ISRCTN16518737 https://doi.org/10.1186/ISRCTN16518737

Time-course of balance training-related changes on static and dynamic balance performance in healthy children

Submission date	Recruitment status	[_] Prospectively registered
14/08/2023	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/08/2023	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/03/2024	Other	

Plain English summary of protocol

Background and study aims
In children, there is evidence of improvements in static and dynamic balance performance following balance training. However, the time course of balance training-related changes is unknown. In fact, the time course of changes in balance with training has so far only been studied in older adults. Yet, transferring these findings to children is not legitimate, as older adults are subject to age-related degradation processes in the sensory and motor systems. Therefore, the aim of the study was to investigate the time course of balance training-related changes (i.e., after 1, 3, and 6 weeks of BT) on measures of static and dynamic balance in healthy children.

Who can participate?
Healthy children aged between 6 and 12 years old

What does the study involve?
This study investigates the effects of balance training on measures of static and dynamic balance in participants in an intervention group who will undertake 2 x 25 minutes of balance exercises per week compared with those in the control group who will undertake 2 x 25 minutes of track and field exercises and soccer practice per week. Participants will undergo tests for their static (i.e., stance time in the One-Legged Stance test) and dynamic (i.e., step number in the 3-m Beam Walking Backward test) balance performance at 1, 3 and 6 weeks.

What are the possible benefits and risks of participating?
The benefits are improvements in static and dynamic balance performance and there is a risk of muscular fatigue after training.

Where is the study run from?
The study was performed in public schools and is run by the University of Duisburg-Essen (Germany)

When is the study starting and how long is it expected to run for?
April 2023 to June 2023

Who is funding the study?
Division of Training and Movement Sciences/Biomechanics of Sport at the University of Duisburg-Essen (Germany)

Who is the main contact?
Thomas Muehlbauer, thomas.muehlbauer@uni-due.de

Contact information

Type(s)
Principal Investigator

Contact name
Prof Thomas Muehlbauer

ORCID ID
http://orcid.org/0000-0001-7774-8664

Contact details
University of Duisburg-Essen
Gladbecker Str. 182
Essen
Germany
45141
+492018137333
thomas.muehlbauer@uni-due.de

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Time-course of balance training-related changes

Acronym

TCBT

Study objectives
We hypothesised that BT would result in balance improvements, which take place in as little as two sessions per week (i.e., after 1 week of BT).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/07/2017, Human Ethics Committee at the University of Duisburg-Essen, Faculty of Educational Sciences (University of Duisburg-Essen, University Street 2 Room: S06 S03 A31, Essen, 45141, Germany; +49 (0) 201 / 183 7237; ethik-psychologie@uni-due.de), ref: TM_10.07.2017

Study design
Cluster-randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
School

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
Promotion of balance performance

Interventions
The study employed cluster randomization based on school class. The study consisted of balance training given in an intervention group: balance training 2 x 25 minutes of balance exercises per week, 6 weeks in total; and an active control group: 2 x 25 minutes of track and field exercises and soccer practice per week, 6 weeks in total; participants are randomly assigned to the intervention group or control group; both treatments were supervised by two graduated students (i.e., sports scientists); group-based treatments provided in the school-gym.

Intervention Type
Behavioural

Primary outcome measure

Static and dynamic balance performance was measured using stance time in the One-Legged Stance test and by counting step number in the 3-m Beam Walking Backward test before and after 1, 3, and 6 weeks of treatments

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
20/03/2017

Completion date
13/06/2023

Eligibility

Key inclusion criteria
1. Voluntary participation
2. Aged between 6 and 12 years old

Participant type(s)
Healthy volunteer

Age group
Child

Lower age limit
6 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
42

Total final enrolment
44

Key exclusion criteria
Neurological or musculoskeletal impairment

Date of first enrolment
11/04/2023

Date of final enrolment
17/04/2023

Locations

Countries of recruitment
Germany

Study participating centre
Hartmannschule
Hartmannstraße 85
Oberhausen
Germany
46145

Sponsor information

Organisation
University of Duisburg-Essen

Sponsor details
Universitätstrasse 2
Essen
Germany
45141
+492011837224
uta.schmitz@uni-due.de

Sponsor type
University/education

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
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
The dataset generated during the current study will be available upon request from Thomas Muehlbauer, thomas.muehlbauer@uni-due.de. *.csv data will be shared upon request; the time limit for availability is 5 years; written informed consent and subject's assent were obtained from all participants before the start of the study. In addition, parents' approval was obtained for minors; data were anonymized; there are no ethical or legal restrictions.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/03/2024	20/03/2024	Yes	No