

# 'You are okay'

No registrations found.

|                              |                  |
|------------------------------|------------------|
| <b>Ethical review</b>        | Positive opinion |
| <b>Status</b>                | Recruiting       |
| <b>Health condition type</b> | -                |
| <b>Study type</b>            | Interventional   |

## Summary

### ID

NL-OMON21135

### Source

NTR

### Brief title

COPMI

### Health condition

Mild Intellectual Disability (ID), Mental Illness, Substance use disorder, psychopathology in parents

## Sponsors and support

### Primary sponsor: Initiator:

Pluryn Research & Development

Postbus 53

6500AB Nijmegen

### Source(s) of monetary or material Support: ZonMw

Anthona Wilhelmina Fonds

## Intervention

## Outcome measures

### Primary outcome

Feelings of competence in children

Emotional and behavioural problems in children

## **Secondary outcome**

Social support in children and parents

Feelings of parental competence

Involvement of parents with their child

Parenting behaviour

## **Study description**

### **Background summary**

In this randomized controlled trial the effectiveness will be studied of a support group-intervention for children with mild intellectual disabilities (ID) of parents with mental health problems in combination with an online intervention for parents. The intervention group will be compared to care as usual. Children in the experimental group receive ten weekly sessions and a booster session. Parallel to the child sessions, their parent will be offered two online individual sessions. Measurements take place before start, after ten weeks and after three months. We expect that children in the experimental group show an increase in feelings of competence and a decrease in behavioural and emotional problems. We also expect an increase in parental involvement with their child's treatment and feelings of parental competence. The aims of the intervention for children are to increase children's knowledge about the mental health problems of their parent, to increase children's knowledge about basic feelings and emotions, to increase children's social skills and coping skills and to increase children's awareness about their social network. The aims of the intervention for parents are to increase parents knowledge about possible influence of their problems on their child, to increase parents communication skills, to increase parents awareness about their social network and to increase parents awareness of positive parenting behaviour.

### **Study objective**

COPMI (Children of Parents with a Mental Illness) have an increased risk for developing problems themselves. A low IQ is an extra risk factor for developing psychosocial problems. By offering a support-group intervention for children with mild intellectual disability (ID) and a short online intervention for their parents, we expect an increase in risk factors and a decrease in protective factors. In children we expect an increase in feelings of competence and a decrease in emotional and behavioural problems. In parents we expect an increase in feelings of competence and involvement with their child. Hypothesis is that the combined program 'you are okay' for children and parents will be more effective on these goals than

care as usual.

## **Study design**

1. Baseline
2. 10 weeks
3. 3 months

Measurements:

- Children's feelings of competence (CBSA) (self worth and social acceptance)
- Children's COPMI specific feelings of competence (self-developed questionnaire)
- Children's emotional and behavioural problems (SDQ)
- Children's social support (NRI)
- Parent's Involvement with their child (question 1-10)
- Parenting behaviour (Parenting scale)
- Parent's feelings of parental competence (OO&O)
- Severity of the premental health problems parents (BSI)
- Well-being of parents (WHO-5)
- Social support parents (NRI, SSL)

## **Intervention**

'You are okay':

An existing evidence-based support group-intervention for children of parents with a mental illness or substance use disorder was adapted to the needs of children with mild ID. In this support group intervention, children meet in ten sessions and a boostersession. In these sessions, children learn several skills to cope with difficult situations according their parent with problems. They provide each other with support and practice new skills through for example, role playing games. By practising these skills, we expect that their feelings of competence will increase. Each session has a different theme, such as basic emotions, coping with difficult situations and social skills.

Parallel to the support-group intervention for the youngsters, their parents are offered a short online intervention of two sessions. This online intervention is also an adaptation of an intervention which is offered to parents of children without ID. In the two online sessions parents receive psycho-education, discuss their role as a parent and learn about the possible influence of their problems on their child. Parents are supported by completing the sessions if necessary.

## Contacts

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## Eligibility criteria

### **Inclusion criteria**

- Youngsters between ten and twenty years old with a mild intellectual disability.
- At least one of the parents has mental health problems or a substance use disorder. The parent recognizes these problems.
- When youngsters are in any kind of treatment facility or residential care, their lives should have reached some stability in order to be able to reflect on their parent's illness. Hence, we only include youngsters in this study who are at least one year in treatment .

### **Exclusion criteria**

- Youngsters who have severe emotional or behavioral problems which impede participation

in a group intervention.

- Presence of a crisis situation

- Risk for loyalty conflicts between children and parents (e.g. parent is aversive about the child discussing the parent's illness with others).

## Study design

### Design

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

### Recruitment

|                           |             |
|---------------------------|-------------|
| NL                        |             |
| Recruitment status:       | Recruiting  |
| Start date (anticipated): | 01-11-2014  |
| Enrollment:               | 80          |
| Type:                     | Anticipated |

## Ethics review

|                   |                  |
|-------------------|------------------|
| Positive opinion  |                  |
| Date:             | 09-10-2014       |
| Application type: | First submission |

## 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                        |
|----------|---------------------------|
| NTR-new  | NL4416                    |
| NTR-old  | NTR4845                   |
| Other    | ZonMw : 70-72900-98-13201 |

## Study results