

Trial Description

Title

App-based Training Study Employing the Computer-based Program Zirkus Empathico: Analysis of Behavioral and Neural Correlates of Socio-Emotional Competences in Four-to Six-Year-Old Children

Trial Acronym

Zirkus Empathico 2

URL of the trial

<http://www.zirkus-empathico.de/>

Brief Summary in Lay Language

Psychological and psychosomatic diseases in childhood and adolescence play an increasing role in Germany. First indicators for dysfunctional, psychological behavioral pattern can be found in deficits of socio-emotional competences. Fostering of these competences supports the development of personal and social resources, which are important pillars to handle stressful life circumstances and their negative consequences. This study examines whether socio-emotional competences can be effectively fostered with the computer-based program Zirkus Empathico. Its efficiency is evaluated by investigating empathy as primary outcome and emotion knowledge as well as prosocial behavior as secondary outcomes with questionnaires and brain waves collected through electroencephalography (EEG).

The study design includes a training group, which receives the Zirkus Empathico training, and an active control group which receives the Squirrel & Bär training to foster English language competences. Participants are randomly assigned to the groups. Questionnaires are filled in before and after the training. Between these measurements, families receive a tablet computer with which their children can play with one of the training programs. Children practice under the guidance of one parent for six weeks, one hour per week.

Zirkus Empathico comprises exercises for emotion detection in emotional facial expression and contextual videos as well as exercises for empathy. Within the Squirrel & Bär application, children get in touch with the English language, including learning first words and grammatical rules.

It is expected that the training group improves in empathy, emotion knowledge, and prosocial behavior in comparison to the control group. In addition, it is assumed that the EEG components are influenced by participating in the Zirkus Empathico training.

Brief Summary in Scientific Language

To interact successfully with others is positively correlated with life satisfaction, health and academic success. Socio-emotional competences are important

personal and social resilience factors which contribute to handle stressful life circumstances and their negative consequences effectively. Though their significance has been shown, first deficits are already apparent within childhood. This longitudinal study therefore aims at investigating the efficiency of the tablet-based training Zirkus Empathico to foster these competences in children aged four to six years. Measures for empathy as primary outcome and emotion knowledge as well as prosocial behavior as secondary outcomes are assessed before and after the training. Socio-emotional competences are examined with questionnaires (GEM, EMK 3-6, SDQ), behavioral assessments (EMK 3-6) and electroencephalographic (EEG) measures.

The study examines whether (1) participants of the training group show increased values of empathy, emotion knowledge and prosocial behavior in comparison to participants of the control group and (2) whether amplitudes of the event-related components (ERPs) of early sensory processing (P1, N170) and late processing (P300) are modulated by participating in the training.

Behavioral correlates are measured in a pre/posttest design with one training group and one active control group. The measurement of EEG correlates is carried out at posttest only. The training group receives the Zirkus Empathico training to foster socio-emotional competences. The active control group receives the application Squirell & Bär to practice their knowledge of the English knowledge. The training with one of the programs is executed over a period of six weeks (two times per week for 30 minutes) under parental supervision.

Participants are assigned randomly to the groups. Potential developmental effects are controlled with covariate-adaptive randomization and the minimization procedure. The randomization ratio is 0.7 with two stratifying variables (age [two factors], gender [two factors], software MinimPy: [<http://minimpy.sourceforge.net>]).

The estimation of sample size was conducted with the software G*Power. With regard to previous studies of computer-based training of emotion knowledge in children (e.g. Grynszpan et al., 2014), a small effect was assumed. In addition, a repeated-measures ANOVA with the parameters group (two factors) and time (two factors) was used ($\alpha = 0.05$, Power = 0.80, correlation between time points of the primary outcome GEM: 0.69 [Neumann et al., 2014]). In total, a number of 31 participants per group is needed (total sample size: 62 participants). Additionally, a drop-out rate of 20 % was assumed (based on attrition rates of former studies with children within this age range). Consequently, 74 participants will be collected.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

■ DRKS-ID: **DRKS00015789**

■

DRKS-ID: **DRKS00015789**Date of Registration in DRKS: **2018/10/24**

- 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.: **2018-06 , Ethikkommission der Lebenswissenschaftlichen Fakultät der Humboldt-Universität zu Berlin**

Secondary IDs

Health condition or Problem studied

- ICD10: **F93 - Emotional disorders with onset specific to childhood**
- ICD10: **F98 - Other behavioural and emotional disorders with onset usually occurring in childhood and adolescence**
- ICD10: **F91 - Conduct disorders**
- ICD10: **F92 - Mixed disorders of conduct and emotions**
- ICD10: **F93 - Emotional disorders with onset specific to childhood**
- ICD10: **F94 - Disorders of social functioning with onset specific to childhood and adolescence**

Interventions/Observational Groups

- Arm 1: **Training group (TG) - Training of socio-emotional competences with the help of the computer-based program Zirkus Empathico (<http://www.zirkus-empathico.de/>). The training lasts 6 weeks for 60 minutes per week and is administered at home under parental supervision. In addition, the family receives a training manual which informs about all aspects of the training and tablet computer.**
- Arm 2: **Active control group (CG): Training of the English language with the help of the mobile app Squirrel & Bär (<http://squirrel-baer.de/>). The training lasts 6 weeks for 60 minutes per week and is administered at home under parental supervision. In addition, the family receives a training manual which informs about all aspects of the training and the tablet computer.**

Characteristics

- Study Type: **Interventional**
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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: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

1. Training component: Empathy

• **Empathy is measured from the parental perspective with the help of the Griffith Empathy Measure (GEM; Dadds, et al., 2008, Greimel et al., 2011) and the sub-test empathy of the Inventar zur Erfassung emotionaler Kompetenzen bei Drei- bis Sechsjährigen (EMK 3-6; Petermann & Gust, 2016) from the perspective of the parents and the child.**

• **The parental questionnaire GEM examines empathy with 23 items. The EMK 3-6 screening questionnaire contains of four items for empathy. The EMK 3-6 behavioral assessment uses dolls to present the child with different child-typical situations. The child then describes what the doll thinks and feels in this moment.**

• **GEM and EMK 3-6 are administered at first (T1) and second (T2) measurement.**

Secondary Outcome

2. Training component: Emotion knowledge

• **EMK 3-6 from the parental perspective: sub-test emotion knowledge, from child's perspective: sub-test primary emotions**

• **Results of the EEG measurement after training completion, with special regard to the differentiation of emotion within the ERPs; collected from child's perspective**

3. Training component: Prosocial behavior

• **Strength and Difficulties Questionnaire (SDQ; Goodman, 1997), measurement of behavioral disruptions, emotional problems, hyperactivity, problems with peers and prosocial behavior, from parental perspective**

• **EMK 3-6 sub-test: prosocial behavior, from child's perspective**

• **EMK 3-6 and SDQ are collected during first (T1) and second measurement (T2) after the training period. EEG collection is administered at T2 only.**



Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **Humboldt-Universität zu Berlin, Berlin**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2018/10/29**
- Target Sample Size: **74**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **4 Years**
- Maximum Age: **6 Years**

Additional Inclusion Criteria

German as native language, no bilingualism (English)

Exclusion criteria

- **Nonverbal IQ ≤ 70 (Coloured progressive matrices intelligence test; Raven, Bulheller & Häcker, 2001)**
- **Inadequate understanding of language (verbal age $< 4;0$ years; Peabody Picture Vocabulary Test; Lenhard et al., 2015)**
- **Neurological or psychological disorders**
- **Other training- or EEG-impairing disorders/medication/illnesses**
- **Parallel participation in other socio-emotional trainings**
- **Parallel participation in other clinical trials**

Addresses



■ **Primary Sponsor**

Humboldt-Universität zu Berlin
Unter den Linden 6
10099 Berlin
Germany

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: [---]*

■ **Contact for Scientific Queries**

Berlin School of Mind and BrainHumboldt-Universität zu Berlin
Ms. Sandra Naumann
Luisenstraße 56
10117 Berlin
Germany

Telephone: **030/20931740**

Fax: [---]*

E-mail: **sandra.naumann at hu-berlin.de**

URL: [---]*

■ **Contact for Public Queries**

Berlin School of Mind and BrainHumboldt-Universität zu Berlin
Ms. Sandra Naumann
Luisenstraße 56
10117 Berlin
Germany

Telephone: **0176/76867649**

Fax: [---]*

E-mail: **sandra.naumann at hu-berlin.de**

URL: [---]*

Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

Humboldt-Universität zu Berlin
Unter den Linden 6
10099 Berlin
Germany

Telephone: [---]*

Fax: [---]*



Institutional budget, no external funding (budget of sponsor/PI)

Humboldt-Universität zu Berlin

Unter den Linden 6

10099 Berlin

Germany

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: [---]*

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

* 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.