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

Submission date
22/12/2017

Recruitment status
No longer recruiting

Registration date
14/01/2018

Overall study status
Completed

Last Edited
29/03/2018

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
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Netherlands
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure

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

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

Overall study start date
13/10/2014

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

Age group
All

Sex
Both

Target number of participants
100

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
Franeker
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

Sponsor details
De Boelelaan 1109
Amsterdam
Netherlands
1081 HV

Sponsor type
University/education

ROR
https://ror.org/03cfsyg37

Funder(s)

Funder type
University/education

Funder Name
Inholland University of Applied Sciences

Results and Publications

Publication and dissemination plan
The manuscript has been submitted to BMC Psychiatry.

Intention to publish date
27/01/2018

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?
Results article	results	27/03/2018		Yes	No