The NEURAPRO-E Study: A multicenter RCT of Omega-3 Fatty Acids and Cognitive-Behavioural Case Management for Symptomatic Patients at Ultra-High Risk for Early Progression to Schizophrenia and Other Psychotic Disorders

Published: 22-08-2012
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Replication of the study of Amminger et al (2010) in a larger sample.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON39984

Source
ToetsingOnline

Brief title
NEURAPRO-E

Condition

- Other condition

Synonym
psychosis, ultra high risk for developing psychosis

Health condition

symptomatische patiënten met een verhoogd risico op een eerste psychose

Research involving
Human

Sponsors and support

Primary sponsor: Orygen Youth Health Research Centre
Source(s) of monetary or material Support: Orygen Youth Health Research Centre;Australië

Intervention

Keyword: Cognitive behavioural case management, Omega-3 fatty acids, Psychosis, Ultra high risk

Outcome measures

Primary outcome

Transition to psychosis

Secondary outcome

Severity of symptoms

Level of functioning

Study description

Background summary

A recent study of Amminger et al published in the Archives of General Psychiatry showed that in a group of 81 patients with an ultra high risk for developing a first psychosis, the risk of making the transition to psychosis was reduced significantly in the patient group treated with fishoil compared to the patient group treated with a placebo. Since antipsychotic medication is not indicated in the ultra high risk phase because of side-effects, it would be highly relevant to replicate this finding. If this replication study also reveals that fishoil can reduce the chance of transition to a first psychosis, this result could have implications for the treatment of subjects wit a high risk for developing psychosis.

Study objective

Replication of the study of Amminger et al (2010) in a larger sample.

Study design

337 patients with an ultra high risk for developing psychosis will be randomised into treatment condition (fishoil and cognitive behavioural therapy plus case management) and placebo condition (placebo and cognitive behavioral management plus case management). Treatment duration is six months and total study duration is one year.

Intervention

Condition 1: fishoil and cognitive behavioural therapy plus casemanagement
Condition 2: placebo and cognitive behavioural therapy plus casemanagement

Study burden and risks

Few risks are involved (only when taking blood samples and fishoil may lead to mild gastro-intestinal problems or burping) and there are obvious benefits for the patients because they receive treatment for their symptoms and the risk for transition to a first psychosis may be reduced. In the first 6 months, patients will be interviewed monthly to rate the severity of symptoms. These interview appointments can be combined with treatment appointments. Thereafter, subjects will be interviewed at 9, 12 and 24 months. Total research burden is estimated at 27,5 hours.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

A. General inclusion criteria:
i. Ability to give informed consent
Where participants are of legal childhood age, consent will also be obtained from one of the participant*s parents. Both the parent and participant will be required to sign the consent form in such a case. It will be the investigator*s responsibility to determine whether a participant of legal childhood age has the capacity to consent to the study.
ii. Age 13 - 40 yrs
B. Membership of one of the following *at-risk* groups:
i. Vulnerability (Trait and State Risk Factor) Group: Individuals with a combination of a trait risk factor (schizotypal personality disorder or a family history of psychotic disorder in a first degree relative) and a significant deterioration in mental state and/or functioning or sustained low functioning during the past year.
ii. Attenuated Psychotic Symptoms (APS) Group: Individuals with subthreshold (intensity or frequency) positive psychotic symptoms. The symptoms must have been present during the past year and be associated with a significant reduction in or sustained low functioning.
iii. Brief Limited Intermittent Psychotic Symptoms Group (BLIPS): Individuals with a recent history of frank psychotic symptoms that resolved spontaneously (without antipsychotic medication) within one week. The symptoms must have been present during the past year and be associated with a significant reduction in or sustained low functioning.

Exclusion criteria

i. Past history of a treated or untreated psychotic episode of one week*s duration or longer
ii. Organic brain disease, e.g. epilepsy, inflammatory brain disease

iii. Abnormal coagulation profile parameters or thyroid function test results >10% above or below the limits of the normal range.
iv. Any physical illness with psychotropic effect, if not stabilized
v. Current treatment with lithium, methyl phenidate or ketamine, or recreational use of ketamine.
vi. Past neuroleptic exposure equivalent to a total lifetime haloperidol dose of >50 mg. [Refer to Appendix IV for a list of equivalent doses for other neuroleptic agents.]
vii. Diagnosis of a serious developmental disorder, e.g. Asperger's syndrome
viii. Premorbid IQ < 70 and a documented history of developmental delay or intellectual disability
ix. Current aggression/dangerous behaviour (CAARMS 5.4 severity score 6)
x. Current suicidality/self harm (CAARMS 7.3 severity score 6)
xi. Current pregnancy
xii. Current attenuated symptoms that are entirely explained by acute intoxication (e.g., current attenuated symptoms entirely explained by LSD use).
xiii. > than 4 weeks of regular omega-3 supplementation (>2 capsules standard strength providing >600 mg combined EPA/DHA) within the last 6 months.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-10-2012
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	22-08-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-11-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-02-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL35421.018.11