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An Automated Blood Pressure Display for Self-Measurement in Patients With Chronic Kidney Disease (iHealth Track): Device Validation Study.

Mazoteras-Pardo V(#)(1), Becerro-De-Bengoa-Vallejo R(#)(1), Losa-Iglesias ME(#)(2), López-López D(#)(3), Calvo-Lobo C(#)(1), Rodríguez-Sanz D(#)(1), Martínez-Jiménez EM(#)(4), Palomo-López P(#)(5).

Author information:
(1)Facultad de Enfermería, Fisioterapia y Podología, Universidad de Complutense de Madrid, Madrid, Spain.
(2)Faculty of Health Sciences, Universidad Rey Juan Carlos, Alcorcón, Spain.
(3)Research, Health and Podiatry Group, Faculty of Nursing and Podiatry, Departament of Health Sciences, Universidade da Coruña, Ferrol, Spain.
(4)Facultad de Fisioterapia y Enfermería, Departamento de Enfermería, Universidad Castilla la Mancha, Toledo, Spain.
(5)University Center of Plasencia, Universidad de Extremadura, Plasencia, Spain.
(#)Contributed equally

BACKGROUND: Hypertension is a global public health issue and is closely related to chronic kidney disorder (CKD). In people with CKD, strict monitoring of blood pressure is an important part of therapy.
OBJECTIVE: The aim of this research was to validate the iHealth Track blood pressure monitoring device for patients with CKD according to the European Society of Hypertension International Protocol 2010 (ESH-IP2).
METHODS: In total, 33 patients who received hemodialysis in Plasencia participated in the study. There were 9 successive measurements made, which conformed to the ESH-IP2. We calculated the differences between the standard reference device (Omron M3 Intellisense) and the test device (iHealth Track) for blood pressure and heart rate values. For 99 total comparisons of paired measurements, we classified differences into various categories (≤5 mmHg, ≤10 mmHg, and ≤15 mmHg for blood pressure; ≤3, ≤5, and ≤8 beats per minute for heart rate).
RESULTS: In 90 of 99 systolic blood pressure and 89 of 99 diastolic blood pressure comparisons between the devices, measurement differences were within 5 mmHg. In 81 of 99 heart rate comparisons between the devices, measurement differences were within 3 beats per minute. The mean differences between the test and reference standard measurements were 3.27 (SD 2.99) mmHg for systolic blood pressure, 3.59 (SD 4.55) mmHg for diastolic blood pressure, and 2.18 (SD 2.75) beats per minute for heart rate. We also observed that for both systolic and diastolic blood pressure, 31 of 33 participants had at least two of three comparisons between the devices with measurement differences less than 5 mmHg. For heart rate, 28 of 33 patients had at least two of three comparisons between the devices with measurement differences less than 3 beats per minute.
CONCLUSIONS: To our knowledge, this is the first study to show that iHealth Track meets the requirements of the ESH-IP2 in patients with CKD. Therefore, the iHealth Track is suitable for use in renal patients.

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