



PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Training-induced plasticity of multitasking in everyday-like motor behavior

Trial Acronym

MIND2

URL of the trial

<https://www.uni-muenster.de/Sportwissenschaft/Neuromotor-Behavior/forschung/mind/index.html>

Brief Summary in Lay Language

In everyday life we are often confronted with situations in which we have to carry out several tasks at the same time, so-called multitasking (e.g. driving a car while talking to a passenger, walking through the city while writing a message on the smartphone, etc.). With increasing age, multitasking becomes more difficult; the consequences are reduced performance, failure, and increasing risks of accidents and injuries. In long-term this can even lead to the loss of an independent and autonomous life. Scientific studies suggest that age-related changes in cognitive and motor functions and the associated restrictions in everyday life can be counteracted by targeted and tailored training. The aim of this project is to find out how exactly such a training intervention has to be designed in order to successfully improve multitasking skills. Study participants between 65 and 75 years of age are monitored for several months. They take part in different training interventions that train both mental and physical fitness. The success of the training is assessed by motor, neurophysiological and cognitive tests before and after the training phase.

Brief Summary in Scientific Language

The objective of the project is to investigate the benefits of individualized, adaptive training ("tailored training") to improve cognitive-motor multitasking. In a randomized, single-blind, three-armed, twelve-week intervention-study, subjects will be assigned to one of three experimental groups: (1) motor training, (2) cognitive training (3) cognitive-motor multitasking-training. Different motor, cognitive, physiological and neuronal measures are assessed in pre- and post-tests. The study aims to find out whether (1) subjects with motor deficits benefit more from a purely motor training than from multitasking-training, (2) subjects with cognitive deficits benefit more from a purely cognitive training than from multitasking-training, and (3) subjects without motor and cognitive deficits benefit more from multitasking training than from a purely motor or purely cognitive training.

Do you plan to share individual participant data with other researchers?**Yes****Description IPD sharing plan**

Anonymized individual participant data is made available to the public within open access publications. A peer-reviews and published study protocol contains a description of the methods and the statistical analysis plan.

Organizational Data

- DRKS-ID: **DRKS00022407**
- Date of Registration in DRKS: **2020/08/26**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **V-280-17-CVR-Multitasking-29062018 ,
Ethikkommission der Fakultät Human- und Sozialwissenschaften der
Technischen Universität Chemnitz**

Secondary IDs**Health condition or Problem studied**

- Free text: **healthy elderly people, aged between 65 and 75 years**

Interventions/Observational Groups

- **Arm 1: Twelve-week cognitive training. The contents are composed of different cognitive tasks. The sessions take place in groups twice a week for 45-60 minutes. Before and after the intervention, cognitive and motor performance as well as other personal and psychological variables are assessed.**
- **Arm 2: Twelve-week motor training. The contents consist of various balance, flexibility and strengthening exercises. Except for the contents of the training, all variables are kept the same as in Arm 1.**
- **Arm 3: Twelve-week cognitive-motor multitasking-training. The contents consist of the same exercises as in cognitive and motor training and are executed in combination (i.e. a simultaneous execution of cognitive and motor tasks). Except for the contents of the training, all variables are kept the same as in Arm 1 and Arm 2.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Randomized controlled trial**
- Blinding: [---]*
- Who is blinded: **assessor**
- Control: **Active control (effective treatment of control group)**
- Purpose: **Basic research/physiological study**
- Assignment: **Parallel**
- Phase: **I-II**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

The primary endpoint is the identification of the influence of training effects on the behavioral (cognitive and motor) and neural level in regard to the initial cognitive and motor performance in (virtual) scenarios containing multiple tasks. All examinations are carried out in longitudinal section at two measurement points at a time interval of twelve weeks (before and after the intervention).

Measurement instruments:

- Tracking task (in combination with a motor-auditiv task)
- Virtual driving task (realistic multitasking task)
- Virtual walking task (realistic multitasking task, in combination with the Stroop test and the Digit Symbol Substitution test)
- fNIRS

Secondary Outcome

The secondary endpoint is the assessment of general physical and cognitive fitness. All examinations are carried out in longitudinal section at two measurement points at a time lag of twelve weeks (before and after the intervention).

Measurement instruments:

- Questionnaire to determine subjective and objective health, and social participation
- Campimetry test
- German adaptation of the Baecke Physical Activity questionnaire
- German adaptation of the Falls Efficacy Scale
- Questionnaire on the number, location and causes of falls
- Mini Mental Status Examination
- Keep-track test
- Spatial 2-back test
- Simon test
- Switching test
- Tapping test
- Pegboard test



- **Posture test**
- **Chairstand test**

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- other **Universität Chemnitz, Chemnitz**
- other **WWU Münster, Münster**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/03/04**
- Target Sample Size: **150**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **65 Years**
- Maximum Age: **75 Years**

Additional Inclusion Criteria

- **right handed**
- **car driving practice (e.g., at least once a week within the last 6 months)**
- **ability to walk without walking aids / ability to walk for 30 minutes without negative physical conditions (e.g., - - - difficulty to breath, pain, and cardiac palpations)**
- **medical clearance certificate (e.g., negative exercise ECG and clinically unremarkable medical history)**

Exclusion criteria

- **BMI > 30**
- **non-corrected low vision**
- **red-green deficiency or red-green-colour blindness**
- **orthopedic handicaps**

- **perceived health problems**
- **neurological diseases**
- **cardiovascular disorders**
- **previous heart attack or stroke**
- **previous surgery at the head/brain.**

Addresses

■ Primary Sponsor

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■ Contact for Scientific Queries

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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URL: **www.dfg.de**

Status

- Recruitment Status: **Recruiting suspended on temporary hold**
- Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

- Approval of ethics comm. (mandatory for transfer to Studybox) **Ethikvotum**
- Paper <style fontName='DejaVu Sans' isBold='true'>Bock, O., Drescher, U., van Winsum, W., Kesnerus, T. F., & Voelcker-Rehage, C. (2018). A Virtual-Reality Approach for the Assessment and Rehabilitation of Multitasking Deficits. International Journal of Virtual and Augmented Reality (IJVAR), 2(1), 48-58.</style>
- Further trial documents **Projektbeschreibung**
- Paper <style fontName='DejaVu Sans' isBold='true'>Bock, O., Drescher, U., Janouch, C., Haeger, M., van Winsum W., & Voelcker-Rehage, C.(2018). An experimental paradigm for the assessment of realistic human multitasking. Virtual Reality 23, 61–70.</style>
- Paper <style fontName='DejaVu Sans' isBold='true'>Haeger, M., Bock, O., Memmert, D., & Hüttermann, S. (2018). Can driving-simulator training enhance visual attention, cognition, and physical functioning in older adults?. Journal of Aging Research, 2018, 1-9.</style>
- Paper <style fontName='DejaVu Sans' isBold='true'>Wechsler, K., Drescher, U., Janouch, C., Haeger, M., Voelcker-Rehage, C., & Bock, O. (2018). Multitasking during simulated car driving: a comparison of young and older persons. Frontiers in Psychology, 9: 910.</style>
- Paper **Bock O., Haeger M., Voelcker-Rehage C. (2019). Structure of executive functions in young and in older persons. PLoS ONE 14(5):e0216149.**
- Paper <style fontName='DejaVu Sans' isBold='true'>Broeker, L., Haeger, M., Bock, O., Kretschmann, B., Ewolds, H., Künzell, S., & Raab, M. (2020). How visual information influences dual-task driving and tracking. Experimental Brain Research, 238:675–687.</style>

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.