Comparison of pure tone, dichotic digit test and speech in noise in Persian language using a mobile-based approach (Shenava® application) with the audiometer device: Protocol of the randomized controlled trial

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ABSTRACT

Introduction: The global prevalence of hearing loss is around 5 percent in low to middle-income countries. The main purpose of this study is validating a mobile-based Pure Tone Audiometry (PTA), Dichotic Digit Test (DDT) and Speech in Noise (SIN) hearing tests for hearing loss screening purposes in Persian people comparing with routine audiometry exam results.

Material and Methods: This is a single blind randomized controlled trial for comparing a mobile application for hearing screening exams. We designed and standardized PTA, DDT and SIN tests for Persian people and settled them into a specific developed mobile application called "Shenava®". In the audiology clinic, we will recruit at least 100 healthy adult participants, 50 for the case and 50 for the control group. The first group will pass "Shenava®" and standard test respectively and the other group will pass the tests vice versa to prevent order bias.

Results: The results of the tests performed by "Shenava®" and audiometry exam will be analyzed to ensure the accuracy and validity of the "Shenava®" in comparison with standard audiometric exam results.

Conclusion: Hearing tests are costly even for time and money and need a lot of efforts for audiologists and the patients. By designing a mobile app for hearing tests, we hope to be able to make diagnostic screening easier for hearing loss, and relying on the diagnostic value of this tool, it may encourage the patients to have a better follow up and effective treatment plan.

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INTRODUCTION

Overview

Deafness is known as silent disability. According to the World Health Organization definition, "disabling hearing loss" refers to hearing loss greater than 40 dB in the better hearing ear in adults (15 years or older) and greater than 30 dB in the better hearing ear in children (0 to 14 years). The global prevalence of hearing loss is around 5 percent and most of the patients live in low and middle-income countries [1].

The prevalence of hearing loss in Iran is about 14.7

percent of general population [2]. The prevalence of hearing loss in Iran is lower than in USA (15%), Brazil (26.1%), Australia (44.6%), Oman (33.5%) and China (58.1%) [3-7]. Despite the high prevalence of hearing loss in Iran, the access to audiology services is not sufficient and somehow difficult for rural population.

In terms of the burden of disease, hearing loss is one of the diseases that is evaluated by the percentage of total years of life with a disability to determine the burden of the disease. According to this index, hearing loss is ranked twelfth after prenatal conditions and respiratory infections [8]. Most of current screening programs for hearing loss in Iran

are focused on newborns and some of them also run for school children. But based on our knowledge, there is not an official screening program for adults conducting with official or governmental organizations [9-11].

Hearing loss in adults affects the quality of life. It may lead to individuals' inability to communicate with others, loneliness, isolation and unemployment [8, 12-15].

Routine hearing tests are costly even for time and money to test a patient for hearing impairment; and it needs a lot of efforts for audiologist and for the patient. It is better to diagnose the patient with hearing loss as soon as possible; otherwise the illness could cause lifelong or even serious problems in daily activities [15]. The most important challenge in this matter, is lack of awareness of people and families about their own hearing loss or their relatives [16].

Mobile technology is improving so fast. The number of mobile phone users is 4.77 billion worldwide and the number of smartphone users is 2.1 billion [17, 18]. According to the high penetration of mobile phones among people in the world, it can be used effectively for purposes such as hearing screening [19, 20]. Several mobile applications are available for hearing tests in online stores; for example: "hearScreen™" application is designed for the Android and iOS. It helps to perform PTA in less than one minute on average [21]. "Ear Trumpet" application is designed for iOS. This application performs the PTA like the "hearScreen™". The accuracy of "EarTrumpet" application is similar to the accuracy of the traditional method of performing this test to determine the hearing threshold in patient without congenital or acquired deformities of the ears [22, 23]. Also "UHear" application performs PTA for screening hearing loss in the elderly (aged 65 years or older), with 100% sensitivity and 60% specificity compared with the audiometer [12].

A review on audiologic tests: routine techniques

PTA assesses one's hearing threshold for pure sound with a range of 25 to 8,000 Hz frequency [24, 25]. The results of this test indicate the sensitivity of the inner ear, auditory nerve and external ear and middle ear canal [25]. This test is performed in a routine audiologic exam in an acoustic room with an audiometry device. Another common and important test used to check whether Central Auditory Processing Disorder (CAPD) exists, is the Dichotic Digit Test (DDT). In this test the examiner set the device appropriately and two synchronized pre-recorded human voice plays through a headset, reading single numbers from 1 to 10 at the same time, but different numbers for each ear, and patient should be able to differentiate and repeat both numbers [26]. In Persian, number 4 has two syllables in spelling (Cha-Har), so we should ignore this

number but all other numbers from 1 to 10 are used. This test is available in single, double and triple forms. In single, just a pair of numbers are played, in double, two pairs of numbers are played in certain timing and in triple, and three pairs of numbers are played as well. Double DDT is the most common type for CAPD screening. Currently, the available versions of these tests for audiometry devices have problems such as: the lack of time matching between the two numbers; and the intensity of saying numbers are not the same in decibel (Table 1 and 2) and are slightly different for timing and frequency (Fig 2). The time matching between the two numbers is very important because patients must be able to distinguish the two numbers that are simultaneously played in the two ears and then must be able to repeat those numbers exactly, otherwise, if the test isn't accurate enough and the patient has a disorder, it may not be diagnosed correctly.

Another common test to diagnose hearing loss in adults is Speech in Noise (SIN). This test provides information for hearing ability and identifies a person's Sensory-Neural Hearing Loss (SNHL) [25, 27]. When performing this test, white noise is played via headphone for both ears by the audiometer device. Meanwhile the examiner reads a list of one syllable words from outside of the acoustic room in front of the visor glass via microphone, covering his/her mouth with hand or a cardboard, and the person should repeat those words. It is difficult to distinguish the words when noise is playing back, but important to help the diagnosis of SNHL.

The considered problem in this method, is the subjective effect of the examiner and the costs of the tools for performing the tests. To remove the examiner's role and to reduce the high costs due to audiometry devices and audiology acoustic room in audiology center, it is supposed to have a mobile based application. By a well-designed and using a standard voice for test, we can perform all the PTA, DDT, and SIN tests with a least subjective effect of the examiner. This method may remove any physical difference for performing the tests and help to lower costs for both patients and examiners because we use a mobile for performing the tests that has lower cost than audiometry devices. The environment for performing the tests can be a simple silent room in a house or in a physician private office and there is no need to build an acoustic room or use expensive headphones.

We hope this tool can quickly and accurately perform initial screening for large population who might have hearing loss and will encourage to follow an appropriate treatment plan.

MATERIAL AND METHODS

This study is a Randomized Controlled Trial study

and we will do it during 2018-2019.

First phase

We use Python programming language (v. 3.6.5) to design the mobile-based application and for user interface, we use the React Native (v. 52). Based on the necessity, the database to be used will be MongoDB or Neo4j.

The process of application development will be completed in four steps including need assessment, design, implementation and testing. PTA will be performed in frequencies from 250 Hz to 8000 Hz and also single, double and triple DDT and SIN will be performed by the mobile application (Fig 1 and 2). To ensure that the quality and the extent of the sound frequency will be accurate enough, we will use appropriate mobile devices or new tablets. In testing phase, we will use a tablet (Samsung Galaxy Tab A6 T585 LTE 10.1, 2017) in audiology ward of Shafa Hospital.

Fig 1: Capture of the app interface, PTA for left ear

To create the DDT and SIN in Acoustic Room in Electronic Educational Affairs of Kerman University of Medical Sciences, we recorded the voices of ten adult men with fluent and official Persian dialect. The tone of the monotonous voice recorded saying the numbers 1 to 10, except for 4 (because number 4 has two syllables in Persian) and 10 single syllable words from a predefined list. We then explained for the narrators to try to be punctual for time spacing and their voice intensity for each word. A microphone (Blue Bluebird) placed approximately 15 cm from the narrator's mouth during recordings and a silent visual metronome used to adhere the time interval between numbers and also words. After checking the recorded test voices for frequency and

quality of saying the words and numbers, we selected two of them and recorded their voices in exact conditions for all of the required things. Finally, after editing and consulting with an audiologist and medical informatics specialist, we selected the best recorded voice clips to make them implemented into "Shenava®" Mobile App.

Fig 2: Capture of the app interface, DDT with all Persian numbers excluding 4

Rules about the tests

In the DDT, each item has numbers from 1 to 10 except for 4, but no number will be repeated in each dichotic-pair. The free time between saying each pair in single dichotic-digit test is 4 seconds for the patient to recall the numbers. In double and triple DDT, the lag time between each pair of the numbers is exactly 500 milliseconds and the recall time is similar to single DDT.

We used the Cubase (v. 5) and Audacity software (v. 2.3.0) to match both voice channels and if necessary, for sound compression to matching numbers, we used the AVS Audio Editor (v. 8.5). Numbers are compressed or expanded until $\pm 16\%$. Recorded numbers are randomized according to the type of DDT that means in the single DDT only two numbers should be matched and 4 seconds will be for the response. After 4 seconds the next two numbers will be played in the application. Also in the double DDT, two numbers will be played and the next two numbers will be played after 500 milliseconds and will exist 5 seconds to pause for the response; then the next four numbers will be played. In the triple

dichotic digits test, three pairs of numbers will be played and the lag time between each pair of the numbers is exactly 500 milliseconds. After playing 6 numbers, 8 seconds will be for the response. Finally, we created an MP3 audio file for each test.

In the new version of DDT, numbers have been highly matched for onset time, for the intensity of sound or voice (decibel) and for the frequency range of sound. (Fig 3 and 4) and (Table 1 to 5).

After creating these tests, we will recruit about 20 normal people and all of the above tests will be performed for them both by a standard audiometer (Madsen Astra 2) and by “Shenava®” in the audiology clinic. For creating SIN, we will ask the narrators to say a list of single syllable words that are commonly used in the audiology center. In Cubase software we put words in 5 seconds from each other. Finally, this test will be created as a sound file with MP3.

Fig 3: The lack of matching between the two numbers for timing and intensity in old version of double Dichotic Digit Test

Fig 4: The slightly difference for frequency and intensity of the two numbers played in each ear in triple Dichotic Digit Test

Fig 5: Matching time and intensity for the two pair of numbers after recording and adjusting the numbers in re-designed the Dichotic Digit Tests

Table 1: Comparison of intensity for different 25 paired numbers in old double dichotic digit test before adjusting the sound level for each number

ID	Left Ear		Right Ear		ID	Left Ear		Right Ear	
	Numbers	Intensity (dB)	Numbers	Intensity (dB)		Numbers	Intensity (dB)	Numbers	Intensity (dB)
1	10	73.9	2	79.7	14	5	78	3	78.7
	3	76.5	9	79.2		2	75.2	8	77.4
2	10	79.1	3	79.1	15	10	79.3	8	77.2
	6	77.5	8	77.4		7	79.4	1	79.0
3	10	77.4	5	78.4	16	6	77.6	8	77.1
	8	78.8	1	78.3		2	75.8	10	77.5
4	6	77.7	5	78.3	17	8	79.4	5	78.2
	9	76.5	8	77.7		7	80.1	3	78.7
5	1	76.2	2	79.4	18	3	77.6	1	77.6
	3	77.2	5	77.5		7	79.6	2	79.5
6	5	78.7	10	77.4	19	3	77.3	7	78.5
	2	75.3	1	77.9		9	76.8	5	77.7
7	3	78	6	79.0	20	9	77.9	5	77.5
	5	78.1	9	79.2		3	77	7	79.5
8	8	79.6	9	79.7	21	10	79.2	6	79.2
	10	79.2	1	78.3		2	75.7	7	78.9
9	7	79.7	5	77.8	22	8	79.9	10	77.6
	6	77.8	2	79.5		6	77.9	7	79.8
10	10	78.8	7	78.9	23	5	78.8	6	79.7
	8	80	5	77.7		10	79.3	7	79.7
11	7	79.5	8	77.4	24	3	76.8	10	77.7
	9	77.4	2	79.4		2	76	6	79.7
12	5	78.9	9	79.5	25	10	78.4	1	77.9
	10	78.4	2	79.3		9	76.9	3	78.7
13	1	76.4	9	79.4					
	10	79.5	3	77.7					

Table 2: Comparison of intensity for different 25 paired numbers in old triple dichotic digit test before adjusting the sound level for each number

ID	Left ear		Right ear		ID	Left ear		Right ear	
	Numbers	Intensity (dB)	Numbers	Intensity (dB)		Numbers	Intensity (dB)	Numbers	Intensity (dB)
1	2	73.7	1	78	14	3	76.9	8	77.3
	10	78.5	8	77.8		9	78.3	7	78.4
	7	81.3	6	79.9		1	76.3	2	79.7
2	8	79.4	10	77.9	15	7	80.3	6	80.3
	3	76	7	78		2	75.1	8	77.4
	6	77.1	9	79		5	79	1	78
3	10	79.2	8	77.6	16	5	78.9	1	77.8
	6	76.8	5	78.2		9	78.4	3	79.4
	9	78.6	7	78.1		6	77.8	10	78
4	1	75.5	7	78.1	17	5	79	2	79.7
	3	76	9	79		10	79.6	3	79.5
	8	80.7	5	78.2		8	80.3	1	77.8
5	6	76.6	2	79.6	18	9	78.4	5	77.7
	8	80.4	5	77.6		7	80.6	1	77.9
	7	80.5	3	79.3		6	77.8	8	77.4
6	6	76.5	7	77.4	19	1	76.4	2	80
	9	77.8	5	78.3		9	78.3	6	79.8
	8	79.7	10	77.9		3	76.9	5	78.6
7	6	76.6	1	77.7	20	7	80.7	10	78.5
	7	80.5	10	77.7		9	77.7	1	77.5
	5	79	8	77.2		5	78.7	6	80.1
8	6	76.8	10	78.2	21	10	79.5	3	79.1
	8	79.6	1	77.8		6	77.5	7	78.6
	2	73.4	7	77.8		8	80.6	9	79.3
9	1	75.3	6	80.2	22	10	79.3	9	79.5
	3	76	5	78.9		3	76.9	8	77.5
	2	74.4	10	77.8		6	77.7	2	80
10	5	78.7	10	77.2	23	8	80.5	7	78.2
	2	73.1	3	79		3	77.1	2	79.6
	7	80.5	8	77.1		9	78.2	5	77.1
11	1	74.9	3	79.1	24	3	77.2	6	80.3
	9	78.9	2	79.6		1	76.4	5	78
	7	81.1	5	77.7		9	78.1	10	78
12	7	80.3	3	79.7	25	3	76.9	2	79.4
	5	78.5	2	79.6		5	79.6	8	77.4
	9	77.3	1	78.3		10	79.2	6	79.6
13	7	80.6	8	77.3					
	5	79	6	80.4					
	10	79.1	1	78.7					

Table 3: Comparison of intensity for different 25 paired numbers in new double dichotic digit test after recording the voices and adjusting the sound level for each number

ID	Left Ear		Right Ear		ID	Left Ear		Right Ear	
	Numbers	Intensity (dB)	Numbers	Intensity (dB)		Numbers	Intensity (dB)	Numbers	Intensity (dB)
1	10	70.7	2	70.7	14	5	70.8	3	70.8
	3	70.8	9	70.7		2	70.7	8	70.7
2	10	70.7	3	70.8	15	10	70.7	8	70.7
	6	70.7	8	70.7		7	70.7	1	70.8
3	10	70.7	5	70.8	16	6	70.7	8	70.7
	8	70.7	1	70.8		2	70.7	10	70.7
4	6	70.7	5	70.8	17	8	70.7	5	70.8
	9	70.7	8	70.7		7	70.7	3	70.8
5	1	70.8	2	70.7	18	3	70.8	1	70.8
	3	70.8	5	70.8		7	70.7	2	70.7
6	5	70.8	10	70.7	19	3	70.8	7	70.7
	2	70.7	1	70.8		9	70.7	5	70.8
7	3	70.8	6	70.7	20	9	70.7	5	70.8
	5	70.8	9	70.7		3	70.8	7	70.7
8	8	70.7	9	70.7	21	10	70.7	6	70.7
	10	70.7	1	70.8		2	70.7	7	70.7
9	7	70.7	5	70.8	22	8	70.7	10	70.7
	6	70.7	2	70.7		6	70.7	7	70.7
10	10	70.7	7	70.7	23	5	70.8	6	70.7
	8	70.7	5	70.8		10	70.7	7	70.7
11	7	70.7	8	70.7	24	3	70.8	10	70.7
	9	70.7	2	70.7		2	70.7	6	70.7
12	5	70.8	9	70.7	25	10	70.7	1	70.8
	10	70.7	2	70.7		9	70.7	3	70.8
13	1	70.8	9	70.7					
	10	70.7	3	70.8					

Table 4: Comparison of intensity for different 25 paired numbers in new triple dichotic digit test after adjusting the sound level for each number

ID	Left ear		Right ear		ID	Left ear		Right ear	
	Numbers	Intensity (dB)	Numbers	Intensity (dB)		Numbers	Intensity (dB)	Numbers	Intensity (dB)
1	2	70.7	1	70.8	14	3	70.8	8	70.7
	10	70.7	8	70.7		9	70.7	7	70.7
	7	70.7	6	70.7		1	70.8	2	70.7
2	8	70.7	10	70.7	15	7	70.7	6	70.7
	3	70.8	7	70.7		2	70.7	8	70.7
	6	70.7	9	70.7		5	70.8	1	70.8
3	10	70.7	8	70.7	16	5	70.8	1	70.8
	6	70.7	5	70.8		9	70.7	3	70.8
	9	70.7	7	70.7		6	70.7	10	70.7
4	1	70.8	7	70.7	17	5	70.8	2	70.7
	3	70.8	9	70.7		10	70.7	3	70.8
	8	70.7	5	70.8		8	70.7	1	70.8
5	6	70.7	2	70.7	18	9	70.7	5	70.8
	8	70.7	5	70.8		7	70.7	1	70.8
	7	70.7	3	70.8		6	70.7	8	70.7
6	6	70.7	7	70.7	19	1	70.8	2	70.7
	9	70.7	5	70.8		9	70.7	6	70.7
	8	70.7	10	70.7		3	70.8	5	70.8
7	6	70.7	1	70.8	20	7	70.7	10	70.7
	7	70.7	10	70.7		9	70.7	1	70.8
	5	70.8	8	70.7		5	70.8	6	70.7
8	6	70.7	10	70.7	21	10	70.7	3	70.8
	8	70.7	1	70.8		6	70.7	7	70.7
	2	70.7	7	70.7		8	70.7	9	70.7
9	1	70.8	6	70.7	22	10	70.7	9	70.7
	3	70.8	5	70.8		3	70.8	8	70.7
	2	70.7	10	70.7		6	70.7	2	70.7
10	5	70.8	10	70.7	23	8	70.7	7	70.7
	2	70.7	3	70.8		3	70.8	2	70.7
	7	70.7	8	70.7		9	70.7	5	70.8
11	1	70.8	3	70.8	24	3	70.8	6	70.7
	9	70.7	2	70.7		1	70.8	5	70.8
	7	70.7	5	70.8		9	70.7	10	70.7
12	7	70.7	3	70.8	25	3	70.8	2	70.7
	5	70.8	2	70.7		5	70.8	8	70.7
	9	70.7	1	70.8		10	70.7	6	70.7
13	7	70.7	8	70.7					
	5	70.8	6	70.7					
	10	70.7	1	70.8					

Table 5: Comparing old and new version of recorded numbers in both double and triple dichotic digit tests for each playing number

Recorded Numbers	2 DDT Old Version		2 DDT New Version		3 DDT Old Version		3 DDT New Version	
	Mean	Std. Dev	Mean	Std. Dev	Mean	Std. Dev	Mean	Std. Dev
1	77.7	0.9	78.8	0	77.1	1.1	70.8	0
2	77.7	1.9	70.7	0	77.6	2.8	70.7	0
3	77.4	0.7	70.8	0	77.8	1.4	70.8	0
5	78.1	0.4	70.8	0	78.4	0.6	70.8	0
6	78.4	0.9	70.7	0	78.4	1.5	70.7	0
7	79.4	0.4	70.7	0	79.5	1.3	70.7	0
8	78.5	1.1	70.7	0	78.6	1.4	70.7	0
9	78.2	1.2	70.7	0	78.4	0.6	70.7	0
10	78.6	0.7	70.7	0	78.4	0.7	70.7	0

Second phase

In this phase, we will compare the effect of the tool designed with the medical engineering equipment. In the audiology center we will select a sample size of at least 100 people and take PTA, DDT and SIN tests by an audiometer and by "Shenava®". Finally, we will compare the results of the tests performed by the audiometry and "Shenava®" by SPSS version 25 to ensure the accuracy and validity of the designed mobile application.

Eligibility criteria

1. Right-handed native speaker of Persian
2. The participant declares normal hearing in both ears without complaining of hearing impairment
3. Lack of speech impairment, language or learning in the family
4. Lack of speech or speech disorders
5. Lack of chronic infections of the middle ear
6. Lack of ear, throat or nose surgery
7. Lack of hearing impairment and history of epileptic seizure
8. Lack of head trauma causing fracture

RESULTS

Results of this study is reported in Tables 1 to 5. As it could be clearly seen, Table 1 shows intensity for different 25 paired numbers in old double dichotic digit test before adjusting the sound level for each number, while Table 2 is including intensity for different 25 paired numbers in old triple dichotic digit test before adjusting the sound level for each number.

Table 4 shows intensity for different 25 paired numbers in new double dichotic digit test after recording the voices and adjusting the sound level for each number, and comparison of intensity for

different 25 paired numbers in new triple dichotic digit test after adjusting the sound level for each number showed in Table 4.

Finally, old and new version of recorded numbers in both double and triple dichotic digit tests is compared using mean and standard deviation of intensity for each playing number (Table 5).

DISCUSSION

We are Persian and live in Iran, so we need local and standard exams in our language to be able to make good screening test. Some of the hearing exam tests which are routine for screening the hearing impairment, like DDT and SIN, are designed for Persian people with Persian digits and words, but when a test is going to be performed by an audiologist, it depends on human in general. In a SIN test, the audiologist says the words from a predefined list in front of the visor window for the patient out of the audiology acoustic room and it is possible that the results are strictly related to audiologist effect.

There are a lot of human factors that may affect his/her voice intensity, quality, clarity and even how to pronounce words in different local accents. All of these factors can make a SIN test to become invalid to be simply acceptable for a doctor, resulting in wasting time, energy and money.

Another important problem is the lack of a smooth and equivalent saying Persian digits in a single or double or triple dichotic digit test and actually the existing tests were not enough accurate for sound concordance and sound level in each ear. There were also some degrees of discrepancies in the intensity and the length of digit words in the recorded audio file in routine audiometry exam test. In addition to these problems, there were no existing or designed mobile applications in Persian including the PTN, DDT and SIN altogether.

We planned this study to make a reliable tool and we expect that tests will be made successfully in a robust and accurate state and could be used in any smartphone device. Also it is probable that the

redesigned simple and diagnostic tests of hearing will lead to decrease the need for a patient to go to audiology center just for initial screening tests, but it may serve the people an accurate exam only by using their own smartphone and only the results of this exam will be sent to the referral audiology centers.

If the main objectives of the study are achieved, considerable savings will be made in time and energy and cost. We tried a lot to make the standard sounds and methods of testing as much as possible to be similar for all patients without any physical difference, as well as without human intervention and any distracting subjective decision making.

CONCLUSION

The final conclusion is considered that the results of the mobile-based tests (by “Shenava®”) are close enough and similar to the results of the tests performed with the “Madsen Astera2®” - an audiometer device - that could affirm the hypothesis that “Shenava®” as a standard mobile app has accurate diagnostic value for large population hearing screening exams.

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The study protocol was approved by the ethical committee of Kerman University of Medical Sciences (Code: IR.KMU.REC.1397.037) and this study will be conducted according to common standard guidelines for clinical trials (IRCT20141221020380N2).

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AUTHOR'S CONTRIBUTION

All authors declare that the manuscript is a result of original work with collaboration of all contributors listed above.

FK: preparing the initials, designing the application interface, preparing and evaluating the hearing tests for participants and manuscript writing and preparing the data analysis.

JA: supervising the development of the hearing tests for application, patient examination and checking the correctness of actions, and manuscript writing,

MA: consultant for specific parts, guiding the team for making the accurate evaluation, supervision for patient examination, interpretation of data, and manuscript writing.

ASN: basic idea, conception and design of the study, supervision in sound recording and development of hearing tests and application, interpretation of the results, conducting the application development, critical revision of manuscript and supervision in all parts of the study.

All authors read and approved the final manuscript.

CONFLICTS OF INTEREST

The author declare no conflicts of interest regarding the publication of this study.

FINANCIAL DISCLOSURE

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