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Ups & downs in mental health-effectiveness of flexible assertive community treatment in general mental health services - the UDiM-FACT trial

Submission date
30/09/2025

Recruitment status
No longer recruiting

Registration date
08/10/2025

Overall study status
Completed

Last Edited
01/07/2026

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Background and study aims
No care model exists for the group of persons with alarming, fluctuating and complex mental health needs, often with self-harm behaviours and a high risk of suicide, who are in desperate need of both crisis interventions and sustainable community support that benefits their mental health and functioning in everyday life. Extensive criticism has been raised by the Swedish government about the disintegration of mental health services. There is a call for holistic and cross-sectoral work between welfare services that ensures a gathering of power around mental health. Current interventions fail to integrate outpatient and inpatient care, and mental health and social services. Both service users and professionals express frustration with such a care model. These circumstances call for a radical change of new perspectives, organisation and delivery of care. To create a cohesive care model with realistic goals, this study planning began in January 2018. A collaborative research network was formed that included staff and managers in mental health and social services, service users, and researchers. In the co-creation of research questions, a Flexible Assertive Community Treatment (FACT) model that meets the ups and downs of users' mental health is forwarded. A multidisciplinary team upscales and downscales the intensity of care to fit users' needs at critical points in time and in relation to everyday life, with a seamless transition of care in which user-professional relationships are kept throughout the chain of events. Notably, the service user representatives determined that a randomly allocated trial design was needed to enhance the opportunities to make a difference in future policy and further research development. The overall aim of the UDiM-FACT-trial is to improve the understanding of whether a multiprofessional team using the FACT model can significantly affect health and everyday functioning (primary outcome), in comparison to existing care and support initiatives, among outpatients with fluctuating and complex needs at 12 months in the context of Swedish Mental Health Services of Region Skåne. The project will further inform us of the effect on clinical recovery (symptoms) and personal recovery, as well as care use (secondary outcomes) and the health economy. Issues related to the implementation process, development of collaboration competence of the FACT team and service user experiences will also be targeted.

Who can participate?
Participants aged between 18 and 67 with a) mental disorder (one or multiple diagnosis of mood, personality, substance abuse, post-traumatic stress, attention deficit disorders), b) low community functioning associated with mental disorder, c) need of integrated mental health and community mental health services, who reside in Helsingborg, Lund or Malmö municipality catchment areas and be assigned to general mental health outpatient services.

What does the study involve?
This trial will compare two approaches to mental health care: FACT and Care As Usual (CAU). FACT is a team-based model where a group of professionals, including psychiatrists, psychologists, nurses, peer supporters, and others, work together to support people with mental health needs. The team meets daily, adjusts care intensity based on the person's situation, and stays with the individual throughout their treatment. It focuses on the person's strengths and everyday life, aiming to prevent crises like suicide or isolation through proactive planning and shared decision-making.

In contrast, CAU reflects the typical mental health care setup, where individuals usually see one professional and receive fragmented support. Treatments like CBT or DBT are available but not well integrated with other services or the person's daily life. Hospital admissions are common and often lengthy, and there's little coordination between mental health and social services.

What are the possible benefits and risks of participating?
Possible benefits are increased health and functioning for those receiving the FACT intervention and an integrated and person-centred mental health and recovery service, and for all participants, of being able to impact on future interventions provided. No risks are related to the FACT intervention according to previous single-group cohort trials. The survey includes questions concerning, for example, health and perceived participation in society, which may be considered sensitive. However, all self-assessment instruments have previously been employed by the research group in earlier studies without any reported issues related to confidentiality, discomfort, or risks. Organising care in accordance with the FACT model appears instead to promote safer care, with enhanced collaboration between outpatient and inpatient services as well as social services, aimed at mitigating risk.

Where is the study run from?
Lund University in Sweden is managing the study while the interventions are taking place in the Mental Health Services in the County Council of Region Skåne and the Social Services of 11 municipalities.

When is the study starting and how long is it expected to run for?
January 2018 to October 2025

Who is funding the study?
Research planning, performance, analysis and dissemination are funded by grants from the Swedish Research Council for Health, Working Life and Welfare and the Swedish Research Council, as well as the FRF Foundation-The Foundation for Rehabilitation and Medical Research Fundraising Foundation, Sweden.

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Protocol serial number
Forte Dnr 2019-00073

Study information

Scientific Title
Ups and downs in mental health-effectiveness of flexible assertive community treatment on health and everyday functioning among persons with alarming and complex mental health needs as compared to care as usual

Acronym
UDiM-FACT trial

Study objectives
It is hypothesized that Flexible Assertive Community Treatment is more effective as compared to CAU at 12 months in terms of significantly improving 1) health and functioning as assessed by WHODAS (WHO 2018) (primary outcome), 2) personal recovery, and 3) clinical recovery (symptoms), and 4) reducing care use of outpatient and inpatient care (secondary outcomes).

Ethics approval required
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Ethics approval(s)
1. Approved 12/06/2019, Swedish Ethical Review Authority (Postal Box 2110, Uppsala, 750 02, Sweden; +46 10-4750800; registrator@etiksprovning.se), ref: 2019-02866

2. Approved 20/12/2022, Swedish Ethical Review Authority (Postal Box 2110, Uppsala, 750 02, Sweden; +46 10-4750800; registrator@etiksprovning.se), ref: 2022-05512-02

3. Approved 04/10/2023, Swedish Ethical Review Authority (Postal Box 2110, Uppsala, 750 02, Sweden; +46 10-4750800; registrator@etiksprovning.se), ref: 2023-05527-02

Primary study design
Interventional

Study design
Randomized assessor-blinded multicenter trial

Study type(s)
Diagnostic, Efficacy, Quality of life, Treatment

Health condition(s) or problem(s) studied
Outpatients in general mental health services with mental health disorders (one or multiple diagnosis of mood-, personality-, substance abuse-, post traumatic stress-, attention deficit disorders).

Interventions
This is a randomised, assessor-blinded, multicenter trial that will be performed. Participants will be randomly assigned to FACT and care as usual (CAU).

Randomisation and blinding:
Randomisation will be performed centrally by an independent statistics unit, not part of the research group. The treatment allocation ratio is 1:1, and the allocation will be concealed from researchers. All data will be encrypted, generated and downloaded to the RedCap digital data management system and stored according to the safe data-secure LUSEC system of Lund University. Study participants and professionals in FACT and CAU will not be blinded to allocation, but the research nurse will be, who assists participants with data completion if necessary. The assistant will inform the participant about the non-disclosure situation. Information with regard to non-disclosure will also be provided verbally at the information meeting and written in the consent form.

The FACT intervention is a manual-based version of team-case management. It involves a multidisciplinary team of 11–12 full-time professionals who provide services to 200–220 users per 50,000 citizens. The team includes psychiatrists, psychologists, nurses, IPS-employment specialists, social workers, peer supporters (staff with own experience of having mental health problems and being a service user), occupational therapists, and experts on housing, addiction and physical health care and support. The team meets daily in face-to-face or digital interactions. The flexibility in the team regards systematic coordination of scaling up and down intensive care, using clear criteria for this, and the entire team is involved. In times of crisis, the user is actualised on a digital FACT ACT board, at which point care is switched to assertive community care that is person-centred and thus makes mental, emotional, and practical sense to the user. The team focuses on user strengths, and on personal, social, practical and symptomatic domains connected to mental health and everyday functioning. Stigmatisation by the team and self-stigmatisation by the user are counteracted. The peer supporters in the team have a critical role to play in that sense. The team applies a PDSA cycle (plan, do, study, act), which involves the user /private network, and routine outcome measurements to develop practice. Assertive proactive crisis plans are performed to prevent suicide, social isolation, aggression and crime. The caseload

of providing intensive team-based care is about 20%. This incorporates shared caseloads and frequent visits at any time of the day. The flow between the intensity levels is mediated without referrals by using routine team decision-making that departs from shared decision-making with the user. Furthermore, the service user remains in the same team, which enhances continuity and seamless care and support.

The CAU intervention comprises a variety of single mental health services with little organisation, standardisation, or integration of services. This model typically focuses on medical treatment and includes a supportive contact with a single professional in the general MHS team, with little integration of support from other professionals or services. In addition, a time-limited psychotherapeutic treatment period, e.g., Cognitive Behaviour Therapy (CBT), and Dialectic Behaviour Therapy (DBT), are also available. Such a treatment period is not integrated with other interventions in a distinct manner, nor is it connected to the everyday life situation and community environment of the service users. Psychiatric admissions (voluntary/involuntary) to hospitals are reactive and frequent among users, who stay there for long periods. No systematic collaboration between the general MHS and the social services of municipalities exists, which means that the service user is subjected to little continuity in care and support.

Intervention Type
Behavioural

Primary outcome(s)
1. Health and functioning measured using the WHO Disability Assessment Scale, WHODAS 2.0 (36-items), linked to the International Classification of Functioning, Disability and Health (ICF) theoretical framework, at baseline, 6 and 12 months

Key secondary outcome(s)
Secondary outcome measures:
Personal recovery:
1. Well-being, measured using the WHO-5 well-being index, at baseline, 6 and 12 months
2. Quality of Life, measured using the Manchester Short Assessment of Quality of Life Scale, at baseline, 6 and 12 months
3. Quality of life, measured using European Quality of Life-5 Dimensions (EQ-5D9) at baseline, 6 and 12 months (also for calculations of quality-adjusted life-years (QALYs) among persons with MHP)
4. Perception of support in relation to connectedness, hope, identity, meaningfulness, and empowerment, measured using the Brief Inspire, at baseline, 6 and 12 months
5. Status of employment, housing, friends, family/partnership roles, measured using Objective Social Outcome Index (SIX), at baseline, 6 and 12 months
6. Personal recovery process, measured using the Questionnaire about the Process of Recovery (QPR) at baseline, 6 and 12 months
7. Self-stigma, measured using the Brief Internalized Stigma of Mental Illness (ISMI) scale, at baseline, 6 and 12 months

Clinical recovery:
8. Emotional regulation measured using the Difficult in Emotional Regulation Scale (DERS), at baseline, 6 and 12 months
9. Depression measured using the Montgomery-Asberg Depression Scale-Self rating, at baseline, 6 and 12 months
10. Anxiety measured using the General Anxiety Disorder (GAD), at baseline, 6 and 12 months
11. Self-harm using the Deliberate Self-Harm Inventory (DSHI), at baseline, 6 and 12 months

12. Alcohol- and drug consumption measured using the Alcohol- and Drug Use Identification Tests, at baseline, 6 and 12 months.
13. Care use will be measured using inpatient and outpatient care use indicators and will be retrospectively collected from medical journals and a complementary questionnaire at single points in time.

Implementation:
14. FACT fidelity assessment measured using a Swedish version. No study participants will partake.

Completion date
31/10/2025

Eligibility

Key inclusion criteria
1. Residing in Helsingborg, Lund or Malmö municipality catchment areas
2. Being assigned to and being a patient in the general Mental Health Services
3. Age between 18-67
4. Being diagnosed with a mental disorder (one or multiple diagnoses of mood-, personality-, substance abuse-, post-traumatic stress-, attention deficit disorders)
5. Expressing having low everyday functioning associated with a mental disorder
6. Expressing a need for integrated mental health and community Mental Health Services
7. Attending an information meeting (or individually) about the trial study

Participant type(s)
Patient, Service user

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
67 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Being diagnosed with a psychotic mental health disorder
2. Being assigned to mental health services for persons with psychosis

Date of first enrolment
07/05/2020

Date of final enrolment
31/10/2024

Locations

Countries of recruitment
Sweden

Study participating centre
Adult Psychiatry Clinic Södergatan Helsingborg
Södergatan 11A
Helsingborg
Sweden
25218

Study participating centre
Adult Psychiatry Centre
Baravägen 1
Lund
Sweden
21185

Study participating centre
General Psychiatry Centre
Ahlmansgatan 1
Malmö
Sweden
20502

Sponsor information

Organisation
Lund University

ROR
https://ror.org/02d290r06

Funder(s)

Funder type
Government

Funder Name
Forskningsrådet om Hälsa, Arbetsliv och Välfärd

Alternative Name(s)
Swedish Research Council for Health, Working Life and Welfare, Forskningsrådet om Hälsa, Arbetsliv och Välfärd, FORTE

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Funder Name
FRF Foundation - The Fund for Rehabilitation and Medical Research Fundraising Foundation

Funder Name
Vetenskapsrådet

Alternative Name(s)
Swedish Research Council, VR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Sweden

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will we be stored according to ethical guidelines at LUSEC, https://www.intramed.lu.se/en/research/managing-your-data-secure-manner/managing-data-high-security-environment-using-lusec?q=research/managing-your-data-secure-manner/managing-data-high-security-environment-lusec. Please contact ulrika.bejerholm@med.lu.se for availability request.

IPD sharing plan summary

Available on request, Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	Qualitative research exploring the collaboration process	22/06/2026	01/07/2026	Yes	No