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Validity of the iHealth-BP7 and Withings-BP800 Self Measurement Blood Pressure Monitor

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Physical Activity in Health Promotion

ABSTRACT

PURPOSE: The purpose of this study is to validate the wireless iHealth-BP7 and Withings-BP800 monitors according to the European Society of Hypertension (ESH) International Protocol revision 2010.

METHODS: Data from 11 participants (31.2 ± 9.4 years) were initially examined according to the ESH International Protocol revision 2010 for the validation of BP measuring devices in adults. Participants were asked to sit and relax for 10-15 min with legs uncrossed, and back supported prior to the test. In all participants, sequential left arm measurements were performed by two trained observers using a mercury sphygmomanometer and one supervisor using the device. Collected data were screened according to the ESH protocol for both systolic BP (SBP) and diastolic BP (DBP). ESH International Protocol requires 33 subjects, but currently only 11 subjects participated in this study. Thus, the adjusted criteria of the protocol were applied to establish the standard for the 11 subjects.

RESULTS: The mean differences between the monitor and sphygmomanometer readings were -0.55 ± 3.75 (SBP) and 0.54 ± 3.62 (DBP) for iHealth-BP7 and 3.18 ± 4.37 (SBP) and -0.35 ± 5.42 (DBP) for Withings-BP800. The iHealth-BP7 monitor passed all of the modified requirements, however the Withings-BP800 did not meet the last phase of the modified criteria of the ESH international protocol.

CONCLUSION: The iHealth-BP7 monitor is recommended as a valid home BP monitoring device, however the Withings-BP800 fails to meet the ESH criteria in this study potentially due to the small sample size. Since the ESH protocol requires 33 subjects, further study with additional participants is warranted to determine validation of both devices.

INTRODUCTION

- Blood pressure (BP) control among treated people with hypertension remains poor.
- Home BP monitoring devices have led to their widespread adoption, and are now consistently utilized for the evaluation and management of hypertension.
- The purpose of this study is to validate the wireless iHealth-BP7 and Withings-BP800 monitors according to the European Society of Hypertension (ESH) International Protocol revision

METHODS

Protocol

- Participants were asked to sit and relax for 10-15 min with legs uncrossed, and back supported prior to the test. In all participants, sequential left arm measurements were performed by two trained observers using a mercury sphygmomanometer and one supervisor using the devices (iHealth-BP7 and Withings-BP800).

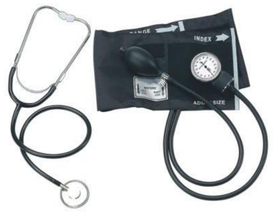
METHODS (Cont.)

Participants

- 11 participants (31.2 ± 9.4 years) participated in this study

Table 1. Participants details

Sex	Male : female	6 : 5
Age	Range (low : high)	25 : 56
	Mean (SD)	31.2 (9.4)
Arm Circumference (cm)	Range (low : high)	23.4 : 34.8
	Mean (SD)	30.0 (3.8)
Cuff for test device (cm)	Standard	33 (22-42)
Wrist Circumference	Range (low : high)	13.4 : 18.5
	Mean (SD)	15.6 (1.5)
Recruitment BP (mmHg)	SBP	
	Range (low : high)	87.5 : 117.5
	Mean (SD)	103.5 (11.1)
	DBP	
	Range (low : high)	54 : 76
	Mean (SD)	63.7 (6.6)



· Stethoscope & Sphygmomanometer

· iHealth-BP7

· Whithings-BP800

Instruments

- iHealth-BP7 (iHealth Lab, Inc., Mountain View, CA) is a wireless, noninvasive blood pressure measurement system connected by Bluetooth technology to smartphones or tablet PCs. It is designed to measure the systolic, diastolic blood pressure and pulse rate by inflatable cuff wrapped around the wrist.
- Withings-BP800 (Withings, Inc., Lewes, DE) measures blood pressure by the cuff oscillometric method. It is directly connected to smartphones or tablet PCs, monitoring blood pressure and pulse.

RESULTS

Table 2.1. Validation Results of iHealth-BP7

Part 1		≤5mmHg	≤10mmHg	≤15mmHg	Grade 1	Mean	SD
Pass Requirement	Two of	24.3	29	32			
	All of	21.6	27	31			
Achieved	SBP	28	33	33	Pass	-0.55	3.75
	DBP	26	33	33	Pass	0.54	3.62

Part 2		2/3 ≤ 5mmHg	0/3 ≤ 5mmHg	Grade 2	Grade 3
Pass Requirement		≥ 8	≤ 1		
Achieved	SBP	10	0	Pass	Pass
	DBP	9	0	Pass	Pass

Part 3	Result
	Pass

- The mean differences between the iHealth-BP7 and sphygmomanometer readings were -0.55 ± 3.75 (SBP) and 0.54 ± 3.62 (DBP).

Table 2.2. Validation Results of Withings-BP800

Part 1		≤5mmHg	≤10mmHg	≤15mmHg	Grade 1	Mean	SD
Pass Requirement	Two of	24.3	29	32			
	All of	21.6	27	31			
Achieved	SBP	21	33	34	Pass	3.18	4.37
	DBP	25	30	33	Pass	-0.35	5.42

Part 2		2/3 ≤ 5mmHg	0/3 ≤ 5mmHg	Grade 2	Grade 3
Pass Requirement		≥ 8	≤ 1		
Achieved	SBP	8	2	Fail	Fail
	DBP	9	1	Pass	Pass

Part 3	Result
	Fail

- The mean differences between the Withings-BP800 and sphygmomanometer readings were 3.18 ± 4.37 (SBP) and -0.35 ± 5.42 (DBP).

CONCLUSIONS

- The iHealth-BP7 monitor is recommended as a valid home BP monitoring device, however the Withings-BP800 fails to meet the ESH criteria in this study potentially due to the small sample size.
- Since the ESH protocol requires 33 subjects, further study with additional participants is warranted to determine validation of both devices