Comparing the effects of mHealth application based on micro-learning method and face-to-face training on treatment adherence and perception in haemodialysis patients: a randomised clinical trial

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ABSTRACT

Objectives Comparing the effects of a mobile health (mHealth) application based on the micro-learning method with face-to-face training on treatment adherence and perception among patients undergoing haemodialysis.

Design A single-blind randomised clinical trial.

Setting A haemodialysis centre in Isfahan, Iran.

Participants Seventy patients.

Intervention Patients were trained individually for 1 month via the mHealth application or face-to-face training.

Outcome measures Treatment adherence and perception in patients were measured and compared.

Results The scores of treatment adherence in the mHealth and the face-to-face training groups were not significantly different at the pre-intervention stage (720.43±209.61 vs 702.86±181.47, p=0.693) and immediately after the intervention (1007.14±134.84 vs 947.86±124.46, p=0.060), while 8 weeks later, treatment adherence in the mHealth group was significantly higher than the face-to-face training group (1018.57±129.66 vs 914.29±126.06, p=0.001). The scores of both groups before the intervention did not differ in various dimensions of treatment adherence and perception (p>0.05). Scores of these variables also elevated significantly after the intervention (p<0.05).

Conclusions The mHealth based on micro-learning and face-to-face training as interventions augmented treatment adherence and perception among the haemodialysis patients, but such improvements were detected much more in the patients trained with mHealth based on the micro-learning method than face-to-face training.

Trial registration number IRCT20171216037895N5.

INTRODUCTION

Treatment adherence denotes contributing actively to the therapeutic process, following the recommendations, and receiving healthcare services provided by professionals, along with their manifestations in patients’ behaviours. Studies indicate that haemodialysis (HD) patients have poor treatment adherence, which can accelerate disease progression and the need for immediate hospitalisation and treatment. Illness perception is another factor affecting treatment outcomes, mortality rates and medical complications in patients with end-stage renal disease (ESRD), referring to the patient’s perception of their illness and its consequences, wherein positive perception can cause a rising trend in their ability to adapt to a health condition. Such perceptions are also one of the most significant factors affecting treatment adherence in patients, which means patients with negative perception fail to adhere to treatments properly.

Results of a cohort study showed 20% of patients with ESRD had low or possible inadequate health literacy, which is inadequate knowledge and lack of awareness reduce treatment adherence and raise negative attitudes and perceptions of patients with ESRD. Numerous training programmes have been used to broaden knowledge and increase awareness of these patients. Researchers recommended paying attention to the quality of these training programmes to introduce.
identify and evaluate the experience of successful teaching-learning styles and start the cycle of modification and improvement of the training process. Face-to-face training is among the most commonly used interventions for educating such patients. Another training method is the growing usage of educational software, mainly mobile health (mHealth) applications. Most studies have recommended new technologies such as mobile applications to inform patients with chronic diseases. A variety of methods have been used to improve the efficacy of mHealth applications. One method is micro-learning usually 1–10 min, focused small learning units consisting of condensed learning activities. It is possible to provide information in a face-to-face training method and involve patients in the healthcare and training processes to reduce HD complications, treatment adherence and patients’ attitude and perception. The new technologies and methods, such as smartphones and micro-learning can be used along with other training methods to train the patients. Some studies showed the effects of such intervention programmes on quality of life, self-care, intersessional weight gain and the serum parameters in HD patients. In addition, it is found that while there is a considerable desire to use new technologies like mHealth or web-based applications among these patients, this opportunity has not been used enough and some steps should be taken to address this gap. According to the authors’ search, no study had compared the effects of mHealth based on the micro-learning method and traditional training programmes on treatment adherence and perception among HD patients. Therefore, this study aimed to compare the effects of an mHealth application, which was developed based on micro-learning and was branded as the Di Care application and face-to-face training on treatment adherence and illness perception of HD patients.

**METHODS**

**Design**

This two-group and single-blind randomised clinical trial was conducted in 2021–2022 in Isfahan, Iran. This study was registered in April 2021 in the Iranian Registry of Clinical Trials (Supplemental Clinical Trial Protocol).

**Patient and public involvement**

The main points to design this study were based on clinical experience and observation of authors and the patients’ treatment outcomes. Therefore, patients were not involved directly in designing and conducting the study (no patient involved). The results of this research have been announced to the study setting’s authorities to inform all patients. The patients received all healthcare services provided to other counterparts and were not charged any fees for their participation in the study.

**Participants**

The sample size was estimated with a 95% CI which is 1.96, 80% test power which is equal to 0.84, and the SD of the treatment adherence from a previous study which was 4.9, using the sample size formula below:

\[
 n = \frac{(2\sigma)^2(Z_{1-\alpha/2} + Z_{1-\beta})^2}{d^2} = \frac{(2\times4.90)^2(1.96+0.84)^2}{(0.7\times4.90)^2} = 64
\]

Then, with a 10% probability of attrition in each group, 35 individuals were estimated. The participants’ inclusion criteria were willingness to participate in the study, age over 18, reading and writing abilities, access to a smartphone with an Android operating system, presence in the study setting as a permanent patient, undergoing three HD sessions a week, undergoing HD for at least 6 months, no use of other educational applications about HD during the study, lack of mental illnesses or other advanced chronic diseases, such as chronic heart failure and no disabilities leading to disruptions in receiving the training. But reluctance to continue the study, transferring the patient to other medical centres or undergoing a kidney transplant during the study, not using the application concerned for over 1 week, not attending the face-to-face training for over three sessions, and the improper performance of the application on the smartphone were the exclusion criteria.

Seventy patients were recruited using convenience sampling and randomly assigned to the groups receiving the mHealth application based on the micro-learning method (n=35) and face-to-face (n=35) training by coin flipping by first researcher-assistant blind to the study process and groups. To avoid contamination information among the HD patients in both groups, they were explained the study objectives and asked not to swap information until the study completion.

**Data collection**

Before the interventions, patients’ treatment adherence was assessed by the End-Stage Renal Disease Adherence Questionnaire (ESRD-AQ) and was completed by a second researcher-assistant blind to group allocations. This tool, designed and validated by Kim et al, consisted of 46 items in five dimensions, (1) general information (items 1–5), (2) HD treatment (items 6–19), (3) medication therapy (items 20–28), (4) limitation of fluid intake (items 29–38) and (5) dietary restrictions (items 39–46). Here, items 14, 17, 18, 26, 31 and 46 were to score treatment adherence, item 14 was about the number of sessions in which a person had been absent over the past month, with a score between 0 and 300. Item 17 was also concerned with the number of sessions in which a person had shortened the HD duration in the past month, and scored between 0 and 200. Item 18 was on the average reduction in the duration of HD sessions, which ranged from 0 to 100. Item 26 was further on the frequency of not taking the prescribed medications in the previous week, with scoring between 0 and 200, items 31 and 46 were related to the recommendations for fluid intake.
and diet, respectively, each scored between 0 and 200. Of note, each item had five options. On adding the scores, the minimum and maximum values of the questionnaire were 0 and 1200, wherein 1200 indicated the highest level of treatment adherence.31 The treatment adherence total scores were divided into three categories, that is, poor (less than 700), moderate (700–999) and suitable (1000–1200). In this questionnaire, items 11, 22, 32 and 41 assessed patients’ treatment perception, so the responses to such items were examined via descriptive statistics, which varied between very important and not important intervals.4 The ESRD-AQ had been translated into Persian by Rafiei et al, and its validity and reliability had been confirmed. The content validity of the Persian version was 0.98, and its reliability was 0.85.5

Intervention
In the mHealth group, patients used an application on the Android operating system developed by the researchers. Before designing the application, patients’ needs and other similar applications were investigated and checked by the researchers, and the final version was published after a long-term revision, which was held by the researchers and application developers. During the first training session, the Di Care application was installed on the mHealth patients’ smartphones and its proper performance was ensured. To confirm the proper performance of the application, one researcher, with a master’s degree in nursing and 2 years of working experience in HD wards, met these patients weekly and answered their possible questions.

The Di Care application comprised different parts. Its educational materials were based on the micro-learning method in 3-min videos on seven topics for the HD patients were prepared. The topics reflected on the importance of HD, management of HD complications, dietary recommendations, limitation of fluid intake, physical activities, care for vascular access and medication use. The educational content, which was published finally as a book named hemodialysis cares for patients, was gathered from updated guidelines and literature. When the final version was proven by the Authoring and Translation Committee of Aja University of Medical Sciences, Tehran, Iran, the researchers started creating videos based on the mentioned topics. Totally, 78 videos were created before developing the final version of the application. In these videos, images, texts, and audios were simultaneously used (figure 1). Three notifications were further sent offline to the users at certain times of the day. By touching the notifications, the users would see one of the educational videos and answers the questions. At the end of each session, the patients could ask questions and raise their problems related to the topics taught. After the sessions, the written training content was delivered to the HD patients.

In the first session after the interventions, that is, the 5th week and 12 weeks after their onset (viz. 8 weeks after the last training session), patients’ treatment adherence was assessed by the ESRD-AQ by the second researcher-assistant. As is shown in the study process is shown in figure 2, none of the participants excluded from the study after randomisation.

Analysis
The data were analysed using the SPSS software package (V.16). The descriptive statistics (ie, mean, SD, frequency and percentage) and analytical tests (ie, repeated measures analysis of variance (RM-ANOVA), \( \chi^2 \), Fisher’s, exact test, Friedman test, independent samples t-test and Mann-Whitney U test) were used to data analysis. The significance level of \( p<0.05 \) was considered. The data was analysed by a biostatistician, unaware of patient groups and interventions.

RESULTS
The mean±SD age of the patients was 46±8.84 (20–60 years), with an average of 3.34±1.26 (1–6) years undergoing HD. 49% were men. Besides, both study groups were not significantly different in terms of age (\( p=0.486 \)), gender (\( p=0.794 \)), duration of HD treatment (\( p=0.341 \)), dry weight (\( p=0.108 \)), type of vascular access (\( p=0.738 \)) and level of education (\( p=0.476 \)) (table 1).

Online supplemental table 1 shows the patients’ treatment adherence before and after the interventions. The independent-sample t-test showed that the total mean scores of treatment adherence before (\( p=0.693 \)) and immediately after the interventions (\( p=0.060 \)) in the mHealth and face-to-face groups were not different. However, 8 weeks after the interventions were over, the
mean scores in the mHealth group were higher than those in the face-to-face training group (p=0.001). Based on Cohen’s method, the overall effect sizes of mHealth and face-to-face on the treatment adherence were 0.62 and 0.48, respectively.

The independent-sample t-test revealed that the mean scores of both groups before the interventions were not significantly different in various dimensions, including HD treatment (p=0.614), medication therapy (p=0.255), adherence to limitation of fluid intake (p=0.443) and dietary restrictions (p=0.785). Immediately after the interventions, the mean scores of HD treatment (p=0.615), adherence to limitation of fluid intake (p=0.61) and dietary restrictions (p=0.189) were not significantly different between the two groups, but the mean scores of medication therapy in the group trained with the mHealth was significantly higher than those in the face-to-face training (p=0.035). Eight weeks after the interventions,
the mean scores of HD treatment ($p=0.041$) and medication therapy ($p<0.0001$) were significantly higher than those in the face-to-face training group, while the mean scores of adherences to limitation of fluid intake ($p=1.00$) and dietary restrictions ($p=0.067$) were not significantly different between both groups (online supplemental table 2).

The RM-ANOVA demonstrated that the total mean score of treatment adherence in the HD patients during the study in the mHealth group had an ascending trend, while there was a decline in the face-to-face training group immediately after the intervention (online supplemental table 1 and figure 3).

The results showed that 51.40% of the patients in the mHealth group and 57.14% of the face-to-face training group had poor treatment adherence before the interventions. The training via the Di Care application increased the number of HD patients with suitable adherence, so that 54.29% and 65.73% of the patients immediately after the intervention and 8 weeks later had suitably adhered to treatment, respectively. Overall, training with this application significantly improved the total score of the patients’ treatment adherence ($p<0.0001$).

The face-to-face training programme comparably elevated the number of patients with suitable treatment adherence. Before the intervention, 8.58% had adhered...
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Table 1 Comparison of individual characteristics of patients in mHealth and face-to-face training groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>mHealth</th>
<th>Face-to-face</th>
<th>Statistical value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>t</td>
</tr>
<tr>
<td>Age (year)*</td>
<td>45.26 (1.42)</td>
<td>46.74 (1.57)</td>
<td>0.70</td>
</tr>
<tr>
<td>Duration of haemodialysis treatment (year)*</td>
<td>3.23 (0.201)</td>
<td>3.46 (0.22)</td>
<td>–</td>
</tr>
<tr>
<td>Dry weight (Kg)*</td>
<td>71.60 (2.14)</td>
<td>66.51 (2.27)</td>
<td>1.62</td>
</tr>
<tr>
<td>Sex†</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>24 (49.0)</td>
<td>25 (51.0)</td>
<td>1</td>
</tr>
<tr>
<td>Female</td>
<td>11 (52.4)</td>
<td>10 (47.6)</td>
<td></td>
</tr>
<tr>
<td>Vascular access†</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arterial-venous fistula</td>
<td>13 (56.5)</td>
<td>10 (43.5)</td>
<td>–</td>
</tr>
<tr>
<td>Arterial-venous graft</td>
<td>4 (44.4)</td>
<td>5 (55.6)</td>
<td></td>
</tr>
<tr>
<td>Catheter</td>
<td>18 (47.4)</td>
<td>20 (52.6)</td>
<td></td>
</tr>
<tr>
<td>Education‡</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elementary</td>
<td>6 (17.14)</td>
<td>10 (28.57)</td>
<td>–</td>
</tr>
<tr>
<td>Guidance</td>
<td>11 (31.43)</td>
<td>12 (34.29)</td>
<td></td>
</tr>
<tr>
<td>High school</td>
<td>13 (37.14)</td>
<td>11 (31.43)</td>
<td></td>
</tr>
<tr>
<td>Academic</td>
<td>5 (14.29)</td>
<td>2 (5.71)</td>
<td></td>
</tr>
</tbody>
</table>

*Independent t-test. †Fisher’s exact test. ‡Χ² test.

mHealth, mobile health.

to suitable treatment, which reached 34.29% and 40.01% immediately after the intervention and 8 weeks later, respectively. This type of intervention also augmented the total score of the patients’ treatment adherence (p<0.0001) (online supplemental table 1).

The Friedman test showed that 17.14%, 34.29%, 8.57% and 5.71% of the patients in the mHealth group received a complete score before the intervention in terms of HD treatment, medication therapy, adherence to limitation of fluid intake and dietary restrictions. Immediately and 8 weeks after training via the Di Care application, the number of patients in these dimensions increased significantly (p<0.05). The results showed in online supplemental tables 1, 2.

In the face-to-face training group, 11.43%, 20%, 5.71% and 8.57% of the HD patients received complete scores before the intervention in HD treatment medication therapy, adherence to limitation of fluid intake and dietary restrictions, respectively. The results showed that the number of HD patients who received full scores in

Figure 3 Comparison of the total treatment adherence score in different steps. While before the intervention the total adherence score in both groups was almost the same, it rose immediately after the intervention was done and the total score of the mHealth group was more than the face-to-face group. Furthermore, this score had a downward trend in the face-to-face group when it was measured 8 weeks after the intervention, whereas in the mHealth group, it face a slight increase. mHealth, mobile health.
these dimensions increased immediately and 8 weeks after the face-to-face training. This rising trend was significant in the dimensions of HD treatment (p=0.015) and adherence to limitation of fluid intake (p=0.039), while it was not so for medication therapy (p=0.444) and dietary restrictions (p=0.867) (online supplemental table 2).

The Friedman test results confirmed that the Di Care application use significantly boosted the patients’ perception of the importance of adherence to HD sessions (p<0.0001), prescribed medication use (p<0.0001), limitation of fluid intake (p=0.0001) and dietary restrictions (p=0.0001) (online supplemental table 3). This test also proved that the face-to-face training did not have a significant effect on patients’ perception of the importance of adherence to HD (p=0.066), but the impact of this intervention on the HD patients’ perception of the importance of prescribed medication use (p<0.0001), limitation of fluid intake (p=0.001) and dietary restrictions (p<0.0001) were significant (online supplemental table 3).

The Mann-Whitney U test established that the patients’ perception in both groups about the importance of taking prescribed medications in both groups before (p=0.245), immediately (p=1.00) and 8 weeks after the interventions (p=0.154) were not significantly different. And the patients’ perception of the importance of taking prescribed medications in both groups before (p=0.901) and immediately (p=0.723) after the interventions were not significantly different, but 8 weeks after the interventions, the patients who used the Di Care application were significantly better than those face-to-face training (p=0.019). The HD patients’ perception of the importance of limitation of fluid intake before (p=0.985), immediately (p=0.166) and 8 weeks after the interventions (p=0.740) were not also significantly different. There was even no significant difference between both study groups before (p=0.802), immediately after (p=0.097) and 8 weeks after the interventions (p=0.514) in terms of the patients’ perception of the importance of dietary restrictions (online supplemental table 3).

**DISCUSSION**

This study aimed to compare the effects of mHealth based on the micro-learning method and face-to-face training on treatment adherence and illness perception in patients undergoing HD, and the results demonstrated that the mean scores of treatment adherence in all dimensions increased after implementing both training methods. Findings showed that the overall effect sizes of mHealth method (d=0.6) was greater than face-to-face education (d=0.5) on treatment adherence. These effect sizes imply that these methods had moderate effects on patients’ treatment adherence based on Cohen’s eta squared effect size. The lowest mean scores obtained by the HD patients before the intervention were related to fluid and dietary restrictions, respectively. The total mean scores of treatment adherence in most patients (54.29%) also reached the suitable level immediately after the training via the Di Care application. This value was 65.73% after 2 months. The Di Care application additionally improved adherence to HD treatment, medication therapy, limitation of fluid intake and dietary restrictions in the patients and generally increased their treatment adherence scores. A study confirmed the positive effect of a mobile messaging programme on treatment adherence in patients undergoing HD. Another report on heart transplant patients also revealed that using educational software packages had improved adherence to medication therapy. Results of another study which used a micro-video health education programme in HD patients showed this method significantly improved self-management and self-efficacy. Contrary to the results of the present study, kidney transplant patients in another investigation had about 63.6% treatment adherence with no adherence to medication using a mobile application. Considering the differences in the statistical populations in both studies, the Di Care application provided reminders for medication use and other related training. In the study by Ham et al, the application provided patients with medication reminders and information about immunosuppressive agents.

The face-to-face training also increased the overall scores of treatment adherence in the HD patients. Unlike the mHealth group, immediately after the intervention and 8 weeks later, most patients had moderate treatment adherence, the face-to-face training improved adherence to HD treatment and limitation of fluid intake, but it did not have a significant effect on adherence to medication therapy and dietary restrictions. The previous study revealed that the face-to-face training had enhanced treatment adherence in the patients undergoing HD. In another study, this type of training had boosted adherence to HD treatment, limitation of fluid intake and medication therapy, but did not affect adherence to dietary restrictions. The discrepancies in the number and duration of the training sessions could be the reasons for the differences in the results of previous and current studies.

Before the intervention, most patients had a poor treatment adherence. Only 10.02% had properly adhered to HD treatment. The previous studies on HD patients, using the same tools, showed that most HD patients had a moderate treatment adherence, which conflicted with the findings in the present study. To report treatment adherence rates qualitatively, these studies had also considered the total mean±SD scores for the moderate treatment adherence, which had not been in the main study. However, the mean scores in all three investigations showed that the lowest values were related to the dietary and limitation of fluid intake, like the present study. Another study assessed the rate of adherence to dietary and limitation of fluid intake in most patients undergoing HD as mild-to-moderate. Therefore, dietary and fluid intake restrictions seemed to be the various dimensions of treatment adherence, which had been less considered among HD patients, so there is a need to take effective measures in this line.
The results of assessing the patients’ treatment perception also showed that most patients considered full attendance at HD sessions before the interventions and at the recommended time to be highly and highly important, respectively, while adherence to prescribed medication use was highly important for only 28.56% of the patients. This value was 44.28% and 48.56%, respectively, adherence to fluid and dietary restrictions. A previous study had also reported that the majority of patients had considered the importance of adherence to HD sessions to be high. However, unlike the present study, the importance of adherence to medication therapy, limitation of fluid intake and dietary restrictions in this study was high among the bulk of the patients (4). Contrary to the results, Strugala et al found that illness perception in the patients undergoing HD was moderate, and one of the effective measures to improve it was patient education.38 Another study also showed that patients’ perception of HD were much lower than those of peritoneal dialysis cases who needed more education and psychological support.39 The different results of these studies were their various study settings and tools. But several factors such as the previous information and the psychological support could shape their illness perception.

The present study demonstrated that training via the Di Care application improved the patients’ perception regarding attendance at HD sessions, medication therapy and fluid and dietary restrictions. In contrast, the face-to-face training boosted the patients’ perception of adherence to medication therapy, limitation of fluid intake and dietary restrictions, but had no significant effect on adherence to attendance at HD sessions. Statistically, the effect of both interventions on patients’ perception in different dimensions was not significantly different. Another study on HD patients showed that the face-to-face training had upgraded their illness perception.39 Yang et al reported that mHealth use in patients undergoing HD increased their clinical outcomes, quality of life and patients’ acceptance and satisfaction.40 A previous study revealed that the interventions that enriched illness perception in HD patients could perfect treatment adherence in some dimensions.41

The limitations of the present study were the effect of mental conditions, economic status and the amount of information and knowledge of patients before the interventions on their treatment perception and treatment adherence, which were controlled much by randomly assigning the patients to two groups. The sample also was from a setting where the first author works. So, probably there was a social desirability effect present, which was not controlled. Therefore, we suggest that sampling be performed by a blinded researcher-assistant in future studies. Moreover, illiterate individuals were not included in the study and it is suggested to further studies to consider this point. In addition, the variable of illness perception as a mental issue was measured by a questionnaire, because it was impossible to check the accuracy of patients’ answers with other methods. It was difficult to compare the results of the studies with different data interpretations by various questionnaires. The questionnaire administered in this study had been already used in other studies. However, reviewing these studies uncovered that their scoring systems differed from the main study, which could outweigh the published results. Due to some shortcomings in the scoring systems and the ambiguities in this respect, an email was sent to the author to correctly interpret the results of treatment perception, but no reply was received. Therefore, similar results were interpreted as those in the previous study (4).

CONCLUSIONS
Totally, treatment adherence in the patients trained with the Di Care application based on micro-learning method significantly improved in all dimensions, including adherence to HD treatment, medication therapy, fluid and dietary restrictions and adherence to general treatment. However, the face-to-face training, despite enhancing the overall treatment adherence, did not have a significant effect on adherence to medication therapy and dietary restrictions. Besides, the HD patients who used the mHealth based on micro-learning method scored higher than those who received the face-to-face training adherence to the medication therapy. Treatment adherence in the patients who benefited from the Di Care application also had a rising trend over time compared with the patients who were trained with the face-to-face method.

The mHealth based on the micro-learning method and face-to-face training had a significant effect on patients’ treatment perception. Both interventions improved treatment perception in the patients undergoing HD, and those who were trained with the Di Care application were more affected. It is concluded that while the educational content of both methods was the same, the results were different. As a result, it seems that in addition to the attraction of new technologies, other factors like using reminders, follow-ups and repetitive and continual education significantly affect and strengthen the durability of treatment adherence and perception in the patients undergoing HD. This point should be investigated in further studies and considered in clinical approaches.

Besides increasing the number of samples, it is suggested to lengthen the duration of the interventions and follow-ups in future studies, to allow a more detailed examination of the changes in the HD patients’ treatment adherence rates. It is also recommended to implement research tools that can be quantitatively compared with evaluating treatment perception.

Acknowledgements We would like to thank the Office of the Vice Chancellor for Research and Development, Aja University of Medical Sciences. We would also like to express our great appreciation to all patients and hospital staff for their collaboration and assistance to run this study.

Contributors MTK: The study conception and design, study execution, data extraction and interpretation and preparation of the initial draft of manuscript. ZF: The study conception and design, study search, data analysis and interpretation and critical revision of the manuscript. She is responsible for the overall content.
as guarantor. SAS: Study search, data interpretation and critical revision of the manuscript. All authors read and approved the final manuscript.

**Funding** This work was supported by Aja University of Medical Sciences (Grant number: 1400.006, 20 April 2021).

**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

**Patient consent for publication** Consent obtained directly from patient(s).

**Ethics approval** This study was approved by the Research Ethics Committee of Aja University of Medical Sciences, Tehran, Iran. ID: IR.AJAUMS.REC.1400.006. Participants gave informed consent to participate in the study before taking part.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data availability statement** Data are available upon reasonable request.

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