

(Economic) Evaluation of E-mental Health Interventions for Children of Parents with Mental Illness (e³ COPMI).

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Children of parents with a mental illness or substance use disorder have high elevated risks to develop (mental and behavioural) problems themselves. Hypothesis is that the online Kopstoring intervention will be effective and cost-effective...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27797

Bron

NTR

Verkorte titel

e³ COPMI

Aandoening

Mental Illnesses
Substance use disorders
Preventative trial

Ondersteuning

Primaire sponsor: ZonMW

prevention Programme

Overige ondersteuning: ZonMW

prevention Programme

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

For the Effectiveness study and Cost-effectiveness study: Reduction of symptoms and complaints as measured by the Youth Self Report Questionnaire will be used this is a self reported version of Child Behaviour Checklist.

Toelichting onderzoek

Achtergrond van het onderzoek

DESIGN: We will conduct a pragmatic randomized controlled trial (RCT) in two parallel groups. The Kopstoring program will be compared with a waiting list control condition which reflects Care-As-Usual. The duration of the interventions is 8 weeks and the total time frame of the study will be six months, with a prolonged measurement of outcomes in the intervention group after 12 months. 50% of the participants receive the Kopstoring program; the others receive Care-As-Usual which usually consists of non-standardized care while they are waiting for six months. In the economic evaluations the additional costs and additional outcomes of the Kopstoring will be compared with Care-As-Usual. This economic evaluation will involve a combination of a cost-effectiveness analysis (CEA) and a cost-utility analysis (CUA). In a CEA effects are presented in clinical outcomes, in this case the YSR. The primary outcomes measure for the cost-utility analysis will be Quality Adjusted Life Years (QALYs), based on the EQ-5D utility scores. This economic evaluation will be performed from a societal perspective.

Doel van het onderzoek

Children of parents with a mental illness or substance use disorder have high elevated risks to develop (mental and behavioural) problems themselves. Hypothesis is that the online Kopstoring intervention will be effective and cost-effective preventing future problems and illnesses compared to care as usual.

Onderzoeksopzet

1. Baseline;
2. 3 Months;
3. 6 Months;
4. 12 Months.

Onderzoeksproduct en/of interventie

1. Kopstoring: Online psycho-educative program. The program exists of 8 online sessions over 8 weeks and an evaluation session in a protected chat box (chat room). The aim of the intervention is to strengthen social and emotional functioning, coping skills and the relationship of the child with the parent. This will be achieved by interaction, self-assessments and education;

2. Care-As-Usual: This will be a “waiting-list control group with unrestricted access to Care-as-Usual”. The Care-As-Usual will consist of preventive CBT sessions in groups under professional guidance, help offered by psychologists, etc, but the choices are not regulated by guidelines and remains the responsibility of the family’s GP. Often, the problems go undetected and the child receives nothing.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

The adolescent:

1. Has to have at least one parent suffering from a mental illness or substance use disorder;
2. Has to be qualified as child who fits the cut-off scores of the Youth Self Report questionnaire. The child has to fit in the scores to the groups that are equivalent to the child barely having symptoms and having medium symptoms;
3. Sufficiently fluent in the Dutch language;
4. Has access to the internet;
5. Ability to use a chat box: able to participate actively and able to listen to other participants;
6. When aged 16-17 years informed consent of both child and parent; when aged 18 and over, informed consent of the adolescent only (mandatory under the Dutch law).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Children younger than 16 and adults older than 25 years old;
2. Too heavy symptoms and already developed psychological problems.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland
Status: Werving nog niet gestart
(Verwachte) startdatum: 01-01-2010
Aantal proefpersonen: 112
Type: Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1869
NTR-old	NTR1982
Ander register	ZonMW : 50-50110-96-648
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A