Non-Adherence with Psychoeducation in patients with Schizophrenia Study (NAPSS): prevalence, risk factors and outcomes

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Schizophrenia and other psychotic disorders
Study type	Observational non invasive

Summary

ID

NL-OMON32019

Source
ToetsingOnline

Brief title
NAPSS: Non-Adherence with Psychoeducation in Schizophrenia Study

Condition

- Schizophrenia and other psychotic disorders

Synonym
Schizophrenia and psychotic disorders

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cohort study, Non-adherence, Psychoeducatie, Schizophrenia

Outcome measures

Primary outcome

Time to (re)hospitalisation.

Secondary outcome

- The prevalence and risk factors of non-adherence with psychoeducation in

patients with schizophrenia.

- adherence with antipsychotics, change in medication regimen, global

functioning, quality of life, living situation and occupation between adherents

and non-adherents with psychoeducation.

Study description

Background summary

Schizophrenia is characterised by psychotic relapses and hospitalisations. Antipsychotics are the main medical treatment to reduce symptoms and prevent psychotic relapses. However, non-adherence with antipsychotics is common in patients with schizophrenia. Psychoeducation is an additional effective intervention in reducing relapses and rehospitalisation rates.
However, we conducted a systematic review on non-adherence with psychoeducation in patients with schizophrenia to assess the prevalence, the risk factors of non-adherence and patient outcomes of adherents versus non-adherents. We concluded that there is a lack of data in the published literature.
In this cohort study we will study the difference in patient outcomes between adherents versus non-adherents with psychoeducation and we will assess the prevalence and risk factors of non-adherence. If, for example, substantial proportions of patients do not adhere and non-adherence with psychoeducation - like non-adherence with antipsychotics - would increase the risk of relapse, the development and testing of interventions to improve adherence would become more urgent. Secondly, the specific risk factors found may help to develop

interventions so health care professionals can target their interventions to minimise non-adherence with psychoeducation.

Study objective

1. To compare patient outcomes during follow-up between adherents versus non-adherents with psychoeducation in patients with schizophrenia. We selected *time to (re)hospitalisation* as the most important outcome.
2. To assess the prevalence and risk factors of non-adherence.

Study design

Multi-centre prospective cohort study with candidate predictors assessed at baseline and outcome variables at 6 months intervals during follow-up

Study burden and risks

We expect that participation will have no positive or negative consequences for the patients themselves. That is, participation will not jeopardise the emotional or physical health of the participants; the impact will not paralyse daily functioning or cause (severe) trauma to participants. However, the assessments in patients will take 2 and 1/2 hour of the patients* time, in 3 or 5 contactmoments.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Dutch speaking patients with schizophrenia spectrum disorders according to DSM-IV criteria
- Age: 18 years and above
- Offered to start group psychoeducation

Exclusion criteria

- Less than two years of high school/secondary school

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2009
Enrollment:	270
Type:	Actual

Ethics review

Approved WMO Date:	09-09-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL22000.041.08