# Family Check-Up. A pilotstudy of a preventive family intervention for youth with behavioral and/or emotional problems in regular and special educational schools.

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1. To develop a Dutch version of the FCU, adapted to the Dutch cultural context and target group of youth with psychological and/or behavioral problems in regular and special education2. To evaluate the implementability of the FCU in the Netherlands...

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

# Summary

## ID

NL-OMON44228

**Source** ToetsingOnline

Brief title Family Check-Up

## Condition

• Other condition

### Synonym

Substance use; psychosocial problems

### Health condition

middelengebruik en psychosociale problemen

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#### **Research involving** Human

Sponsors and support

**Primary sponsor:** Trimbos-instituut **Source(s) of monetary or material Support:** FNO

## Intervention

Keyword: family intervention, prevention, substance use, vulnerable youth

## **Outcome measures**

#### **Primary outcome**

Family conflict (child report for 10-14 year olds, parent report for 6-9 year

olds). The instrument has been succesfully applied in earlier studies on the

FCU in the U.S.

### Secondary outcome

Parenting, monitoring, schoolperformance, coping, psychological and behavioral

problems, relationship with peer, psychological health of the parents.

# **Study description**

### **Background summary**

In the Netherlands, evidence based, preventive family interventions for children with emotional or behavioral problems, that are short and accesible, are scarce. Youthcare organisations have expressed the whish to improve the care for those families by a more outreaching approach. For that, they need a protocolled, low threshold and evidence based method, which also reaches 'difficult' groups like low SES families and ethnic minority families. The Family Check-Up, which is developed in the USA, seems to be a promising approach for this purpose. In this project we aim to adapt the Family Check-Up to the Dutch context en target group and to assess the implementability and the effects.

### **Study objective**

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1. To develop a Dutch version of the FCU, adapted to the Dutch cultural context and target group of youth with psychological and/or behavioral problems in regular and special education

2. To evaluate the implementability of the FCU in the Netherlands in order to be able to support and advise on a possible wider implemention of the FCU in the Netherlands in the future

3. To assess the effects of the FCU on family factors (which are expected to mediate the effects of the FCU on alcohol use and smoking) among youth (6-14 years) with mild intellectual disabilities and/or psychological and/or behavioral problems.

## Study design

In order to study the three aims we wil use:

Ad 1: Intervention mapping Ad 2: Procesevaluation Ad 3: Pre-post design (75 families, 2 follow-up measurements at 3 and 6 months).

## Intervention

The Family Check-Up is a short family intervention consisting of 3 sessions: (1) interview (2) assessment (3) feedback session. Both child and parents take part in all three sessions.

## Study burden and risks

Three sessions of one hour each and two follow up measurements consisting of a questionnaire for both child and parent of approx. 20 minutes. The sessions and administration of the quesionnaire will take place at the home of the family. The risks for negative effects are considered very small (also based on experiences with the FCU in the US).

# Contacts

**Public** Trimbos-instituut

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Da Costakade 45 Utrecht 3521 VS NL

# **Trial sites**

## **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

Adolescents (12-15 years) Adolescents (16-17 years) Adults (18-64 years) Children (2-11 years) Elderly (65 years and older)

## **Inclusion criteria**

Adolescent:

- 6-14 years
- emotional and/or behavioral problems and/or borderline or mild intellectual disability,
- 6 t/m 14 jaar
- Emotionele en/of gedragsproblemen bij het kind

• Sterk vermoeden dat ouderfactoren een rol spelen in de problematiek of kunnen bijdragen aan het oplossen daarvan

## **Exclusion criteria**

A caregiver assesses the problems of the adolescent and his/her family. When these problems are too complex, the Family Check-Up will not be offered. These families will be referred to more intensive types of care.

# Study design

## Design

| <b>Study type:</b> Interventional<br>Masking: | Open (masking not used) |
|-----------------------------------------------|-------------------------|
| Control:                                      | Uncontrolled            |
| Primary purpose:                              | Prevention              |

## Recruitment

| NL                        |                     |
|---------------------------|---------------------|
| Recruitment status:       | Recruitment stopped |
| Start date (anticipated): | 24-10-2017          |
| Enrollment:               | 75                  |
| Туре:                     | Actual              |

# **Ethics review**

| Approved WMO<br>Date: | 14-09-2017       |
|-----------------------|------------------|
| Application type:     | First submission |
| Review commission:    | METC NedMec      |
| Approved WMO<br>Date: | 25-10-2017       |
| Application type:     | Amendment        |
| Review commission:    | METC NedMec      |
| Approved WMO<br>Date: | 14-12-2017       |
| Application type:     | Amendment        |
| Review commission:    | METC NedMec      |

# **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

ССМО

**ID** NL61692.041.17