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Preventing compulsory admission to psychiatric inpatient care through psycho-education and crisis focused monitoring

Submission date
24/08/2011

Recruitment status
No longer recruiting

Registration date
06/09/2011

Overall study status
Completed

Last Edited
24/01/2019

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
The high number of compulsory admissions of people with mental disorders to psychiatric inpatient care is a major public health issue in Switzerland and other European countries. New methods are needed to improve this situation. The aim of this study is to assess the usefulness of a programme for patients at high risk of compulsory admission to psychiatric hospitals. The usefulness of the programme will be assessed in terms of a reduced number of psychiatric hospitalisations and days of inpatient care. Furthermore, the study aims to increase patient empowerment and satisfaction and reduce the degree to which the patients see treatment as coercive (perceived coercion).

Who can participate?
Patients aged 18-65 who are admitted to the participating psychiatric hospitals, who have been compulsorily admitted at least once during the past 24 months

What does the study involve?
Participants are randomly allocated to either the intervention or to the control group. The control group are treated according to the standard care procedures. Participants in the intervention group receive a 24-month intervention programme that consists of the following elements. First of all, participants attend one to three instruction sessions before they are discharged from the psychiatric hospital. These sessions are individually adapted to the patient's specific needs and experiences. They address information on relapses in mental disorders, treatment and adequate behaviour to prevent a crisis, as well as individual risk factors for a potential crisis. These risk and protective factors are discussed at the regular monitoring contacts after discharge. During the last instruction session an individualised crisis card is drawn up and handed out to the participants. Crisis cards contain information on the patient, professional or personal contact persons, diagnostic data, treatment, medication, and an individual action plan in case of a relapse. After discharge from the hospital, each participant is contacted every fourth week by telephone. These contacts cover the complete follow-up period (24 months). At each contact, the participant’s present status is assessed along with opportunities to discuss issues or to intervene in case of problems. Participants in both groups

undergo an assessment at the start of the study including interviews and questionnaires, and detailed follow-up assessments are scheduled again 12 and 24 months later.

What are the possible benefits and risks of participating?
All participants will also receive psychiatric treatment as usual (regular out- or inpatient mental health care). There are no known risks to participants.

Where is the study run from?
The study takes place at four psychiatric hospitals in the Canton of Zurich, Switzerland: Integrierte Psychiatrie Winterthur - Zürcher Unterland, Sanatorium Kilchberg AG - Privatklinik für Psychiatrie und Psychotherapie, Klinik für Affektive Erkrankungen und Allgemeinpsychiatrie Zürich Ost der Psychiatrischen Universitätsklinik Zürich and Klinik für Soziale Psychiatrie und Allgemeinpsychiatrie Zürich West der Psychiatrischen Universitätsklinik Zürich (which is the lead centre).

When is the study starting and how long is it expected to run for?
April 2010 to May 2014

Who is funding the study?
Department of Health Canton Zurich (Switzerland)

Who is the main contact?
Dr Barbara Lay

Study website
http://www.zinep.ch/pvz

Contact information

Type(s)
Scientific

Contact name
Dr Barbara Lay

Contact details
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8021

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Preventing compulsory admission to psychiatric inpatient care through psycho-education and crisis focused monitoring: a randomised controlled trial

Study objectives
1. Number and length of compulsory inpatient episodes in a psychiatric hospital during the follow-up is lower in the intervention group, compared to the control group.
2. Treatment satisfaction and level of empowerment are increased, level of internalised stigma is decreased in the intervention group, compared to the control group.
3. The outcomes are associated with a number of covariates on the patient level (treatment history, diagnosis, social network, treatment adherence in the two-year follow-up).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Zurich Cantonal Ethics Committee (CEC), Division 3 (Kantonale Ethik-Kommission Zürich (KEK) Abteilung 3), 30/11/2009, Ref E-60/2009

Study design
Multicentre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Patient information can be found at http://www.zinep.ch/pvz/flyer (German)

Health condition(s) or problem(s) studied
Severe mental illness

Interventions
1. A programme of individualised psycho-educational instruction focusing on behaviours prior to and during a illness related crisis
2. The distribution of an individualised crisis card containing essential information and guidelines for preventing an acute crisis or for acting properly prior to or during a relapse

2. A 24-month preventive monitoring of individual risk factors of relapse or inadequate disorder-treatment-related behaviour
Total duration of intervention per subject is 24 months.

The control group receives treatment as usual. For the purpose of evaluation, the control group is contacted by phone every three months only in order to gather information on health care use.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Number and length of compulsory inpatient episodes in a psychiatric hospital during the follow-up (t0 t2). This outcome criterion will be analysed in terms of both "time in hospital" and "health care costs" (measured using the Sociodemographic and Service Receipt Inventory CSSRI-EU: number and length of voluntary and involuntary psychiatric inpatient episodes; frequency and length of stays in forensic facilities, frequency of use of outpatient psychiatric care and of other services during follow-up)
1.1. All major endpoints and outcomes of the study will be compared between the intervention and the control group. The group comparability will be tested by control variables (age, sex, length of illness, severity of illness, social support).

Secondary outcome measures
1. Treatment satisfaction [baseline (t0) end of intervention (t2)], Client Satisfaction Questionnaire CSQ-8
2. Level of empowerment (t0 t2; Empowerment-Scale)
3. Internalised Stigma (t0 t2; Internalised Stigma of Mental Illness Inventory)

Overall study start date
01/04/2010

Completion date
01/05/2014

Eligibility

Key inclusion criteria
1. People with mental disorder in psychiatric inpatient treatment who have been compulsorily admitted to psychiatry at least once during the past 24 months
2. Aged 18-65 years at admission
3. Are residing in the Canton of Zurich
4. Have sufficient language skills to give meaningful information on study instruments
5. Are willing and able to consent

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
400, of which 200 each will be assigned to the intervention group or to the control group

Key exclusion criteria
1. Patients who cannot be contacted by telephone (no telephone or mobile phone available)
2. Main diagnosis of organic mental disorder International Classfication of Diseases (ICD-10 F0), mental retardation (ICD-10 F7), behavioural syndromes associated with physical factors (ICD-10 F5), developmental or behavioural disorders with onset usually occurring in childhood and adolescence (ICD-10 F8-F9)

Date of first enrolment
01/04/2010

Date of final enrolment
01/04/2012

Locations

Countries of recruitment
Switzerland

Study participating centre
Psychiatric University Hospital Zurich
Zurich
Switzerland
8021

Sponsor information

Organisation
Department of Health Canton Zurich (Gesundheitsdirektion Kanton Zürich) (Switzerland)

Sponsor details

Obstgartenstr. 19/21 - Postfach
Zurich
Switzerland
8090

Sponsor type
Government

ROR
https://ror.org/038jmw351

Funder(s)

Funder type
Government

Funder Name
Department of Health Canton Zurich (Gesundheitsdirektion Kanton Zürich) (Switzerland)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	05/09/2012		Yes	No
Results article	results	18/11/2015	24/01/2019	Yes	No
Results article	results	01/04/2018	24/01/2019	Yes	No
Results article	results	01/07/2016	24/01/2019	Yes	No
Results article	results	01/04/2015	24/01/2019	Yes	No