(Economic) Evaluation of E-mental Health Interventions for Children of Parents with Mental Illness (e^3 COPMI).

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27797

Source
NTR

Brief title
e^3 COPMI

Health condition

Mental Illnesses
Substance use disorders
Preventative trial

Sponsors and support

Primary sponsor: ZonMW
prevention Programme
Source(s) of monetary or material Support: ZonMW
prevention Programme

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

For the Cost-utility analysis: QALYs and Utilities will be based on the utilities derived from the EuroQol (EQ-5d).
- CES-D replaces SCL-90

Study description

Background summary

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.

Study objective

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 futire problems and illnesses compared to care as usual.

Study design

1. Baseline;

2. 3 Months;

3. 6 Months;

4. 12 Months.

Intervention

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.

Contacts

Public
Maastricht University
Department of HOPE
PO Box 616
Marla Woolderink
Maastricht University
Department of HOPE
PO Box 616
Maastricht 6200 MD
The Netherlands
+31 (0)43-3882286
Scientific
Maastricht University
Department of HOPE
PO Box 616
Marla Woolderink
Maastricht University
Department of HOPE
PO Box 616
Maastricht 6200 MD
The Netherlands
+31 (0)43-3882286

Eligibility criteria

Inclusion criteria

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).

Exclusion criteria

1. Children younger that 16 and adults older than 25 years old;

2. Too heavy symptoms and already developed psychological problems.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2010
Enrollment:	112
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable
Application type: Not applicable

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	NL1869
NTR-old	NTR1982
Other	ZonMW : 50-50110-96-648
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A