# Trial implementation of an Item response Based Computerized Test for psychosocial Problems in Dutch Preventive Child Health Care for Children Aged 7-12

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON32045

**Source**
ToetsingOnline

**Brief title**
Trial implementation of an IRT based CAT

### Condition

- Other condition

**Synonym**
emotional and behavioural problems, Internalizing and externalizing problems

**Health condition**

psychosociale problemen

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** TNO
**Source(s) of monetary or material Support:** ZonMw

## Intervention

**Keyword:** Child Health Care, Computerized Adaptive Test, Identification, Psychosocial problems

## Outcome measures

### Primary outcome

Overview of factors, based on the implementation model of Fleuren (2004) which

may be considered relevant for a succesful adoption and implementation of a CAT

in Dutch PCH

Data on the validity (sensitivity, specificity) of the CAT in daily PCH practice

Data on the results of early detection based on the CAT in terms of number of

correctly identified cases and cases for whom follow up was undertaken

### Secondary outcome

not applicable

# Study description

### Background summary

-The project is a follow up on a previous successful study in the ZonMw program *Prevention* and is a necessary step in valorising the results of this. The primary aim of this study is to establish which factors are important for a successful implementation of a newly developed effective instrument for the detection of children with psychosocial problems. Additionally the proposal aims to test in real life how effective the method is in improving detection by JGZ. The project also aims to determine the efficiency in terms of demand

placed on the parents (number of questions to be answered) and the ease of use for the JGZ (for example in terms of a higher specificity of the findings and the time saved).

-Benefit to society
Society can benefit considerably from this project. Psychosocial problems are highly prevalent and a good early detection increases the chance of an effective treatment and a healthy development. This project aims to realize a fundamental improvement in the quality of this detection using methods that have already demonstrated their potential. Successful implementation will therefore result in an improved detection and a more specific advice to and/or referral of (parents of) the children. Moreover, a good detection by the JGZ prevents the referral of children who do not have serious problems. The introduction of this method is therefore a way of implementing the recommendations of the Invent group. The method is cost-effective for the JGZ, as no time needs to be spent on manual scoring. In the future, the results of the measurement can be automatically incorporated in the Electronic Child File (Dutch acronym EKD for Elektronisch Kind Dossier).

-Improved efficiency and effectiveness compared to standard alternatives
Questionnaires the JGZ currently uses and the questionnaires currently being developed are based on traditional psychometry. For practical reasons the JGZ cannot use long questionnaires and short questionnaires are less sensitive and specific. Also they only provide global information: the exact severity and, as subscales are even less reliable, the precise nature of the problem remain unclear. A CAT can therefore lead to a considerable improvement in the quality and effectiveness of detecting psychosocial problems.

**Study objective**

Aim of the project is to determine whether it is possible to implement a CAT for the identification of children with psychosocial problems in Dutch JGZ. Additionally the study will evaluate the CAT as it is being used in practice. The trial implementation will be evaluated and the following questions will be answered.
1. Which factors can facilitate or impede a successful implementation of an IRT CAT such as that which has been developed;
2. Can the validity of the IRT CAT as established in the simulation study be replicated in real life and;
3. Does the use of the method result in an improved detection and more specific follow-up actions by JGZ.
Based on these results regarding the first question an implementation strategy well be developed, after which the trial implementation will be carried out. During this trial, additional information on factors relevant for implementation will be gathered, mainly based on actual experiences of individual users with the application.

**Study design**

The study design has four phases:

1 Survey of factors relevant for a succesful adoption and implementation
2 Development of an implementation strategy
3 Trial implementation
4 Analysis and reporting.

Phase 1: Survey of factors relevant for a succesful adoption and implementation
In the first phase four workshops will be organized, spread over the Netherlands, during which we will discuss relevant implementation factors with Preventive Child Health Care (PCH) professionals. This after a presentation of the CAT as it was developed. The discussion will be structured using the implementation model of Fleuren et al (2004). Questionnaires, based on the same model will be used to stimulate the participants.

Phase 2: Development of an implementation strategy
The work in this phase is strongly dependent on the results of phase 1, but will include the development of a training for a co-ordinating staff member of each individual PCH centre that will participate in phase 3 and of trainings for each individual staff member who will participate. The existing application may need some adaptation and possibly UMTS laptops need to be made available, in order to enable the CAT to be completed on the PCH centre, in stead of at home.

Phase 3: Trial
After training participating PCH professionals will send parents a letter, asking them to co-operate in the study. Only parents who are invited for a regular health check up will be invited for the study. Parents are asked to fill in and sign an informed consent form and to give that to the PCH professional.
When parents are willing to cooperate they have to fill in a paper and pencil questionnaire and, if possible, the CAT via the internet. The questionnaire consists of the Child Behavior Checklist (CBCL) which is used as the primary criterion measure. It also contains a limited set of demographic questions. Finally, those parents who answered the CAT will be asked how they valued it. Parents who did not answer the CAT, will be asked, why not.
The questionnaires are put in a closed envelope, anonymously, but with a code enabling linking information from the parents to information provided by PCH (see below). The envelopes are returned, unopened, to TNO by PCH.
During the regular health examination, PCH professionals use the results from the CAT for their assessment of the presence of psychosocial problems. They register whether such problems are present and also which follow up actions are undertaken. When parents are not willing to participate, they register their

reasons and some demographic characteristics, but only if parents allow them to do so.
Each participating PCH professionals rates the extent to which the CAT contributed to the assessment, after 30 health examinations each. These ratings are not linked to individual children.

After completion of the trial a workshop will be organized during which the experiences with the CAT will be evaluated and possible improvements are determined.

Phase 4: Analysis and reporting
De results of the workshops will be described, using descriptive statistical analyses of the questionnaires answered during the workshops. ROC analysys between CAT results and CBCL data (dichotomized, first criterion measure) will establish sensitivity, specificity and Area Under Curve.
We will establish the number of cases for whom psychosocial problems are detected and for whom follow up actions will be undertaken. It will be tested whether these percentages exceed those found in an earlier study among children aged 7-12 (Vogels et al, 2005)

**Study burden and risks**

The study takes place in the context of the regular health examination for which children in the age of 7-12 are regularly invited. For the purpose of this study, their parents will be asked to fill in a written questionnaire (about 150 items) and, if possible, to answer the CAT via the Internet (35 items at most). It is estimated that this will take up to 30 minutes and implies no risk.

# Contacts

**Public**
TNO

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**Scientific**
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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

parents of children aged 7 to 12 who are invited to the regular helath examination by Dutch Preventive Child Health care

## Exclusion criteria

parents from children below 7 or above 12

# Study design

## Design

**Study type:** Observational non invasive

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 15-03-2008 |
| Enrollment: | 955 |

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| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 24-10-2008 |
| Application type: | First submission |
| Review commission: | METC Leids Universitair Medisch Centrum (Leiden) |

## 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 | NL23252.058.08 |