KOPPeling: help from within

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Primary Objective: The aim of the study is to investigate the effect of KOPPeling. Therefore, the primary objective of the study is to answer the following question: 1) To what extent does KOPPeling lead to an increase in QoL among COPMI? Secondary...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON55897

Source
ToetsingOnline

Brief title
KOPPeling

Condition

- Other condition

Synonym
Children Of Parents with a Mental Illness (COPMI), Parents with mental illness

Health condition

Psychiatric conditions interfering with the fulfillment of parental tasks

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: COPMI, mental illness, prevention, social participation

Outcome measures

Primary outcome

The main study parameter is the QoL of COPMI, which will be assessed with the KIDSCREEN-27 (6).

Secondary outcome

The secondary study parameters are:

1) The psychological complaints of COPMI, which will be assessed with the Strengths and Difficulties Questionnaire (SDQ), which psychometric properties are rated sufficient to good (7,8)

2) The parental stress of COPMI parents, which will be assessed with the Nijmeegse Ouderlijke Stress Index (NOSI-K) (11), which is an adaption of the Parenting Stress Index (12)

3) The engagement in outdoor activities of COPMI, which will be assessed with an Ecological Momentary Assessment diary (EMA) (10)

4) The associated guilt when engaging in outdoor activities and shame of COPMI, which will be assessed within the EMA, which will be assessed with a validated shortened version of the Guilt and Shame Questionnaire for Adolescents of Parents with a Mental Illness (9) and additional questions

5) The experiences of the social network with KOPPeling, which will be assessed in a qualitative interview with a purposive sample of individuals taken from the social networks of included families

6) The experiences of family members with KOPPeling, which will be assessed in a qualitative interview with a purposive sample of individuals taken from families of the intervention group

7) The promoting and hindering factors for making the intervention widely applicable, which will be assessed with the Measuring Instrument for Determinants of Innovations (MIDI) (13)

8) The long-term effects of KOPPeling by re-assessing the effect of KOPPeling on the parental stress of COPMI parents and psychological complaints and QoL of COPMI three months after the intervention ended

Other study parameters (if applicable)

Other study parameters include socio-demographic data, such as age, gender of each family member participating in KOPPeling, family constellation, diagnosed psychiatric conditions, and family socio-economic status (SES) indices.

Study description

Background summary

The Netherlands has more than 550,000 children of parents with mental illnesses (COPMI) (1). COPMI are at risk of parentification, which term is used to describe the role reversal between parents and their offspring, whereby the offspring is taking over the parental role (2). This includes overtaking logistic and household, but also emotional tasks. Due to loyalty to their parents, parentified children often try to fulfil all the emotional and household tasks, at the expense of their own well-being and time. The emotional burden of their parents* mental illness causes children to stay at home as they want to watch over their parents. Often, COPMI feel unfree to leave their parents unattended. When COPMI engage in free-time activities, they might feel

guilty leaving their parents unattended. However, the engagement in free-time activities contributes to the socio-emotional development of children. Insufficient socio-emotional development has been found to be a risk factor for the development of psychiatric conditions and negative life outcomes (3). Up to two thirds of COPMI have developed an anxiety or mood disorder themselves in their thirties (4), proposing a circle of parentification and psychiatric conditions through generations.
While genetic factors associated with the development of psychiatric conditions are difficult to alter, interventions can help to reduce environmental factors associated with the development of psychiatric conditions, such as parentification. A pedagogical civil society, defined as the communal activities of the entire society, which focuses on raising children (5), can establish a supportive safety network for COPMI. This network does not only include family members and friends, but also staff members of schools, youth work organisations and the municipalities. Within such supportive networks, COPMI are relieved from parentification but also receive the necessary emotional support. The relief from parentification, but also the emotional support, contributes to a positive socio-emotional development, which in turn can buffer the development of psychiatric conditions. Interventions supporting COPMI families exist. However, the uptake of these interventions, such as free childcare- and after-school care for COPMI families, is low. One of the reasons is that parents are reluctant to ask for help, due to shame or the condition itself. Beyond this, COPMI families often remain undetected although COPMI and their parents are often treated within mental health care institutions. The effects of the disorder on the family functioning are often not discussed within treatments which implies that clinicians are not aware of the potential impact of the condition on COPMI. Furthermore, COPMI often remain loyal to their parents and do not talk negatively about the home situation.

To overcome these issues, KOPPeling (Dutch for COPMIling) has been developed in collaboration with experts and clinicians. KOPPeling is an intervention activating the social network. KOPPeling aims at activating the social network of COPMI families so that family, neighbours, friends or other members of this network can take over tasks that parents are unable to perform themselves. In this way, COPMI are relieved of parental tasks and can give priority to spending time on activities that are important for their socio-emotional development. To assure the uptake of this intervention, we developed a screening test that aims to make professionals more aware of the vulnerable situation of COPMI and that helps in offering KOPPeling to these families.

We hypothesize that KOPPeling leads to various improvements, including an increase in Quality of Life, a reduction of psychological problems, and an increase in engaging in outdoor activities without feeling guilty among COPMI, but also a reduction in parenting stress and guilt among the parents. In this study, we will test whether KOPPeling is an effective intervention for COPMI families and what is needed to make KOPPeling a widely applicable and

sustainable intervention.

Study objective

Primary Objective:
The aim of the study is to investigate the effect of KOPPeling. Therefore, the primary objective of the study is to answer the following question:

1) To what extent does KOPPeling lead to an increase in QoL among COPMI?

Secondary Objectives:
Furthermore, this study aims to answer the following questions:

1) To what extent does KOPPeling lead to a decrease in psychological complaints among COPMI?
2) To what extent does KOPPeling lead to a reduction of parenting stress among COPMI parents?
3) To what extent does KOPPeling lead to an increase in outdoor activities among COPMI?
4) How does KOPPeling affect the feelings of guilt of COPMI when engaging in outdoor activities?
5) What experiences have the social networks had with KOPPeling?
6) What experiences have the family members had with KOPPeling?
7) What pre-conditions are needed to make KOPPeling widely applicable?
8) What are the long-term effects of KOPPeling on the QoL and psychological problems among COPMI and parental stress among COPMI parents?

Study design

The design of the study is a Randomized Clinical Trial with a waiting list control group. The waiting list control group will receive the intervention after ten to twelve weeks. A waiting list control group is used for comparison. The intervention lasts about ten to twelve weeks. The start of the intervention is set when the practitioner identifies that a parent has trouble fulfilling the parental role and children*s socio-emotional development might be at risk. To detect the situation, practitioners will use the so-called KOPP-check. The check includes questions like: are parents aware of the influence of their disease on family functioning, are the children aware of their parents* condition, are the parental mental health problems discussed in the family, are children already parentified or can they give priority to their own desires and needs above their parents* needs. In case of a positive screen, meaning potential risk for the children*s development, the clinician invites the family to participate in the intervention. If the family agrees to participate and the parents and children sign informed consent, socio-demographic data, and baseline measurements will be taken (T0). This includes the KIDSCREEN-27 (6), the Strengths and Difficulties Questionnaire (SDQ) (7,8), the Guilt and Shame

Questionnaire for Adolescents of Parents with a Mental Illness (9) and an EMA diary for children (10), that will be developed for this intervention, and the Nijmeegse Ouderlijke Stress Index (NOSI-K) (11) for the parents. For children younger than 4 years, we will not assess quality of life or psychological complaints. These assessments will be used to determine the effectiveness of KOPPeling on the afore-mentioned study parameters. Children aged 12 or older will participate in the diary study, within the first and last week of KOPPeling or waiting list. For ten to twelve weeks the family will receive the intervention. At the end of the intervention for families in the intervention group and after ten to twelve weeks for families in the control group (T1), the children and parents will fill in the questionnaires once again. After the intervention, a purposive sample of the families* social network members will be interviewed to discuss their experiences with KOPPeling, and professionals involved in the intervention will complete an implementation instrument, the MIDI (13), to establish what preconditions are needed to make KOPPeling a widely applicable intervention. Lastly, after three months, the family (families in the intervention group) will be invited again for a follow up meeting to discuss the current situation and experiences with KOPPeling within a qualitative interview and a re-assessment of the Quality of Life and psychological complaints among COPMI and parental stress among COPMI parents, i.e. the KIDSCREEN-27, the SDQ and the NOSI-K.

Intervention

The investigational intervention is the KOPPeling intervention.

The KOPPeling intervention consists of five phases listed in the following:

1) Psycho-educating the family on the impact of the psychiatric condition on the family dynamics, family functioning and the parenting, and on parentification
2) Identifying which tasks are performed within the family, who is currently performing the tasks and whether the task distribution is desirable
3)Identifying who belongs to the social network of the family and who from the network, as well as who from the municipality can be activated to support the family to unburden the child
4)Creating a week plan and distributing the tasks within the social network
5)Carrying out and evaluating the intervention

Per phase, one to three sessions of 60 to 90 minutes are needed. If needed, additional sessions can be planned in. The sessions can take place at home or at the aforementioned facilities, such as the UCP and GGZ Friesland locations. Children aged eight or older are invited to the sessions, excluding the first phase. The family may be asked to do homework assignments in preparation for the next phase or session. Although the intervention is not aimed at detecting or discussing child abuse or neglect, it may happen that abuse or neglect will be detected. In this case, the practitioners will follow the protocol of the

reporting core of the Kindcheck (14) and meldcode huiselijk geweld en kindermishandeling.

Study burden and risks

The potential benefits of this study, such as the improvement on QoL, psychological problems for COPMI and parental stress for COPMI parents are likely to outweigh the burden, which includes attending the sessions, doing the homework assignments, and filling in the questionnaires and diaries.

Contacts

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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)

Inclusion criteria

To be eligible to participate in this study, a subject, in this case the family, must meet the following criteria:
1) The family has children aged 0-18 living at home
2) The clinician detects that the parental disorder influences the parent*s (or parents*) ability to carry out several important parental tasks, placing their offspring at risk of taking over these tasks which would then harm the child*s development.
3) At least one of the family members need to be in treatment in one of the participating research centers

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
1) The family has no existing social network. Families without an existing social network will be referred to an intervention that is suitable for their situation
2) The family does not speak Dutch sufficiently

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-04-2024
Enrollment:	128

Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	16-11-2023
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Not approved Date:	05-06-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	30-10-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
ClinicalTrials.gov	NCT05829408
CCMO	NL83856.042.23