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Effects of balance training on balance performance in youth: role of training difficulty

Submission date 03/06/2020	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 19/06/2020	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 26/01/2021	**Condition category** Other	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Sufficient postural control is important to succeed in activities of daily living such as standing (static balance), walking (dynamic balance), or in situations where balance is particularly challenged to avoid a fall as for instance when leaning forward while reaching (proactive balance). Regular balance training knowingly improves these measures of balance performance. However, balance training can include exercises of various task difficulties. For example, a one-legged stance may represent a rather simple task as long as it is executed on firm ground with eyes opened, but pose a higher challenge to an individual once it is executed on unstable ground and/or with eyes closed. Thus, it is assumed that the effectiveness of balance training is affected by the difficulty of the exercises performed. Therefore, this study aims to investigate whether conducting balance training with a high level of task difficulty (BT-high) is more effective than a comparable training with a low level of task difficulty (BT-low) in healthy male adolescents.

Who can participate?
Healthy male adolescents aged 10-15

What does the study involve?
Participants are randomly allocated to one of two groups who both receive a standardized balance training (BT) program for 7 weeks (two sessions per week, 30-35 minutes each). One group (BT-low) performs balance exercises with a low level of task difficulty while the other group (BT-high) conducts balance exercises with a high level of task difficulty. The balance exercises performed during each training session will be similar in nature in both groups. However, exercises in the BT-high group will be performed under more challenging conditions. For example, the BT-low group will perform squats in two-legged stance with eyes opened, whereas the BT-high group conducts the same exercise with eyes closed. Other methods to influence task difficulty will be to allow (BT-low) or prohibit (BT-high) arm support and to exclude (BT-low) or include (BT-high) additional motor (e.g., throwing and catching a ball) and cognitive (e.g., counting backwards) tasks during the exercise. Before and after 7 weeks of balance training balance performance is assessed under static (i.e., time in balance during one-legged stance), dynamic (i.e., gait velocity during normal walking), and proactive (i.e. reach

distance in the Y-balance test; time to complete the timed-up-and-go test) conditions to find out whether both types of training are effective at improving balance performance and whether one training regime is more effective than the other.

What are the possible benefits and risks of participating?
The benefits include improved physical performance and especially balance performance. These may be associated with increased health as well as with a reduced risk of an injury or a fall. Besides temporary fatigue following the training sessions, there are no risks associated with the participation in the study.

Where is the study run from?
University of Duisburg-Essen (Germany)

When is the study starting and how long is it expected to run for?
April 2018 to April 2019

Who is funding the study?
University of Duisburg-Essen (Germany)

Who is the main contact?
Prof. Thomas Muehlbauer
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
BT2020a

Study information

Scientific Title
Effects of balance training on balance performance in youth: role of training difficulty - a parallel interventional study using a randomized design

Acronym
BTdose

Study objectives
Balance training leads to enhanced balance performance in youth. Improvements will be larger following balance training conducted with a high level of task difficulty compared to balance training with a low level of task difficulty.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/12/2018, Human Ethics Committee at the University of Duisburg-Essen, Faculty of Educational Sciences (Universitaetsstr. 2, Essen, 45141, Germany; +49 (0) 201 1837237; ethik-psychologie@uni-due.de), ref: TM_06_12_2018

Study design
Parallel interventional study using a randomized design

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Balance performance

Interventions

Two groups receive a standardized balance training (BT) program for 7 weeks (2 sessions/week, 30-35 minutes each). One group (BT-low) performs balance exercises with a low level of task difficulty while the other group (BT-high) conducts balance exercises with a high level of task difficulty. Participants are randomly assigned to either the BT-low or BT-high group using research randomizer software (www.randomizer.org).

Both groups will conduct a progressive balance training two times per week with single-sessions lasting to about 30-35 minutes for 7 weeks. The balance exercises performed during each training session will be similar in nature in both groups. However, exercises in the BT-high group will be performed under more challenging conditions. For example, the BT-low group will perform squats in two-legged stance with eyes opened, whereas the BT-high group conducts the same exercise with eyes closed. Other methods to influence task difficulty will be to allow (BT-low) or prohibit (BT-high) arm-support and to exclude (BT-low) or include (BT-high) additional motor (e.g., throwing and catching a ball) and cognitive (e.g., counting backwards) tasks during the exercise.

Before and after 7 weeks of balance training balance performance will be assessed under static (i.e., time in balance during one-legged stance), dynamic (i.e., gait velocity during normal walking), and proactive (i.e. reach distance in the Y-balance test; time to complete the timed-up-and-go test) conditions to find out whether both trainings are effective to improve balance performance and whether one training regime is more effective than the other.

Intervention Type
Behavioural

Primary outcome(s)
1. Static balance performance is assessed using a one-legged stance (non-dominant leg) under three conditions (1. firm ground, eyes opened; 2. firm ground, eyes closed; 3. foam ground, eyes opened) that are subsequently applied to the participant. The time in balance under each condition is measured to the maximum of 60 s and used for analysis.
2. Dynamic balance is assessed using a 10-m walk test. Participants are given one meter to accelerate and deccelerate before and after the walkway and are asked to walk at their preferred speed. The time to cover the 10 m distance is measured using a standardized stopwatch and subsequently gait velocity is calculated.
3. Proactive balance is measured using the Lower-Quarter Y-Balance Test (YBT). The maximal reach distance in anterior, posteriomedial, and posteriolateral direction is assessed and normalized to leg length. Further, the normalized composite score is calculated.
All outcomes will be measured before and after the 7 weeks intervention period

Key secondary outcome(s))
Proactive balance assessed using the timed-up-and-go test conducted before and after the 7 weeks intervention period

Completion date
26/04/2019

Eligibility

Key inclusion criteria

1. Age range: 10-15 years
2: Gender: male
3. Health status: healthy without any known neurological, orthopedic, or musculoskeletal disease

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
10 years

Upper age limit
15 years

Sex
Male

Total final enrolment
40

Key exclusion criteria
1. Neurological disease
2. Orthopedic disease/impairment
3. Musculoskeletal disease

Date of first enrolment
07/01/2019

Date of final enrolment
18/01/2019

Locations

Countries of recruitment
Germany

Study participating centre
AFC Assindia Cardinals Essen 1983 e.V.
Planckstraße 42
Essen
Germany
45147

Sponsor information

Organisation
University of Duisburg-Essen

ROR
https://ror.org/04mz5ra38

Funder(s)

Funder type
University/education

Funder Name
Universität Duisburg-Essen

Alternative Name(s)
University of Duisburg-Essen, UDE

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Thomas Mühlbauer (thomas.muehlbauer@uni-due.de).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/11/2020	26/01/2021	Yes	No