

Effectiveness of Alles Kidzzz: an indicated preventive intervention for externalizing problem behavior in school age children

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| Ethical review | Approved WMO |
| Status | Recruitment stopped |
| Health condition type | Other condition |
| Study type | Interventional |

Summary

ID

NL-OMON31717

Source

ToetsingOnline

Brief title

Effectiveness of Alles Kidzzz

Condition

- Other condition

Synonym

externalizing problem behavior; aggressive behavior

Health condition

externaliserend probleemgedrag van kinderen

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Utrecht

Source(s) of monetary or material Support: ZonMW 80-82405-98-027;programma Zorg voor Jeugd

Intervention

Keyword: externalizing problem behavior, indicated preventive intervention, parent management training, social skills training

Outcome measures

Primary outcome

Main parameters are decline of externalizing problem behavior and aggression and increase of pro-social behavior.

Secondary outcome

Alles Kidzzz attempts to influence theory-relevant and empirically proven risk and protective factors for the development of anti-social behavior: increase of competence in children, promoting anger reduction, thinking and acting in a less aggressive and more assertive and pro-social way. Alles Kidzzz selects intervention modules tailor-made based on a competence analysis of the child.

We investigate whether Alles Kidzzz will also stimulate parents to approach their child in a more positive way at home (more positive parenting and less negative parenting).

With the Parent Management Training Ouders als Coach, the aim is to influence parenting behavior more directly: we expect to see more positive and less

negative parenting behavior for parents in this condition at follow-up.

We consider the child outcomes self-esteem and social-information processing and the parent outcomes positive and negative parenting as mediators in this study.

Finally we will determine circumstances in which Alles Kidzzz yield or does not yield beneficial outcomes by examining possible moderators of treatment effectiveness: child characteristics (gender, IQ), family characteristics (ethnicity, family structure, SES), school features (situation in city or village, religious background, size of school and class, teacher/child ratio, special school wide programmes for social skills like ****Vreedzame school****) and treatment integrity (attendance, involvement of child, parent and teacher).

Study description

Background summary

According to several longitudinal studies an elevated level of externalizing problem behavior (prevalence 5-10%) in elementary school is relatively stable and predictive of poor mental health. These children are more at risk for developing a Conduct Disorder (CD) and delinquency in adolescence, CD with a co-morbidity of mood disorder and substance abuse in adulthood, and the longitudinal societal costs are largely elevated. Whereas in a recent meta-analysis parent-management-training (PMT) as well as child cognitive-behavioral treatment (CBT) both proved to be effective interventions, in the Netherlands an evidence based indicated preventive intervention for externalizing problem behavior in school is lacking. Alles Kidzz (AK), a manualized individual social skills training based on the principals of the cognitive behavior therapy, for 9- to 12-year-old children with externalizing behavior problems has been developed by Dutch mental health care centers and has been implemented in schools. A quasi-experimental pilot study showed

promising results in terms of decrease of externalizing problems.

Study objective

The purpose of this study is to evaluate in a Randomized Controlled Trial (RCT) study the effectiveness of AK alone and in combination with parent-management-training (PMT). The PMT component is added because parental involvement increases effectiveness of individual child interventions. We hypothesize that 1) children receiving AK will show less externalizing behavior and more pro-social behavior after intervention and at follow up, compared to children in the control condition and; 2) effectiveness will be moderated by several child, family and school factors and mediated by child social information processing, parenting behavior and parental involvement and treatment integrity and 3) effectiveness of AK plus PMT on child outcome will be more enduring at follow-up compared to AK alone, whereas parents receiving individualized PMT after AK training will show more positive and less negative parenting behavior at follow-up compared to parents in the AK only and in the control condition.

Study design

The RCT design is an intervention study (pre- and post measurement, follow-up at 6 and 12 months after intervention) with two experimental conditions a) AK alone and b) AK plus PMT and c) a non-intervention control condition. Participating schools (n = 48) are randomized into three groups of 16, and each school participates in each condition in a prescribed order during three years. Every year two children per school participate (N= 288 children; N=192 parents in PMT).

Intervention

(1) AK: children receive an individualized manualized training programme during school time at school during 8 weeks; parents and teachers are weekly involved receiving a written report. At start, after three weeks and after completion parents are informed orally by the trainer. (2) PMT (Parents as Coach): after completion of AK, parents receive a written manual and are contacted every week for 8 weeks by telephone or email or home visit (if necessary) by their child*s trainer.

Study burden and risks

Without these child participants the study could not be executed. We aim to study the intervention in a way as close as possible to the regular practice; trainers are encouraged to perform in the same way as they are used to for years now. The aim of the study is to keep the burden of the research demands as minimal as possible for all involved (schools, teachers, parents, children, trainers). Questionnaires for teachers, children, parents and trainers are

added at four moments during 1,5 years. Protocols for research demands (contact with parents, dosage of information, informed consent forms, questionnaires etc) are developed in close consultation with trainers and schools. The risks are negligible using well known world wide used questionnaires. Benefit of the study hopefully will be an evidence-based effective intervention for a recognized important every day problem in school age children.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Children (2-11 years)

Elderly (65 years and older)

Inclusion criteria

The teacher of every 4th grade class of a participating school nominates 3 to 6 children showing an elevated level of externalizing problem behavior. For each of these children the teacher fills in the TRF (Teacher Report Form, Achenbach, 1991). The 2 or 3 children with the

highest scores (when $T > 60$) per class on the TRF externalizing scale will be included in/selected for the study.

Exclusion criteria

Diagnosed Autism Spectrum Disorder; Participation outside school in social skills training provided by a mental health institution

Study design

Design

| | |
|---------------------|-----------------------------|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |

Primary purpose: Prevention

Recruitment

| | |
|---------------------------|---------------------|
| NL | |
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 10-12-2008 |
| Enrollment: | 480 |
| Type: | Actual |

Ethics review

| | |
|--------------------|---|
| Approved WMO | |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |

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 | ID |
|-----------------|----------------|
| CCMO | NL19535.041.08 |