



EVALUATION OF THE RELATIVE VIABILITY OF ANTHROPOMETRIC PARAMETERS, AEROBIC CAPACITY, SPINAL MOBILITY, ABDOMINAL MUSCULAR ENDURANCE, BACK AND LOWER LIMB MUSCLE STRENGTH IN PREDICTING THE BALANCE PERFORMANCE OF YOUNG ADULT MALES

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ABSTRACT

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Keywords

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Background: The physical-and-physiological factors that modulate balance performance are currently not well elucidated in the extant literature. Objectives: This study investigated the viability of using demographic factors, physical and physiological variables to predict balance performance. Methods: 150 adult males consented and completed all the 17 tests required. Their anthropometric indices (leg length, thigh and calf circumferences, height, body weight, quotelet index, body surface area), dominant leg isometric muscle strength (quadriceps femoris, hamstrings, plantar flexors and dorsiflexors), spinal mobility (back extension and forward flexion), aerobic capacity, isometric back extensor strength, abdominal muscular endurance and the non-timed criterion unipedal stance performance with eyes opened and eyes closed were measured using standard protocols. Results: Significant positive correlations were obtained between several of the independent variables. Thigh circumference was significantly related to quadriceps femoris strength ($r = 0.545$, $p < 0.001$), hamstrings strength ($r = 0.457$, $p < 0.001$), plantar flexor strength ($r = 0.249$, $p < 0.002$), and dorsiflexors strength ($r = 0.2496$, $p < 0.002$). The 17 independent variables combined contributed significantly ($F = 2.051$, $p < 0.05$) to the prediction of balance performance with eyes opened. Unexpectedly, only 20.9% of the variance in balance performance was accounted for by the 17 independent variables. Stature and the plantar flexor muscle strength were the two viable predictors of balance performance when the eyes is opened; stature contributed 5.5% and the plantar flexor muscle strength contributed 3.8%. Abdominal muscular endurance contributed 3.1% out of the combined 14.4% variance in balance performance when the eyes are closed. Conclusions: From a practical perspective, the contribution of the 17 physical-and-physiological variables monitored in this study to the prediction of balance performance is dreary; therefore, follow-up studies should explore other independent variables.

Contribution/ Originality: This study is the first to evaluate the viability of using multiple combinations of physical-and-physiological variables to predict balance performance. The regression equations derived in this study can be used to estimate the balance performance of young adult males.

1. INTRODUCTION

Balance impairment or dysfunction is common in individuals with musculoskeletal and neurological injuries such as peripheral neuropathy, head injuries, stroke, or vestibular disorders [1-3]. Balance impairment is also associated with the deconditioning of the cardiovascular and musculoskeletal systems and the aging process [4-6]. Postural instability (increased postural sway) has been demonstrated in apparently healthy individuals after 40 years of age and among the elderly [3]. A direct link has been found between postural instability and unexplained falls among the elderly [6, 7].

In the laboratory setting, the degree of sway is measured by a force plate [8] ataxiometer [9] accelerometer [10] or stabilometer [11]. These devices are complex, bulky and costly and therefore limit their application in clinical practice. A simple assessment method used for evaluating balance impairment is the timed unipedal stance test, also referred to as timed single limb stance, unipedal balance test, one-leg standing balance and one-leg stance test [12]. Several modifications of the timed unipedal stance test have emerged. Balogun, Ajayi, and Alawale in 1977 proposed that the maximum time that an individual could stand during the unipedal stance test will allow for better differentiation of balance performance [13]. The non-timed criterion unipedal stance testing protocol is today widely used in the clinical setting for tracking the static aspects of balance because it requires minimal equipment or training time on the part of the clinician.

Aside from its well-known role in medical rehabilitation, evaluation of balance plays a critical role in the training and preparation of athletes. For example, the training regimen of classical ballet dancers includes complex balance performance maneuvers in addition to intermittent exercises of different durations, interspersed by a vast range of rest periods and coordinated sequences of both static and dynamic whole body muscle actions [14]. Moreover, the training sessions of gymnasts are characterized by rigid technical maneuvers such as pivots, jumps, and poise, along with high levels of joint flexibility and unipedal stance performance [14]. The rigorous training of gymnasts and ballet dancers imposes high demands on the aerobic and anaerobic systems coupled with a strict diet in order to maintain low levels of body adiposity [15].

The physical-and-physiological factors that modulate balance performance are currently not well elucidated in the extant literature. Specifically, there is limited data on the impact of anthropometric parameters, joint flexibility, muscle strength, and muscular-and-cardiovascular endurance on postural stability. In our previous study, we established the balance performance norms for the first seven decades of life [16]. In addition, we investigated the viability of using age, gender and anthropometric indices to predict balance performance. Our findings revealed that stature and weight were the two viable anthropometric determinants of postural stability; the contribution of body surface area and body adiposity to the prediction of postural stability was negligible [16]. The paradoxical findings led us to speculate that balance performance is a complex neuro-motor task, not only influenced by demographic factors and anthropometric parameters, but also by muscle strength, spinal mobility, and cardiovascular-and-muscular endurance. This study sets out to investigate the hypothesis.

The primary aim of this study was to determine the relative viability of using demographic factors, anthropometric indices, aerobic capacity, and spinal mobility, back and lower limb muscle strength and abdominal muscular endurance to predict balance performance. If the physical-and-physiological variables investigated in this study are found to be determinant of postural stability, the information that emerged on their relative viability will find a useful application in focusing the balance training program of gymnasts and ballerinas.

2. METHODS

2.1. Ethics Approval

Approval for this study was provided by the Human Experimentation Committee of the College of Health Sciences at the Obafemi Awolowo University (OAU), Ile-Ife, Nigeria. Participation in the study was voluntary and no stipends or incentive was offered to the subjects.

2.2. Research Design

A repeated measures research design was employed in this study [17]. The study participants were recruited purposively from consenting university students at OAU, Ile-Ife, Nigeria. A total of 169 undergraduate male students representing several academic disciplines within the university participated in this study. However, only 150 (i.e. 89%) subjects completed all the tests required in the study. Females and male individuals with neurological or musculoskeletal injuries or any form of disability were excluded from the study.

2.3. Procedures and Outcomes

Prior to data collection, the subjects were informed of the purpose of the study and subsequently screened for musculoskeletal and neurological injuries such as peripheral neuropathy, head injuries, stroke, or vestibular disorders. Informed consent was then obtained from the subjects. First, we determine the maximum duration that the subjects could maintain balance while standing barefooted on the dominant leg inside a 50.8 cm by 45.7 cm rectangular wooden frame placed on a smooth, hard and level surface and the sole of the raised leg was at the level of the knee of the contra lateral limb [13, 16]. The postural stability procedure was timed with a stopwatch with eyes opened and with eyes closed.

Anthropometric indices (leg length, thigh and calf circumferences) were measured with a standard metric tape. Height (cm) and weight (kg) were taken using a stadiometer. The quotelet index (kg.m^{-2}) of each subject was calculated using the standard formula:

$$\frac{\text{Weight (kg)}}{\text{Height (cm)}^2}$$

The body surface area (m^2) for each subject was estimated from standard nomogram by Boyd and West [18] using their height (cm) and weight (kg) measurements.

The lower extremity isometric muscle strength (quadriceps femoris, hamstrings, plantar flexors and dorsiflexors) for the dominant leg was measured by a cable tensiometer (kgf) following the protocol described by Balogun and Onigbinde [19]. Aerobic capacity (mL/kg.m) was estimated from standard nomogram using the time taken for the subjects to complete the 1.5 miles endurance run test described by Cooper [20].

Isometric back extensors strength (kgf) was measured using the back and leg dynamometer following the protocols described by Balogun, et al. [21]. The spinal mobility (cm) - forward flexion and back extension was measured following the protocols described by Balogun and Songonuga [22]. The abdominal muscular endurance (# of correctly performed sit-ups in 60 sec.) was measured using a modified sit-up timed test described by the American Alliance for Health Physical Education Recreation and Dance [23].

Testing of the subjects occurred on different days and times until all the measurements were completed. For each subject, all the testing was completed within a two week period. The order of presentation of the experimental conditions was randomized for each subject. Two measurements were taken for each test, except the endurance run test which was completed once, and the highest reading was recorded and used for data analysis. Several of the testing, when feasible, was done in groups to foster a positive and competitive effort among the subjects.

2.4. Statistical Analysis

We coded the data collected, as reflected on the study questionnaire, into SPSS version 16 software (SPSS, Chicago, IL, USA). Both descriptive (range, mean \pm standard deviation (SD) and inferential statistics were computed. To discern the presence of the multicollinearity phenomenon in our dataset, we computed the Pearson's product moment correlation coefficient to establish a relationship between the 17 predictor variables. Multiple analysis of variance (ANOVA) regression and stepwise regression models were utilized to determine the individual and combined contribution of the 17 independent variables - anthropometric parameters, lower extremity isometric strength, spinal mobility, aerobic capacity, isometric back extensors strength and the abdominal muscular

endurance - to the prediction of balance performance (i.e., the criterion (dependent) variables) during the eyes opened and eyes closed testing conditions. See Table 1 for the detail list of the independent (predictor) variables.

Balance performance prediction (Y) was accomplished by the following equation:

$$Y'_i = b_0 + b_1X_{1i} + b_2X_{2i} + \dots + b_kX_{ki}$$

X_{ki} are the independent variables; "b" values are the regression weights and are computed in a way that minimizes the sum of squared deviations.

$$\sum_{i=1}^N (Y_i - Y'_i)^2$$

The stepwise regression procedure selects the independent variable in the order of their relative strength in predicting the criterion variable. The tolerance level for the analyses was set at the F ratio of 4.0 and the probability level of .01 [24].

3. RESULTS

3.1. Physical Characteristics of the Subjects and Descriptive Data for all the Variables

Table 1 shows the profile of the study participants and the descriptive data for the independent and dependent variables.

Table-1. Subjects' Physical Characteristics and Descriptive Statistics for all the Variables (N = 150)

S/N	Variables	Minimum	Maximum	Mean	SD (±)
	Demographic Factor				
1	Age (years)	19.0	30.0	22.9	2.1
	Anthropometric Indices				
2	Height (cm)	159.0	192.0	173.3	6.1
3	Weight (kg)	46.0	82.0	60.9	6.7
4	Quotelet index (kg.m ⁻²)	16.7	26.4	20.3	1.9
5	Leg length (cm)	86.0	113.0	100.2	5.1
6	Calf circumference (cm)	24.0	45.0	33.1	3.1
7	Thigh circumference (cm)	39.0	60.0	49.1	3.9
8	Body surface area (m ²)	1.3	1.9	1.5	0.1
	Spinal Mobility				
9	Forward flexion (cm)	11.0	48.0	33.0	6.8
10	Back extension (cm)	12.0	56.0	24.4	7.5
	Isometric back strength				
11	Back extensors (kgf)	90.0	180.0	125.6	18.8
	Cardiovascular Endurance				
12	Aerobic capacity (mL/kg.m)	34.0	67.0	46.7	6.4
	Abdominal Muscular Endurance				
13	Modified forward flexion- sit up (# in 60 sec)	20.0	54.0	35.3	7.4
	Lower Limb Muscle Strength				
14	Quadriceps femoris (kgf)	36.0	80.0	54.7	9.3
15	Hamstrings (kgf)	12.0	46.0	25.2	6.6
16	Plantar flexors (kgf)	11.0	28.0	18.5	3.8
17	Dorsiflexors (kgf)	11.0	36.0	22.0	4.5
	Balance Performance				
	Balance Performance with Eyes Opened (sec) - BPEO	85.0	2175.0	487.5	356.7
	Balance Performance with Eyes Closed (sec) - BPEC	12.0	660.0	157.2	119.7

The mean age was 23.0 ± 2.1 years; mean height and weight were 173.3 ± 6.1 cm and 61.0 ± 7.9 kg, respectively. Their body adiposity was 20.3 ± 1.8 kgm⁻² and body surface area was 1.59 ± 0.11 m.²

Overall, the subjects in this study were of average physical fitness as attested to by their average aerobic capacity, back and lower extremity strength and abdominal muscular endurance. Their mean postural stability with eyes opened was 487.5 ± 356.7 seconds and 157.2 ± 119.7 seconds with eyes closed.

3.2. Relationship between the Predictor Variables

The result of the Pearson's product moment correlation coefficient computed to explore the relationship between the 17 independent (predictor) variables revealed a significant positive correlation between several of the variables. For example, thigh circumference was significantly related to quadriceps femoris strength ($r = 0.545$, $p < 0.001$), hamstrings strength ($r = 0.457$, $p < 0.001$), plantar flexor strength ($r = 0.249$, $p < 0.002$), and dorsiflexors strength ($r = 0.2496$, $p < 0.002$). These findings portend the presence of the multicollinearity phenomenon within the dataset.

3.3. Determinants of Balance Performance with Eyes Opened

The result of the multiple regression ANOVA for the eyes opened test revealed that all the 17 independent variables combined contributed significantly ($F = 2.051$, $p < 0.05$) to the prediction of balance performance.

Table-2. Summary of the Multiple and Stepwise Regression Analyses Showing the Contribution of each of the Independent variable to the Prediction of Balance Performance with the Eyes Opened (N = 150)

S/N	Variables	R	R ²	% R ² change	B	F-ratio
	Demographic Factor					
1	Age (years)	0.042	0.002	0.18	0.41	0.001
	Anthropometric Indices					
2	Height (cm)	0.300	0.090	5.49	45.3	2.847
3	Weight (kg)	0.304	0.092	0.24	1.26	0.001
4	Quotelet index (kg.m ⁻²)	0.306	0.094	0.13	1.47	0.022
5	Leg length (cm)	0.080	0.006	0.46	-30.38	7.474
6	Calf circumference (cm)	0.142	0.020	1.38	-12.45	0.991
7	Thigh circumference (cm)	0.187	0.035	1.50	-10.32	0.689
8	Body surface area (m ²)	0.359	0.139	0.12	-1584.02	1.203
	Spinal Mobility					
9	Forward flexion (cm)	0.308	0.095	0.09	1.29	0.083
10	Back extension (cm)	0.342	0.117	2.22	2.82	0.445
	Isometric Back Strength					
11	Back extensors (kgf)	0.344	0.118	0.12	-0.82	0.177
	Cardiovascular Endurance					
12	Aerobic capacity (mL/kg.m)	0.368	0.139	0.64	2.11	0.202
	Abdominal Muscular Endurance					
13	Modified forward flexion- sit up ((# in 60 sec)	0.398	0.158	2.26	7.19	3.105
	Lower Limb Muscle Strength					
14	Quadriceps femoris (kgf)	0.402	0.162	0.35	1.10	0.068
15	Hamstrings (kgf)	0.409	0.167	0.51	0.778	0.019
16	Plantar flexors (kgf)	0.453	0.205	3.81	26.71	7.011
17	Dorsiflexors (kgf)	0.457	0.209	0.40	-5.97	0.665
	Prediction Equation Constant				-2066.53	

The multiple regression equation relating balance performance with eyes opened (BPEO) to the independent variable is as follows:

$$BPEO = -2066.53 + 0.41(\text{age, years}) - 30.38(\text{leg length, cm}) - 12.45(\text{calf circumference, cm}) - 10.32(\text{thigh circumference, cm}) + 45.31(\text{height, cm}) + 1.26(\text{weight, kg}) + 1.47(\text{quotelet index, kgm}^{-2}) + 1.29(\text{forward flexion, cm}) + 2.82(\text{back extension, cm}) - 0.82(\text{isometric back extensor strength, kgf}) - 1584.02(\text{body surface area, m}^2)$$

area, m²) + 2.11 (aerobic capacity, mL/kg.m) + 7.19 (abdominal muscular endurance, # of sit ups performed in 60 secs.) + 1.10 (quadriceps femoris strength, kgf) + 0.79 (hamstrings strength, kgf) + 26.71 (plantar flexors strength, kgf) - 5.97 (dorsiflexors strength, kgf). (R² = 0.209; adjusted R² = 0.107; SEE = ± 337.04)

The coefficient of determination (R²) for the multiple regression equations was 20.9%. The stepwise regression analysis showed that only stature and the plantar flexor muscle strength were the two viable predictors of balance performance when the eyes is opened. Stature contributed 5.5% and the plantar flexor muscle strength contributed 3.8% to the explained variance in balance performance.

3.4. Determinants of Balance Performance with Eyes Closed

The multiple regression ANOVA for the eyes closed test showed that the 17 independent variables combined did not contribute significantly (F = 1.304, p>.05) to the prediction of balance performance.

Table-3. Summary of the Multiple and Stepwise Regression Analyses Showing the Contribution of each of the Predictor Variables to the Prediction of Balance Performance with the Eyes Closed (N = 150)

S/N	Variables	R	R ²	% R ² change	B	F-ratio
	Demographic Factor					
1	Age (years)	0.028	0.000	0.08	2.22	0.182
	Anthropometric Indices					
2	Height (cm)	0.173	0.030	0.33	2.03	0.047
3	Weight (kg)	0.195	0.038	0.82	4.39	0.123
4	Quotelet index (kg.m ⁻²)	0.208	0.043	0.53	-2.02	0.339
5	Leg length (cm)	0.118	0.014	1.32	-5.64	2.111
6	Calf circumference (cm)	0.123	0.015	0.11	1.49	0.117
7	Thigh circumference (cm)	0.163	0.027	1.15	-1.91	0.193
8	Body surface area (m ²)	0.256	0.065	0.23	-230.66	0.209
	Spinal Mobility					
9	Forward flexion (cm)	0.217	0.047	0.37	1.12	0.521
10	Back extension (cm)	0.250	0.063	1.55	0.831	0.317
	Isometric Back Strength					
11	Back extensors (kgf)	0.251	0.063	0.04	-0.43	0.391
	Cardiovascular Endurance					
12	Aerobic capacity (mL/kg.m)	0.289	0.081	1.81	1.74	1.129
	Abdominal Muscular Endurance					
13	Modified forward flexion- sit up ((# in 60 sec)	0.338	0.115	3.11	2.75	3.714
	Lower Limb Muscle Strength					
14	Quadriceps femoris (kgf)	0.340	0.116	0.11	0.01	0.000
15	Hamstrings (kgf)	0.356	0.127	1.12	1.59	0.642
16	Plantar flexors (kgf)	0.376	0.141	1.46	5.62	2.548
17	Dorsiflexors (kgf)	0.379	0.144	1.21	-1.44	0.318
	Prediction Equation Constant				578.796	

The multiple regression equation relating balance performance with eyes closed (BPEC) to the independent variable is as follows:

BPEC = - 578.80 + 2.22 (age, years) - 5.64 (leg length, cm) + 1.49 (calf circumference, cm) - 1.91 (thigh circumference, cm) + 2.03 (height, cm) + 4.39 (weight, kg) - 2.02 (quotelet index, kgm⁻²) - 1.12 (forward flexion, cm) + 0.83 (back extension, cm) - 0.43 (isometric back extensor strength, kgf) - 230.66 (body surface area, m²) + 1.74 (aerobic capacity, mL/kg.m) + 2.75 (abdominal muscular endurance, # of sit ups performed in 60 secs.) + 0.01 (quadriceps femoris strength, kgf) + 1.59 (hamstrings strength, kgf) + 5.62 (plantar flexors strength, kgf) - 1.44 (dorsiflexors strength, kgf). (R² = 0.144; adjusted R² = 0.33; SEE = ± 117.72)

The coefficient of determination (R²) for the regression equation was only 14.4%. Abdominal muscular endurance contributed 3.1% out of the combined 14.4% variance in balance performance when the eyes are closed.

Table 4 presents the relative viability (R^2 in %) of the multiple regression equations at each stage of addition of a new independent variable for the eyes opened and eyes closed balance performance testing conditions.

Table-4. Comparison of the Relative Viability (R^2 in %) of the Multiple Regression Equation at each stage of the Addition of a New Independent Variable during Eyes Opened and Eyes Closed Postural Stability Testing Conditions

S/N	Variables	Balance performance with eyes opened R^2 (in %)	Balance performance with eyes closed R^2 (in %)
	Demographic Factor		
1	Age (years)	0.2	0.0
	Anthropometric Indices		
2	Height (cm)	9.0	3.0
3	Weight (kg)	9.2	3.8
4	Quetelet index ($\text{kg}\cdot\text{m}^{-2}$)	9.4	4.3
5	Leg length (cm)	0.6	1.4
6	Calf circumference (cm)	2.0	1.5
7	Thigh circumference (cm)	3.5	2.7
8	Body surface area (m^2)	13.9	6.5
	Spinal Mobility		
9	Forward flexion (cm)	9.5	4.7
10	Back extension (cm)	11.7	6.3
	Isometric Back Strength		
11	Back extensors (kgf)	11.8	6.3
	Cardiovascular Endurance		
12	Aerobic capacity ($\text{mL}/\text{kg}\cdot\text{m}$)	13.9	8.1
	Abdominal Muscular Endurance		
13	Modified forward flexion- sit up (# in 60 sec)	15.8	11.5
	Lower Limb Muscle Strength		
14	Quadriceps femoris (kgf)	16.2	11.6
15	Hamstrings (kgf)	16.7	12.7
16	Plantar flexors (kgf)	20.5	14.1
17	Dorsiflexors (kgf)	20.9	14.4

For the eyes opened condition, age accounted for 0.2 % of the variance in balance performance. When age and height are added to the multiple regression equations, the two independent variables combined accounted for 9.0% of the variance in balance performance. The variance accounted for increased slightly to 9.2% when age, height, and weight are in the multiple regression equations. When all the 17 independent variables are added to the multiple regression equations, 20.9% of the variance in balance performance was accounted for. Similarly, for the eyes closed condition, age accounted for 0.0 % of the variance in balance performance. When age and height were added to the multiple regression equations, the two independent variables combined accounted for 3.0% of the variance in balance performance. When age, height, and weight are added to the multiple regression equations, the variance accounted for increased slightly to 3.8%. With the 17 independent variables in the multiple regression equations, 14.4% of the variance in balance performance was accounted for.

4. DISCUSSION

This exploratory study set out to investigate the relative viability of using age, anthropometric parameters, aerobic capacity, and spinal mobility, back and lower limb muscle strength and abdominal muscular endurance to the prediction of balance performance. Our expectation, based on the findings in our previous studies [13, 16] was that the 17 independent variables considered in this study will contribute significantly to the prediction of balance performance. We found the 17 independent variables combined contributed significantly ($p < 0.05$) to the prediction of balance performance with eyes opened, but only 20.9% of the variance in balance performance was accounted for

by the 17 independent variables. Stature and the plantar flexor muscle strength were the two viable predictors of balance performance when the eyes is opened; stature contributed 5.5% and the plantar flexor muscle strength contributed 3.8%. These findings are partially supported the research hypothesis, but we expected the contribution of the 17 independent variables to be significantly higher than the 20.9% that we obtained in this study.

Paradoxically, we found that the 17 independent variable combined did not contribute significantly ($p>0.05$) to the prediction of balance performance with eyes closed. Abdominal muscular endurance contributed 3.1% out of the combined 14.4% variance in balance performance when the eyes are closed. This finding is inconsistent with the research hypothesis. In our previous study that included both male and female subjects, with their age spanning 6 to 85 years, we found that gender, age, and anthropometric indices (height, body weight, body surface area and quotelet index) combined contributed significantly to the prediction of balance performance at all ages [16]. Gender was the best determinant of balance performance after the second decade of life. The contribution of the six independent variables in the study to balance performance with eyes opened ranges from 39% in the first decade of life, to 95% in the eighth decade of life. The contribution of the six independent variables range from 11% in the seventh decade of life to 60% in the fourth decade of life for balance performance with eyes closed. At 20-29 years of age, similar to the age range of the male subjects in this study, the contribution of the six independent variables to balance performance with eyes opened was 80% and 44% with eyes closed [16]. These percentages are exceedingly higher than we obtained in the present study.

We attributed the paradoxical findings in our present study, in part, to the relatively smaller sample size and the large number of independent variables being considered. In addition, the multicollinearity phenomenon observed in the data set and the homogeneity of the sample in the present study which consisted of only adult male subjects may have contributed to the unexpected findings. The subjects in our previous study were larger and more diverse. The sample consisted of 640 males and 640 females ranging in age from 6 to 85 years.

Follow-up studies should explore the viability of other independent variables. For comparative purposes, it will be insightful to replicate the study among young female subjects. Since the outcomes of this study potentially have practical implication in sports, the study should be replicated among gymnasts and ballerinas. This is because a previous study demonstrated among professional ballet dancers that their rigorous physical training enabled their nervous systems to coordinate their muscles more precisely than individuals with no dance training experience [25].

5. CONCLUSION

Although we found the 17 physical-and-physiological variables monitored in this study statistically contributed significantly to the prediction of balance performance with eyes opened, but the 20.9% accounted for by the independent variables is not of practical significance. A cause-and-effect conclusion cannot be inferred from this correlation study because none of the variables was manipulated and no random assignment of the study participants.

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