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Primary prevention of psychosis through interventions in the prodromal phase

Submission date
14/10/2014

Recruitment status
No longer recruiting

Registration date
31/10/2014

Overall study status
Completed

Last Edited
29/10/2015

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Psychosis is a state of mind where people experience a distortion of loss of contact with reality, leading to delusions, hallucinations and thought disorder. Other symptoms can include depression, anxiety, and withdrawing from family and friends. The causes are complex and there are a number of biological, psychological, social and environmental factors - for example, drugs, physical illness (such as infection) and mental illness (such as bipolar or schizophrenia). The aim of this study is to identify people about to become psychotic (i.e. at the prodromal phase) so they can be treated early enough to prevent it from developing. People at the prodromal stage of psychosis may display subtle changes in behavior and in how they think and feel. They might start to feel that everyday life is confusing or overwhelming and have begun to withdraw from their social circle. We want to reduce the number of psychotic disorders developing per year within a particular catchment area through detection and treatment in the prodromal phase of the disorder. If we can identify people about to become psychotic with high accuracy, we can track them to understand more about how psychosis unfolds. Appropriate intervention (treatment) at this stage could also prevent or delay the onset of psychosis and subsequent deterioration, for example, social problems, suicide, aggressive behavior, and cognitive deficits.

Who can participate?
People identified as being at the prodromal phase of psychosis, aged between 13-65 years and living in the catchment areas of Stavanger, Fonna, Bergen, and Østfold.

What does the study involve?
Catchment areas are randomly allocated to either be control or intervention areas and the number of people developing psychosis per year are compared. A prodromal intervention program is introduced to the intervention areas. Prodromal patients are recruited through information campaigns modelled on the Scandinavian early Treatment and Intervention in Psychosis (TIPS) study and assessed for psychosis. The program includes one-to-one monitoring of clinical status, management of disorder, and individual cognitive behavioural therapy (CBT) as appropriate. Medication is also supplied as necessary. The prodromal intervention program is not introduced to the control areas.

What are the possible benefits and risks of participating?
The participants in this study are help-seeking individuals at the prodromal phase of psychosis. All participants go through extensive mental health symptom/ diagnostic assessments. The patients receiving the intervention are offered an extensive treatment 'package', which includes CBT, single-family treatment, Omega-III fatty acids, in the form of 2g fish oils. This treatment is more extensive than this patient group is usually offered and is low risk.

Where is the study run from?
Stavanger University Hospital, Norway

When is the study starting and how long is it expected to run for?
March 2012 to December 2017

Who is funding the study?
1. Norwegian Extra Foundation for Health and Rehabilitation (Norway)
2. Health West Trust (Norway)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Primary Prevention Of Psychosis through interventions in the symptomatic prodromal phase. A pragmatic Norwegian Ultra High Risk study.

Acronym
POP study

Study objectives
Objectives: The primary aim of the current study is to test the effect of a Prodromal Detection and Treatment program at the health care systems level. The study will investigate:
1. If the combination of information campaigns and detection teams modelled will help in identifying individuals at high risk of developing psychosis early
2. If a graded, multi-modal treatment program will reduce rates of conversion compared to the rates seen in follow-along assessments

Ethics approval required
Old ethics approval format

Ethics approval(s)
Norwegian National Committee for Medical and Health Research Ethics, 08/09/2009, ref. 2009 /949

Study design
Parallel control design comparing incidence of first episode psychosis between 2 catchment areas with Prodromal Detection and Treatment (PDT) (with two catchment areas without PDT program.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
First episode psychosis, schizophrenia/prodromal, ultra-high risk state/primary prevention

Interventions
The study consenting prodromal patients will participate in an individual 2 year follow-along containing the following elements:
1. One-to-one monitoring of clinical status, symptom levels (prodromal and psychotic), risk profiles (suicidality, dangerousness), instrumental and social functioning
2. One-to-one case management to help deal with clinical, familial, social and vocational crises, needs and deficits
3. Omega-III fatty acids, in the form of 2g fish oils containing approx. 1.5 g Etyl-Eicosapentaeonic Acid/DHA with 80 mgs Vitamin E per day for 12 weeks
4. Individual cognitive behavioral therapy (CBT) to deal with social/cognitive distortions and deficits and to maintain real world investment (based on the EDIE II study. They will be offered 26 sessions of CBT within a six months period. The CBT sessions will be based on established cognitive models, be collaborative, problem orientated, formulation driven, normalizing, educational and time-limited with Socratic questioning/ guided discovery
5. Individuals that experience functional loss will in addition receive single-family psycho-education to inform patients and families about current problems, how to understand and cope with them, especially within the family.
6. Anti-anxiety agents and anti-depressants will be available if the patient is so symptomatic that they otherwise would be prescribed these agents by their GPs
7. Antipsychotic medication will be available if the patient either enters the study with any SIPS positive symptom score at the level of 5, or if any positive prodromal symptom score(s) moves from a level of 3 or 4 to a 5. Use will be open labeled based on the patients' current symptom

profile. The type and dose of medication will be reviewed by an independent clinical practice safety monitoring board.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The primary outcome will be the rate of conversion to psychosis. This is ascertained by the Structured Interview for DSM-IV (SCID) (Kiddie SADS for adolescents (13-17 years)) assisted by the Positive and Negative Syndrome Scale (PANSS).

Key secondary outcome(s))
1. If the combination of information campaigns and detection teams modelled will help in identifying individuals at high risk of developing psychosis early
2. If a graded, multi-modal treatment program will reduce rates of conversion compared to the rates seen in follow-along assessments.
3. Study number of days to convertion for those who develop first episode psychosis
4. Study number of/and days in treatment for individuals who progress to a state below prodromal/UHR state criteriea
Assessed monthly for the first six months and then every three months for the next eighteen months.

Completion date
31/12/2017

Eligibility

Key inclusion criteria
Incidence study inclusion criteria:
1. The patient is listed in the national register and residing in the catchment areas of Stavanger, Fonna, Bergen, and Østfold
2. Between 13 and 65 years
3. Meet diagnostic criteria in DSM-IV for first episode schizophrenia, schizophreniform disorder, schizoaffective disorder, delusional disorder, brief psychotic disorder, affective psychoses (Bipolar I disorder, Bipolar II disorder with psychotic symptoms, Major depressive disorder with psychotic symptoms) or psychotic disorders NOS
4. The patient is (or has recently been) active psychotic with symptoms of delusions, hallucinations, disturbed thinking, unsuitable/bizarre behaviour which cannot clearly be explained by organic reasons. The symptoms must have lasted the whole day for several days or several times a week for several weeks, not limited to some brief moments corresponding to a score of at least 4 on one or more of the following positive and negative symptom scale (PANSS) symptoms: P1 (delusions), P3 hallucinations), P5 (grandiose thinking), P6 (suspiciousness) and G9 (unusual thought content); 5. This is the first episode of the condition that is being adequately treated. i.e. the patient has not received antipsychotic treatment corresponding to 75% of a defined daily dosage for more than eight weeks (shorter if the symptoms remit)
6. There are no known neurological or endocrine disorders that may have caused the presenting psychotic symptoms
7. The patient is not mentally retarded with an IQ below 70

8. Able to understand and speak Norwegian
9. Able to understand and sign informed consent/assent for minors' document.
Prodromal inclusion and exclusion criteria
1. The patient is listed in the national register and residing in the catchment areas of: Stavanger and Fonna
2. Between 13 and 65 years
3. Meet diagnostic criteria for prodromal syndrome SIPS criteria
4. Does not meet current or life-time criteria for any psychotic disorder
5. The symptoms are not better accounted for by an axis I, axis II or substance use disorder with the exception of schizotypal personality disorder (the presence of any of these disorders in itself is not an automatic reason for exclusion)
6. Does not use any antipsychotic medication currently and have not used antipsychotic medication (regardless of dosage) for more than four weeks lifetime
7. No known neurological or endocrine disorders that may have caused the presenting psychotic symptoms
8.The patient is not mentally retarded with an IQ below 70
9. The patient must be able to understand and speak Norwegian
10. The patient must be able to understand and sign an informed consent or assent for minors' document

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
All referals not fullfilling inclusion criteria described above

Date of first enrolment
01/03/2012

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
Norway

Study participating centre
Stavanger University Hospital
Stavanger

Norway
4068

Sponsor information

Organisation
Stavanger University Hospital (Norway)

ROR
https://ror.org/04zn72g03

Funder(s)

Funder type
Other

Funder Name
The Norwegian Extra Foundation for Health and Rehabilitation through EXTRA funds (Norway)

Funder Name
Health West trust grant (grant 911508 and grant 911881) (Norway)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	22/04/2015		Yes	No