

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	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 29/01/2021	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 11/03/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> 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

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

No participant information sheet available

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 measure

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

Secondary outcome measures

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

Overall study start date

02/02/2020

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

500 (RCT)

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 type

Hospital/treatment centre

Website

<http://lds.no/>

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

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, sorost

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Norway

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal during Q3-4 2022.

Follow-up publications in high-impact peer-reviewed journals from Q3 2022 until Q3 2026.

National / local dissemination in peer-reviewed and popular / public journals as well as video dissemination.

Intention to publish date

15/07/2026

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?
Protocol article		16/02/2022	17/02/2022	Yes	No
Results article		06/03/2024	07/03/2024	Yes	No