

# Evaluation of an interaction-skills training for reducing the burden of family caregivers of patients with severe mental illness

<b>Submission date</b> 22/12/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 14/01/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 29/03/2018	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Family members who care for patients with severe mental illness experience emotional distress and report a higher incidence of mental illness than those in the general population. They report feeling inadequately prepared to provide the necessary practical and emotional support for these patients. The MAT training, an Interaction-Skills Training program (IST) for caregivers, was developed to meet those needs. The aim of this study is to examine the impact of the training on caregivers' sense of competence (self-efficacy) and burden.

### Who can participate?

Family caregivers who care for patients with a severe mental illness

### What does the study involve?

Family caregivers participated in the training over 10 weeks. Family caregivers' burden and self-efficacy are assessed using questionnaires before and after the training and 3 months later.

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

The possible benefits of participation in the interaction-skills training are increased self-efficacy and reduced burden when caring for their family member with severe mental illness. No harm or discomfort is expected.

### Where is the study run from?

1. Vincent van Gogh Instituut, Venlo (Netherlands)
2. Vincent van Gogh Instituut, Venray (Netherlands)
3. GGZ Friesland, Franeker (Netherlands)
4. GGZ Friesland, Heerenveen (Netherlands)
5. Propersona Lokatie Braamberg, Arnhem (Netherlands)

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

October 2014 to October 2016

Who is funding the study?  
Inholland University of Applied Sciences (Netherlands)

Who is the main contact?  
Yassamin Gharavi

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Ms Yassamin Gharavi

**Contact details**  
Lange Leidsedwardsstraat  
Amsterdam  
Netherlands  
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## Additional identifiers

**Protocol serial number**  
N/A

## Study information

**Scientific Title**  
Evidence of the effectivity of an interaction-skills training for reducing the burden of family caregivers of patients with severe mental illness: a pre-posttest design

**Study objectives**  
After following the IST program, family caregivers of patients with severe mental illness experience a greater sense of competence and a significant decrease in burden.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
Under Dutch law and legislation, no medical ethical approval was needed for this study, see CCMO. Only medical studies need to receive the approval of the Central Committee on Research Investigating Human Subjects (CCMO). This research does not fall under the scope of the Medical Research Involving Human Subjects Act (WMO). The following reference supports this point: "Centrale Commissie Mensgebonden Onderzoek (CCMO), (2015)". After receiving verbal and written information on the study, all participants signed for informed consent.

**Study design**  
Pre-posttest design

**Primary study design**

Interventional

**Study type(s)**

Quality of life

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

Clinical health psychology, severe mental illness

**Interventions**

The interaction skills training (IST) program was offered at three mental health institutions in various parts of the Netherlands. Within these three hospitals, there was an open registration for family members to participate in the training. The training was announced through the mental health professionals, local media, or a brochure. Family members were recruited through their registered patients, through local media, or a brochure. One hundred family caregivers recruited from three mental health institutions participated in the training. The duration of the training program was 10 weeks.

The trialists examined the effect of the program on self-efficacy and burden, which were measured on three occasions: at T0 (baseline), T1 (after the training/at 8 weeks) and T2 (3 months after termination of the training). The third measurement also included a brief evaluation of the caregivers' perspective on the training. Burden was assessed using the Involvement Evaluation Questionnaire, and self-efficacy using the Self-Efficacy Questionnaire. Analysis of variance with repeated measures was used to investigate whether participation in the training changed the level of family caregivers' burden and self-efficacy. Pearson's correlation was used to examine the relationships between self-efficacy and burden.

**Intervention Type**

Behavioural

**Primary outcome(s)**

Measured at T0 (baseline), T1 (after the training/at 8 weeks) and T2 (3 months after termination of the training):

1. Burden assessed using the Involvement Evaluation Questionnaire
2. Self-efficacy assessed using the Self-Efficacy Questionnaire

**Key secondary outcome(s)**

Appreciation of the components of the training, measured with a short survey at T2 (3 months after termination of the training)

**Completion date**

25/10/2016

**Eligibility****Key inclusion criteria**

Being a family member of, and caring for, a patient with a severe mental illness, defined as not being free of symptoms, having had the mental illness in the long term (>2 years), and having serious limitations in personal and social functioning

**Participant type(s)**

Carer

**Healthy volunteers allowed**

No

**Age group**

All

**Sex**

All

**Key exclusion criteria**

Being a family member and caring for a patient who does not meet the specific criteria for a severe mental illness

**Date of first enrolment**

01/02/2015

**Date of final enrolment**

01/03/2016

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

Netherlands

**Study participating centre**

**Vincent van Gogh Instituut**

Tegelseweg 210

Venlo

Netherlands

5912BL

**Study participating centre**

**Vincent van Gogh Instituut**

Stationsweg 46

Venray

Netherlands

5803 AC

**Study participating centre**

**GGZ Friesland**

Burgemeester J. Dijkstraweg 6

Franeke

Netherlands  
8801 PG

**Study participating centre**

**GGZ Friesland**  
Kastanjelaan 1  
Heerenveen  
Netherlands  
8441 NC

**Study participating centre**

**Propersona Lokatie Braamberg**  
Wagnerlaan 2  
Arnhem  
Netherlands  
6815 AG

## **Sponsor information**

**Organisation**

Inholland University of Applied Sciences / Department of Nursing

**ROR**

<https://ror.org/03cfsyg37>

## **Funder(s)**

**Funder type**

University/education

**Funder Name**

Inholland University of Applied Sciences

## **Results and Publications**

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

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Berno van Meijel (Berno.vanMeijel@Inholland.nl). Type of data: SPSS

dataset with background characteristics of the participants and data on experienced burden (measured with the Involvement Evaluation Questionnaire / IEQ) and perceived self-efficacy (measured with the Self-Efficacy Questionnaire / SEQ) of family members of patients with severe mental illness. Complete data on IEQ and SEQ are available from 75 patients at three measurements: at T0 (before the start of the training program), at T1 (after termination of the training / 8 weeks) and at follow-up (3 months after termination of the training program). Data will be available from 01/01/2018 indefinitely. Data are made available for collaborative research with the initial researchers, based on an approved research protocol by participating research organizations and relevant ethical committees. Informed consent was obtained from all participants in this study. Data in this dataset are anonymized.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	27/03/2018		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes