Lovisenberg Open Acute Door Study (LOADS) –

a pragmatic, randomized controlled trial to compare open-door policy with usual-care services in acute psychiatric wards

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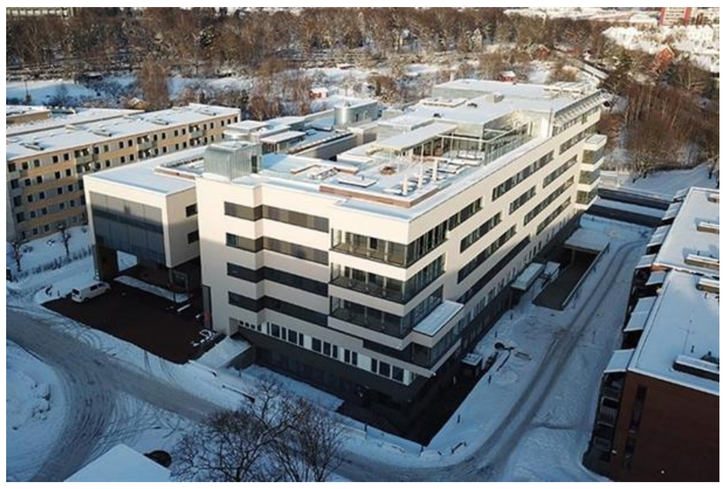
Why Open-door Policy?

Open-door policy (ODP) is a framework for acute psychiatric services that includes increased freedom of movement, use of peer support workers, as well as training of staff in coercion prevention, de-escalation, recovery thinking, and shared decision making.

More recently, there has been debate whether routinely locking the main doors is a necessary precaution or constitutes a form of coercive measure that is destructive to the wards' therapeutic mandate. Observational data from open-door psychiatric wards suggest considerable reductions in the use of coercive measures when compared to traditional, closed-door services [1-5]

Lovisenberg Diakonale Sykehus



Status September 2021:

- 9 months with ODP at two acute psychiatric wards
- The main doors have been open 85 % of the time
- The doors to the 'side-wing' (a separate area or 'skjerming' inside the ward) have been unlocked 80% of the time
- There has been no increase in serious adverse events in open-door policy wards relative to standard policy wards

Objectives

The objective of the Lovisenberg Open Acute Door Study (LOADS) is to implement and evaluate an Open-door policy service framework for acute psychiatric services and conduct a randomized controlled comparison to usual-treatment (TAU) acute psychiatric services.

Research setting

The Lovisenberg diaconal hospital (LDH) catchment area includes three inner-city boroughs (St. Hanshaugen, Grünerløkka, and Gamle Oslo) and an additional 12% patients admitted from surrounding boroughs. The inner-city Oslo catchment area includes the main railway station and the city's main open drug scenes and has some of Norway's highest accumulated levels of social - and mental health problems.

The study location, the LDH Department of Psychiatry, is located in a high-rise building, the 'L21F', located on the Lovisenberg campus. The L21F includes a psychiatric intensive care unit (PICU) on the ground floor, and six regular wards with ten beds each.

The Department of Psychiatry in 2020 had a total of 800 patients with approximately 1100 admissions, of which around 40% were brief stays (1-2 days) at the PICU. Patients in need of more inpatient treatment are transferred to regular wards situated on the upper floors of the building. It is these upper wards that are the main setting of the LOADS trial. Around 2/3 of patients treated in regular wards are involuntarily admitted and stay for an average of 18 days. The acute responsibilities of the hospital generates significant diversity among referred patients, but the majority of in-study patients are referred for treatment or observation of psychotic symptoms.

Participants

Participants will be adult patients (18 years old or older) from the Lovisenberg Diaconal Hospital's (LDH) catchment area, admitted from the Psychiatric Intensive Care Unit (PICU) at LDH and referred to ordinary acute ward care.

Study design

The evaluation of LOADS will be conducted as a pragmatic, randomized controlled trial combined with a process evaluation. The primary source of data will be electronic patient records.

Evaluation of primary outcome:
Hypotheses RCT (12 mo) - Non-inferiority
Hypotheses pre-post (24-48+ mo) - Superiority

Randomization

1. **Ward-level randomization:** Two of the five eligible wards were randomly allocated to commence implementing ODP in February 2021.
2. **Patient-level randomization:** Upon referral, patients are randomly allocated to either Open door policy (ODP) on two wards or regular acute psychiatric ward services on the remaining three wards using a simple 2/5 vs 3/5 random list distribution generated using random.org
Patients evaluated by the PICU to be at high - and imminent risk of violent behavior will be referred to the high-security acute ward that has an increased staffing factor.

Primary outcome

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

Secondary outcome

- Safety outcomes: reported violent events, completed suicides
- Experienced coercion (ECS - Nyttingnes et al.)
- Ward climate (EssenCES - Schalast et al.)
- Substance use
- Absconding
- Threats and violence against staff

Picture of staff *Dagens medisin April 17. 2020*

Ethical considerations

The regional Ethical committee for research South-Eastern Norway has designated LOADS as a healthcare services study and granted LOADS exemption from ordinary consent rules. The decision was based on the importance of LOADS in National hospital prioritization plan, and the risk of introducing selection bias. The study is approved by the Scientific Committee of Lovisenberg Diaconal Hospital (LDH), the LDH Privacy Ombudsman as well as the LDH Board of users. LOADS thus complies with the declaration of Helsinki. LOADS has 'stop rules' similar to pharmacological trials based on the number of serious adverse events attributable to ODP.

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