

## Effect of training using the Biodex system on dynamic balance and physical performance: a randomized controlled balance-training trial in hemodialysis patients with osteopenia

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**A** – Study Design, **B** – Data Collection, **C** – Statistical Analysis, **D** – Data Interpretation, **E** – Manuscript Preparation, **F** – Literature Search, **G** – Funds Collection

**Summary Background.** The Biodex Balance Training System (BBTS) has been utilized as an imbalance assessment/treatment tool in various populations and diseases.

**Objectives.** The aim of this study was to investigate the effect of BBTS on dynamic balance and physical performance in hemodialysis (HD) patients with osteopenia.

**Material and methods.** 58 women with HD and osteopenia were randomly assigned to a 12-week Biodex-training group (BTG,  $n = 29$ ) or a non-trained group ( $n = 29$ ). The training, 3 times per week, was conducted using BBTS and lasted for 10 minutes, with the two types of training – weight shift and postural stability – each lasting 5 minutes, allowing the HD patients to relax for 2 minutes between each type of exercise. HD patients' femoral bone mineral density (T-score) was assessed in both groups. Dynamic balance was assessed in both groups via the HD participants' BBTS-extracted overall stability index (OASI), BBTS-extracted anteroposterior stability index (APSI), and BBTS-extracted mediolateral stability index (MLSI). The HD patients' physical performance was also evaluated using a 6-minute walking distance (6MWD) test and total scored points of a 3-component Short Physical Performance Battery (SPPB) test.

**Results.** After using BBTS in a balance-training program, significant improvements in HD participants' OASI, APSI, T-score, MLSI, SPPB, and 6MWT were recorded in the BTG, while all outcomes of the NTG did not show the same results.

**Conclusions.** It can be concluded that utilizing BBTS in a 12-week balance-training program improves participants' OASI, APSI, T-score, MLSI, SPPB, and 6MWT in HD patients with osteopenia.

**Key words:** physical functional performance, renal dialysis, metabolic bone diseases.

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## Background

The Documented Egyptian Renal Registry proposed that in 2008, there were 483 cases/patients with end-stage renal disease (ESRD) per million registered Egyptian patients receiving dialysis services out of a total of 40,000 ESRD Egyptian patients/cases using around 3,000 hemodialysis (HD) machines/devices in over 600 dialysis facilities or hospitals spread throughout the different Egyptian public (25%) and private (75%) healthcare sectors [1].

If renal replacement therapy is not initiated, ESRD will cause a high rate of mortality. Dialysis is the main recommended course of treatment for the majority of ESRD sufferers. In people with HD, low bone mineral density (BMD) is a major cause of

a lower quality of life and morbidity/mortality. Dialysis sufferers are more likely than the general population to experience low BMD, repeated fractures, and fracture-repeated morbidities as HD patients have a high prevalence of osteopenia and osteoporosis, particularly around the femoral neck [2].

Among several/common factors, such as aging, malnutrition, low body mass, myopathies, neuropathies, altered parathyroid hormone and albumin levels, and drug-induced complications, a decrease in physical activity and muscular strength may also contribute to the low BMD in dialysis patients [2].

Dialysis-induced low physical activity/performance (due to decreased maximal oxygen uptake), reduced exercise capacity, and decreased muscle strength not only cause osteopenia/



osteoporosis but also distort dialysis patients' locomotion and balance. Dysregulation of dialysis patients' static and dynamic balance activities results in limitations/restrictions in their ability to perform traditional activities of daily living. Due to all of the aforementioned factors, dialysis individuals had a 4.4 times higher incidence of bone fractures (especially at the hip bone) than healthy/normal age-matched control individuals [3].

The efficiency of the Biodex Balance Training System (BBTS) in accurately measuring the level of imbalance, in addition to its use in treating imbalance, makes it an effective, excellent, and preferred method for physical therapists in measuring and treating imbalance in various diseases [4]. It is a relatively new instrument, and there is no published literature or data regarding its use in improving dynamic balance and physical performance in HD patients with osteopenia.

## Objectives

The aim of this study was to investigate the effect of BBTS on dynamic balance and physical performance in HD patients with osteopenia.

## Material and methods

### Ethics

This HD study conducted on osteopenia patients with HD was approved by the Cairo-University Ethical Review Board (Approval ID: P.T.REC/012/004928, grant from the Faculty of Physical Therapy). Other ethical criteria such as consenting HD patients and Helsinki recommendations were also managed.

## Design

This HD study was a randomized controlled balance-training trial conducted from November 8, 2023, to March 8, 2024.

## Settings

Patients with HD and osteopenia were recruited from the Nephrology Unit of 6 October Hospital, Egypt.

## Inclusion criteria

58 HD women who were 35–45 years of age and received three dialysis sessions/treatments per week were eligible for inclusion in this balance-training randomized trial. Patients with HD received maintenance dialysis for a minimum of 6 months. The included patients had osteopenia. According to the World Health Organization, osteopenia is defined as a patient's bone density that is abnormal but not as low as osteoporosis. Osteopenia patients with a bone-densitometry T-score between -1 and -2.5 were included in this study.

## Exclusion criteria

HD patients with autoimmune diseases, glucose-metabolism disorders, uncontrolled cardiac or hypertensive episodes, pregnancy, cancer, muscle disorders, acquired immunodeficiency syndrome, neurological disorders, amputated limbs or inflamed articulations of lower limbs, bariatric surgery, or psychological/mental disorders were excluded. HD patients who participated in regular exercise, those > 65 years of age, or those that took catabolizing drugs were also excluded. HD patients whose body mass was over 120 kg were not allowed to participate in this study as the maximal allowed weight on the BBTS platform is less than 120 kg.

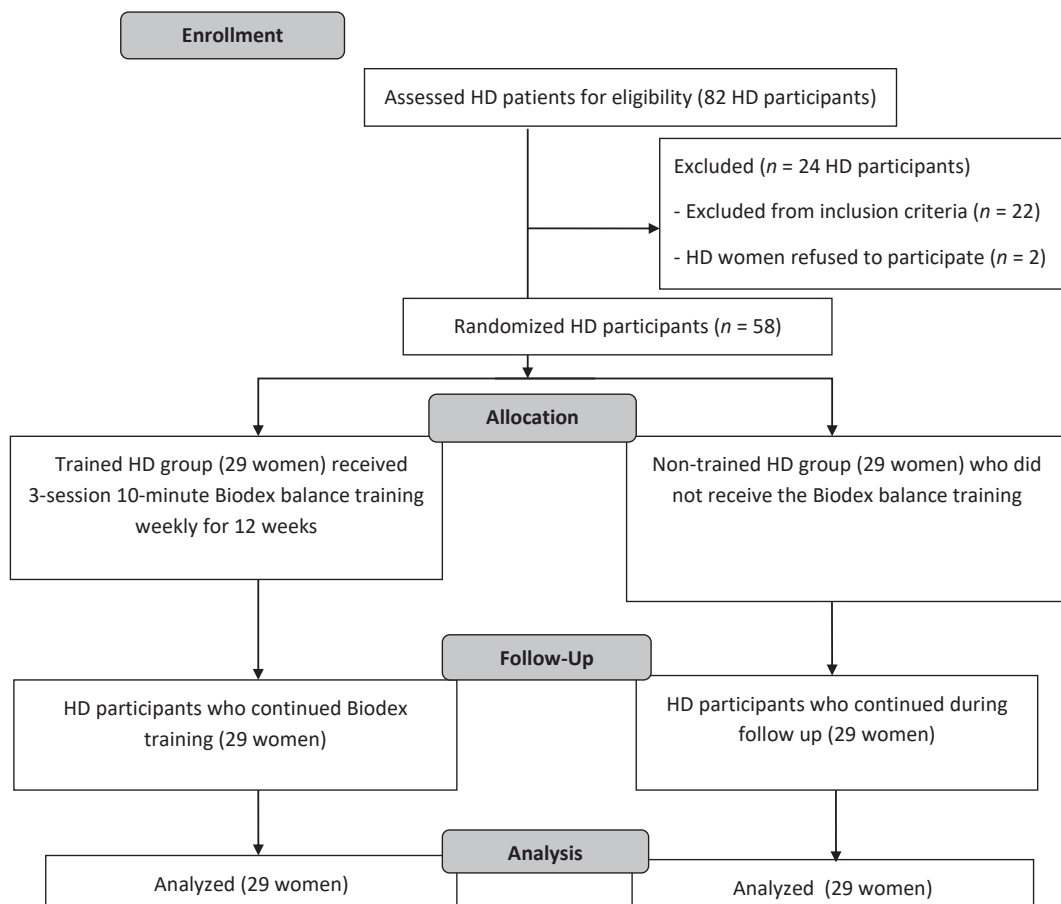


Figure 1. Flow chart of participating HD women with osteopenia during the 12-week Biodex training study

## Randomization

HD patients were randomly assigned to a group trained using the BBTS ( $n = 29$ ) and a non-trained group (NTG,  $n = 29$ ) (Figure 1). The physical therapist who randomly distributed the HD patients to NTG or a group trained with BBTS via the closed envelope randomization technique did not participate in this balance-training study, and moreover was not informed of the cause of the random distribution of HD into two groups to avoid bias in distributing patients in favor of a particular group.

## Interventional steps

This 12-week Biodex system balance-training trial was applied 3 times weekly. The training phase on the BBTS lasted for 10 minutes, with the two types of training – weight shift and postural stability – each lasting 5 minutes, allowing the HD patients to relax for 2 minutes between each type of exercise. The HD patients' name, height, and weight (in kg) were entered into the BBTS software for the HD patients' postural stability training mode. Additionally, HD patients' training parameters/variables such as training duration (in minutes), different levels of stability fluctuating throughout of postural-stability training time (graded from the most stable level of 8 to the least stable level of 1), target configuration/settings, and on-screen tracing were also set. HD patients were advised to maintain/hold their barefoot posture/position for the entire BBTS session while standing on the BBTS platform in a manner that increased their foot control and comfortability. All HD patients were ordered to look continuously at the BBTS display screen with their eyes open. To give the HD patient the greatest possible view or visual feedback, the BBTS screen height and position were changed. The BBTS handles were placed in a very secure position/level. The BBTS exercise session began, and every HD patient was advised to direct the BBTS platform's motion/fluctuation by moving the cursor to the BBTS screen's designated target before returning to the starting point and repeating the trials [5].

The BBTS setup procedures for weight shift-training mode (2<sup>nd</sup> part of BBTS session) were the same as those for postural stability-training procedures (1<sup>st</sup> part of BBTS session). In order to complete the 2<sup>nd</sup> part of the session, the HD patient had to move and try to maintain a center of gravity between two designed parallel lines while moving in the different BBTS planes (medial/lateral, anterior/posterior, and diagonal planes). The spacing between the two designed parallel lines was fitted to become wider for HD patients who showed better balance scores to further challenge their ability/skills of controlled weight shifting [5].

## Primary outcome of this balance-training trial

This balance-training trial utilized a Dual-energy X-ray Absorptiometry Apparatus (DP3 Model, Madison, USA) to measure HD patients' femoral bone mineral density (T-score, as a primary outcome of this balance-training trial in all HD patients) before and after 12 weeks.

## Secondary outcomes of this balance training trial

### 1. Dynamic balance parameters

BBTS is an assessment and treatment tool for balance deficits, thus the BBTS utilized in this study was used in assessment and treatment of imbalance of HD patients. By monitoring HD participants' capacity to manage the BBTS platform's tilt angle during the posture stability test (dynamic balance test), we assessed the HD patients' deviation from the center at stability level 8 (the BBTS-platform stability ranged from 1–8, with 1 denoting the greatest instability).

The measures of the BBTS-extracted dynamic balance test were: BBTS-extracted overall stability index (OASI), which denotes the HD patients' ability to maintain their balance/postural

stability in all directions; BBTS-extracted anteroposterior stability index (APSI), which denotes HD participants' ability to maintain their balance/postural stability from forward to backward direction; and BBTS-extracted mediolateral stability index (MLSI), which denotes HD participants' ability to maintain their balance/postural stability from side-to-side directions. High values of BBTS-extracted indices indicate that HD participants had difficulty in controlling their balance [6].

### 2. Physical performance parameters

HD patients' physical performance was evaluated using:

#### A. Six-minute walking distance (6MWD)

This is defined as the distance (in meters) covered by HD patients in 6 minutes [7, 8].

#### B. Total scored points of 3-component Short Physical Performance Battery (SPPB)

This 3-component physical performance test assessed: HD patients' gait speed (time consumed by HD participants to cover a 4-m walking distance comfortably), repeated 5-time chair stands with arms crossed from sitting position on armless chair, and 3-type standing balance forms/tests (10-second side-by-side stand, 10-second semi-tandem stand, and 10-second tandem stand). Scores of 0–4 points were assigned for each HD patient's SPPB component [9]. Every HD patient's total SPPB scores/points ranged from 0 (the lowest/worst level of physical performance) to 12 (the best level of physical performance) points [10].

## Considered blinding procedures during measurements of outcomes

The physical therapist who assessed HD participants' outcomes was not an author in this study and did not know the name, details, or concept of the provided balance-training program in this study to avoid bias in patient results in favor of one of the two trial groups.

## Sample size of this balance-training trial

G\*Power analysis revealed the need for 48 HD patients to complete this balance-training trial (effect size = - 0.83 for HD patients' femoral bone mineral density) (T-score as a primary outcome of this balance-training trial with testing the sample size at a power equal to 80%). The authors of this balance-training trial raised the number of HD participants to 58 HD patients with osteopenia to avoid an estimated 20% drop in HD participants.

## Statistical analysis

To check the normal distributional format of HD participants' data (OASI, APSI, T-score, MLSI, SPPB, 6MWT, and demographic data), the Kolmogorov-Smirnov test was the intended test to be used. In this balance-training trial, this test confirmed the normality of HD subjects' data. SPSS18 software was used, with a  $p$ -value less than 0.05 considered significant. Both paired and unpaired tests were used to test and handle all HD patient data.

## Results

Before using BBTS in applying the balance-training program, the SPSS program recorded no significant difference between both groups' basic data (Table 1) or both groups' assessed outcomes (OASI, APSI, T-score, MLSI, SPPB, and 6MWT) (Table 2). After using BBTS in the balance-training program, the SPSS program recorded significant improvement in OASI, APSI, T-score, MLSI, SPPB, and 6MWT in the trained group, while all outcomes of NTG – using the same SPSS program – did not show the same results. In the direction of the trained group by BBTS, after ending the balance-training program, a comparison between groups of post-value outcomes (OASI, APSI, T-score, MLSI, SPPB, and 6MWT) showed significant improvement (Table 2).

	Biodex training group	Control group	<i>p</i>
Age of HD participants (years)	40.13 $\pm$ 3.75	40.34 $\pm$ 3.30	0.821
Weight of HD participants (kg)	76.62 $\pm$ 6.37	73.89 $\pm$ 7.27	0.133
Height of HD participants (m)	159.58 $\pm$ 5.59	161.65 $\pm$ 5.43	0.158
Body mass index of HD participants (kg/m <sup>2</sup> )	29.57 $\pm$ 2.65	28.52 $\pm$ 2.77	0.145
HD duration (months)	42.13 $\pm$ 6.82	41.86 $\pm$ 7.35	0.885

SD – Standard deviation; HD – Hemodialysis; All *p*-values of hemodialysis participants' demographic data are non-significant (*p*-value > 0.05).

Parameters of the 12-week trial	Biodex group	Control group	<i>p</i> -value (between Biodex and control HD groups)
<b>Overall stability index of HD participants</b>	<b>Mean <math>\pm</math> SD</b>	<b>Mean <math>\pm</math> SD</b>	
Before Biodex training	4.80 $\pm$ 1.28	5.12 $\pm$ 1.27	0.343
After Biodex training	2.65 $\pm$ 0.84	5.22 $\pm$ 1.09	0.0001*
<i>p</i> -value (within HD group)	< 0.001*	0.082	
<b>Antero-posterior stability index of HD participants</b>	<b>Mean <math>\pm</math> SD</b>	<b>Mean <math>\pm</math> SD</b>	
Before Biodex training	4.06 $\pm$ 1.35	4.64 $\pm$ 1.39	0.112
After Biodex training	2.29 $\pm$ 0.79	4.67 $\pm$ 1.4	0.0001*
<i>p</i> -value (within HD group)	< 0.001*	0.666	
<b>Medio-lateral stability index of HD participants</b>	<b>Mean <math>\pm</math> SD</b>	<b>Mean <math>\pm</math> SD</b>	
Before Biodex training	2.87 $\pm$ 1.16	3.40 $\pm$ 0.99	0.066
After Biodex training	1.59 $\pm$ 0.78	3.41 $\pm$ 0.96	0.0001*
<i>p</i> -value (within HD group)	< 0.001*	0.860	
<b>HD patients' femoral bone mineral density (T-score)</b>	<b>Mean <math>\pm</math> SD</b>	<b>Mean <math>\pm</math> SD</b>	
Before Biodex training	-1.76 $\pm$ 0.35	-1.78 $\pm$ 0.44	0.848
After Biodex training	-1.44 $\pm$ 0.32	-1.79 $\pm$ 0.53	0.003*
<i>p</i> -value (within HD group)	< 0.001*	0.862	
<b>HD patients' 6-minute walk distance (meters)</b>	<b>Mean <math>\pm</math> SD</b>	<b>Mean <math>\pm</math> SD</b>	
Before Biodex training	350.72 $\pm$ 16.25	351.62 $\pm$ 12.52	0.814
After Biodex training	376.31 $\pm$ 16.39	347.89 $\pm$ 12.27	0.0001*
<i>p</i> -value (within HD group)	< 0.001*	0.155	
<b>HD patients' SPPB total score (points)</b>	<b>Mean <math>\pm</math> SD</b>	<b>Mean <math>\pm</math> SD</b>	
Before Biodex training	7 $\pm$ 2.03	7.89 $\pm$ 1.79	0.082
After Biodex training	8.89 $\pm$ 2.12	7.72 $\pm$ 1.75	0.025*
<i>p</i> -value (within HD group)	< 0.001*	0.466	

HD – Hemodialysis; SD – Standard deviation; SPPB – Short physical performance battery; \**p*-values of hemodialysis participants' data are significant (*p*-value < 0.05).

## Discussion

Our study achieved the first investigation in dialysis literature concerning the effect of BBTS on dynamic balance and physical performance in HD patients with osteopenia. This study revealed that HD participants who received 12-week balance-training via BBTS not only improved their objective measures of dynamic balance (OASI, APSI, and MLSI) but also improved their 6MWD and their T-score of femoral bone density. Our study was the first to document these results.

As the users practice via the BBTS balancing task/training, the BBTS employs a movable platform to supply the users with varying degrees of postural stability. This type of balance-training program has its physiological justifications because, as varying degrees of instability are practiced/repeated, the patient's movements may cause an intentional and/or non-intentional shift in body mass. This shift induces a balancing reaction in the patient's lower extremities, which forces the body to promote various neuromuscular reflexive stabilizing reactions. Increased/

challenged instability may increase the amount of repeated sensory interplay between different body responses (equilibrium reactions, mechanoreceptors, and vision). The augmentation of these responses evokes various open-looped techniques to maintain the balance of a subject using BBTS [11].

Augmented various functional characteristics (increased skeletal muscle co-contraction, improved articular dynamic stabilization, elevated lower limb joint compression, and increased facilitation of proprioception) required during this type of activity create/achieve a strong kinesthetic and/or neuromuscular control. This control may justify the improved balance after using BBTS as a balance-training program [11].

Regarding the improved bone mineral density in the trained group of this study, regular physical exercise – such as weight-bearing exercise – stimulates the subject's resident osteocytes to produce different signaling molecules that balance the process of bone production and resorption, hence the HD-associated high levels of bone resorption and low levels of bone production are re-corrected with regular physical activity [12].

Regarding the improved physical performance in the trained group of this study, besides an improvement in depressive symptoms, regular exercise training in HD patients was documented to reduce their raised triglyceride levels, raise their low hemoglobin levels, decrease their high levels of insulin, improve their dynamic balance and muscle strength, and elevate their bone mineral density. All of these regular exercise-gained benefits have been documented to have a great effect on HD patients' physical performance [13].

As mentioned above, our study is the first that reports an improvement in HD participants' dynamic balance parameters (OASI, APSI, and MLSI) after using BBTS in this 12-week balance-training trial. In agreement with us, but in patients with diabetic polyneuropathy, a 10-session balance-training program using BBTS significantly improved the patients' OASI, APSI, and MLSI [4]. Again, in patients with diabetic polyneuropathy, a study published in 2012 reported that OASI, APSI, and MLSI could be enhanced after a 10-session balance-training program [14]. An 8-week balance-training program using BBTS also significantly improved chronic obstructive pulmonary disease patients' OASI, APSI, MLSI, and functional balance (assessed via the Berg balance scale) [5]. An 8-week balance-training program using BBTS also significantly improved older women's OASI, APSI, and MLSI [15].

Supporting us, a regular physical activity program conducted for 24 weeks in HD patients showed a significant improvement in their femoral bone mineral density [2]. In agreement with us, besides improved 6MWD, femoral bone mineral density was also significantly attenuated in a 1-year follow-up after 3-month aerobic cycling in HD patients [16]. The MLSI, APSI, and bone mineral density of older patients with osteopenia or osteoporosis also showed improvements after a long-term multi-component exercise program including balance training [17]. In a study published in 2017, femoral bone density was significantly improved after adherence to a 12-week exercise intervention in kidney transplant patients [18]. A study conducted on older osteoporotic women in 2005 also reported an improvement in walking speed and bone mineral density after a 12-month weight-bearing exercise program [19].

Consistent with our results, physical performance (chair-stand test, stand on one leg, and time up and go test) was significantly improved after a 12-week whole-body vibration program in elderly individuals with HD [20]. Physical performance (assessed via 6MWD) and functional balance (assessed by Physical Activity Scale for the Elderly) also showed significant improvement after 8-week exercise training in HD patients [21]. Physical performance (assessed via 6MWD) and functional balance (assessed by Berg Balance Scale) also showed significant

improvement after 12-week exercise training in HD patients [15]. The physical performance assessed by different tests such as sit to stand, time up and go, and 6MWT was also significantly improved after a 4-month endurance-resistance exercise intervention in Tunisian HD patients [22]. Physical performance (assessed via sit-to-stand test) and balance (assessed via single-leg stand) also showed significant improvement after an 8-week virtual-reality exercise program in HD patients [23]. Adding virtual-reality training to 12-week endurance training also significantly improved HD patients' physical performance (walking speed and time up and go test) [24]. Adding balance training to 6-month resistance-endurance training also significantly improved 6MWD and dynamic postural balance assessed via different tests, such as time up and go test and Berg Balance Scale, in elderly individuals with HD [25].

SPPB is a common tool in assessing improvements in physical performance after exercise interventions in HD patients. Our results showed a significant improvement in SPPB after using BBTS in this 12-week balance-training trial. Consistent with our results, 6-month [9] or 24-month exercise-training studies that used exercise to improve HD patients' physical performance showed an improvement in patients' SPPB [9, 10].

Contrary to our results, postural control (assessed via trunk sway amplitude in the anteroposterior and mediolateral directions), functional balance (assessed via Berg Balance Scale), sit-to-stand test, and 6-minute walk test did not show significant improvements after 12-week aerobic exercise in HD participants, which may be due to focusing the training on lower limbs (via cycling sessions performed in sitting position) and the small number of HD participants ( $n = 7$ ) [26]. Contrary to us, despite the improved results of the chair-stand test and 6MWD, the T-score results of the femoral neck did not improve after 6 months of exercise training in dialysis patients due to the loss of supervision on all of the executed home-based exercise-program sessions [27].

### Limitations of the study

Follow-up to HD participants' OASI, APSI, T-score, MLSI, SPPB, and 6MWT was the main limitation of this balance-training trial. Future-designed balance-training programs using BBTS should cover this limitation in HD patients with osteopenia.

### Conclusions

It can be concluded that utilizing BBTS in a 12-week balance-training program improves the OASI, APSI, T-score, MLSI, SPPB, and 6MWT in HD patients with osteopenia.

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