

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

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|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>03/06/2020   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>19/06/2020 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>26/01/2021       | <b>Condition category</b><br>Other                | <input type="checkbox"/> 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

thomas.muehlbauer@uni-due.de

## Contact information

### Type(s)

Scientific

### Contact name

Mr Simon Schedler

### Contact details

Gladbecker Str. 182

Essen

Germany

45141

+492011837350

simon.schedler@uni-due.de

### Type(s)

Scientific

### Contact name

Prof Thomas Muehlbauer

### Contact details

Gladbecker Str. 182

Essen

Germany

45141  
+492011837333  
thomas.muehlbauer@uni-due.de

## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

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

### Secondary study design

Randomised parallel trial

### Study setting(s)

Other

## **Study type(s)**

Prevention

## **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet.

## **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](http://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 measure**

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 decelerate 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, posteromedial, 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

**Secondary outcome measures**

Proactive balance assessed using the timed-up-and-go test conducted before and after the 7 weeks intervention period

**Overall study start date**

02/04/2018

**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

**Age group**

Child

**Lower age limit**

10 Years

**Upper age limit**

15 Years

**Sex**

Male

**Target number of participants**

40

**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

## Sponsor details

Division of Movement and Training Sciences/Biomechanics of Sport

Gladbecker Str. 182

Essen

Germany

45141

+49 (0)2011837333

thomas.muehlbauer@uni-due.de

## Sponsor type

University/education

## Website

<https://www.uni-due.de/en/>

## 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

**Publication and dissemination plan**

There is no protocol available for this study. Following post-intervention assessments, data shall be analyzed. The results shall be published through one original research article within 18 months from the end of the study.

**Intention to publish date**

26/10/2020

**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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 23/11/2020   | 26/01/2021 | Yes            | No              |