering, School of Engineering, University of Isfahan, Isfahan, Iran
2- Assistant Professor, Department of Biomedical Engineering, School of Engineering, University of Isfahan, Isfahan, Iran
3- Associate Professor, Department of Orthotics and Prosthetics, School of Rehabilitation Sciences, Isfahan University of Medical Sciences, Isfahan, Iran
Corresponding Author: Javad Rasti, Email: rasti@eng.ui.ac.ir

changes occur naturally in the structure of cartilage and ligaments. Frequent pressure due to daily activities in this very mobile area, accelerates this phenomenon. Cervical osteoarthritis starts in the intervertebral disc and secondarily affects the facet joints. Moreover, the Range of Motion (ROM) of the neck is reduced to such an extent that the person's rotational and other movements are impaired (5-8). Cervical osteoarthritis often takes place due to prolonged work and lack of exercise, with the symptoms improved with difficulty. Complete treatment of advanced cervical osteoarthritis is difficult due to the need for regular counseling and medical exercises. The symptoms of cervical osteoarthritis are less likely to go away on their own. However, they may last for weeks and structural changes. Therefore, the goal of treatment in these patients is to help reduce temporary inflammation or soft tissue edema. Treatments for mild cases include inflammatory painkillers and muscle relaxants. Various methods of physiotherapy include ultrasound, short-wavelength heat waves, massage, intermittent stretching, and exercise therapy. Exercises to increase patients' mobility and neck muscle strength have been somewhat helpful. Therefore, for patients in the early stages or people who do not have the disease but only have pain in the shoulder area, neck exercise is a good choice to prevent cervical osteoarthritis (9,10).

A typical neck exercise program includes isometric neck exercises (11). Some factors can positively or negatively affect the adherence of individuals with osteoarthritis to the prescribed exercises, as well as their health. Boredom is one of the negative factors, since neck exercises involve multiple repetitions, fatigue is an important factor to consider (9,12). Therefore, in the present study, a system was introduced that motivated users to perform neck exercises by immersing themselves in a serious exergame. A review of previous studies shows that the most beneficial exercise for reducing pain and weakness and improving neck muscle strength in subjects with chronic neck pain in different age ranges is three times a week for 4 to 6 weeks, with the best duration of exercise being between 10 and 45 minutes. The isometric neck exercise is prescribed for individuals with neck pain with an intensity of 20 to 70% of maximum voluntary contraction (MVC) (1). In various studies, the effect of different methods of treating cervical osteoarthritis on patients is generally measured using the Neck Disability Index (NDI) and Visual Analog Scale (VAS) in three stages (baseline, last session, and one month after treatment) (11,13).

According to previous studies, the anthropometric indices of height, weight, Body Mass Index (BMI), gender, age, and occupation should be registered before the study to ensure the similarity of the groups (14,15). To the best of our knowledge, no exergame has been designed and developed for the treatment of patients with cervical osteoarthritis with the standard protocol of clinical evaluation of treatment and exercise, so far (9,12,16).

In the present study, an exergame was designed and developed for the treatment of patients with cervical osteoarthritis , using the standard protocol of clinical evaluation of treatment (measurement of neck functional disability, pain, and isometric strength of neck muscles during the three stages of baseline, last session, and one month after treatment) via the NDI and VAS scales, as well as a Hand-Held Dynamometer (HHD) and standard training protocol (intensity, duration, and repetition), respectively. It seems that performing the isometric neck exercises increases the isometric strength of the neck muscles and reduces pain and the level of neck functional disability in both groups of exercise with exergame and normal exercise.

Materials and Methods

This study was a pilot clinical trial with dependent variables including neck pain and disability, and neck muscles strength before, immediately after, and four weeks after the treatment. The exercise program with exergame and the normal program were performed for four weeks and three sessions per week, with each session lasting about 20 to 30 minutes, which formed the study independent variables. The study population included patients referred to the physiotherapy clinic of Shariati Hospital in Isfahan, Iran, after May 11, 2018. The participants were selected from individuals referred by an orthopedic surgeon in this center. Patients with a history of clinical symptoms such as neck pain, subcapsular or shoulder muscle pain, neck stiffness, and muscle tension with severe symptoms such as weakness, tenderness, gait instability, a VAS score of at least 3, and unusual numbness were included in the study. Individuals with a history of trauma to the neck or upper part of the spinal cord from the first to sixth vertebrae, a history of cervical spine surgery, severe cervical osteoarthritis (grade 4) based on radiographs, spinal stenosis, and non-skeletal symptoms, history of severe vertebral fracture or osteoporosis and rheumatoid arthritis, obvious congenital abnormalities of the spine, vertebral artery dysfunction, pregnancy, epilepsy or other neurological diseases, cardiovascular or respiratory disorders affecting physical function,

history of brain injury, and history of receiving any physiotherapy treatment for neck pain during the last six weeks were excluded from the study. In total, 30 individuals participated in the study, of whom 4 patients did not meet the inclusion criteria and 3 patients did not want to continue cooperation after being informed about the treatment process. Thus, 23 patients with grade 2 (mild) and grade 3 (moderate) cervical osteoarthritis who met the inclusion criteria were included in the study.

The participants were randomly divided into two groups by selecting the numbers 1 (exergame group) and 2 (normal exercise group) from inside a sealed envelope. The groups included exercise with exergame (conventional physiotherapy treatment along with isometric neck exercise using the exergame) and normal exercise (conventional physiotherapy treatment with isometric exercise without a game). In the present study, tools and instruments such as the patient information form and consent form, NDI questionnaire, VAS, and HHD (JTECH Medical Industries, Salt Lake City, Utah, USA) were used.

NDI: is a 10-part scale completed by patients. Each section examines different neck pain problems. Most of these sections relate to limitations in the daily activities, and each section is described in six subsets in the score range of 0 to 5; with 0 and 5 indicating no disorder and the highest disability, respectively. The total score of this questionnaire is between 0 and 50. This scale is used to assess the functional disability and is a fast tool, with a repeatability of 0.69-0.70 and moderate to high internal consistency (IC) associated with disability assessment. The important features of this tool are standard and repeatable capabilities. In the present study, the Persian version of this tool was used, where in reproducibility and validity were statistically acceptable in the population of patients with neck pain examined in the study (17).

VAS: VAS is used to measure pain intensity in centimeters.. It measures the amount of pain which a patient experiences on a scale of 0 to 10, indicating no pain and highest pain, respectively. The validity of VAS has been proven as a repeatable and generalizable pain assessment tool with IC associated with clinical and experimental studies. Here,, the subjects were asked to rate the level of pain they felt at the time of assessment (18). In order to measure the isometric strength of the neck and based on previous studies (14,19), a stand was designed whose height was adjusted according to the patient's height. A HHD, the reliability of which was proven in the study by Catenaccio et al. (19), was utilized to measure the strength of the neck muscles. The HHD load cell was placed on the stand cap and the patient was asked to apply force to the load cell from all four sides of his/her head. After warming up the neck muscles, the patient was trained on the correct way to perform the test . Especially, the patient was asked not to use the trunk muscles during the test, keep his/her torso relaxed and perform the test using only the neck muscles. Then, in order to better learn the test and warm up the muscles, the patient performed the test three times with maximum contraction, and finally, the maximum isometric strength of the neck was measured and recorded in four directions: flexion, right lateral flexion, left lateral flexion, and extension with three repetitions in each direction (15,20) (Figure 1).

Figure 1. Measurement of cervical extensor muscle strength using hand-held dynamometer (HHD)

The neck functional disability level, the amount of pain and the neck maximum isometric strength (in four directions of flexion, right lateral flexion, extension, and left lateral flexion, respectively) were measured before the study, immediately after the study, and four weeks after the treatment sessions. The treatment process took long for 4 weeks (12 sessions).. For these participants, the treatments was planned, according to the treatment method of the relevant group . In other words, the treatment was carried out by performing isometric neck exercises with exergames along with conventional physiotherapy (exergame group) and performing routine isometric neck exercises with manual resistance along with conventional physiotherapy (normal exercise group). The exercise with exergame and the routine exercise groups were treated three sessions per week and were evaluated in the first and twelfth sessions and four weeks after the end of the treatment sessions. The treatment time of the exercise with exergame group and the normal exercise group lasted 60 and 50 minutes, respectively. The exergame consisted of hardware part and a software

parts. The hardware part consisted of gloves equipped with a pressure sensors, and a wristband that the patient wore, and a receiver module that was connected to a laptop. The software part was a video game developed in the Unity engine, which was controlled via the pressure applied by the patient to his head through the gloves (Figure 2).

Figure 2. System designed to perform isometric neck exercises in the exergame group

On the homepage of the game, the the training protocol (exercise intensity, duration, rest period, repetition of exercise, and the intensity of the pressure applied on the gloves) can be defined (Figure 3).

Figure 3. Settings page of the exergame designed for patients with cervical osteoarthritis

F: Maximum isometric flexion strength, RF: Maximum isometric right flexion strength, E: Maximum isometric extension strength, LF: Maximum isometric left flexion strength

How to do the exercises using the smart gloves and exergame is shown in figure 4.

The data were collected three times including before the first treatment session, after the last treatment, and four weeks after the treatment sessions. Independent t-test was used to compare the demographic characteristics of patients between two groups and repeated measures analysis of variance (ANOVA) was employed to determine the effect of

Figure 4. Performing exergame with smart gloves

treatment (at baseline, last treatment session, and four weeks after treatment). Finally, the data were analyzed in SPSS software (version 16.0, SPSS Inc., Chicago, IL, USA) and $P < 0.05$ was considered as the significant level.

Results

In the present study, 30 patients (7 males and 23 females) were studied, of whom only 26 patients met all the inclusion factors. Finally, 23 patients with grade 2 (mild) and 3 (moderate) cervical osteoarthritis were included in the study. Figure 5 displays the entry process of the individuals with cervical osteoarthritis and the rate of sample loss.

The demographic information and the results of patients' evaluation before starting the treatment are presented in table 1. Accordingly, at the beginning of the study, there was no significant difference in terms of mean age, height, weight, and BMI between two groups.

In terms of gender distribution, 9 (75.0%) females and 3 (25.0%) males participated in the exergame group and 10 (90.9%) female and 1 (9.1%) male participated in the normal exercise group. Since the population frequency in the study was between 20 and 40, Fisher's exact test was employed to examine the dependency between the two groups of men and women, leading to the results indicating that there was no significant difference in the frequency distribution of gender between two groups ($P = 0.330$).

Table 1. Average demographic characteristics in two groups

Variable	Group		P
	Exergame group	Normal group	
Age (years)	45.58 ± 9.49	51.54 ± 9.83	0.15
Height (m)	1.63 ± 0.08	1.60 ± 0.08	0.46
Weight (kg)	73.02 ± 13.19	67.43 ± 9.66	0.26
BMI (kg/m^2)	27.43 ± 3.78	26.35 ±3.95	0.51

BMI: Body Mass Index
Data are reported based on mean ± standard deviation (SD)

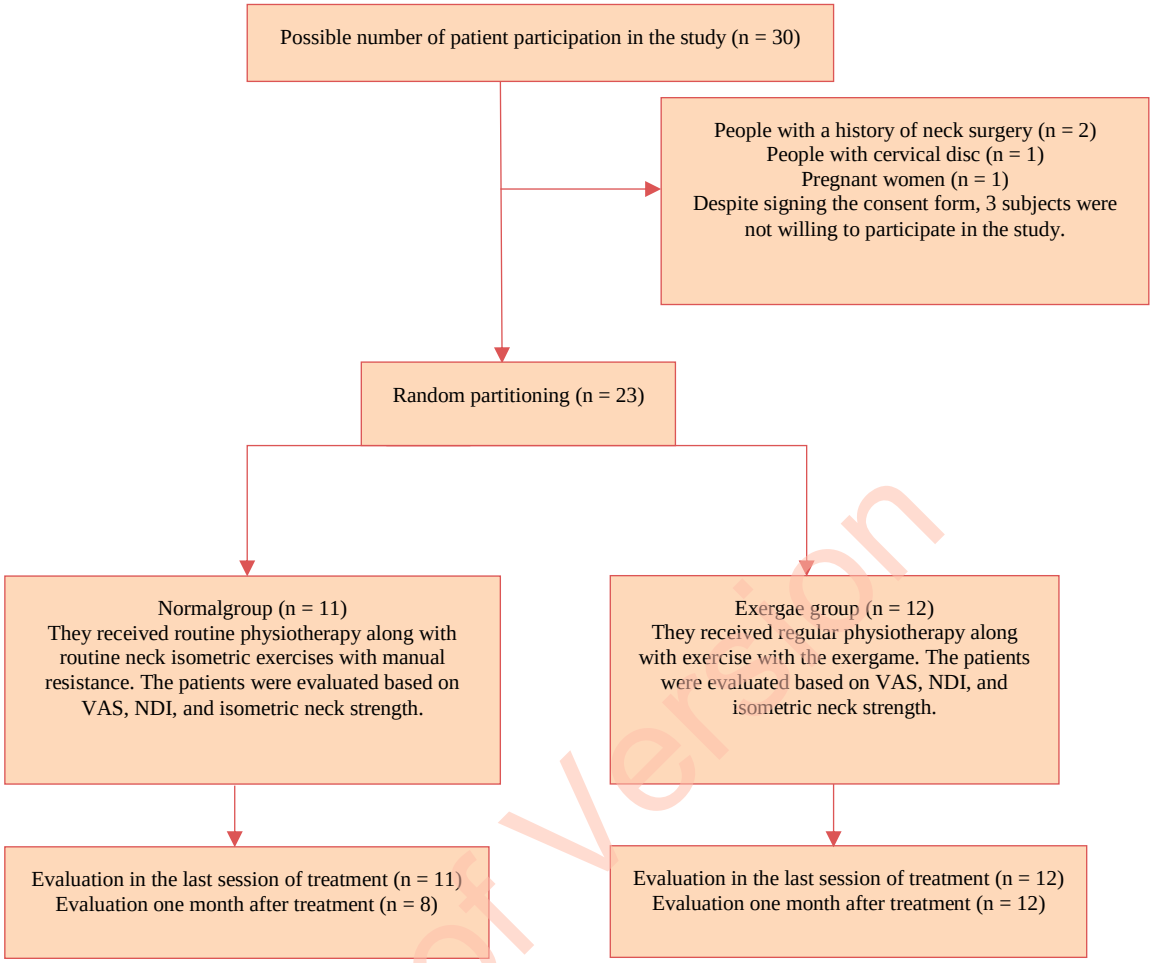

Figure 5. Study entry process and the rate of sample loss
NDI: Neck Disability Index; VAS: Visual Analogue Scale

In order to evaluate the significance of the patients' job frequency between two groups, χ^2 test was used. where, no significant difference was observed ($P \leq 0.350$) (Table 2).

Repeated measures ANOVA test was used in both groups to evaluate the significance of each variable at baseline, last session, and four weeks after treatment.

In order to study the main effects, i.e. the effect of group (intergroup) and time (intragroup), first the interaction between group and time was investigated using Mauchly's test of sphericity, showing that the interaction was not significant ($P_1 \leq 0.080$). Therefore, the main effects were interpreted and the effect of time became significant ($P \leq 0.001$) and the mean NDI changed significantly over time. Since the group effect was not significant ($P = 0.639$), the mean NDI was statistically the same among the treatment groups (Table 3). The results revealed that over time, the mean NDI decreased in both groups, but in general there was no significant difference in the mean NDI between two groups; This means that the decrease in NDI score was reported to be somewhat the same in two groups.

Table 2. Frequency distribution of patients' jobs in two groups under study

Occupation	Group		P
	Exergame group	Normal group	
Housekeeper	7 (58.3)	6 (54.5)	0.35
Employee	2 (16.7)	3 (27.3)	
Heavy work	2 (16.7)	0 (0)	
Retired	0 (0)	1 (9.1)	
Domestic jobs	1 (8.3)	1 (9.1)	

Data are reported based on n (%).

Table 3. Mean variables in different evaluation times in two groups

Variable	Evaluation time	Exergame group	Normal group	P_1	P_2
NDI	Baseline	42.11 ± 18.49	42.75 ± 16.79	≤ 0.001*	0.639
	Last session	28.10 ± 17.42	31.80 ± 17.57		
	One month after treatment	25.97 ± 16.63	32.33 ±17.82		
VAS (cm)	Baseline	7.19 ±2.17	7.92 ± 1.99	≤ 0.001*	0.048*
	Last session	3.08 ±2.39	5.57 ±2.38		
	One month after treatment	2.24 ± 2.26	4.54 ± 1.61		
Isometric neck flexion strength (Newton)	Baseline	32.90 ± 14.29	30.25 ±17.63	≤ 0.001*	0.778
	Last session	43.15 ± 13.94	44.10 ± 22.97		
	One month after treatment	49.33 ±14.37	45.00 ± 16.06		
Isometric neck right flexion strength (Newton)	Baseline	31.32 ± 11.04	28.30 ± 16.00	≤ 0.001*	0.976
	Last session	40.16 ± 9.93	45.17 ±13.01		
	One month after treatment	48.12 ± 16.94	45.65 ± 11.48		
Isometric neck extension strength (Newton)	Baseline	38.28 ± 21.34	44.00 ±21.07	≤ 0.001*	0.664
	Last session	51.66 ± 16.87	59.17 ±24.67		
	One month after treatment	62.53 ± 22.87	61.42 ± 21.60		
Isometric neck left flexion strength (Newton)	Baseline	29.32 ± 12.97	29.70 ± 15.47	≤ 0.001*	0.788
	Last session	38.57 ±11.97	44.52 ±21.31		
	One month after treatment	45.03 ± 14.23	43.68 ± 13.68		

P_1: Time effect (treatment); P_2: Group effect; *significant difference at the level of P < 0.050;
VAS: Visual Analogue Scale; NDI: Neck Disability Index

To compare VAS in two groups, the Mauchly's Test of Sphericity was examined. After interaction effect test (P = 0.06), the main effects (group and time) were interpreted, wherein the effect of time was significant (P1 ≤ 0.001); This means that in general, the mean VAS decreased significantly over the time. According to the results of Table 3, the effect of the group was significant (P2 = 0.048) too, and the pain in the exergame group decreased more than the normal exercise group. Comparison of isometric neck strength in four directions (flexion, right flexion, extension and left flexion) in two treatment groups was evaluated using Mauchly's Test of Sphericity. The results reveal the significance of time (P1 ≤ 0.001), which means that the average isometric strength of the neck increases over the time. Also, the findings in Table 3 showed that the group effect on the isometric strength indices of flexion (P2 = 0.778), right flexion (P2 = 0.976), extension (P2 = 0.664) and left flexion (P2 = 0.778) were not significant. The results of ANOVA Repeated measures test show that the mean of VAS and NDI increase and the isometric strength of the neck decrease over the time in both groups.

Discussion

The aim of this study was to investigate the clinical effect of exergame on neck pain and strength in 23 patients with cervical osteoarthritis in two groups of exercise with exergame and normal exercise. The results of the present study in terms of the effects of exergame, including reduced pain in VAS, increased isometric strength of the neck muscles, and reduced level of neck functional disability, were consistent with the findings of the study by Bagheripour et al. (13). Given the results of the present study, both methods of treatment over time (first session, last session, and four weeks after treatment) had positive effects on reducing neck functional disability, capable of reducing the mean neck functional disability. Although this decrease was greater in the exergame group in comparison to the normal exercise group, the difference in the mean values was not significant. In other words, each of the two treatment groups was able to reduce neck functional disability in the patients, but there was no significant difference between the effectiveness of each of these two groups. The results of the present study on the application of isometric neck training in reducing neck functional disability were consistent with the findings of studies by Hu et al. (11) and Bagheripour

et al. (13). Due to the lack of similar studies on the benefits of isometric exercise with exergames in reducing neck functional disability compared to the routine exercise group, it is necessary to repeat this study with a larger statistical population.

A HHD was utilized to measure the neck isometric strength on four sides of the head (flexion, extension, right flexion, and left flexion), showing that the mean isometric neck strength in both treatment groups increased significantly over time. Although this mean increase was higher in the exergame group compared to the normal exercise group, this difference was not statistically significant. In other words, each of the two treatment groups was able to increase the neck isometric strength in patients, but no significant difference was observed between the effectiveness of either group. The findings of the present study on the application of isometric neck training in increasing the average isometric neck strength were in line with the findings of the study by Strimpakos et al. (21). Based on the analysis performed in this study, the amount of pain in patients who exercised with exergame was significantly reduced compared to the normal exercise group. In other words, the exergame therapy was more effective in reducing patients' pain than the routine therapy. According to the results of the present study, the pain status of patients not only improved in each group during the treatment sessions, but also this improvement in pain status also continued in the follow-ups of four weeks after treatment. These results were consistent with those of Strimpakos et al. (21) regarding the effectiveness of isometric neck training in reducing pain (21). It seems that exergames had a significant effect on improving the severity of pain and functional disability in patients. Therefore, exergames can be used to reduce pain, improve neck muscle strength, and reduce the level of neck functional disability in patients with cervical disorders.

Limitations

Short follow-up time was one of the limitations of the present study.

Recommendations

In the designed exergame, it is better to upgrade the game's audio and video effects; So that the patient can hear beautiful music when the exercise is finished. The patients in this study reported improvement in neck pain after treatment, but still reported pain in their shoulders. It is suggested to include exercises for the shoulders in the game in order to improve the mentioned pain.

Conclusion

The designed exergame had a significant effect on improving the severity of pain and functional disability in patients. Therefore, this game can be applied to reduce pain, improve neck muscle strength, and reduce the level of neck functional disability.

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Authors' Contribution

Reihaneh Atashkar: Data collection, analysis and interpretation of results, manuscript preparation, specialized evaluation of manuscript in terms of scientific concepts, approval of the final manuscript to be submitted to the journal office, the responsibility of maintaining the integrity of the study process from the beginning to the publication, and responding to the referees' comments; Javad Rasti: Study design and ideation, attracting financial resources for the study, supportive, executive, and scientific study services, providing study equipment and samples, analysis and interpretation of results, manuscript preparation, specialized evaluation of the manuscript in terms of scientific concepts, approval of the final manuscript to be submitted to the journal office, the responsibility of maintaining the integrity of the study process from the beginning to the publication, and responding to the referees' comments; Ebrahim Sadeghi-Demneh: Study design and ideation, supportive, executive, and scientific study services, providing study equipment and samples, analysis and interpretation of results, manuscript preparation, specialized evaluation of the manuscript in terms of scientific concepts, approval of the final manuscript to be submitted to the journal office, the responsibility of maintaining the integrity of the study process from the beginning to the publication, and responding to the referees' comments.

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Conflict of Interest

The authors declare no conflict of interest.

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