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Young adults living with mental illness and their family in community mental health care settings

Submission date	Recruitment status	☐ Prospectively registered
23/10/2017	No longer recruiting	☐ Protocol
Registration date	Overall study status	☐ Statistical analysis plan
25/10/2017	Completed	☒ Results
Last Edited	Condition category	☐ Individual participant data
27/08/2021	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Young adults (aged 18-25) living with mental illness may be less prepared to care for themselves than peers because of their mental illness. In addition, mental illness also affects family members' everyday lives, health, and everyday life (family is a self-identified group of two or more individuals whose association is characterized by special terms, who may or may not be related by bloodlines or laws, and who function in such a way that consider themselves to be a family). It is essential that health care professionals take a family perspective, expanding the focus of the service to support family everyday life, through viewing the family as a system in mutual interaction with strengths and resources. The aim of this study is to test a family-centered support conversation intervention (FCSCI) with young adults living with mental illness and their families.

Who can participate?
Young adults (aged 18-25) living with mental illness, receiving treatment and care from health care professionals in community health settings, and their families

What does the study involve?
Health care professionals conduct a series of three Family Centered Support Conversations with families, lasting 45-60 minutes during a period of 6 to 10 weeks. Family Centered Support Conversations are in addition to regular treatment and care in community health service related to mental illness. Questionnaires and family interviews are used to collect data before and after the families participate in family-centered support conversations.

What are the possible benefits and risks of participating?
This study will provide knowledge about the impact of a family-centered support conversation intervention on young adults living with mental illness and their families. The knowledge will enable community health services to substantially improve care and support for families living with mental illness. There may be a risk of participants experiencing some questions in the questionnaires and family interview as offensive. This risk is minimized through voluntary participation and the right to withdraw consent. The participants will also be taken care of by health professionals and the project manager.

Where is the study run from?
Norwegian University of Science and Technology (Norway)

When is the study starting and how long is it expected to run for?
October 2016 to May 2021

Who is funding the study?
Norwegian Ministry of Education and Research (Norway)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Family-centered support in community health settings related to mental illness: applying a family strength and resource conversation intervention to increase support in everyday life, family sense of coherence and quality of care

Acronym
Family Centered Support Conversation Intervention (FCSCI)

Study objectives

Based on research and the conceptual framework that guides the study, it is hypothesized that families receiving the Family-Centered Support Conversation Intervention (FCSCI) will report higher level of perceived family support, increased confident family illness beliefs, sense of coherence and quality of care than other families receiving standard of care.

Research questions:
1. How do young adults living with mental illness and their family describe everyday life in relation to illness beliefs, perceived support, quality of care and sense of coherence?
2. What are their experiences of participating in the FCSC intervention and perceptions of everyday life before and after the conversations?
3. What are their responses to everyday life in relation to family illness beliefs, family perceived support, family sense of coherence and quality of care after participating in the FCSCI intervention?
4. Comparing baseline and follow-up how do young adults living with mental illness and their families describe everyday life in relation to family illness beliefs, family perceived support, family sense of coherence and quality of care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

This study does not require ethics approval because it will not give new knowledge about health and disease, but rather about family experiences of everyday life and health care services. The project therefore falls outside the Regional Ethics Committee's (REK) mandate under the Norwegian Health Research Act, which assumes that the purpose of the project is to provide "new knowledge of health and disease", see § 2 and § 4 letter a).
The Data Protection Official for Research at the NSD - Norwegian Centre for Research data finds that the processing of personal data in relation to the project is in accordance with the Norwegian Data Act, project nr 54696.

Study design

Single-centre interventional quasi-experimental explorative study using mixed methods

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Community

Study type(s)

Other

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Mental illness which includes health conditions involving changes in thinking, emotion or behavior (or a combination of these), and is associated with distress and/or problems functioning in social, work or family activities and family everyday life

Interventions

Health care professionals conduct Family Centered Support conversations after completing a two-day seminar on the Calgary family assessment and the intervention model and skill-training with different clinical vignettes from mental illness care. The program also includes supervision after health care professionals have conducted the first conversation with the family and offered a second supervision if needed.

Health care professionals will conduct a series of three Family Centered Support Conversations with families, lasting 45-60 minutes during a period of 6 to 10 weeks.
1. Engagement and assessment – Health care professionals exercise skills that invite to establish and maintain therapeutic relationship. Each family member is invited to tell their story/narrative about how they experience the family's situation. The family and health care professionals together agree what to talk about and what changes might be desirable and possible for the family to accomplish. Four areas are explored; problem identification, relationship between family interactions and the health problem, attempted solutions to solving problems, and goals. Health care professionals explore and assess relevant categories of family structure, development, and function in order to later together reflect on aspects of family functioning, strengths, and resources that can have an impact on family everyday life. Exploring the family’s illness beliefs in the first meeting is particularly important.
2. Intervention - The focus is mainly on the cognitive and affective domain and strength and resources within and outside the family to cope with everyday life. The families are invited to reflect on the nature of their problems and coping strategies. Health care professionals use interventive questions to engage all family members, to assess the impact of the problem/illness on the family, to elicit problem-solving skills, coping strategies and strengths and to invite change.
3. Intervention and termination - The focus is on the families experience on everyday life and the future. Emphasis on identify, affirming, step up and set changes occurred within and between family members in everyday life. Routinely commend family and individual strengths, competencies, and resources. It serves as a closure of conversation. Four to six weeks after last conversation health care professionals make contact with the family to monitor on how they are coping.

Family Centered Support Conversations should be in addition to regular treatment and care in community health service related to mental illness.

Both quantitative methods with pre/post test and qualitative methods of data collection and analysis will be used.

Intervention Type

Behavioural

Primary outcome measure

Primary outcome measure as of 04/10/2018:
Quantitative:
For patients and family members:
1. Illness beliefs about cause of illness (etiology), control of illness on family and control of family on illness, effect of illness on the individual and family, illness suffering and support received from health care professionals during illness, measured using the Iceland- Family Illness

Beliefs Questionnaire (ICE-FIBQ)(N). Measured in November 2018- June 2019
2. Family's perceptions of support provided by health professionals, measured using the Iceland – Family Perceived Support Questionnaire (ICE-FPSQ) (N). Measured in November 2018- June 2019

Qualitative:
1. Young adult living with mental illness and their family's experiences of participating in family-centered support intervention and perceptions of everyday life before and after the intervention. Family interviews one month after the last conversation will be analyzed and described with phenomenography. Phenomenography investigates the qualitative different way people perceive, understand and experiences or thinks about a phenomenon. In accordance with the FCSC intervention where perceptions on the family situation are essential. Measured in February 2018

Previous primary outcome measure:
Quantitative:
For patients and family members:
1. Illness beliefs about cause of illness (etiology), control of illness on family and control of family on illness, effect of illness on the individual and family, illness suffering and support received from health care professionals during illness, measured using the Iceland- Family Illness Beliefs Questionnaire (ICE-FIBQ)(N). Measured in October 2017, January 2018 and April 2018
2. Family's perceptions of support provided by health professionals, measured using the Iceland – Family Perceived Support Questionnaire (ICE-FPSQ) (N). Measured in October 2017, January 2018 and April 2018
3. Family's global sense of coherence, measured using the Family Sense of Coherence Scale (FSOC) in October 2017, January 2018 and April 2018
4. Degree of psychological distress in the patient (primarily symptoms of anxiety and depression) within the last week, measured using the Hopkins Symptom Checklist-10 (HSCL-10) in October 2017, January 2018 and April 2018

Qualitative:
1. Young adult living with mental illness and their family's experiences of participating in family-centered support intervention and perceptions of everyday life before and after the intervention. Family interviews one month after the last conversation will be analyzed and described with phenomenography. Phenomenography investigates the qualitative different way people perceive, understand and experiences or thinks about a phenomenon. In accordance with the FCSC intervention where perceptions on the family situation are essential. Measured in February 2018

Secondary outcome measures
Secondary outcome measures as of 04/10/2018:
Secondary outcome measures
For patients:
1. Quality of care from a patient perspective, measured using Quality in Psychiatric Care - Your experiences of community psychiatric care (QPC-OPC)(N) in November 2018- June 2019
For family members:
2. Quality of care, measured using Quality in Psychiatric Care - Your experiences as next of kin of community psychiatric care (QPC-OPNC)(N) in November 2018- June 2019

Previous secondary outcome measures:
For patients:

1. Quality of care from a patient perspective, measured using Quality in Psychiatric Care - Your experiences of community psychiatric care (QPC-OPC)(N) in October 2017, January 2018 and April 2018

For family members:
2. Quality of care, measured using Quality in Psychiatric Care - Your experiences as next of kin of community psychiatric care (QPC-OPNC)(N) in October 2017, January 2018 and April 2018

Overall study start date
01/10/2016

Completion date
30/05/2021

Eligibility

Key inclusion criteria
Patients:
1. Young adults between 18-25 years old
2. Living with mental illness facing problem and strain, impaired function associated with distress, symptoms, and diagnosable mental disorders
3. No diagnosis is required
3. Living alone or with family and/or friends and/or others
4. Speak and read Norwegian
5. Contact with community health services related to mental illness

Family members:
1. Family members over 18 years old
2. Defined by the young adult to be in the family
3. Able to speak and read Norwegian

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Upper age limit
25 Years

Sex
Both

Target number of participants
Patients: 100 and family members; up to 200 (each patient can choose up to 2 family members).

Total final enrolment

106

Key exclusion criteria
Patients:
1. Cognitive impairment
2. Psychotic state
3. Alcohol or drug dependence
4. Living in a residential home for mentally ill persons

Family members:
1. Cognitive impairment
2. Psychotic state
3. Alcohol or drug dependence

Date of first enrolment
02/10/2017

Date of final enrolment
30/06/2019

Locations

Countries of recruitment
Norway

Study participating centre
Norway - Municipalities
Norway
2816

Sponsor information

Organisation
Norwegian University of Science and Technology

Sponsor details
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Sponsor type

University/education

Website
http://www.ntnu.edu/ihg/

ROR
https://ror.org/05xg72x27

Funder(s)

Funder type
Government

Funder Name
Norwegian Ministry of Education and Research

Results and Publications

Publication and dissemination plan
Publication and dissemination plan as of 05/07/2019:
Article I -Submitted in march, now in the revision process and (hopefully) published in the early autumn 2019- qualitative study
Article II- Publication late autumn 2019 – qualitative study
Article III- Spring 2020 – quantitative study
Spring 2021 – Dissemination

Publication and dissemination plan as of 14/11/2018:
The study protocol will be submitted for publication
Article I - publication spring 2019 - quantitative study
Article II - publication autumn 2019 - qualitative study
Article III - publication spring 2020 - quantitative study
Spring 2021 - Dissemination

Publication and dissemination plan as of 04/10/2018:
The study protocol will be submitted for publication
Article I - publication spring 2019 - qualitative study (changed from quantitative to qualitative)
Article II - publication autumn 2019 - qualitative study
Article III - publication spring 2020 - quantitative study
Spring 2021 - Dissemination

Previous publication and dissemination plan:
The study protocol will be submitted for publication
Article I - publication autumn 2018 - quantitative study
Article II - publication autumn 2019 - qualitative study
Article III - publication spring 2020 - quantitative study
Spring 2021 - Dissemination

Intention to publish date
30/05/2022

Individual participant data (IPD) sharing plan
The dataset will not be available before after further analysis of the data. After the PhD dissertation the publication of the dataset will be reconsidered. The data will be secured at the university.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/11/2020	27/08/2021	Yes	No
Results article		03/05/2021	27/08/2021	Yes	No