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The Lovisenberg Open Acute Door Study (LOADS): a trial of an open-door policy for psychiatric wards

Submission date
29/01/2021

Recruitment status
Recruiting

Registration date
29/01/2021

Overall study status
Ongoing

Last Edited
11/03/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Freedom of movement is a fundamental human right that is systematically restricted in acute psychiatry to address safety, prognosis and/or staffing concerns. The legitimacy and therapeutic impact of the current state-of-the art 'locked door' practice has recently been called into question by the United Nations, the WHO, user organisations, and the Norwegian Government. In this study, the Lovisenberg Diaconal Hospital will implement and test a new service model, open-door policy, to investigate their potential to reduce coercion on our inner-city acute psychiatric wards.

Who can participate?
Adults 18 - 65 years, referred to an acute psychiatric ward from a psychiatric intensive care unit.

What does the study involve?
In this healthcare services RCT, the Lovisenberg Open Acute Door Study (LOADS), staff will randomly assign admitted acute psychiatric patients to two open-door policy wards or three state-of-the-art locked-door wards for 12 months. The RCT will be followed by a 4-year observational period to report on any post RCT effects on violent and coercive events, patient feedback, or the treatment stay (duration, type/intensity of treatments received, readmission). All wards are located in the same building facility at Lovisenberg campus in Oslo, Norway. The hypothesis is that open-door care will be equivalent to locked-door care on safety and coercive measures, and equivalent- or superior to locked-door care on patient experiences of treatment.

What are the possible benefits and risks of participating?
The benefit may be an improvement in care.
The risk of participating in any study arm can be considered equivalent to or better than standard care, as Lovisenberg's regular (locked-door) services have previously been acclaimed for user-orientation and ability to minimise coercion.
Standard clinical data (including patient feedback/experience measures) will be utilised.

Where is the study run from?
Lovisenberg Diaconal Hospital Clinic of Psychiatry (Norway)

When is the study starting and how long is it expected to run for?
February 2020 to December 2025

Who is funding the study?
1. Lovisenberg Diaconal Hospital (Norway)
2. The Research Council of Norway
3. The South-Eastern Norway Regional Health Authority

Who is the main contact?
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
RCN 309903

Study information

Scientific Title
The Lovisenberg Open Acute Door Study: a randomised clinical trial of open-door policy services for ward-based, acute psychiatric healthcare services

Acronym
LOADS

Study objectives
An open-door policy service model does not cause more incidents of violence, coercive measures or suicide than a standard, locked-door service model.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved as a healthcare services study with exemption from consent requirements on 02/02/2020, Regional Ethical Committee South-East D (P.O. Box 1130, Blindern, 0318 Oslo, Norway; +47 22 84 55 11; rek-sorost@medisin.uio.no), ref: 29328

Study design
Interventional randomized controlled single-centre study with observational follow up

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Minimisation of violent incidents and of unnecessary coercive measures in acute inpatient treatment of patients with serious psychiatric disorders or states.

Interventions
All patients referred to acute ward care from an admissions ward or psychiatric intensive care unit (PICU) are randomly allocated to either:
1. Two wards with an open-door policy service model that provides peer service workers, treatment planning based on open dialogue with next of kin or collaborating outpatient/city services, and free mobility during daytime hours (09.00-21.00) through the ward door (contingent on frequent, accurate risk assessment)

2. Three wards with a standard, locked-door policy including de-escalation training. As a healthcare services trial, the type and duration of interventions are applied by ward staff based on individual assessment of the patient's needs.

To minimise the ethical and clinical burden of random allocation of patients to wards, patients returning from a recent (2020) admission are allocated using a 'home ward' principle, while new patients are allocated using a randomisation list. This randomised phase lasts 12 months, after which an observational phase commences during which more wards adopt the open-door policy model provided study hypotheses are supported. Standard acute ward observational statistics will be collected for monthly, quarterly, and annual reports for 4 years on violent and coercive events, types and doses of treatments, length of stay, unauthorised leave/absconding, patient feedback measures, readmission (time to- and general rates). The design permits pre-post analyses of effects as well as randomised parallel groups comparisons.

Intervention Type
Behavioural

Primary outcome(s)
Number of patient stays with one or more coercive measures (including involuntary medication, isolation/seclusion, mechanical- or manual/physical restraints) is measured by summarising registered coercive measures per study arm in patient records at 12 months (RCT), and (observational) 24, 36, and 48 months

Key secondary outcome(s))
1. Violent events, including suicides, are measured using the hospital incident registry at 12 months, 24, 36, and 48 months
2. Individual coercive measures (including medications, seclusion, mechanical or manual/physical restraints) are measured using patient records and summarised at 12 months, 24, 36, and 48 months
3. Duration of separate involuntary/coercive measures are measured in patient records at 12 months (RCT), and (observational) 24, 36, and 48 months
4. Patients' experience of coercion and treatment environment are measured by patient-reported experience measures (PREMs) continuously and summarised at 12 months, 24, 36, and 48 months
5. Absconding from inpatient care is measured in the patient records of all involuntarily admitted patients at 12 months (RCT), and (observational) 24, 36, and 48 months
6. Type and extent of in-building use of illicit substances and alcohol abuse is measured by continuous on-site measuring of substances and metabolites in wastewater and comparing this to baseline (2020) samples.
7. Type and extent of pharmaceutical treatments are measured by patient records at 12 months (RCT), and (observational) 24, 36, and 48 months
8. The amount of time main doors are open to patients (as opposed to locked due to emergencies) is measured using in-ward door records at 12 months (RCT), and (observational) 24, 36, and 48 months

Completion date
31/12/2025

Eligibility

Key inclusion criteria

1. Adults aged 18 - 65 years
2. Referred to acute psychiatric ward from a psychiatric intensive care unit (PICU)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
556

Key exclusion criteria
1. Forensic category patient (assessed as having a high risk of committing violence)
2. Police or criminal justice custody patient without legal option to utilise the open-door service

Date of first enrolment
10/02/2021

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
Norway

Study participating centre
Lovisenberg Diaconal Hospital Clinic of Psychiatry
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Sponsor information

Organisation
Lovisenberg Diakonale Sykehus

ROR
https://ror.org/03ym7ve89

Funder(s)

Funder type
Government

Funder Name
Norges Forskningsråd

Alternative Name(s)
Forskningsrådet, Norwegian Research Council, Research Council of Norway, The Research Council of Norway

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Norway

Funder Name
Helse Sør-Øst RHF

Alternative Name(s)
South-Eastern Norway Regional Health Authority, Southern and Eastern Norway Regional Health Authority, helsesorost, Helse Sør-Øst RHF, helse-sor-ost-rhf, HSØ RHF - South-Eastern Norway Regional Health Authority, sorost

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Norway

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available.
The Privacy Ombudsman of Lovisenberg Diaconal Hospital has requested participant-level data not be made available to external parties due to the sensitive nature of psychiatric diagnoses and acute psychiatric admissions.

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		06/03/2024	07/03/2024	Yes	No
Protocol article		16/02/2022	17/02/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes