### ARTICLE





# A mobile-based educational intervention on sexo-marital life in Iranian men with spinal cord injury: a randomized controlled trial

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#### Abstract

Study design: A randomized controlled trial.

**Objective:** To assess the effectiveness of a mobile-based educational intervention on sexo-marital life in Iranian men with spinal cord injury (SCI).

Setting: Foundation of Martyrs and Veterans Affairs', "Spinal Cord Injury Association", and the "Protection Center of Spinal Cord Disables".

**Methods:** Participants were men with SCI aged at least 18 years old. The effectiveness of a mobile App was evaluated on 70 married men with SCI. Sexual adjustment, sexual satisfaction, marital adjustment, and marital satisfaction were assessed by valid and reliable questionnaires at baseline, 4 and 8 weeks after the intervention.

**Results:** The between-group mean difference (95% CI) of sexual adjustment (4.2, CI: 3.6–4.8) after 4 weeks as well as 8 weeks (8.6, CI: 7.6–9.5) after baseline was significant (P < 0.001). The between-group mean difference (95% CI) of sexual satisfaction (6.9, CI: 8–11.2) after 4 weeks as well as 8 weeks (16.4, CI: 14.1–18.7) after baseline was significant (P < 0.001). There were significant increases in all the domains of marital satisfaction's between-group mean differences after 4 weeks as well as 8 weeks after baseline (P < 0.001). Repeated measures ANOVA showed there was no statistically significant increase in marital adjustment's between-group mean difference (95% CI) after 4 weeks (-0.1, CI: -0.1-0, P < 0.16) as well as 8 weeks (0.4, CI: -0.3-1.1, P < 0.25) after baseline.

**Conclusion:** The application-based educational intervention showed the positive effect of education on sexo-marital life in men with SCI. We recommend the rehabilitation team's healthcare providers embrace this educational strategy for individuals with SCI.

# Introduction

Globally, sexual problems are frequently seen in individuals with spinal cord injury (SCI), especially among males [1].

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In Iran, the prevalence rates of sexual problems among men and women with spinal cord injury are 32 and 14%, respectively [2].

Sexual and marital relationships are affected by SCI [3]. SCI affects sexual satisfaction specifically and marital satisfaction generally. Results of a study showed that 62% of men and 44% of women with SCI were dissatisfied with their sexo-marital life [4]. Seventy percent of individuals with this disorder were also dissatisfied with their sexual activity and declared that their sexual issues were not seriously addressed by the healthcare system [5]. Thus, it appears that sexual health education following SCI has not been a high priority in medical care, and few studies have been conducted on post-SCI sexo-marital education programs [6, 7]. However, the current literature emphasizes sexual needs assessment and the development of educational intervention programs for individuals with SCI [8]. Therefore, sexo-marital issues of individuals with SCI should be addressed in their rehabilitation plan [6, 9].

Online education should be commonly used to educate individuals with physical limitations [10]. Apart from the significance of having a proper educational strategy in accordance with the characteristics of the target audience and the socio-cultural considerations of sexo-marital post-SCI education, other points should also be taken into account. Among other reasons in favor of online post-SCI education is the high load of rehabilitation care [6]. The complexity of the sexo-marital scenario in special target groups, as well as the online educational approaches available in the literature drove us toward the objective of this study, namely, to assess the effectiveness of a mobile-based educational intervention on sexo-marital life in Iranian men with SCI.

# Methods

#### Study design and eligibility criteria

This study was a randomized controlled trial (IRCT code: 20181205041861N2). Participants were men with SCI from the "Foundation of Martyrs and Veterans Affairs", "Spinal Cord Injury Association", and the "Protection Center of Spinal Cord Disables (PCSCD)". The main variable in this study was sexo-marital life. We defined sexo-marital life as a married life in which commitment as well as sexual relations were interwoven with each other. To assess this core concept, we assessed four relevant variables; sexual adjustment, sexual satisfaction, marital adjustment, and marital satisfaction.

The inclusion criteria were: having SCI, willingness to participate in the study, being able to share one's experiences, being Iranian and Persian-speaking, being diagnosed as tetraplegic, having lived with SCI for at least one year, being older than 18 years, being married, having no history of couple therapy, having at least an elementary education, owning an Android smartphone, and having had no ejaculation after SCI. The exclusion criteria were: individuals with non-traumatic SCI, individuals with a depression score of 11 or higher (based on HADS = Hospital Anxiety and Depression Scale), those with a history of addiction and substance abuse and psychiatric drugs use in the past 6 months, and couples where the wife had a history of sexual dysfunction.

# Sampling

Sample size was calculated using the G\*power 3.1.0 program [11] using  $\alpha = 0.05$ , effect size = 0.5, and  $1-\beta$  (power 8 for a repeated-measures analysis of variance (ANOVA). The minimum sample size required for SD = 3.8, d = 1.8 (10% total Score SIS) [12], and alpha = 0.05 was 70 (experimental group = 35, control group = 35).

Initially, 123 men were assessed for eligibility. Of the 53 men who were excluded, 40 did not meet the inclusion criteria, and 13 declined to participate. Seventy participants were enrolled into two parallel groups; 35 were assigned to the experimental group (smartphone application group) and 35 were assigned to the control group. The balance block randomization of 4 blocks was used to ensure balanced representation in the two arms (experimental and control) as recruitment progressed. Randomization was done electronically by an interactive web response system at the time of recruitment. Once the participants had given their consent, each participant was given a study identification number and was briefed about the goal of the study based on his randomization group. Allocation concealment was ensured by keeping the randomization lists in the care of one of the investigators (AH) who was not involved in the study intervention (Fig. 1: Consort diagram).

# Data collection tool

Data were gathered using four separate questionnaires including (a) Sexual adjustment questionnaire (SAQ), (b) Larson's sexual-satisfaction scale, (c) Spinner's marital adjustment scale, and (d) ENRICH marital satisfaction scale.

To assess sexual adjustment in individuals with SCI, the Persian version of the SAQ was used. It contains 11 Items with five-point Likert-scale responses ranging from "completely agree" to "completely disagree". SAQ's score ranges between 11 and 55, where the higher the score, the greater the sexual adjustment [13]. Cronbach's alpha coefficient and intra-class correlation of the questionnaire were reported to be 0.5 and 2.5, respectively.

To assess sexual satisfaction in people with SCI, the Persian version of Larson's Sexual-Satisfaction scale was used. This consists of 25 items with five-point Likert-scale responses ranging from "completely agree" to "completely disagree" [14]. Larson's Sexual-Satisfaction scale's score ranges from 25 to 125, where the higher the score, the greater the sexual satisfaction. The reliability of the Persian version of this tool has been reported at 0.86 [15]. To assess marital adjustment the Persian version of Spinner's marital adjustment scale was used, which has 32 items, is unidimensional and consists of six parts. The first part includes 15 items with six-point Likert-scale responses. The second part includes 9 items and the third part includes 2 items with five-point Likert-scale responses. The fourth part includes 2 items with two-choice answers. The fifth and sixth parts include 2 items with six-point Likert-scale responses. The score range in Spinner's marital adjustment scale is from 0 to 151 and the Persian version of this questionnaire was confirmed to have high internal consistency (0.95) [16].



Fig. 1 Study enrollment and randomization. Depicted is the CONSORT diagram describing participant flow and randomization into the conventional or study bundles, and subjects analyzed for outcomes.

To assess marital satisfaction, the Persian version of the ENRICH marital satisfaction scale was used. It consists of 35-items with five-point Likert-scale responses ranging from "completely agree" to "completely disagree". The ENRICH marital satisfaction scale's score ranges from 35 to 175. The items of this tool have been classified into four

domains; marital satisfaction, communication, conflict resolution, and ideal distortion. The score for each respondent consisted of the algebraic sum of the scores of the items. Cronbach's alpha coefficient for the aforementioned dimensions of the Persian version were reported at 0.62, 0.78, 0.68, and 0.77, respectively [17].

# Development and evaluation of the educational content

To prepare the content of the app, a literature review was first conducted on three thematic areas of adjustment following SCI, interpersonal communication skills, and sexual relations in participants with SCI. The content was then written in the form of long and short messages in cognitive, emotional, and psychomotor domains. The provided content was approved by a panel of experts including sexologists, neurosurgeons, psychiatrists, psychologists, health professionals, and medical education specialists for accuracy, comprehensibility, rhetoric, purposefulness, and simplicity.

# Designing the mobile application

This step included three sub-sections:

(A) Designing the Algorithm and Flowchart of the SAMAR-App Content: The research team called this app "SAMAR" by using the initials of the main variables of this study (Sexual Satisfaction, Sexual Adjustment, Marital Adjustment, and Marital Satisfaction; the R stands for Relationship). The educational content of the mobile app was designed by the research team.

(B) U I and UX design for the SAMAR-App: this was done by a technical team.

(C) The SAMAR-App evaluation: at this stage, the beta version of the SAMAR-App was given to 10 couples with spinal cord injury to assess face validity. These couples were not part of the study. The performance of the SAMAR-App was evaluated in terms of user-friendliness, understandability, content relevance, and applicability. After receiving the target audience's feedback, modifications were made and the final version of the application was built.

## Procedure

All participants with the inclusion criteria attended a meeting held at the PCSCD. The objectives of the study were explained by the corresponding author (RM). With the help of a trained assistant the SAMAR-App was then installed on the participants' smartphones in both the experimental and control groups. The assistant then explained how the app functioned. For privacy considerations, accessibility to the app for each person was personalized with their own username and password which was provided at the initial registration. SAMAR is an Android-based app that was designed in three main stages, pre-test, educational, and post-test.

## Pre-test stage

included the four aforementioned questionnaires. Given the multitude of questions, the SAMAR user could save some of the answers and continue to respond later.

#### Educational stage

SAMAR was designed to enable the educational stage for the intervention group once the pre-test was complete. The intervention group could access the educational content at any time and place for 8 weeks.

### Post-test stage

After 4 weeks, the first post-test was activated for both the intervention and control groups. At the end of the first post-test, SAMAR users received a notification that reminded them to complete the questions in another 4 weeks.

The control group only had access to the pre-test and post-test after installing the SAMAR on their smartphones. In other words, the educational content stage was inactive for the control group. Nevertheless, at the end of the intervention period (8 weeks), the control group too received the educational content via SAMAR. Activation and deactivation of the three time-based stages of the SAMAR were done automatically.

# Data analysis

IBM SPSS statistics version 16.0 was used for the statistical analysis. Proportions, mean values and standard deviations were calculated for the baseline data. Homogeneity between the two groups was tested using Chi-square tests, Fisher's exact test, and independent t-tests. The primary outcomes of this study included sexual adjustment, sexual satisfaction, marital adjustment, and marital satisfaction. The self-reported assessment was done using valid questionnaires such as the SAQ, Larson's SAQ, Spinner's marital adjustment questionnaire and the ENRICH marital satisfaction scale, respectively. The primary and secondary outcomes were assessed by the same tools, and to this end, their mean scores were evaluated. All these variables were assessed at baseline, and at 4 and 8 weeks after the intervention. The between-group mean difference at baseline, and at 4 and 8 weeks after the educational intervention were analyzed using repeated-measures ANOVA.

# **Ethical considerations**

The data-gathering phase was initiated after receiving ethical approval from Tehran University of Medical Sciences' Ethics Committee under the Code of Ethics registration no. IR.TUMS.REC.2016.2049. A trained research assistant visited the centers under study and briefed the participants on the purpose of the study.

## Results

The participants of this study were men with SCI whose spouses were not disabled. Both experimental and control groups were homogeneous in terms of demographic and clinical variables (Table 1).

### Sexual adjustment

Since the interaction between group (experimental and control) and time (baseline, week 4, week 8) was significant

Table 1 Participants' demographic and clinical characteristics (n = 70).

Variables	Experimental group $(n = 35)$ Mean ± SD	Control group $(n = 35)$	<i>P</i> value 0.08*	
Age (years)	(36.7, 39.5)	(35.3, 37.7)		
Spousal age (years)	(33.3, 37.6)	(32.4, 35.1)	0.21*	
Duration of marriage (years)	(9.7, 15.9)	(9.1, 13.8)	0.49*	
Duration of spinal cord injury (months)	(47.8, 50.5)	(35.5, 60.8)	0.07*	
Level of Education	Frequency (%)			
Elementary	5 (14.3)	6 (17.1)	0.96**	
Intermediate	6 (17.1)	5 (14.3)		
High school diploma	19 (54.3)	18 (51.4)		
Bachelor and above	5 (14.3)	6 (17.1)		
Level of Education of Spouse	Frequency (%)			
Elementary	4 (11.4)	6 (17.1)	0.77**	
Intermediate	7 (20.0)	5 (14.3)		
High school diploma	16 (45.7)	18 (51.4)		
Bachelor and above	8 (22.9)	6 (17.1)		
Employment status	Frequency (%)			
Freelancer	6 (17.1)	5 (14.3)	0.74**	
Unemployed	29 (82.9)	30 (85.7)		
Employment status of spouse	Frequency (%)			
Housewife	30 (85.7)	30 (85.7)	0.53***	
Employee	2 (5.7)	4 (11.4)		
Housewife	3 (8.6)	1 (2.9)		
Number of children	Frequency (%)			
0–2	28 (80.0)	26 (74.3)	0.57**	
3 = <	7 (20.0)	9 (25.7)		
ASIA	Frequency (%)			
А	14 (40.0)	12 (34.3)	0.77**	
В	12 (34.3)	10 (28.6)		
С	6 (17.1)	8 (22.9)		
D	3 (8.6)	5 (14.3)		

Independent sample *t*-test (\*) Chi-square test (\*\*) Fisher exacted test (\*\*\*).

(F = (15.30), P < 0.001, Partial Eta Squared = 0.18), sexual adjustment was compared over time between the two groups. Repeated measures ANOVA showed a statistically significant increase in sexual adjustment's between-group mean difference (95% CI) after 4 weeks (4.2, CI: 3.6–4.8, P < 0.001) as well as 8 weeks (8.6, CI: 7.6–9.5, P < 0.001) after baseline (Table 2).

# Sexual satisfaction

Similarly, since the interaction between group (experimental and control) and time (baseline, week 4, week 8) was significant (F = (54.52), P < 0.001, Partial Eta Squared = 0.44), sexual adjustment was compared over time between the two groups. Repeated measures ANOVA showed a statistically significant increase in sexual satisfaction's between-group mean difference (95% CI) after 4 weeks (6.9, CI: 8–11.2, P < 0.001) as well as 8 weeks (16.4, CI: 14.1–18.7, P < 0.001) after baseline (Table 2).

# **Marital adjustment**

Here, the interaction between group (experimental and control) and time (baseline, week 4, week 8) was not significant (F = (1.49), P < 0.22, Partial Eta Squared = 0.02). Repeated measures ANOVA showed no statistically significant increase in marital adjustment's between-group mean difference (95% CI) after 4 weeks (-0.1, CI: -0.1-0, P < 0.16) as well as 8 weeks (0.4, CI: -0.3-1.1, P < 0.25) after baseline (Table 2).

# **Marital satisfaction**

The interaction between group (experimental and control) and time (baseline, week 4, week 8) was significant (marital satisfaction: F = (6.42), P < 0.014, Partial Eta Squared = 0.08; communication: F = (15.58), P < 0.001, Partial Eta Squared = 0.18; conflict resolution: F = (18.44), P < 0.001, Partial Eta Squared = 0.21; Idealistic distortion: F = (79.92), P < 0.001, Partial Eta Squared = 0.21; Idealistic distortion: F = (79.92), P < 0.001, Partial Eta Squared = 0.54). Therefore, all domains of marital satisfaction were compared over time between the groups. Repeated measures ANOVA showed a statistically significant increase in all domains of marital satisfaction's between-group mean differences (95% CI) after 4 weeks as well as 8 weeks after baseline. More details are shown in Table 3.

# Discussion

The results of this study showed the positive effect of the mobile-based educational intervention on sexual adjustment, sexual satisfaction, and marital satisfaction. However,

Table 2 Comparison of sexual adjustment, sexual satisfaction, and marital adjustment before, 4 and 8 weeks after intervention in the experimental and control groups (n = 70).

	Baseline mean (SD)		4 weeks Mean (SD)		8 weeks Mean (SD)		Between-group differences Mean (95% CI), <i>P</i> value	
	Exp	Control	Exp	Control	Exp	Control	Baseline to 4 weeks	Baseline to 8 weeks
Sexual adjustment	19.7 (4.7)	19.8 (4.7)	24.0 (4.5)	19.9 (4.4)	28.4 (4.6)	19.9 (4.5)	4.2 (3.6, 4.8) <i>P</i> < 0.001	8.6 (7.6, 9.5) <i>P</i> < 0.001
Sexual satisfaction	39.0 (4.2)	38.1 (5.5)	47.8 (6.4)	37.3 (5.4)	54.3 (7.6)	37.0 (5.6)	9.6 (8.0, 11.2) <i>P</i> < 0.001	16.4 (14.1, 18.7) <i>P</i> < 0.001
Marital adjustment	47.5 (8.2)	46.7 (8.2)	47.4 (8.1)	46.7 (8.2)	46.9 (7.8)	45.7 (7.9)	-0.1 (-0.1, 0.0) P = 0.160	$\begin{array}{l} 0.4 \ (-0.3, \ 1.1) \\ P = 0.259 \end{array}$

Table 3 Comparison of marital satisfaction dimensions before, 4 and 8 weeks after the intervention in the experimental and control groups (n = 70).

	Baseline mean (SD)		4 weeks mean (SD)		8 weeks mean (SD)		Between-group differences Mean (95% CI), <i>P</i> value	
	Exp	Control	Exp	Control	Exp	Control	Baseline to 4 weeks	Baseline to 8 weeks
Marital satisfaction	19.9 (4.1)	20.7 (5.8)	24.1 (4.1)	20.8 (5.8)	27.0 (4.4)	20.5 (5.8)	4.1 (3.3, 4.9), <i>P</i> < 0.001	7.3 (6.4, 8.2) <i>P</i> < 0.001
Communication	19.8 (4.2)	19.7 (4.9)	23.7 (4.4)	19.5 (4.7)	27.5 (5.2)	18.8 (5.1)	4.1 (3.4, 4.7), P < 0.001	8.5 (7.2, 9.8), $P < 0.001$
Conflict resolution	20.1 (4.1)	19.2 (5.0)	24.2 (4.4)	19.5 (5.2)	27.6 (4.5)	18.8 (5.1)	3.9 (3.2, 4.6), <i>P</i> < 0.001	7.9 (7.1, 8.7), $P < 0.001$
Idealistic distortion	10.4 (3.1)	8.7 (2.0)	14.1 (2.8)	8.8 (2.0)	16.7 (2.6)	8.9 (2.1)	$3.7~(3.0,~4.4),~P\!<\!0.001$	6.1 (5.2, 7.1), $P < 0.001$

this intervention did not have a statistically significant effect on marital adjustment. The latter finding could be due to the complex nature of this variable and that its complexity is greater in cases of disability.

We have discussed the results of the present study from two following perspectives:

# The effect of the educational intervention on sexomarital life in men with SCI

Based on our results, the educational SAMAR app-based intervention increased the mean score of sexual adjustment at the three designated time intervals in the intervention group, while this change was not observed in the control group. Results of sexual satisfaction and marital satisfaction also showed the same changes, but the mean score of marital adjustment was not statistically significant at either of the three-time intervals or in the comparison between the two groups.

Following spinal cord injury (SCI), many couples experience interpersonal and marital conflict, which overshadows their marital adjustment [18]. It is a multidimensional concept that is affected by several factors such as interpersonal communication skills and marital lifespan [19]. Marital adjustment is the process couples use to modify their relationship throughout their married life to maintain a high level of adaptation.

It seems that couples with SCI should be skilled with strategies for marital adjustment in addition to skills dealing with consequences arising from their disability [20]. The importance of sexual education has also been highlighted in the literature, which suggests that it assists couples with SCI toward gaining a positive outlook of sexuality [21].

In their study, Valtonen et al. showed that sexual satisfaction improved after receiving counseling. The researchers suggested sexual education and counseling to all individuals with SCI and their partners [22]. Although this study's intervention differs from ours, similar variables were studied, and the findings confirm the necessity of providing sexual education and counseling to individuals with SCI and their spouses.

Hocaloski et al.reported that educational interventions are effective in improving women's sexual function and increasing their level of sexual adjustment after injury [23]. Although Hocaloski's study differed in its interventional method it had a similar scope with the current research.

Regardless of gender, literature underscores the significance of education in improving sexo-marital life in individuals with SCI [20]. Thus, consistent with other studies, our study confirmed the need to provide sexual education and counseling to individuals with spinal cord injury.

# The method of education (e-learning) employed in improving sexo-marital life in men with SCI

Irrespective of the effectiveness of an educational intervention, another important point that should be considered in the design of a proper educational program is its educational approach. There were two main reasons to believe in the effectiveness of online education to improve sexual satisfaction, sexual adjustment, marital satisfaction, and marital adjustment among our participants, including, the nature of the issue at hand (i.e. sexo-marital life), and the educational medium. Based on a recent study's findings, Iranians affected with SCI believed their problems arose from a lack of client-based sexual education in their rehabilitation programs, as they had difficulty adjusting to their sexual problems after SCI. In fact, they perceived SCI as a dilemma that affected sexual activity as well [24]. Furthermore, guilt and shame seem to be predominant in these individuals [25]. Thus, it can be easy to avoid talking about sex or to avoid receiving sexual counseling. Online educational sex-related content from a valid source is one of the best methods to receive this kind of education [26]. In the present study, the educational intervention provided experimental groups with messages in an online format via the mobile application. Thus, the participants had no worries regarding access to the educational content. Furthermore, the techniques provided in the SAMAR app were designed to help individuals with SCI to strengthen their sexual relations with their spouses through practice.

To design an accurate educational content aimed at promoting knowledge, modifying current misconceptions, and providing strategies to improve sexo-marital relationships, the right media should be chosen to convey the message to users. E-Learning utilizes electronic technologies to access educational curriculums outside the traditional classroom. This type of learning is popular because it enables much faster delivery; employees can access e-learning material from anywhere and anytime they want, setting their own pace and learning in their own spare time. The effectiveness of the E–learning method has been shown to be six percent greater than face to face training when employed to improve the level of knowledge [27].

Although education is one of the most important strategies for improving sexual and marital relationships in patients with spinal cord injury, differences in the type and method of educational interventions depend on the subjects and characteristics of the target audience [27]. Therefore, one of the most important principles of effective education is to pay attention to the individual and cognitive characteristics of the audience. Some researchers believe that direct education by a licensed professional expert is an effective educational strategy for individuals with SCI. In contrast, given the lack of mobility in these individuals, some studies have referred to online education as a proper method for message transfer [28]. In a quasi-experimental study in 2017, Best et al. concluded that the use of smartphones for health education interventions in individuals with spinal cord injury has certain benefits, such as, reducing the burden on healthcare professionals, and reducing perceived inhibitors like access and transportation [29].

Returning to the main goal posed at the beginning of this paper, it may be said that mobile education is an effective way of improving sexo-marital life in individuals with SCI. The strength of this intervention lies in its research design, variables used, and the fact that this subject has not been addressed in this manner in Iran before. Sex education is the first step of the sexual rehabilitation process [30]. Change in sexual behavior is brought about by raising sexual awareness, knowledge, and reconstruction of sexual beliefs. We believe that the SAMAR app can improve sexo-marital life in couples affected by SCI.

However, the app cannot be installed on smartphones with other operating systems such as iOS (due to the high cost of designing applications for non-Android platforms). As a result of this limitation, the sampling process was prolonged. Moreover, given the participants' physical limitations, we anticipated that they might be worn out by the multitude of questions—as there were four questionnaires to answer—so they periodically received motivational messages at the end of each questionnaire to encourage them to continue. Last but not least, in the intervention group we had two variables, the content and the mobile application. We did not compare these with our control group and observed considerable improvement in the experimental group. However, it is not clear if either or both variables made the difference. Thus, this point should be considered in future studies.

Since the sexual capacity of individuals diminishes following SCI, it is important to accept and adapt to this change. In fact, sexual satisfaction is the first step in achieving sexual adjustment, and the present educational intervention was designed and implemented to achieve this goal. Given the physical limitations of individuals with SCI in receiving in-service training and counseling, we tailormade this mobile application to improve sexual activity in couples affected with SCI in the rehabilitation phase.

#### Data availability

Data supporting the results is reported in the article. The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

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Author contributions FZ was responsible for designing the study and managed the application development phase. SR collected the data. MT contributed to the data analysis. AH analyzed the data and was

responsible for data interpretation. RM was responsible for managing all phases of the study. All authors drafted and revised the manuscript for important intellectual content, and approved the final version.

#### **Compliance with ethical standards**

**Conflict of interest** The authors declare that they have no conflict of interest.

**Ethics statement** We certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of this research.

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