5-year follow up of the MESIFOS cohort

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The objective of the study is to investigate whether the application of the multidisciplinary guidelines for the treatment of schizophrenia leads to a better course of schizophrenia and related disorders.

Ethical review	-
Status	Will not start
Health condition type	Schizophrenia and other psychotic disorders
Study type	Observational non invasive

Summary

ID

NL-OMON33061

Source
ToetsingOnline

Brief title
MESIFOS 5-year follow up

Condition

- Schizophrenia and other psychotic disorders

Synonym
psychotic disorders

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: GGZ Friesland,Janssen-Cilag

Intervention

Keyword: follow-up, Incidence cohort, outcome, schizophrenia

Outcome measures

Primary outcome

Course of the illness is the primary outcome measure. But "course" is a composite construct.

Of the measures used in this study, the following are related to course and thus are primary:

- The number of patients with one or more relapses since the end of the trial
- Number of patients currently in remission (symptoms)
- Number of patients currently recovered (symptoms and functioning)
- Level of socaal functioning
- Quality of Life
- Within the group of successfully discontinued patients: how many are still discontinued without sustaining any relapse.

Secondary outcome

Use of medication and its relationship with relapses.

Quality of life

Study description

Background summary

In 2005 multidisciplinary guidelines were published for the treatment of schizophrenia. These guidelines were made on the basis of research regarding efficacious interventions for this disorder. The aim of these guidelines was to introduce more evidence based interventions in the care for patients suffering

from schizophrenia.
The institutions who participated in MESIFOS are generally at the forefront of changes in patient care. As an example, during the study more than 90% of the patients were treated with second-generation antipsychotics for two years, which is one of he new guidelines.
It is reasonable to assume that the participating institutions applied many of the guidelines for the treatment of this group of patients. The very thought behind the guidelines is that their application could lead to a better course of the disorder.
The present study aims to answer the question whether the intermediate course (approx. 7 years) of the disorder in patients treated according to these guidelines is better than that in earlier comparable cohorts, before the introduction of the guidelines.

Study objective

The objective of the study is to investigate whether the application of the multidisciplinary guidelines for the treatment of schizophrenia leads to a better course of schizophrenia and related disorders.

Study design

This study is a naturalistic follow-up of a previous study: MESIFOS. Seven institutions in seven regions participated in MESIFOS, covering a catchment area of 3.1 million inhabitants: UMCG (Groningen), GGZ Friesland, GGZ Drenthe, Adhesie (now called Dimence), Mediant (Enschede), de Grote Rivieren (Dordrecht), GGnet (Zutphen).

Since this is a follow-up of the same subjects the same instututions will participate again. The research infrastructure that was built for MESIFOS is still intact. The GROUP study is using the same infrastructure today. Many of the research assistants are still active in this study.
After approval of the Medical Ethical Committee the study can begin. The researcher still have the personal data of the subjects. They consented dduring the last MESIFOS interview to be contacted again at a later date. The research assistant will contact the subjects if they do not reply to the invitation to participate.

If the subject consents to participate, the interview will follow. In the informed consent there is also a paragraph about the consent to consult the medical records. The subject can decide to give a partial consent, i.e. for either of the above.
In case of refusal for personal participation the subject can also give consent to obtain information from the attending psychiatrist.

Study burden and risks

The repondents will be interviews that have been used in a large number of studies. No apparent risks have emerged from those studies.

Contacts

Public
Universitair Medisch Centrum Groningen

Postbus 30.001
9700RB
Nederland
Scientific
Universitair Medisch Centrum Groningen

Postbus 30.001
9700RB
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Participation in the MESIFOS trial

Exclusion criteria

Not applicable

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-08-2009
Enrollment:	131
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Not available

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	NL28185.042.09