Heliyon 9 (2023) e17854

Contents lists available at ScienceDirect

Heliyon

journal homepage: www.cell.com/heliyon

# Concurrent validity and reliability of new application for 6-min walk test in healthy adults

Nuttawuth Mekritthikrai [a], Kornanong Yuenyongchaiwat [a,b,*], Chusak Thanawattano [c]

[a] Department of Physiotherapy, Faculty of Allied Health Sciences, Thammasat University, Thailand
[b] Thammasat University Research Unit in Physical Therapy in Cardiovascular and Respiratory Systems, Thailand
[c] National Science and Technology Development Agency (NSTDA), Thailand

ARTICLE INFO

*Keywords:*
Physical performance
Cardiovascular endurance
Six-minute walk test
Mobile device

ABSTRACT

*Background:* Evaluation assessments for physical performance, such as walking tests, are important for measuring a person's well-being. As of current, medical technology is primarily used to administer these assessments. However, medical devices are not easily accessible and are intended for research purposes only, and hence inconvenient for clinical use. Therefore, we aimed to develop a prototype physical performance assessor device with a mobile application and explored concurrent validity and reliability between the standard 6-min walk test (6MWT) and wearable sensor 6MWT using 6-min walk distance in healthy adults.
*Methods:* Sixty healthy males and females, above 18 years of age, were required to attach a sensor to their dominant ankle while the standard protocol for 6MWT was performed. After completing the walking test, the distance from the wearable sensor 6MWT with a mobile application and the standard 6MWT were recorded and compared.
*Results:* There was no significant difference between the distance between the standard 6MWT (410.12 ± 74.03 m) and the distance obtained with the wearable sensor. Concurrent validity was found to be moderate, and Cronbach's alpha was 0.79, which indicated good internal consistency.
*Conclusion:* The innovative prototype wearable walking sensor with a mobile application can effectively evaluate physical performance in healthy individuals.
Clinical trial registration number: TCTR20220801002.

## 1. Introduction

Walking tests are a group of performance-based tests that measure the walking distance at varying intervals, such as 2 min, 6 min, and 12 min [1]. Furthermore, walking tests are technically simple and a widely used method of fitness testing in different areas of healthcare e.g., medicine, physical therapy, and rehabilitation. A 6-min walk with a distance less than 350 m is associated with well-documented thresholds for increased mortality [2] in chronic obstructive pulmonary disease, chronic heart failure and pulmonary arterial hypertension [3]. Therefore, walking tests are helpful in determining current physical status, and in evaluating the treatment in various groups such as patients with heart, lung, and neurological disease in the elderly, and even the general population.

* Corresponding author. Physiotherapy Department, Faculty of Allied Health Sciences, Thammasat University, 99 Moo 18, Paholyothin Road, Klong Luang, Rangsit, Pathumthani, 12120, Thailand.
*E-mail address:* ykornano@tu.ac.th (K. Yuenyongchaiwat).

https://doi.org/10.1016/j.heliyon.2023.e17854
Received 16 October 2022; Received in revised form 28 June 2023; Accepted 29 June 2023
Available online 1 July 2023
2405-8440/

Furthermore, walking tests provide a preliminary assessment of physical fitness, as well as an assessment of nutritional status and cognitive function [4].

Six-minute walk test (6MWT) is straightforward to perform, but they involve costs and some practical limitations. It requires a corridor of at least 15 m long in the hospital or testing area [5], where a therapist will observe and record measurements. Furthermore, patients must travel to the hospital clinic or rehabilitation center for the walking test; hence, economic cost should be considered for transportation, e.g., public transportation cost.

In addition, there are several problems while performing the 6MWT, such as carrying numerous devices before, during and after the test (i.e., worksheets for recording, stopwatch to record the laps, mechanical lap counter, the Borg scale chart, cones to mark the turnaround points) [6]. Consequently, these issues might affect test results because of discrepancies between accessing and measuring the 6MWT.

As mentioned previously, the occurrence of errors by technical personnel were considered. A 6MWT mobile application therefore, might help a therapist to implement the procedure more efficiently, with the mobile phone and the walking sensor detecting the distance during the test. The main purpose of this study was to develop a prototype of 6MWT with a smart band device to record distance and time. Furthermore, the concurrent validity and reliability of the mobile application and standard 6MWT were explored in healthy people.

## 2. Method

A total of 60 participants were included in the study, with 10 females and 10 males recruited for each the following age groups: 1) 18–35, 2) 36–59, and 3) >60 years of age. Fifty participants are the minimum suggested sample size for medical applications in obscure diseases and health research [7,8].

For this reason, this study included at least 50 participants. More specifically, a total 60 participants was enrolled. The inclusion criteria were the following: 1) able to communicate, 2) can understand and follow commands, and 3) can walk independently. All participants were given the information sheet and were required to sign the consent form prior to the test. Further, the informed consent was obtained from the participant for the publication of his images. The study was approved by the Ethics Human committee of Thammasat University, based on the Declaration of Helsinki, the Belmont report, CIOMS guidelines, and the international practice (ICH-GCP) COA No. 108/2563. The clinical trial registration is TCTR20220801002.

The participants were required to attach the prototype walking sensors on the ankle of the dominant leg and the 6MWT followed the American Thoracic Society protocol [6]. Blood pressure, heart rate, oxygen saturation and rate of perceived exertion (RPE) were assessed before and after the 6MWT.

The prototype developed was composed of a Bluetooth 2.0 Multi-Connect BWT901CL 9 Axis inertial measurement unit sensor and a walking sensor. With the axis inertial sensors, the average walking motion pattern accuracy was 97.64%, and the average memory delay was 23.97% of the walking cycle [9]. Furthermore, the prototype passed a high-level standard of electrical and electromagnetic safety test; therefore, it is completely safe.

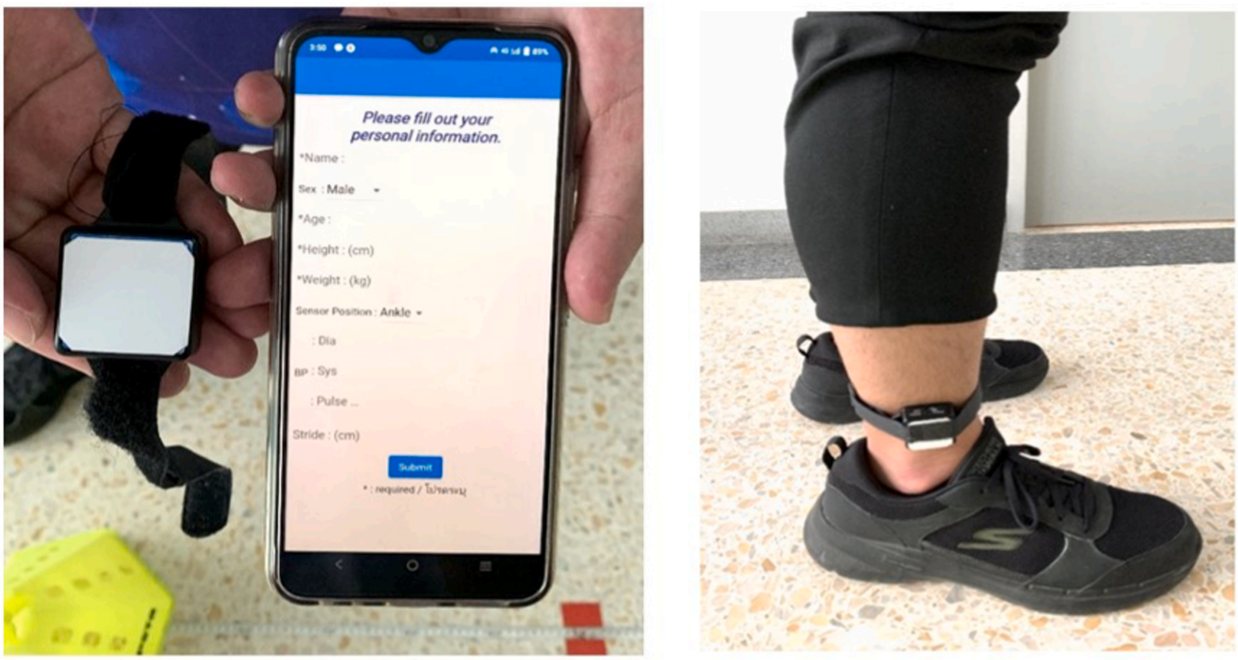


**Fig. 1.** Mobile application and prototype walking sensors device.

## 3. Features of walking sensors

| Features | Prototype |
|---|---|
| Sensor for measuring posture | 3-axis accelerometer capable of measuring at a maximum acceleration reflect 2, 8 and 16 g, a typical measurement of frequency was not less than 20 times per 1 s |
| Total weight | 8 g (without battery) |
| External dimensions | 9 × 60 × 40 mm. (approximately) |
| Enclosure material | Plastic PLA (polylactic acid), melt Temp 157 °C |
| Processor | 32-bit, 24 MHz with Bluetooth Low Energy<br>Power supply voltage 3.0 V CR2016<br>Power consumption at active mode, at 24 MHz, 7.1 mA<br>Power consumption at sleep mode, at 24 MHz, 1.3 μA |
| Bluetooth | Version 4.1 (BLE) Frequency range 2400–2482 MHz<br>Output power 0dBm (1 mW radiofrequency)<br>Power consumption for 0dBm transmission 16.5 mA |
| Power source | Battery type CR2032 coin battery |
| Power consumption (All systems) | <15 mW for active mode |

The distance of the 6MWT was measured using the equation from Terra et al. [10] which is [*Distance (meters)* = *number of steps* × *stride length*], and the distance error varied between 2.7% and 5.6%. Fig. 1 displays the mobile application and prototype walking sensors. All measured data were transferred to a cloud with a RAW data recording for further analysis.

Data are presented as the mean, standard deviation, and frequency. Concurrent validity between the prototype of 6MWT and the standard 6MWT was assessed using Pearson's correlation coefficient (r). In addition, the correlation coefficients of $r < 0.25$ were defined as small, 0.25–0.50 as moderate, 0.50–0.75 as good, and >0.75 as excellent [11]. Intraclass Correlation Coefficient (ICC) was used for intrarater ($ICC_{3,1}$) reliability. The ICC agreement <0.5 was considered as poor, 0.50–0.75 as moderate, 0.75–0.90 ss good and >0.90 as excellent [12]. The level of significance was set at p-value <0.05, using IBM SPSS Statistics version 24.0.

## 4. Results

In this study, we included 60 healthy individuals with an average age of 46.42 ± 21.59 years (Table 1).

The distance from the standard 6MWT was 410.12 ± 74.03 m, whereas the distance from the wearable sensor application was 395.36 ± 67.72 m, with a mean difference of 3.59% (Fig. 2). A significantly moderate correlation was found ($r = 0.66$, $p < 0.001$), and the reliability with Cronbach's alpha was 0.79 ($p < 0.001$) (Table 2).

## 5. Discussion

The aims of the study were to design and develop a device for detection of distance for the 6MWT and to assess the concurrent validity and reliability of the device in healthy adult individuals. The prototype wearable walking sensor was designed with a 3-axis accelerometer and operated with an android OS 4.3 or higher application.

In this study, the distance obtained from the standard 6MWT was 410.12 ± 74.03 m and the distance obtained from the wearable sensor was 395.36 ± 67.72 m, with a mean distance difference of −14.75 ± 58.62 m and a mean difference of −3.59% mean. The distance from the wearable sensor was lower than the standard 6MWT. However, Salvi et al. [13] reported that the mean difference between the approximate distance of their prototype with a mobile phone application and the 6MWT was −2.013 ± 7.84 m and −0.80 ± 18.56 m while measuring at indoor and outdoor places, respectively. In contrast to another study, Shah et al. [14] reported that the mean difference between the inertial sensor and manual distance for 6MWT was 18.36 ± 18.79 m and the ICC was 0.97 [ 95% CI = 0.91–0.99]. In another study, Brooks et al. [15] found the mean difference between the self-administered 6MWT application and the estimated distance in 6MWT to be 7.6 ± 26 m and ICC was 0.89 [95% CI 0.79–0.99]. Therefore, the prototype of the wearable sensor in our study was compatible with the distance from the standard 6MWT. Furthermore, the percentage difference of mean distance

**Table 1**
Characteristic data of the participants.

| | n (%) | Mean ± SD | Maximum | Minimum |
|---|---|---|---|---|
| Gender | | | | |
| Male | 30 (50) | | | |
| Female | 30 (50) | | | |
| Age (years) | | 46.41 ± 21.59 | 86 | 20 |
| 18–35 years (n = 20) | | 22.80 ± 3.41 | 32 | 20 |
| 36–60 years (n = 20) | | 43.40 ± 7.86 | 60 | 36 |
| above 60 years (n = 20) | | 73.05 ± 5.64 | 86 | 67 |
| **Height (cm)** | | 161.83 ± 8.96 | 179 | 142 |
| **Weight (kg)** | | 61.98 ± 10.87 | 85 | 40 |
| **BMI (kg/m$^2$)** | | 23.65 ± 3.87 | 31.99 | 15.34 |

SD:standard deviation; BMI: body mass index.

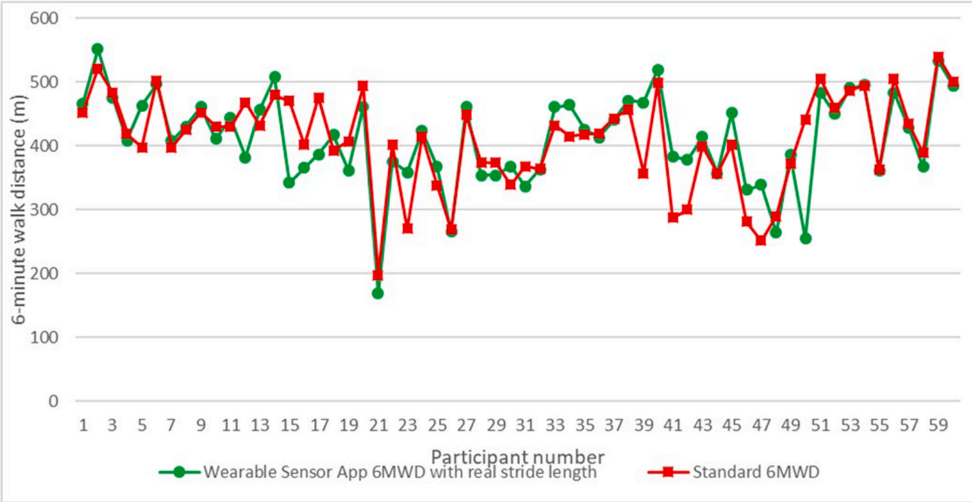


**Fig. 2.** Standard 6MWD and wearable sensor App 6MWD in 6-min walk distance for 60 participants.

**Table 2**
Correlations between standard 6MWD and wearable sensor App 6MWD

| | Wearable sensor App | Standard 6MWT | | | |
|---|---|---|---|---|---|
| | | Concurrent validity | *p-value* | Intra-rater reliability | *p-value* |
| | | Pearson correlation *r* | | Cronbach alpha (95% CI) | |
| Total participants (n = 60) | | 0.661 | <.001 | 0.794 (0.655–0.877) | <.001 |
| Sex group | Male (n = 30) | 0.707 | <.001 | 0.824 (0.629–0.916) | <.001 |
| | Female (n = 30) | 0.629 | <.001 | 0.771 (0.520–0.891) | <.001 |
| Age group | Aged 20–35 years (n = 20) | 0.646 | .002 | 0.778 (0.440–0.912) | .001 |
| | Aged 36–60 years (n = 20) | 0.698 | .001 | 0.799 (0.493–0.921) | <.001 |
| | Aged over 60 years (n = 20) | 0.457 | .043 | 0.627 (0.058–0.852) | .019 |

6MWT: 6-Minute Walk Test.

remained within maximum permissible error or tolerance of medical devices classes at 5% [16,17], indicating that distance from the wearable sensor has acceptable standard of accuracy. In a previous study, it was found that changes in distance of 14.0–30.5 m could be clinically important in adults with pathology [18]. Consequently, the mean difference of the comparison between the standard and the 6MWT wearable sensor (14.75 m) should be interpreted with caution since it may be due to the relatively small number of participants.

In this study, the 3-axis accelerometer was used as a prototype of the wearable sensor. A systematic review with 31 studies examined technological developments to detect the 6-min walk distance (6MWD) and reported that sensors with 3-axis accelerometer showed high accuracy and reliability ($r = 0.89$) and accounted for 81.81% of 31 studies using the sensor with accelerometer [19]. Additionally, Storm et al. [20] reported that accelerometers were most commonly used for the assessment of 6MWT. Therefore, in this study, a prototype wearable walking sensor device by using the 3-axis accelerometer was able to assess functional capacity or physical performance in healthy individuals.

## 6. Limitations of this study

This study had limitations. The prototype wearable walking sensor device with an android OS application was utilized in healthy participants only. Therefore, the wearable 6MWT sensor should be applied in a large sample size for subgroups analysis, within different age ranges and other populations, such as patients with chronic diseases. However, the results of this study have sufficient power to detect effects with retrospective statistical power = 0.95, for a two-tailed alpha = .05. The equation for estimated 6MWD should be explored for improving the validity of the wearable walking sensors because other factors, such as sex and age, are associated with walking distance [21–23]. Further, the prototype walking sensors device was attached at the ankle; thus, pulse rate could not be monitored. Further studies should develop a prototype walking sensors device with monitoring pulse rate. Because the study developed and reported the concurrent validity of the prototype; therefore, the study analyzed all participants and only formed subgroups on. Thus, the results may be potentially biased, and the conclusion may be interpreted cautiously regarding the number and differences in characteristic data in individual participants.

## 7. Conclusions

The prototype wearable walking sensor device of 6MWT is a suitable tool for the assessment of walking distance for 6 min in healthy adults. Given the 6MWT has limited use in the healthy population, future research will require assessment of the wearable walking sensor in populations with limited functional performance.

## Author contribution statement

Nuttawuth Mekritthikrai: Conceived and designed the experiments; Performed the experiments; Contributed reagents, materials, analysis tools or data.

Kornanong Yuenyongchaiwat: Conceived and designed the experiments; Performed the experiments; Contributed reagents, materials, analysis tools or data; Wrote the paper.

Chusak Thanawattano: Conceived and designed the experiments; Contributed reagents, materials, analysis tools or data.

## Data availability statement

Data will be made available on request.

## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

## Acknowledgements

The authors would like to thank all participants participating in the study. This study thank for Thammasat university research unit in physical therapy in cardiovascular and respiratory systems.

## References

[1] D.R. Bassett, M.T. Mahar, D.A. Rowe, J.R. Morrow, Walking and measurement, Med. Sci. Sports Exerc. 40 (7 Suppl) (2008) S529–S536.
[2] C.G. Cote, C. Casanova, J.M. Marín, M.V. Lopez, V. Pinto-Plata, M.M. de Oca, et al., Validation and comparison of reference equations for the 6-min walk distance test, Eur. Respir. J. 31 (3) (2008) 571–578.
[3] P. Agarwala, S.H. Salzman, Six-minute walk test: clinical role, technique, coding, and reimbursement, Chest 157 (3) (2020) 603–611.
[4] T. Reybrouck, Clinical usefulness and limitations of the 6-minute walk test in patients with cardiovascular or pulmonary disease, Chest 123 (2) (2003) 325–327.
[5] D.K. Cheng, M. Nelson, D. Brooks, N.M. Salbach, Validation of stroke-specific protocols for the 10-meter walk test and 6-minute walk test conducted using 15-meter and 30-meter walkways, Top. Stroke Rehabil. 27 (4) (2020) 251–261, https://doi.org/10.1080/10749357.2019.1691815.
[6] ATS Committee on Proficiency Standards for Clinical Pulmonary Function Laboratories, ATS statement: guidelines for the six-minute walk test, Am. J. Respir. Crit. Care Med. 166 (1) (2002) 111–117, https://doi.org/10.1164/ajrccm.166.1.at1102.
[7] K. Vasileiou, J. Barnett, S. Thorpe, T. Young, Characterising and justifying sample size sufficiency in interview-based studies: systematic analysis of qualitative health research over a 15-year period, BMC Med. Res. Methodol. 18 (2018) 148, https://doi.org/10.1186/s12874-018-0594-7.
[8] J. Linacre, Sample size and item calibration stability, Rasch Measurement Transactions 7 (1994) 28. https://www.rasch.org/rmt/rmt74m.htm.
[9] L. Zhu, Z. Wang, Z. Ning, Y. Zhang, Y. Liu, W. Cao, et al., A Novel motion intention recognition approach for soft exoskeleton via IMU, Electronics 9 (12) (2020) 2176, https://doi.org/10.3390/electronics9122176.
[10] R. Terra, L. Figueiredo, R. Barbosa, R. Anacleto, Traveled distance estimation algorithm for indoor localization, Proc. Technol. 17 (2014) 248–255.
[11] L.G. Portney, M.P. Watkins, Foundations of Clinical Research: Applications to Practice, third ed., Prentice Hall, New Jersey, 2007.
[12] T.K. Koo, M.Y. Li, A guideline of selecting and reporting intraclass correlation coefficients for reliability research, J. Chiropr. Med. 15 (2) (2016) 155–163, https://doi.org/10.1016/j.jcm.2016.02.012.
[13] D. Salvi, E. Poffley, E. Orchard, L. Tarassenko, The mobile-based 6-minute walk test: usability study and algorithm development and validation, JMIR Mhealth Uhealth 8 (1) (2020), e13756, https://doi.org/10.2196/13756.
[14] V.V. Shah, C. Curtze, K. Sowalsky, I. Arpan, M. Mancini, P. Carlson-Kuhta, et al., Inertial sensor algorithm to estimate walk distance, Sensors 22 (3) (2022) 1077, https://doi.org/10.3390/s22031077.
[15] G.C. Brooks, E. Vittinghoff, S. Iyer, D. Tandon, P. Kuhar, K.A. Madsen, et al., Accuracy and usability of a self-administered 6-minute walk test smartphone application, Circ. Heart Fail. 8 (5) (2015) 905–913.
[16] A. Thompson, N. Southon, F. Fern, G. Stupfler, R. Leach, Efficient empirical determination of maximum permissible error in coordinate metrology, Meas. Sci. Technol. 32 (10) (2021), 105013.
[17] O. Kheir, S. Smedts, A. Jacoby, S. Verwulgen, Efficient quality management in MedTech start-ups (based on ISO 13485), Med. Devices 14 (2021) 313–319, https://doi.org/10.2147/MDER.S320583.
[18] R.W. Bohannon, R. Crouch, Minimal clinically important difference for change in 6-minute walk test distance of adults with pathology: a systematic review, J. Eval. Clin. Pract. 23 (2) (2017) 377–381.
[19] I.M. Pires, H.V. Denysyuk, M.V. Villasana, J. Sa, D.L. Marques, J.F. Morgado, et al., Development technologies for the monitoring of six-minute walk test: a systematic review, Sensors 22 (2) (2022) 581, https://doi.org/10.3390/s22020581.
[20] F.A. Storm, A. Cesareo, G. Reni, E. Biffi, Wearable inertial sensors to assess gait during the 6-minute walk test: a systematic Rview, Sensors 20 (9) (2020).
[21] P.L. Enright, D.L. Sherrill, Reference equations for the 6-minute walk test in healthy adults, Am. J. Respir. Crit. Care Med. 158 (5 Pt 1) (1998) 1384–1387, https://doi.org/10.1164/ajrccm.158.5.9710086.
[22] V.Z. Dourado, Equações de Referência para o Teste de Caminhada de Seis Minutos em Indivíduos Saudáveis [Reference Equations for the 6-Minute Walk Test in Healthy Individuals.], Arq. Bras. Cardiol. 25 (2011). S0066-782X2011005000024.
[23] L. Cazzoletti, M.E. Zanolin, G. Dorelli, P. Ferrari, L.G.D. Carbonare, E. Crisafulli, et al., Six-minute walk distance in healthy subjects: reference standards from a general population sample, Respir. Res. 23 (2022) 83, https://doi.org/10.1186/s12931-022-02003-y.