*Gezin aan bod'(The family*s turn): A study into the effects and implementation of the Strengthening Families Programme (SFP).

Published: 04-04-2008
Last updated: 10-05-2024

To conduct a randomised trial to test the hypothesis that the experimental condition, i.e. the intervention*Gezin aan bod*, is superior to 'care-as-usual' in exerting a positive effect on a number of the risk factorsfor problematic...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Family issues
Study type	Observational non invasive

Summary

ID

NL-OMON31489

Source
ToetsingOnline

Brief title
RCT Gezin aan Bod

Condition

- Family issues

Synonym
Family Functioning

Research involving
Human

Sponsors and support

Primary sponsor: Trimbos-instituut

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Addiction, Parenting, Prevention, Randomized Trial

Outcome measures

Primary outcome

Family Functioning as measured with the Gezins Klimaat Schaal (Moos & Moos,

1986; Dutch version)

Secondary outcome

(1) Parenting skills as measured with the Parenting Scale (Arnold et al., 1993)

and the "Ouderlijke Opvattingen over Opvoeding" Scale (Eekhof, 2006).

(2) Child functioning as measured with the Strenght and Difficulties

Questionnaire (Goodman, 1997).

Study description

Background summary

Unfavourable circumstances in the family and in the neighbourhood are important risk factors for use of
mental healthcare. The children of parents with a problematic use of alcohol and/or drugs often find
themselves in such circumstances and run a high risk of developing serious mental problems:
depression, behaviour problems, addiction, personality disorders, anxiety disorders, and antisocial
behaviour. Both the size and the problems of this target group are large. Despite these clear risks, few
interventions have been developed in the Netherlands for the children of addicted parents in the age
group 11 years and older. The Strengthening Families Programme (SFP) from the United States is a
promising intervention. The programme comprises 14 sessions for parents and their children (11 years

and older). Each session will begin with a meal for everyone together, followed by separate meetings for
the parents and the children lasting one hour, and then a final hour with all of the families together. The
emphasis is on communicative and parenting skills. The approach of the programme is in agreement
with the NIDA guidelines for the effective prevention of addiction. In the Netherlands, the programme
has been assessed as a promising way of preventing addiction to alcohol and drugs (Cuijpers & Bolier,
2001). SFP comprises a systematic approach: both parents and young people are involved. Between
April 2004 and September 2006, with funds from ZonMw, the SFP was translated and adapted to the
Dutch situation. Subsequently, the programme was implemented on a trial basis (pilot study) under the
name *Gezin aan bod*. The results of the programme were very promising and participants were highly
enthusiastic and positive. We therefore wish to investigate the effects of the SFP in more detail in this
new project. We also wish to expand the knowledge regarding the conditions for the implementation of
the intervention. Objective of the study is to conduct a randomised trial to test the hypothesis that the
experimental condition, i.e. the intervention *Gezin aan bod*, is superior to 'care-as-usual' in exerting a
positive effect on a number of the risk factors for problematic substance use and problematic behaviour
of children in families with problems of addiction. The risk factors concerned are: (A) family functioning
and (B) parenting skills. The second goal is to obtain greater insight into the conditions for the
implementation of *Gezin aan bod*(a process evaluation). Ten institutions for the prevention and
treatment of addiction have agreed in principle to participate in the study. This proportion of participating
institutions is necessary because the target group is difficult to engage. Therefore we opt for
randomisation at institution-level, face-to-face interviewing and incentives for participants in both
conditions.

Study objective

To conduct a randomised trial to test the hypothesis that the experimental condition, i.e. the intervention
Gezin aan bod, is superior to 'care-as-usual' in exerting a positive effect

on a number of the risk factors
for problematic substance use and problematic behaviour of children in families with problems of
addiction. The risk factors concerned are: (A) family functioning and (B) parenting skills. The second
goal is to obtain greater insight into the conditions for the implementation of *Gezin aan bod*(a process
evaluation).

The following questions will be addressed:
1. Will the intervention generate superior effects in terms of family functioning and parenting skills
according to (a) the parents and (b) the children?
2. Will the intervention generate superior effects in terms of how the children function, including
substance use?
3. How did the organisation and implementation of the intervention go? What were the inhibitory and
stimulatory factors, respectively?

Study design

DESIGN
Randomised trial with two groups: the experimental condition (The family*s turn) versus care-as-usual.
Prospective assessment with one baseline (T0) and two follow-up assessments: T1 immediately after
the intervention and T2 six months after T1. The same measurements, and at the same time intervals,
will be done in the experimental group and the control group.

RANDOMISATION
It is difficult to motivate the target group for this study and this intervention to accept care. Experience
during the pilot study has shown that recruitment for the study proceeds with difficulty (Bool et al., 2006).
We have therefore chosen randomisation at the level of the institution or the institution*s location. The
Trimbos Institute will take care of the central randomisation.

THE INTERVENTION
Gezin aan bod is a programme that comprises 14 sessions for parents and their children (11 years and
older). Each session will begin with a meal for everyone together, followed by separate meetings for the
parents and the children lasting one hour, and then a final hour with all of the families together. The

emphasis is on communicative and parenting skills.

CONTROLE GROUP.
We use a care as usual control group. No active intervention is offered to the family.

END TERMS. family functioning, parenting skills, child functioning

MEASUREMENTS.
Before the intervention (t0; baseline-measurement), after the intervention (t1; 3 months after baseline), and 9 months after baseline (t2, 6 months after the intervention).

Study burden and risks

BURDEN ASSOCIATED WITH THE COURSE "GEZIN AAN BOD".
The course consists of 14 sessions (2,5 hours each including a family meal). For each session, homework is assigned (1 hour per session). In advance of the course, the course instructor organizes an introduction meeting (2,5 hour).

BURDEN ASSOCIATED WITH THE STUDY.
Participants complete a questionnaire at three points in time: preceding the course; three months after baseline and nine months after baseline. The participants are helped by an interviewer who will visit the participants at home in a 1 hour visit (filling in the questions will take about 30 minutes for the child and 45 minutes for the parent).

RISKS.
We expent no risks for the respondents because:
(1) the participants apply voluntary to the course and the study,
(2) the intervention consists of a course, not a treatment
(3) based on the pilot study, we expect an improvement in family functioning and parenting skills.

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)
Elderly (65 years and older)

Inclusion criteria

INCLUSION:
(1) one or both parents satisfy the criteria for a diagnosis of substance dependence or substance abuse according to the DSM-IV or the corresponding code from the ICPC (International Classificaton of Primary Care) in the present or in the past,
(2) the family consist of at least one child who is at least 11 years of age and living at home.

Exclusion criteria

EXCLUSION:
(1) not being able to function in a group,
(2) children under treatment for mental problems, and
(3) families participating in family therapy.

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-02-2008
Enrollment:	268
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	04-04-2008
Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

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
CCMO	NL20525.097.07