

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

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

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Contact information

Type(s)

Scientific

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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).

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

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Sponsor information

Organisation

University of Duisburg-Essen

Sponsor details

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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?
Results article	results	23/11/2020	26/01/2021	Yes	No