Open-door policy versus treatment-as-usual in urban psychiatric inpatient wards: a pragmatic, randomised controlled, non-inferiority trial in Norway

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Summary

Background Open-door policy is a recommended framework to reduce coercion in psychiatric wards. However, existing observational data might not fully capture potential increases in harm and use of coercion associated with open-door policies. In this first randomised controlled trial, we compared coercive practices in open-door policy and treatment-as-usual wards in an urban hospital setting. We hypothesised that the open-door policy would be non-inferior to treatment-as-usual on the proportion of patients exposed to coercive measures.

Methods We conducted a pragmatic, randomised controlled, non-inferiority trial comparing two open-door policy wards and three treatment-as-usual acute psychiatric wards at Lovisenberg Diaconal Hospital in Oslo, Norway. An exemption from the consent requirements enabled inclusion and random allocation of all patients admitted to these wards using an open list (2:3 ratio) administrated by a team of ward nurses. The primary outcome was the proportion of patient stays with one or more coercive measures, including involuntary medication, isolation or seclusion, and physical and mechanical restraints. The non-inferiority margin was set to 15%. Primary and safety analyses were assessed using the intention-to-treat population. The trial is registered with ISRCTN registry and is complete, ISRCTN16876467.

Findings Between Feb 10, 2021, and Feb 1, 2022, we randomly assigned 556 patients to either open-door policy wards (n=245; mean age 41·6 [SD 14·5]; 119 [49%] male; 126 [51%] female; 180 [73%] admitted to the ward involuntarily) or treatment-as-usual wards (n=311; mean age 41·6 [4·3]; 172 [55%] male; 138 [45%] female; 233 [75%] admitted involuntarily). Data on race and ethnicity were not available. The open-door policy was non-inferior to treatment-as-usual on all outcomes: the proportion of patient stays with exposure to coercion was 65 (26·5%) in open-door policy wards and 104 (33·4%) in treatment-as-usual wards (risk difference 6·9%; 95% CI –0·7 to 14·5), with a similar trend for specific measures of coercion. Reported incidents of violence against staff were 0·15 per patient stay in open-door policy wards and 0·18 in treatment-as-usual wards. There were no suicides during the randomised controlled trial period.

Interpretation The open-door policy could be safely implemented without increased use of coercive measures. Our findings underscore the need for more reliable and relevant randomised trials also to investigate how a complex intervention such as open-door policy can be efficiently implemented across health-care systems and contexts.

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Research in context

Evidence before this study

Before designing the study, we searched PsycINFO, MEDLINE, Embase, PSYNDEX, and CINAHL from database inception to Feb 1, 2021, with no restriction on language. We repeated the search on May 30, 2023. We used the following search terms ("open door policy") OR ("open door") OR ("locked door") OR ("closed door") AND ("coercion") OR ("coercive practice") OR ("coercive") OR ("coercive measure") OR ("coercive treatment") OR ("involuntary treatment") OR ("involuntary medication") OR ("seclusion") OR ("isolation") OR ("restraint") OR ("mechanical restraint") OR ("physical restraint"). We did not find any systematic literature review on open-door policy and coercive practice. One German-language review of 26 observational studies found that open-door policies tended to reduce coercion but that randomised controlled trials were missing from the literature. We identified several observational studies, mainly from Germany and Switzerland, suggesting potential for reductions in the use of coercive practices such as mechanical restraints, seclusion, and forced medication when compared with traditional, locked-door services. The only identified randomised controlled trial evaluating open-door policies on any outcome was a 6-month intervention with 50 female patients with schizophrenia, conducted in China more than 25 years ago. The trial showed positive effects on chronic residual symptoms but did not evaluate coercive practices.

Added value of this study

This randomised controlled trial is the first to investigate the effect of an open-door policy on coercive measures and addresses the shortcomings of observational designs, for example by using random allocation to ensure comparable groups of patients receive open-door policy or treatment-as- usual care during the same time period. Additionally, random selection, in which two of five wards would implement open- door, reduced the likelihood of staff performance bias effects. The trial was granted exemption from the consent requirement by Norway's Regional Committees for Medical and Health Research Ethics, which enabled inclusion of all the patients referred to these wards in a regular manner. We found that the open-door policy was non-inferior to treatment-as-usual locked wards with respect to the use of coercive measures and that it could be implemented without compromising the safety of patients and staff.

Implications of all the available evidence

Increased voluntary treatment and minimal use of coercive measures have long been recommended by major international and national governing bodies. However, there is a concern among clinical professionals and staff that new practices might compromise the safety of patients and staff. Our findings suggest that open-door policies can be safely implemented in psychiatric wards without an increase in coercive measures or serious adverse events. The limited evidence available underscores the need for more reliable and relevant randomised controlled trials to substantiate the finding that open-door policies are non-inferior to treatment- as-usual locked wards with respect to the use of coercive measures.

Introduction

Finding the balance between collaborative and restrictive practices has been a pressing issue throughout the history of psychiatry, from Philippe Pinel to the recent World Psychiatry Association (WPA)-Lancet Psychiatry Commission on the Future of Psychiatry.[1] On one hand, the use of coercive practices risks violating patients' human rights and increases the risk of physical harm, psychological trauma, antagonism towards healthcare services, and institutionalisation and passivity.[2–4] On the other hand, relying solely on voluntary and collaborative measures might fail to prevent people with mental disorders from causing harm to themselves or others.[5] Thus, in most jurisdictions, coercive practices such as detention in a locked ward, seclusion, or mechanical restraint, are sanctioned during acute psychiatry care under certain legal conditions.

In recent years, major initiatives have been launched to transform mental health care by implementing alternatives to the use of coercion. The WPA Working Group on Implementing Alternatives to Coercion in Mental Health Care[4,5] and WHO's Quality Rights[6, 7] build on key principles of the UN Convention on the Rights of Persons with Disabilities[8] and refer to open-door policy as one approach to reducing coercive practice in mental health care. The Council of Europe[9] and Mental Health Europe[10] also recommend an open-door policy as a hospital-based intervention to create less restrictive care for people with mental health disorders. An open-door policy means increasing collaborative efforts and risk assessment with each patient on a ward to the extent that the main ward door can remain unlocked as much as possible.[11] Only if voluntary and collaborative measures and various types of pressure from health-care staff are ineffective can more restrictive measures be taken to prevent imminent harm to self or others, including coercive practices and locking the ward door temporarily.[11]

As psychiatric wards are known to vary in organisation, judicial framework, and staff resources, an open-door policy permits some flexibility in the number and types ofcollaborative practices needed on a given ward. According to our systematic literature search, the best current research evidence on open-door policy is limited to studies with observational designs, of which some are registry studies of several thousand admissions and others are longitudinal studies with pre-intervention and post-intervention comparisons in one or more hospitals,[12–19] including two quasi-randomised studies.[20,21] Although most reports suggest a reduction in coercive practices relative to standard treatment without a higher risk of harm to patients and staff,[12–16,18,20] their observational designs have been unable to address all

concerns on the effect of open-door policies compared with locked-ward care. In addition, a few clinical reports of open-door policies have observed increased use of coercion[19] or non-significant increases in adverse events,[17] adding emphasis to previous calls for randomised controlled trials.[22]

In this study, we aimed to compare the occurrence of coercion in open-door policy wards and locked treatment-as-usual wards.

Methods

Study design

The Lovisenberg Open Acute Door Study (LOADS) was designed as a 12-month pragmatic randomised controlled non-inferiority trial. A detailed study protocol has been published elsewhere.[23] LOADS was conducted at a single study site, the Department of Mental Health and Addiction at Lovisenberg Diaconal Hospital in Oslo, Norway. The six-floor building includes an admission and psychiatric intensive care unit on the ground floor and five regular acute psychiatric wards with ten beds each on the floors above. The staffing ratio is one to two patients per member of staff during the day and evening, and three to four patients per member of staff at night. In addition to the five regular acute psychiatric wards, patients with a known need for increased care relative to other patients during treatment, for example, due to a police order mandating locked-ward care or persistent high risk of aggression or violence, can be referred to a high-resource ward with eight beds and more staff per patient.

The catchment area of Lovisenberg Diaconal Hospital encompasses three inner-city boroughs in Oslo, Norway (St Hanshaugen, Grünerløkka, and Gamle Oslo). The catchment area has 164000 inhabitants with Norway's highest per capita levels of social and mental health problems and includes the city's major open drug scenes. Around 12% of patients on the acute psychiatric wards in Lovisenberg Diaconal Hospital are admitted from surrounding boroughs. In accordance with Norway's Mental Health Act, people living in these boroughs are admitted via voluntary referral or involuntary commitment by a physician employed outside the hospital, such as the Oslo Municipality Emergency Room, a general practitioner office, or at a referring hospital. More details on Norwegian mental health-care services and legislation are published in the study protocol.[23]

The Department of Mental Health and Addiction receives approximately 1100 acute admissions annually, of which around 40% are brief stays in the admission ward. All admitted patients are routinely screened by a physician for violence risk, suicide risk, and verification of the involuntary admission criteria before being treated and discharged or transferred for acute psychiatric care to one of the other six wards. About two-thirds of patients at the Department of Mental Health and Addiction are involuntarily admitted and have schizophrenia spectrum or psychotic disorders.

The study was approved by the Regional Committees for Medical and Health Research Ethics (REC) in Norway on Jan 15, 2020 (REC South East 29328). The REC designated LOADS as a health services research study and waived ordinary consent and data protection rules based on the importance of coercion prevention and the absence of randomised controlled trials on open-door policies. Strict terms for safe access, analysis, and storage of hospital data were outlined by REC in collaboration with the hospital's privacy ombudsman. This trial is registered in the ISRCTN registry, 16876467.

Patients

In this trial, all patients (aged 18 years or older) referred from the psychiatric intensive care unit to the acute psychiatric ward at Lovisenberg Diaconal Hospital were screened for eligibility. Patients were excluded if they were legally prohibited from admission in an open-door facility due to being under active criminal justice custody or serving a sentence or if they had a documented history of persistent violence even after achieving apparent stabilisation of psychotic symptoms. The decision to exclude these patients from the trial was based on three factors: the recommendation of the REC; the aim of providing the more restrictive setting that this patient group was likely to require; and the desire to ensure that the sample for LOADS better represented the non-forensic patient populations of most mental health institutions worldwide. Unlike most other countries where psychiatric patients with a record of violent crime are often admitted to dedicated forensic psychiatric units run by a criminal justice authority, patients with a record of causing serious injury or death in Norway can be sentenced by a regular court to receive care in designated high-security wards under the Ministry of Health. Therefore, patients under this type of care were excluded from random assignment to any of the five LOADS wards.

As the REC waived consent requirements, all eligible patients admitted to regular acute psychiatric wards during the study period were included in the study.

Randomisation and masking

A year before the study started, lots were drawn to determine which two of the five regular acute psychiatric wards would co-create, prepare, and implement the open-door policy during this 12-month randomised controlled trial. The remaining three wards continued with treatment as usual.

During the trial, patients referred for acute psychiatric ward care from the admission ward were allocated to either one of the two open-door policy wards or one of the three treatment-as-usual wards. The open-label continuous allocation sequence was a simple binomial list allocating participants to either group in a 2:3 ratio for open-door policy and treatment-as-usual wards

(respectively) and was generated by the principal investigator (NK) using a random number generator at random.org. Using the list, a regular group of seven ward nurses (one from each ward), led by the admissions ward chief nurse, administered allocation every day. The binomial list was used if one or more beds were available on wards in both study groups. If all beds in one or both study groups were occupied, patients were allocated the first available bed on any of the study wards. If readmitted during the trial period, patients were allocated to the same ward or trial group as first randomised. Bias in the open allocation was counteracted by having both trial groups represented on the admissions team and instructing them to preserve the integrity of this trial by disregarding any discussion among admitting staff for allocation based on the wards' policy. Adherence to patient randomisation was verified by LOADS management every month and discrepancies were discussed with the admissions staff.

Masking of staff was not considered feasible due to the importance of staff being familiar with the procedures they needed to implement. As LOADS was a health-care services study of pre-existing practices presumed to be equally effective, patients were not provided with any special information on their inclusion or random allocation. General information was available in in-ward information leaflets and specific information on their allocation and the ward intervention was not actively concealed from patients by staff. Study groups were masked with A and B designations before becoming available to the team statistician for analysis.

Procedures

All eligible patients referred from the admission ward for regular acute ward care were enrolled and randomly allocated as described. As LOADS was exempt from consent requirements and designed for maximum integration with clinical practice, participating patients were not exposed to designated study enrolment or consent procedures. Patients in open-door policy wards were informed of the model via written and verbal communication.

User-focused measures aimed at enhancing the therapeutic alliance are hypothesised[11] to be the central component in open-door policies. User-focused measures include co-decision making, network involvement, group and individual psychotherapy, and brief user-controlled admissions. To facilitate implementation in the heterogeneous settings of psychiatric care, open-door policy literature recommends a flexible application of specific user-oriented measures by wards adopting open-door policies building on pre-existing user-focused measures and attitudes in each ward.[11]

The implementation of open-door policy in the psychiatric wards participating in the LOADS trial was co-created by ward staff, a user representative with lived experience, doctors, and psychologists, based on descriptions of open-door policies in the German language and English language literature[11,24] and study visits to wards in Basel, Switzerland, and Berlin, Germany. From May 25, 2020 until the start date Feb 10, 2021, several preparatory activities were carried out on the two open- door policy wards. These preparatory activities included workshops where staff, management, and a user representative collaboratively addressed issues related to the open-door policy. Staff and the user representative were involved in developing the procedure describing when the door could be locked and creating informational materials for patients and relatives. After initiation and the doors were unlocked, the staff working groups continued to have regular meetings to address relevant topics to enhance the therapeutic interaction with the patients. Peer-support workers started working at each open-door policy ward as part of policy training on Nov 2, 2020, and helped to facilitate the therapeutic dialogue between staff and patients.

The main doors were open from 0900 to 2100 every day of the week but could be locked if it was the only solution to ensure safety. The time and reason were documented in cases where the door had to be locked by clinical staff. Before unlocking the door each morning, clinical staff assessed the safety risks of doing so for each patient on the ward and planned for collaborative measures to reduce the risk and avoid unnecessary door locking. Even

though the door was unlocked, patients were expected to have a dialogue and coordinate their leaving with staff, as staff also assessed the need for staff accompaniment.

Patients in the control group received treatment as usual, in which the main door was always locked and patients' freedom to leave the ward would depend on the staff's availability and individual risk assessment. Treatment-as-usual ward staff did not specify their attitude or policy towards patients but adhered to existing values and norms for coercion reduction and prevention at Lovisenberg Diaconal Hospital.

Staff on all wards underwent training in de-escalation and harm minimisation every 3 to 6 months. All wards had equal access to music therapists, physiotherapists, occupational therapists, social workers, an exercise room, and a sensory stimulation room. The COVID-19 pandemic occurred during the study period but caused only few, time-limited pauses in group-based activities such as simulation and skills training for staff and the temporary closing of the sensory stimulation room to comply with the hospital's infection control guidelines.

Outcomes

The primary outcome was the proportion of patient stays with one or more coercive measures, as retrieved from patients' clinical records. The outcome was a composite variable and included all instances of coercive measures, defined as involuntary medication, isolation or seclusion, and physical and mechanical (ie, the use of belts on the

patient's body limbs) restraints. Involuntary or voluntary admitted patients can be subjected to coercive measures.

We included two secondary outcome measures. We assessed separate coercive measures of involuntary medication, isolation or seclusion, and physical and mechanical restraints, measured as the proportion of patient stays with one or more events of the specific type of coercion during the admission. We also assessed patients' experiences of coercion and ward atmosphere. These two patient-reported experience measures (coercion and ward atmosphere) were implemented as part of regular treatment at Lovisenberg Diaconal Hospital and were obtained from patient records in a subset of the randomly assigned patients willing to complete questionnaires on request during admission but usually towards the end of treatment. Considering the state of distress of psychiatric patients who were acutely admitted to the wards, the threshold for successful implementation of patient feedback on these outcomes was set at 30%. Patient experience of coercion was assessed with the Experience of Coercion Scale[25] (ECS; Cronbach's α in the present study 0·95) and patient experience of ward climate was assessed with the Essen Climate Evaluation Scale[26] (EssenCES; Cronbach's α in the present study for therapeutic hold 0·78, experienced safety 0·81, and patient cohesion 0·80). The questionnaires' high Cronbach's α coefficients indicate good internal validity. On both scales, each item is rated on a five-point Likert-type scale (range 0–4). High mean scores on the ECS indicate high experienced coercion and high sum scores on the EssenCES indicate a positive ward atmosphere.

Safety outcomes were incidents of violence against staff, which were obtained from the hospital's incident reporting system during the course of the randomised controlled trial, and incidents of death from suicide, which were obtained from clinical records.

We measured the length of hospital stays by retrieving discharge data from the electronic health record. We planned to include absconding as an outcome, as reported in the protocol.[23] However, due to the extra workload on staff to limit virus spread during the COVID-19 pandemic, these outcomes could not be standardised across wards and recorded prospectively and, therefore, were not included.

Statistical analysis

We chose a non-inferiority study design due to the similarly high standard of care of the two interventions (open-door policy and treatment-as-usual) and the reasoning that similar safety and coercive results would, within a margin of 15%, be a good result for the open-door policy wards given the increased freedom of movement and autonomy for patients. In the absence of identified research evidence to inform our threshold, we chose the limit-based margin on a clinical consensus, including that of the study user representative.

On the basis of the available literature, we assumed that the proportion of coercion would be 33% in the open-door policy group and 34% in the treatment-as- usual group. Keeping power to 90% (β 0·1), significance level at 5%, and non-inferiority margin at 15%, we would need a minimum of 200 patients in each study group to demonstrate non-inferiority. We used risk regression to calculate absolute and relative risk (RR) for the primary outcome and secondary outcomes of specific coercive measures. Mann–Whitney Wilcoxon test was used to compare the number of days hospitalised between groups. Because of the difference in the length of stay between the open-door policy and treatment-as-usual groups, we examined the possible effect of the number of days spent in the ward and did several sensitivity analyses for the primary outcome assessed within 0–7 days, 0–14 days, and 0–21 days after the admission. In addition, to account for the fact that the patients might have a shorter treatment period in the facility in one of the study groups, we compared the outcomes assessed within 8–14 and 15–21 days after the admission. The results were expressed as the estimated proportions (absolute risk), RR of treatment-as-usual compared with open-door policy, and risk difference with 95% CI. To account for a potential effect of being in a special ward (eg, non- ignorable clustering effect), we fitted a fixed intercept for cluster in the regression model to account for the possible additional variation due to patients being admitted to different wards.

For patients' experiences of coercion and ward atmosphere, continuous variables were described with mean (SD) and mean differences (95% CI). Crude between-group comparisons were performed using independent samples t test. All tests were two-sided and we considered p values of less than 0·05 as statistically significant. All analyses were performed using SPSS (28) and Stata (18).

A data monitoring committee was established consisting of the principal investigator (NK), the head of the department, and an administrative data manager. The committee monitored the new procedures introduced with the implementation of the open-door policy, including door-locking statistics and random assignment. The committee also monitored violent and suicide incidents, and was prepared to enact stop rules if an accumulation of incidents could be attributed to the study.

Role of the funding source

The funders of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Figure: *Study flow chart*
** Patients under active criminal justice custody or serving a sentence or having a documented history of persistent violence even after achieving apparent stabilisation of psychotic symptoms.*

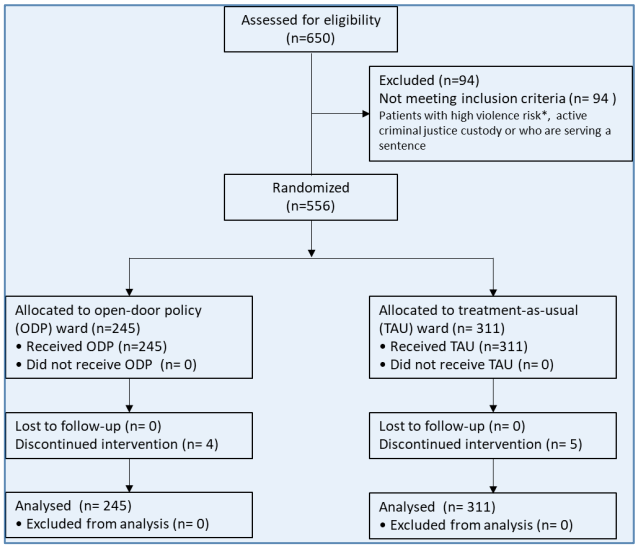

Table 1 *Demographics and clinical characteristics of patients admitted to open-door policy (ODP) and treatment-as-usual (TAU) wards*

Variable	ODP wards (N=245)	TAU wards (N=311)
Age, years mean (SD)	41.6 (14.5)	41.6 (14.3)
Sex, n (%)		
Male	119 (49%)	172 (55%)
Female	126 (51%)	139 (45%)
Admission, n (%)		
Voluntarily	65 (27%)	77 (25%)
Involuntarily	180 (73%)	234 (75%)
Admissions in previous 2 years		
0	103 (42%)	149 (48%)
1	60 (24%)	60 (19%)
2	29 (12%)	41 (14%)
≥ 3	53 (22%)	60 (19%)
Violence risk, n (%)		
Low	98 (40%)	116 (37%)
Moderate	122 (50%)	158 (51%)
High	25 (10%)	37 (12%)
ICD-10 Main diagnoses at discharge from the trial ward		
F0 Organic, including symptomatic, mental disorders	8 (3.3%)	9 (3%)
F1 Mental and behavioural disorders due to psychoactive substance use	25(10%)	33 (11%)
F2 Schizophrenia, schizotypal and delusional disorders	123 (50%)	168 (54%)
F3 Mood [affective] disorders	59 (24%)	73 (23%)
F4-F5 Neurotic, stress-related, eating disorders and somatoform disorders	14 (6%)	13 (4%)
F6 Disorders of adult personality and behaviour	5 (2%)	5 (2%)
Other	11 (4%)	10 (3%)

Data are n(%) unless specified. Data on ethnicity were not collected.

Between Feb 10, 2021, and Feb 1, 2022, 650 patients were assessed for eligibility, of whom 556 were eligible and randomly assigned to either the open-door policy group (n=245) or treatment-as-usual group (n=311; figure).

In total, 94 patients were excluded due to active criminal justice custody or serving a sentence or because of high violence risk. Within the randomised controlled trial period, nine patients changed wards during their stay (discontinued intervention). These cases were considered discharged and the admission to the new ward was not included in the analyses.

Only data related to the primary admission at the ward to which the patient was randomly assigned were included in the analyses. The characteristics of the 556 included patients are listed in table 1.

During this trial, the main doors of the two open-door policy wards were open to exit the ward 73% of the designated opening hours (0900 to 2100), whereas the main doors of the three treatment-as-usual wards remained locked to all patients.

We confirmed our primary hypothesis of non-inferiority regarding the main outcome and the point estimate of risks was in favour of open-door policy: 65 (26·5%) of 245 patients in the open-door policy ward were exposed to coercive measures compared with 104 (33·4%) of 311 patients in the treatment-as-usual wards, reflected in an absolute risk difference of 6·9% (95% CI –0·7 to 14·5; table 2). These results were supported by sensitivity analyses examining weekly intervals for the number of days admitted (0 to 7 days absolute risk difference 1·5% [95% CI –4·8 to 7·9]; 0 to 14 days 5·4% [–1·6 to 12·6]; 0 to 21 days 4·6% [–2·7 to 11·9]). When the possible effect of clustering (type of ward) was accounted for, the risk difference between open-door policy and treatment-as-usual wards was 10·9% (95% CI –1·6 to 23·3). Risk estimates for each ward are presented in the appendix (p 2).

Table 2 *Absolute and Relative Risks for one or more coercive measures during admission to open-door policy (ODP) versus treatment-as-usual (TAU) wards*

	Number (%)			
Main outcome	**Absolute Risk ODP wards (n=245)**	**Absolute Risk TAU wards (n=311)**	**Relative Risk (95% CI)**	**Risk Difference (95% CI)**
One or more coercive measures per admission	65 (26.5%)	104 (33.4%)	1.3 (0.97 to 1.6)	6.9% (-0.7 to 14.5)
Adjusted for clustering effects (wards)	-	-	1.4 (0.95 to 2.1)	10.9% (-1.6 to 23.3)
Sensitivity analysis				
One or more coercive measures during				
day 0 – 7 of admission	42 (17.1%)	58 (18.6%)	1.1 (0.8 to 1.6)	1.5% (-4.8 to 7.9)
day 0 – 14 of admission	52 (21.2%)	83 (26.7%)	1.3 (0.9 to 1.7)	5.4% (-1.6 to 12.6)
day 0 – 21 of admission	58 (23.7%)	88 (28.3%)	1.2 (0.9 to 1.6)	4.6% (-2.7 to 11.9)
Subsample				
One or more coercive measures during				
day 8 – 14 of admission [a]	18 (10.1%)	38 (15.1%)	1.5 (0.9 to 2.5)	5.0% (-1.2 to 11.3)
day 15 – 21 of admission [b]	10 (7.8%)	19 (10.1%)	1.3 (0.6 to 2.7)	2.0% (-4.0 to 8.6)

[a] admissions shorter than 8 days excluded: Open-door policy n=178, TAU n=251. Data are n (%), unless specified.
[b] admissions shorter than 15 days excluded: Open-door policy n=128, TAU n=188

The secondary outcomes of separate coercive measures showed non-inferiority of open-door policy compared with treatment-as-usual and when adjusted for possible clustering effect (table 3).

Moreover, resource use measured as the median length of stay was shorter in the open-door policy group (16 days; IQR 7–31) than in the treatment-as-usual group (21 days; 8–43; p=0·012).

Table 3 *Absolute and Relative Risks for separate coercive measures during admission to open-door policy (ODP) versus treatment-as-usual (TAU) wards*

	Number (%)			
Secondary outcome: separate coercive measures	**Absolute Risk ODP policy wards (n=245)**	**Absolute Risk TAU wards (n=311)**	**Relative Risk (95% CI)**	**Risk Difference (95% CI)**
One or more coercive measures during the admission				
Mechanical restraints	8 (3.3%)	15 (4.8%)	1.5 (0.6 to 3.4)	1.6% (-1.7 to 4.8)
Adjusted for clustering	..	..	0·9 (0·3 to 3·4)	–0·2% (–5·5 to 5·1)
Isolation/seclusion	13 (5.3%)	17 (5.5%)	1.0 (0.5 to 2.1)	1.6% (-3.6 to 3.9)
Adjusted for clustering	..	..	1·0 (0·3 to 3·1)	–0·1% (–5·1 to 5·7)
*Involuntary medication (short-term)**	14 (5.7%)	27 (8.7%)	1.5 (0.8 to 2.8)	3.0% (-1.3 to 7.2)
Adjusted for clustering	..	..	1·0 (0·4 to 2·6)	0·3% (–6·7 to 7·5)
Physical restraints	25 (10.2%)	40 (12.9%)	1.3 (0.8 to 2.0)	2.7% (-2.7 to 7.9)
Adjusted for clustering	..	..	1·4 (0·7 to 3·0)	3·7% (–4·7 to 12·1)
Involuntary medication (long-term)	52 (21.2%)	84 (27.0%)	1.3 (0.9 to 1.7)	1.2% (-1.9 to 4.4)
Ajusted for clustering	..	..	1·4 (0·9 to 2·1)	8·1% (–3·7 to 19·9)

**Single dose administration of short-acting drug solely for sedative purposes.*

Patients in open-door policy wards rated their experience of coercion significantly lower than did patients in treatment-as-usual wards, with a mean difference of 0·5 on the ECS (95% CI –0·8 to –0·2; range 0–4; table 4).

Furthermore, patients admitted to open-door policy wards reported a significantly higher score on therapeutic hold (mean difference 2·4; 95% CI 1·2 to 3·5) and experienced safety (3·5; 1·8 to 5·2), whereas, for patient cohesion there was no significant difference between the wards (0·6; –0·7 to 1·8)

Table 4 *Patients' experience of coercion and ward climate in open-door policy versus treatment-as-usual wards*

	Open-door policy wards	Treatment-as-usual wards	Mean difference (95% CI)
Patients' experience of coercion (ECS) [a]	1.3 (1.0)	1.8 (0.9)*	-0.5 (-0.8 to -0.2)
Patients' experience of ward climate (EssenCES) [b]			
Therapeutic hold	14.5 (4.1)	12.1 (3.6)*	2.4 (1.2 to 3.5)
Experienced safety	12.2 (5.2)	8.7 (5.8)*	3.5 (1.8 to 5.2)
Patients' cohesion	11.4 (4.4)	10.8 (4.0)	0.6 (- 0.7 to 1.8)

Data are mean (SD), unless specified. 76 patients included for ECS open-door policy, 91 for ECS treatment-as-usual, 77 for EssenCES open-door policy, and 92 for EssenCES treatment-as-usual. ECS=Experience of Coercion Scale. EssenCES=Essen Climate Evaluation Scale. *p<0·05

Completion rates for patients providing feedback on their experience of coercion and ward atmosphere reached the pre-set cutoff of 30%, with 77 (31%) patients completing feedback questionnaires in open-door policy wards and 92 (30%) in treatment-as- usual wards. There were no significant differences in background variables, including sex, age, voluntary or involuntary admission, main diagnoses, and violence risk (appendix p 3), between the subgroup of patients who completed the feedback questionnaires and the group who did not provide responses.

No significant differences in the number of reported incidents of violence against staff were observed in treatment groups, with 37 in open-door policy wards (0·15 per patient stay; 95% CI 0·11–0·20) and 56 in treatment-as-usual wards (0·18 per patient stay; 0·14–0·23). There were no suicides during the randomised controlled trial period.

Discussion

To the best of our knowledge, this is the first randomised controlled trial to provide evidence that an open-door policy approach to increase patient autonomy and collaborative practices can be implemented without increasing coercion and violent events, even in an acute psychiatric ward with three-quarters of patients being involuntarily admitted. The results confirmed our main hypothesis and are consistent with observational studies that open-door policies cause no increase in coercive measures.[12,14–16,20] The absence of an increase in suicides and aggressive incidents was also consistent with the open-door policy literature.[13,14,18,20] Our results on patient feedback confirm previous survey data indicating that open-door policies generate more treatment support and a greater sense of safety.[27] In addition, we found that an open-door policy can reduce patients' subjective experience of coercion, a finding that supports the hypothesis that the underlying mechanism of the open-door policy is a strengthened alliance between patients and staff. Concerns that resource use would increase with the open-door policy were unsubstantiated, as the median length of stay on open-door policy wards was more than 20% shorter than on treatment-as-usual wards, possibly caused by staff and physicians on open-door policy wards emphasising more interaction with community resources.

The scarcity of randomised controlled trial evidence on open-door policy is probably due to the challenges of conducting randomised controlled trials in the complex setting of ordinary psychiatric acute wards. In this study, we had to address each of these challenges to fill the need for better knowledge of real-world psychiatric services, as called for by WHO[6,7] and the WPA-Lancet Psychiatry Commission on the Future of Psychiatry.[1] The absence of randomised controlled trials on coercion and autonomy in clinical psychiatry was the main reason that the REC granted us exceptions from consent requirements and permission to collect service data on all admitted patients and enabled us to mitigate sampling bias. One notable strength of our study was the use of a representative population sample of patients from an inner-city acute psychiatric setting.

A challenge to all studies reporting in-clinic psychiatric results are the differences between countries in overall resources and prioritisation of psychiatric care, judicial mandate to initiate involuntary admission and coercive measures, and management structure.[28] These differences partly explain the flexibility permitted in local implementations of the open-door policy,[29] which have been criticised for inconsistency.[30] Key limitations of our study relate to some specific design challenges, as well as the overall generalisability of the findings. Regarding the design, findings are at risk of bias given the lack of concealed allocation of randomisation. Masking of the intervention was impossible to reconcile with the ethical, legal, and clinical responsibilities of everyday clinical care in acute psychiatric ward treatment. This means staff were not masked to the intervention tested in this randomised controlled trial, which might have contributed to potential performance bias among those

working in open-door policy wards. Our choice of a non-inferiority design prohibits more firm conclusions about potential superiority of open-door policy. The low response rate on the feedback questionnaire measuring ward atmosphere and experience of coercion introduces uncertainty regarding the generalisability of results. Additionally, the COVID-19 pandemic challenged the conduct of the trial, resulting in the pre-defined outcome of absconding not being reliably recorded and, therefore, not included in the analyses. Concerning generalisability of our findings, a key question is how open-door policy, as offered to patients in our study with the observed effects, might apply across health-care systems, jurisdictions, and contexts. Overarching challenges reflected in our study include the absence of clear definitions and delineations of what open-door policy entails regarding selection of patients, specific therapeutic ingredients, and resource requirements. First, we cannot determine for which patients an open-door policy might be of particular value as our randomised controlled trial was not designed or powered to do subgroup analyses across diagnoses. Secondly, we cannot establish which components of the open-door policy are the most important to offer and exactly how to implement these components. Finally, we cannot fully discount potential differences in the overall environment and staff-patient relationship in the open-door versus treatment-as-usual wards that might have influenced findings.

Overall, open-door policies can be safely implemented with no increase in coercive measures in an inner-city setting with patients who are predominantly involuntarily admitted. Based on these findings and experiences from the randomised controlled trial period, Lovisenberg Diaconal Hospital has adopted an open-door policy for all wards. To corroborate findings from this randomised controlled trial on open-door policy and coercion, there is a need for more randomised controlled trials from multiple countries to build knowledge on how a complex intervention such as open-door policy can reduce coercive practices without compromising safety concerns, and how such approaches can be efficiently implemented across health-care systems and contexts.

Contributors

NK, HMN, and A-MRI were involved in the design and development of the trial. NK was responsible for funding acquisition. A-MRI, MH, NK, HMN, POV, MT, and JG planned the statistical analyses, which were done by A-MRI and MH. A-MRI, HMN, and NK were responsible for data curation and A-MRI, MH, HMN, and NK had access to and validated the data. All authors interpreted the data. A-MRI and NK drafted the manuscript and all authors revised it for important intellectual content. All authors had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Declaration of interests

We declare no competing interests.

Data sharing

All data requests should be submitted to the principal investigator for consideration.

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References

1 Bhugra D, Tasman A, Pathare S, et al. The WPA-*Lancet Psychiatry* Commission on the Future of Psychiatry. *Lancet Psychiatry* 2017; **4:** 775–818.

2 Gill NS, Parker S, Amos A, et al. Opening the doors: critically examining the locked wards policy for public mental health inpatient units in Queensland Australia. *Aust N Z J Psychiatry* 2021; **55:** 844–48.

3 Kersting XAK, Hirsch S, Steinert T. Physical harm and death in the context of coercive measures in psychiatric patients: a systematic review. *Front Psychiatry* 2019; **10:** 400.

4 Herrman H, Allan J, Galderisi S, Javed A, Rodrigues M. Alternatives to coercion in mental health care: WPA position statement and call to action. *World Psychiatry* 2022; **21:** 159–60.

5 World Psychiatric Association. Implementing alternatives to coercion in mental health care. Discussion paper from the WPA taskforce. https://www.wpanet.org/_files/ugd/e172f3_3702b1a4202c458b85451 e6d74075cbc.pdf (accessed Feb 15, 2023).

6 WHO. Hospital-based mental health services: promoting person-centred and rights-based approaches. Geneva; World Health Organization, 2021.

7 Funk M, Drew N. WHO QualityRights: transforming mental health services. *Lancet Psychiatry* 2017; **4:** 826–27.

8 Márton SM, Polk G, Fiala DRC. Convention on the rights of persons with disabilities. USA: United Nations, 2013.

9 Gooding P. Compendium report: good practices in the Council of Europe to Promote Voluntary Measures in Mental Health services. 2021. https://www.coe.int/en/web/bioethics/compendium-report-good-practices-in-the-council-of-europe-to-promote-voluntary-measures-in-mental-health-#:~:text=This%20report%20provides%20a%20compendium,well%20as%20civil%20society%20 stakeholders (accessed Sept 25, 2023).

10 Mental Health Europe. Promising practices in prevention, reduction and elimination of coercion across Europe. https://mhe-sme.org/wp-content/uploads/2019/01/Coercion-Report.pdf (accessed Sept 25, 2023).

11 Lang U. Innovative Psychiatrie mit offenen Türen: Deeskalation und Partizipation in der Akutpsychiatrie. Berlin: Springer-Verlag, 2012.

12 Hochstrasser L, Fröhlich D, Schneeberger AR, et al. Long-term reduction of seclusion and forced medication on a hospital-wide level: implementation of an open-door policy over 6 years. *Eur Psychiatry* 2018; **48:** 51–57.

13 Schneeberger AR, Kowalinski E, Fröhlich D, et al. Aggression and violence in psychiatric hospitals with and without open door policies: a 15-year naturalistic observational study. *J Psychiatr Res* 2017; **95:** 189–95.

14 Cibis M-L, Wackerhagen C, Müller S, Lang UE, Schmidt Y, Heinz A. Comparison of aggressive behavior, compulsory

medication and absconding behavior between open and closed door policy in an acute psychiatric ward. *Psychiatr Prax* 2017; **44:** 141–47.

15 Jungfer H-A, Schneeberger AR, Borgwardt S, et al. Reduction of seclusion on a hospital-wide level: successful implementation of a less restrictive policy. *J Psychiatr Res* 2014; **54:** 94–99.

16 Kowalinski E, Hochstrasser L, Schneeberger AR, Borgwardt S, Lang UE, Huber CG. Six years of open-door policy at the University Psychiatric Hospital Basel. *Nervenarzt* 2019; **90:** 705–08.

17 Beaglehole B, Beveridge J, Campbell-Trotter W, Frampton C. Unlocking an acute psychiatric ward: the impact on unauthorised absences, assaults and seclusions. *BJPsych Bull* 2017; **41:** 92–96.

18 Huber CG, Schneeberger AR, Kowalinski E, et al. Suicide risk and absconding in psychiatric hospitals with and without open door policies: a 15 year, observational study. *Lancet Psychiatry* 2016; **3:** 842–49.

19 Mann K, Gröschel S, Singer S, et al. Evaluation of coercive measures in different psychiatric hospitals: the impact of institutional characteristics. *BMC Psychiatry* 2021; **21:** 419.

20 Schreiber LK, Metzger FG, Flammer E, Rinke H, Fallgatter AJ, Steinert T. Open Doors by Fair Means: a quasi-experimental controlled study on the effects of an open-door policy on acute psychiatric wards. *BMC Health Serv Res* 2022; **22:** 941.

21 Jin Z. Effect of an open-door policy combined with a structured activity programme on the residual symptoms of schizophrenic in-patients. A six-month randomised controlled trial in Yanbian, Jilin. *Br J Psychiatry Suppl* 1994; **165:** 52–57.

22 Steinert T, Schreiber L, Metzger FG, Hirsch S. Open doors in psychiatric hospitals: an overview of empirical findings. *Nervenarzt* 2019; **90:** 680–89.

23 Kunøe N, Nussle HM, Indregard AM. Protocol for the Lovisenberg Open Acute Door Study (LOADS): a pragmatic randomised controlled trial to compare safety and coercion between open-door policy and usual-care services in acute psychiatric inpatients. *BMJ Open* 2022; **12:** e058501.

24 Kalagi J, Otte I, Vollmann J, Juckel G, Gather J. Requirements for the implementation of open door policies in acute psychiatry from a mental health professionals' and patients' view: a qualitative interview study. *BMC Psychiatry* 2018; **18:** 304.

25 Nyttingnes O, Rugkåsa J, Holmén A, Ruud T. The development, validation, and feasibility of the Experienced Coercion Scale. *Psychol Assess* 2017; **29:** 1210–20.

26 Schalast N, Redies M, Collins M, Stacey J, Howells K. EssenCES, a short questionnaire for assessing the social climate of forensic psychiatric wards. *Crim Behav Ment Health* 2008; **18:** 49–58.

27 Efkemann SA, Bernard J, Kalagi J, et al. Ward atmosphere and patient satisfaction in psychiatric hospitals with different ward settings and door policies. Results from a mixed methods study. *Front Psychiatry* 2019; **10:** 576.

28 Gutiérrez-Colosía MR, Salvador-Carulla L, Salinas-Pérez JA, et al. Standard comparison of local mental health care systems in eight European countries. *Epidemiol Psychiatr Sci* 2019; **28:** 210–23.

29 Gather J, Scholten M, Henking T, Vollmann J, Juckel G. What replaces the locked door? Conceptual and ethical considerations regarding open door policies, formal coercion and treatment pressures. *Nervenarzt* 2019; **90:** 690–94.

30 Nyhuis PW, Zinkler M. Open-door psychiatry and community mental health work. *Nervenarzt* 2019; **90:** 695–99.

Appendix 1 Table presenting Absolute and Relative Risks for one or more coercive measures during admission to separate wards

	Absolute Risk	**Relative Risk**	**Risk Difference**
Main outcome	**N (%)**	**(95% CI)**	**(95% CI)**
One or more coercive measures during the admission			
Ward A	38 (38.0%)	ref	ref
Ward B	38 (38.0%)	0.7 (0.5 to 1.0)	-12.0% (-24.2 to 1.8)
Ward C	38 (38.0%)	0.8 (0.5 to 1.2)	-7.5% (-20.5 to 5.4)
Ward D	38 (38.0%)	0.7 (0.5 to 1.1)	-10.9% (-23.3 to 1.6)
Ward E	34 (32.1%)	0.9 (0.6 to 1.2)	-5.9% (-18.9 to 7.1)

Appendix 2

Table Demographics and clinical characteristics of subgroup of patients who completed the feedback questionnaires and the group who did not provide responses

Variable	**Completed feedback (N=169)**	**Non responders (N=387)**	**P value**
Age, years mean (s.d.)	40.7 (12.6)	42.1 (15.1)	0.156
Sex, n (%)			
Male	96 (56.8%)	195 (50.4%)	0.163
Female	73 (43.2%)	192 (49.6%)	
Admission, n (%)			
Voluntarily	41 (24.3%)	101 (26.1%)	0.648
Involuntarily	128 (75.7%)	286 (73.9%)	
Violence risk, n (%)			
Low	72 (42.6%)	142 (36.7%)	0.413
Moderate	80 (47.3%)	200 (51.7%)	
High	17 (10.1%)	45 (11.6%)	
ICD-10 Main diagnoses at discharge, n (%)			
F0 Organic, including symptomatic, mental disorders	3 (1.8%)	14 (3.6%)	0.185
F1 Mental and behavioural disorders due to psychoactive substance use	12 (7.1%)	46 (11.9%)	
F2 Schizophrenia, schizotypal and delusional disorders	92 (54.4%)	199 (51.4%)	
F3 Mood [affective] disorders	47 (27.8%)	85 (22.0%)	
F4-F5 Neurotic, stress-related, eating disorders and somatoform disorders	8 (4.7%)	19 (4.9%)	
F6 Disorders of adult personality and behaviour	4 (2.4%)	6 (1.6%)	
Other	3 (1.8%)	18 (4.7%)	