ISRCTN16659871 https://doi.org/10.1186/ISRCTN16659871

Metacognitive Reflection & Insight Therapy (MERIT)

Submission date
08/01/2013

Recruitment status
No longer recruiting

Registration date
20/03/2013

Overall study status
Completed

Last Edited
09/03/2022

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The lifetime risk of schizophrenia is generally estimated to be around 1%. Research has shown deficits in metacognitive abilities in more than half of people with schizophrenia and association between deficits and poor course of illness. Metacognition is the ability to think about thoughts and feelings of oneself and others. It is a broad concept and involves several aspects:
- The ability to think about one's own thoughts and emotions
- The ability to think about the thoughts and emotions of others
- Decentration which is the ability to understand that you are not the center of the world and people's lives continue when you are not around
- The ability to use the three aspects above to adapt your behavior to the circumstances.
Research has shown that improvement in metacognitive abilities leads to improvement in social functioning and less experience of symptoms. It also seems to improve the therapeutic relationship and quality of life. Dr. P.H. Lysaker has developed the Metacognitive Reflection and Insight Therapy (MERIT) which aims to improve metacognitive functioning. Initial studies show promising results. We now want to investigate this therapy in a larger study. The aims are to assess how well MERIT works and whether an improvement in metacognitive abilities leads to a better enhanced quality of life for people with psychotic disorders.

Who can participate?
96 participants diagnosed with psychotic disorders and with metacognitive deficits

What does the study involve?
Participants will be randomly allocated to one of two groups; the intervention group (MERIT) or treatment as usual (TAU). 48 participants with psychotic disorders without metacognitive deficits will be added to the first assessment, so we can compare this group with patients with metacognitive deficits on several aspects (for example empathy and quality of life). The treatment group will receive the MERIT therapy which consists of 35-40 hours of individual therapy. In this therapy, the life story (narrative) of the patient is emphasized. Using episodes from his or her narrative, the patient is gradually challenged to perform ever more complex metacognitive acts. The control group will receive treatment as usual (TAU) and will receive the therapy when the trial is completed.

What are the possible benefits and risks of participating?
Assessments, each lasting 2 hours, will take place before and after treatment, with a follow-up assessment after 6 months. Our expectation is that improved metacognitive skills will play an important role in the recovery process of schizophrenia and will help patients to gain more control of their lives. No risks are involved for the participants.

Where is the study run from?
The study is run from the University in Groningen and will take place at clinical sites in the Netherlands: GGZ Friesland, GGZ Drenthe, Parnassia Den Haag, Lentis Groningen en Universitair Medisch Centrum Groningen.

When is the study starting and how long is it expected to run for?
The study will start in June 2013 and will run for three years.

Who is funding the study?
GGZ Friesland, GGZ Drenthe, Postmaster Opleidingen Psychologie (PPO) Groningen and NutsOhra

Who is the main contact?
Dr Steven de Jong
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Study website
http://www.meritonderzoek.nl

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ABR 41317

Study information

Scientific Title
Metacognitive Reflection & Insight Therapy (MERIT): a randomized controlled trial

Study objectives
The primary objective of this study is to investigate if the Metacognitive Reflection and Insight Therapy (MERIT) improves metacognitive abilities in people with schizophrenia.
The secondary objective is to investigate if improvement in metacognitive abilities leads to enhanced quality of life, better course of illness, insight, and social functioning and less depression, stigma and symptoms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multicenter randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Schizophrenia, metacognitive deficits

Interventions
The treatment condition will receive the Metacognitive Reflection and Insight Therapy (MERIT). This psychotherapy seeks to enhance the metacognitive abilities of people with schizophrenia

and is developed by Dr P.H. Lysaker. The therapy will consist of 35-40 hours of individual therapy. In this therapy, the life story (narrative) of the patient is emphasized. Using episodes from his or her narrative, the client is gradually challenged to perform ever more complex metacognitive acts. To monitor metacognitive improvement in a fashion similar to Routine Outcome Monitoring, the transcripts of psychotherapy sessions will be assessed with the Metacognitive Assessment Scale (MAS-NL).

The people in the control group will receive treatment as usual (TAU) and will receive the therapy when the trial is completed.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Metacognitive functioning, which will be assessed using the Metacognitive Assessment Scale (MAS-NL)

The post-treatment assessment is ten months after the baseline assessment; the follow-up assessment is six months after the post-treatment assessment.

Secondary outcome measures
1. Beck Depression Inventory (BDI-II)
2. Manchester Short Assessment of Quality of Life (MANSA)
3. Internalized Stigma of Mental Illness scale (ISMI)
4. Time Use
5. PSP and SF-12 (social functioning)
6. Positive and Negative Symptom Scale (PANSS)
7. Schedule for Assessment of Insight (SAI-E) Trailmaking Test A en B
8. Digit Symbol Task (WAIS I subtest)
9. Interpersonal Reactivity Index (IRI)
10. Faux Pas test
11. Empathic Accuracy Test
12. Work Readiness Questionnaire (WORQ)
13. Clinical Impression (CGI)
14. Care consumption list (zorgconsumptielijst)

The post-treatment assessment is ten months after the baseline assessment; the follow-up assessment is six months after the post-treatment assessment.

Overall study start date
01/05/2013

Completion date
01/05/2015

Eligibility

Key inclusion criteria

1. A diagnosis of schizophrenia according to Diagnostic and Statistical Manual of Mental Disorders, 4th edition text revision (DSM-IV-TR) criteria
2. Impaired metacognitive skills
3. Being able to give informed consent
4. Men and women,18- 65 years old
5. No change in medication in the past thirty days

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
96

Total final enrolment
70

Key exclusion criteria
1. Florid psychosis (mean positive symptoms <4 measured by PANSS)
2. Co-morbid neurological disorder
3. Substance dependence (not substance abuse)
4. IQ <70

Date of first enrolment
01/05/2013

Date of final enrolment
01/05/2015

Locations

Countries of recruitment
Netherlands

Study participating centre

Grote Kruisstraat 2/1
Groningen
Netherlands
9712 TS

Sponsor information

Organisation
University of Groningen (Netherlands)

Sponsor details
Rijksuniversiteit Groningen
Faculteit GMW
Grote Kruisstraat 2/1 9712 TS
Groningen
Netherlands
9712 TS

Sponsor type
University/education

Website
http://www.rug.nl/

ROR
https://ror.org/012p63287

Funder(s)

Funder type
Charity

Funder Name
Fonds NutsOhra

Alternative Name(s)
NutsOhra Foundation, NutsOhra Fund, Stichting Nuts Ohra

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Funder Name
GGZ Drenthe (Netherlands)

Alternative Name(s)
Geestelijke Gezondheidszorg Drenthe

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Funder Name
Geestelijke Gezondheidszorg (GGZ), Friesland (Netherlands)

Alternative Name(s)
Geestelijke Gezondheidszorg Friesland

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Funder Name
Postmaster Opleidingen Psychologie (PPO), Groningen (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available upon request from Dr Steven de Jong (misterdejong@gmail.com) for established researchers (either with a PhD or pursuing one).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	03/02/2014		Yes	No
Results article	results	01/01/2019	20/06/2019	Yes	No