

Selfmanagementtraining for adolescents with a weak social competence; effectivity and predictive factors.

Published: 16-10-2012

Last updated: 26-04-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cognitive and attention disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON37772

Source

ToetsingOnline

Brief title

Selfmanagementtraining for weak social competence.

Condition

- Cognitive and attention disorders and disturbances

Synonym

autism, Klinefelter

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Leiden

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Autism, Cognition, Sex chromosomal disorders, Social competence

Outcome measures

Primary outcome

1. social competence and overall level of well-being, measured with questionnaires and diary methodology and physiological emotion/indicators for participants and behavioural questionnaires for parents and/or third party.
2. building blocks of social competence, measured with social cognitive and neurocognitive tests and visual orientation in social situations
3. Predictive value social cognitive and neurocognitive functions, knowledge level of social competence and coping skills measured with questionnaires for participants, parents and/or third parties and tests for higher order social cognitive and neurocognitive functions

Secondary outcome

Neurocognitive skills, performance testing

Social cognitive skills, performance testing

Overall level of well-being, physiological emotion indicators

Level of knowledge, multiple-choice test

Copingvaardigheid, questionnaire

Study description

Background summary

Development of social competence is of crucial importance for an adolescent willing to function independently in our complex social world. It's absence

leads to mutual misunderstanding, feelings of exclusion and dysfunctional emotion regulation. More than any other stage of life, the stage of adolescence is of crucial meaning for the development of social competence because of a strong development of brain areas that are related to cognitive functions that form the building blocks for social competence. At the same time, this stage of life is characterized by an increasing appeal to an independent way of social functioning. The severe consequences of a discrepancy between limited social skills and social desires and expectations both from the adolescent and his social network give rise to the investigation of the trainability of the cognitive components of social in adolescents with limited social skills. The research questions in this study are: 1) Can social competence in adolescents with a weak developed social competence be strengthened? And 2) which factors are predictive of the effectiveness of the training of social skills?

Although it is known that social competence depends on interacting, biological, psychological and social factors associated with the maturation of the brain, the cognitive functions and behaviour, under the influence of the environment, there is currently no clinical offer when it comes to 1) trainings that focus on the underlying cognitive building blocks of social competence and 2) trainings that focus on adolescents with weak social competence.

A new training will therefore be developed on the basis of the scientific knowledge available on the cognitive functions and skills that are necessary for development of social competence. The effect of the training is determined by means of adolescents with high-functioning Autism (HFA) and adolescents with Klinefelter's syndrome (SK) because serious limited social competence is a key symptom of both disorders. It is important to examine the possibility of training in these adolescents because there is a clear discrepancy between their need for social contact and their lack of social competence. Determining the predictive value of the cognitive profile for the effectiveness of the training, more specific will contribute to a training that is well suited to the competences of the adolescent and will therefore contribute to saving up time and effort for both the adolescent and the therapist.

Study objective

In this study, three main hypotheses are tested. The first hypothesis focuses on the expectation that an intervention aimed at training cognitive components of social competence affect the level of social competence and well-being of adolescents with high functioning autism or Klinefelter's syndrome. Effects are measured using behavioral questionnaires for participants, parents and/or third parties, through a diary method for participants and physiological measurements using heart rate variability, skin conductance, motion and temperature recording and measurement of cortisol in saliva.

The second hypothesis tests the expectation that an intervention aimed at training of cognitive functions that underlie social competence has a positive effect on the neurocognitive and social cognitive components of social competence of young people with high functioning autism or Klinefelter's

syndrome. Effects are measured by social cognitive and neurocognitive tests and of measurements of visual social attention using EyeTracking. The third hypothesis aims at understanding of the social cognitive and neurocognitive functions that predict the effect of participation in the training.

Correlation between function and this effect can be determined by means of questionnaires for participants, parents and/or third parties and on the basis of tests for higher order social cognitive and neurocognitive functions.

Study design

Randomized controlled trial (RCT) with repeated measures.

Intervention

A group-oriented training aimed at improving social competence by influencing social cognitive and neurocognitive components of social competence consisting of 10 training sessions and 2 information sessions for families.

Study burden and risks

Benefits for the participants exist of the participation in a new training aimed at improving social competence. Loss of group effects, participation delivers an insight in the profile of strengths and weaknesses regarding social competence and its building blocks. The result of this increased knowledge could be that the participant wants more information or guidance. In that case, he/she is invited for a follow-up conversation with the trainer. When this question arises after expiry of the research the participant is redirected to his therapist. The main objective of this research, determining the effectiveness of a selfmanagementtraining on social competence, has a direct impact on the participant since he can directly benefit from the results of the research by an increase of his level of knowledge.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- 1) Adolescents (age 14-25) with
- 2) Autismspectrumdisorder, Aspergersyndrome or PDD-NOS (determined by ADOS or ADI) of Klinefeltersyndrome (determined by karyotype)
- 3) TIQ > 80

Exclusion criteria

- 1) TIQ < 80
- 2) No sufficient knowledge of Dutch language
- 3) History of closed-head injury

Study design

Design

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial
Masking: Open (masking not used)

Primary purpose: Treatment

Recruitment

NL
Recruitment status: Recruiting
Start date (anticipated): 01-12-2012
Enrollment: 140
Type: Actual

Ethics review

Approved WMO
Date: 16-10-2012
Application type: First submission
Review commission: METC Leiden-Den Haag-Delft (Leiden)
metc-ldd@lumc.nl

Approved WMO
Date: 12-02-2015
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register

CCMO

ID

NL39057.058.12