

# The effectiveness and cost-effectiveness of interventions for families with multiple problems.

<b>Submission date</b> 18/05/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 27/05/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/06/2022	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Families with multiple problems (FMP) face a wide range of complex and persistent problems. Several studies assessed the effectiveness of interventions targeting these families, but results are inconclusive. This may be due to a different range of elements provided within the interventions, but evidence on effective elements within interventions for FMP is still limited. Therefore, the aim of this study is to identify effective and cost-effective elements for FMP and for FMP subgroups.

### Who can participate?

Families (one parent and one child (12 years or older) that received one of the eight selected interventions targeting FMP were included. [Multisystemic Therapy (MST), Multidimensional Family Therapy (MDFT), Parent Management Training Oregon (PMTO), Intensive Family Treatment (IFT), Family Central (FC), 10 For the Future (10FtF), Families First (FF) and Triple P 4-5].

### What does the study involve?

Participants (one parent and one child) were asked for informed consent to provide self-reported data at the start of treatment, at the end and three months after receiving care. In addition, during the intervention, practitioners registered monthly which practice and program elements were provided within participating families.

### What are the possible benefits and risks of participating?

The participation did not affect the participants' treatment in any way. After every completed questionnaire caregivers and adolescents received a gift token of ten euros.

### Where is the study run from?

Department of Health Sciences, University Medical Center Groningen, the Netherlands.

### When is the study starting and how long is it expecting to run for?

June 2016 to April 2019.

Who is funding the study?  
Netherlands Organization for Health Research and Development (ZonMw) [grant number 729300016].

Who is the main contact?  
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## Contact information

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Scientific

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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
201600009

## Study information

**Scientific Title**  
The effectiveness and cost-effectiveness of elements for families with multiple problems.

**Acronym**  
W2S

**Study objectives**

This study intends to gain insight into effective and cost-effective elements for families with multiple problems (FMP) and for FMP subgroups.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

The study protocol was submitted to the Medical Ethical Committee of the UMCG (protocol METc 2016.005) and received a waiver as the study does not fall under the scope of the Medical Research Involving Human Subjects Act. They considered a formal medico-ethical approval unnecessary for this study, given the Dutch legal regulations at the moment of submission of the proposal.

**Study design**

Quasi-experimental study with propensity score adjustment

**Primary study design**

Interventional

**Secondary study design**

Quasi-experimental with propensity score adjustment

**Study setting(s)**

Home

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet.

**Health condition(s) or problem(s) studied**

Families with severe parenting problems and families with multiple problems

**Interventions**

The eight interventions were: Multisystemic Therapy (MST), Multidimensional Family Therapy (MDFT), Intensive Family Treatment (IFT), Families First (FF) and Family Central (FC), Parent Management Training Oregon (PMTO), 10 for the Future (10FtF) and Triple P 4-5.10

The target group of these interventions are families in which there are severe parenting problems (MST, MDFT, PMTO and Triple P 4/5) and families with multiple and complex problems in different life domains like severe parenting, socio-economic and mental health problems (IFT, FF, FC and 10FtF). In this study, FMPs refers to families that received one of these eight interventions due to their problems in multiple domains.

Parents and adolescents (12 years or older) receiving one of the eight included interventions were included in this study. Measures will be assessed at the start of the intervention (T0), at the end of the intervention (T1) and three months after the end of the intervention (T2). In addition,

for practitioners measures will be assessed at T0 and T1. During the entire intervention, practitioners also registered every month which practice and program elements were provided within a family.

Main effects of practice and program elements on outcome improvement in the outcomes in both the short (that is, from T0 to T1) and long term (that is, from T0 to T2) will be assessed, adjusted for the propensity score (PS). Adjusting for the PS will be used to overcome bias due to differences in observed pretreatment variables. Next, multiple group analyses will be performed to investigate whether the effects of practice and program elements are moderated by subgroup characteristics.

#### Interventions:

- Multisystemic Therapy (MST). MST aims to provide intensive treatment in a home-based situation to prevent out of home placement. The target group is children from 12 to 18 years with severe antisocial/border-crossing behaviour, and their parents. Problems could occur in multiple life domains and could lead to out of home placement of the child. The intervention focuses on the child, family, friends, school and peers. The mean duration of MST is 3-5 months.
- Multidimensional Family Therapy (MDFT). MDFT aims to reduce criminal and addictive behaviour and related behavioural and emotional problems of the child, to enhance communication within the family, and to increase the social cohesion. The target group is youth from 12 to 19 years with multiple problem behaviour like delinquency and/or addiction, complemented by school truancy. At least one parent should join the therapy. The intervention focuses on the child and his family and peers. The mean duration of MDFT is 3-7 months.
- Intensive Family Treatment (IFT). IFT aims to reduce children's problem behaviour and parental stress, and to increase parenting skills and activate the social network of the family. The target group is families with children between 0 and 23 years with multiple and complex problems in different life domains. These families can be stubborn and difficult for the therapist to reach. The intervention focuses on preventing out of home placement or reunification. The mean duration of IFT is 5-7 months.
- Families First (FF). FF aims to reduce the problem behaviour of the child and strengthen the competencies of the family, thereby reducing parenting stress, increasing parenting skills and activating the social network of the family. The target group is families in an acute crisis, serious enough to risk of out of home placement of the child. The focus is on managing the crisis and assuring the safety of the family members. The mean duration of FF is 1 month.
- Family Central (FC). FC aims to enhance communication between family members and collaboration between parents, thereby reducing behavioural problems of the child(ren) and activating the social network of the family. The target group is youth between 0 and 18 years, and their family, who could have serious parenting problems and developmental problems. These families can be stubborn and difficult for the therapist to reach. The focus is on the accumulation of problems and trying to find balance in the various domains of life. The mean duration of FC is 6-12 months.
- Parent Management Training Oregon (PMTO). PMTO aims to provide parents with more systematic and effective parenting strategies to enhance their relationships with their children and reduce the number of conflicts. The target group is parents with children between 4 and 12 years who show severe externalizing problem behaviour in combination with hyperactivity. The focus of the intervention is to reinforce positive behaviour in the parents/child(ren). The mean duration of PMTO is 5 months.
- 10 for the Future (10FtF). 10FtF aims to provide assistance on ten different areas of life: household work, education, self-care, development of the child, enhancing the social network, finance, parenting skills, daily routine, psychosocial and addiction problems and coordination of care. The target group is families with complicated and multiple problems in different life

domains, with a risk of out of home placement of the child. The focus is on a safe environment for the child(ren) and parent(s). The mean duration of 10FtF is 12 months.

- Triple P 4-5. Triple P aims to prevent children from having serious behavioural and emotional problems by enhancing parental competencies. The target group of Triple P 4 is parents who have children with severe behavioural problems and are in need of a targeted training in parenting skills. The target group of Triple P 5 is families with multiple behavioural problems combined with other family related problems. Level 5 is deployed when no or insufficient improvement is seen in the behaviour of the child after level 4 because parenting problems are linked with other problems (e.g., depression, stress or relational problems). The mean duration of Triple P 4-5 is 2-2.5 months.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

At baseline, end of intervention, and three months follow-up:

1. Child internalizing and externalizing problem behavior measured using the Child Behavior Checklist (CBCL)
2. Cost-effectiveness based on internalizing and externalizing problems (societal perspective) measured using the Questionnaire for Costs Associated with Psychiatric Illness (TIC-P) and Child Behavior Checklist (CBCL)

## **Secondary outcome measures**

At baseline, end of intervention, and three months follow-up:

1. Parenting stress measured using the Burden of Parenting Questionnaire (OBVL, Opvoedingsbelasting vragenlijst)
2. Social contacts measured using the Social Contacts subscale of the Questionnaire Family Functioning of Parents (VGFO, Vragenlijst Gezinsfunctioneren van Ouders)
3. Costs measured using the Questionnaire for Costs Associated with Psychiatric Illness (TIC-P)
4. Cost-utility measured using the EuroQol Five Dimensions Questionnaire (EQ5D-5L)

## **Overall study start date**

01/06/2016

## **Completion date**

01/04/2019

# **Eligibility**

## **Key inclusion criteria**

1. Receiving one of the eight selected interventions targeting FMP (e.g., MST, MDFT, FF, FC, IFT, 10FtF, PMTO or Triple P 4-5);
2. Dutch language fluency
3. The child targeted by the intervention was four years or older

## **Participant type(s)**

Patient

## **Age group**

Other

**Sex**

Both

**Target number of participants**

605

**Key exclusion criteria**

Not receiving care from one of the participating care organizations

**Date of first enrolment**

01/01/2017

**Date of final enrolment**

01/07/2018

**Locations****Countries of recruitment**

Netherlands

**Study participating centre**

**University Medical Center Groningen**

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**Sponsor information****Organisation**

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University/education

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**ROR**

<https://ror.org/03cv38k47>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

ZonMw

**Alternative Name(s)**

Netherlands Organisation for Health Research and Development

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

Netherlands

## **Results and Publications**

**Publication and dissemination plan**

A first publication assesses the effectiveness of elements for FMP and FMP subgroups. A second publication assesses the cost-effectiveness of elements for FMP. We plan to submit both publications in a high-impact-factor journal and both manuscripts will also be part of a dissertation on the effective elements of interventions for families with multiple problems.

**Intention to publish date**

01/10/2020

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>			08/06/2020	No	No
<a href="#">Results article</a>		06/06/2022	07/06/2022	Yes	No