ADHD: Medication or Meditation?

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The comparison of the effects (and cost effectiveness) of mindfulness training for the child + Mindful Parenting for the parents versus medication (Methylphenidate) in a randomized controlled trial (RCT) in children with ADHD, aged 9-18.

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

Summary

ID

NL-OMON44743

Source
ToetsingOnline

Brief title
My child has ADHD: Meditation or Medication?

Condition

- Cognitive and attention disorders and disturbances

Synonym
ADHD (Attention Deficit Hyperactivity Disorder)

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Amsterdam
Source(s) of monetary or material Support: NWO subsidie Onderzoekstalent

Intervention

Keyword: 1. Childhood ADHD, 2. Ritalin/medication, 3. Mindfulness training

Outcome measures

Primary outcome

Attention problems (also hyperactivity and impulsivity) as reported by the

parents, child, teacher, and test observer.

Secondary outcome

Symptoms of anxiety, depression, social functioning, stress, tiredness and

quality of life.

Study description

Background summary

Medication is the first choice intervention in the treatment of children and youngsters with ADHD. Methylphenidate works for around 70% of the children. However, for around 30% it does not work, many parents prefer their child not to take medication, the effects are often only short-acting and compliance is often low. It is therefore undesirable that medication is prescribed for (young) children when other effective alternatives are available. Pilot studies show that the effects of mindfulness training for children and youngsters with ADHD (and their parents) are very promising. However, it is unclear how these effects are compared to the effects of medication.

Study objective

The comparison of the effects (and cost effectiveness) of mindfulness training for the child + Mindful Parenting for the parents versus medication (Methylphenidate) in a randomized controlled trial (RCT) in children with ADHD, aged 9-18.

Study design

A RCT with a pre-test, a post-test and two follow-up measurements. After the pre-test participants are randomized. Treatment in both study arms will take 8-9 weeks followed by a post-test. Subsequently, treatment in the medication group continues another block of 8-9 weeks while participants in the mindfulness group will not receive treatment (this is conform regular mindfulness training). Mindfulness training follows the MYmind protocol and in

the treatment with methylphenidate guidelines of the Trimbos institute are followed. Subsequently the first follow-up measurement takes place. After this, participants are free to choose which treatment they want to receive, if any. Thus, at this point in the study -after 16-18 weeks- they have the choice to swap treatment allocation if they wish so. After nine months the last follow-up measurement takes place in order to get an idea about the long term effects of both interventions. In this study four informants are included (parents, children, teachers and test observers) as well as self-reports but also independent neuropsychological and computer tasks (mostly targeting the measurement of attention).

Intervention

The mindfulness training for children consists of 8-9 weekly group meetings of 1.5 hours. Parallel to this parents participate in the weekly Mindful Parenting training which also takes 1.5 hours each time. Children and adolescents are split into different groups (roughly 9-12 year olds and 13-18 year olds are placed together). Children in the medication group are first titrated to their optimal dosage under supervision of a child psychiatrist. After this they take methylphenidate daily for a period of 8-9 weeks (see medication guidelines "Multidisciplinaire richtlijn ADHD" Trimbos instituut) combined with 2 parent guidance sessions focusing on psycho education about ADHD. Parents in both groups receive the same psycho education about ADHD. In the second block of 8-9 weeks children and parents in the mindfulness group don't receive treatment (they are however encouraged to practice at home) apart from the booster session after 8-9 weeks, and the children in the medication group continue to receive daily methylphenidate, this time not combined with parent guidance sessions.

Study burden and risks

Children in the mindfulness group participate in 8-9 weekly group sessions, lasting 1.5 hours in a group of 6-8 children. In addition children are asked to practice 15-20 minutes daily at home. After the first block of 8-9 weeks a period of 8-9 weeks follows with no training for these children apart from the booster session after 8-9 weeks. Parents participate in the parallel Mindful Parenting training which is 1.5 hours a week. In adittion parents are requested to practice 20-30 minutes daily at home. Our clinical impression as well as scores on evaluation forms and questionnaires in the current mindfulness studies show that the burden is minimal. Participants report a decline in complaints, more peace of mind, like the yoga exercises, and they are well informed before the training starts of what the training will involve. In general this is considered as reasonable. Compliance in the mindfulness training for children as well in the Mindful Parenting training for their parents is high so far. Questionnaires can be filled in online at home. For the computer tasks children need to visit the treatment center. They receive a

small reward/incentive for this. Participation in the mindfulness training does not carry any risks. The mindfulness intervention in this project is carried out the same way as in the project "Mindfulness in child and adolescent psychiatry" for which the METC has previously granted permission.

Participants in the medication group experience the same extent of burden with respect to filling out questionnaires and computer tasks as the participants in the mindfulness group. We presume that, for reasons mentioned above, that this is a reasonable burden. Before the start of treatment they need to visit the child psychiatrist a few times to titrate to the optimal dosage of methylphenidate. In this titration period parents and children also keep a record of the side effects (as well as teachers). After this parents will receive 2 parent guidance sessions of a maximum of 1 hour each time, in the first block of 8-9 weeks treatment with methylphenidate. Children take methylphenidate daily. In the second block of 8-9 weeks children keep taking the medication but parents receive no further parent guidance sessions apart from a booster session after 8-9 weeks comparable to the one in the mindfulness group. The burden or risks in this group consist of the possible side effects of methylphenidate on the sleeping, the appetite, and the growth. However, extended literature shows that these side effects are limited in severity and Ritalin is prescribed world wide in the treatment of ADHD. Since methylphenidate is so widely used we assume that the side effects are not harmful and when parents don't want their child to take medication, they always have the right to refuse participation in this project and still receive treatment for their child.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

- The child is between 9 and 18 years of age (also turning 9 during time of study)
- The child has a primary DSM classification of ADHD
- ADHD is verified by standardized structured DSM interview
- (Estimated) IQ is over 80
- At least one parent is willing to participate in the Mindful Parenting training

Exclusion criteria

- (Estimated) IQ is below 80
- Suicidal risk
- Suffering from psychosis, schizophrenia, or untreated PTSD
- Co morbid conduct problems that are so severe, already during intake, that interaction/talking between parent and child is not possible.
- Current or previous use of methylphenidate in the past month
- Current or previous participation in mindfulness training in the past month
- Participation in a currently active other psychological intervention

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-05-2014
Enrollment:	150
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Ritalin
Generic name:	Methylphenidate
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	17-01-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-03-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Not approved Date:	25-11-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2013-003888-59-NL
CCMO	NL46168.018.13
Other	nog onbekend