

Effect of the introduction of immediate judge's decisions in 2018 on the use of coercive measures in psychiatric hospitals in Germany: a population-based study

Erich Flammer,^{1,2,a} Sophie Hirsch,^{1,2,3,b} and Tilman Steinert,^{1,2,4,c*}

¹Clinic for Psychiatry and Psychotherapy I, Ulm University

²Centres for Psychiatry Suedwuerttemberg, Ravensburg, Germany

³Tuebingen University, Dept Neurology

⁴Tuebingen University, Dept Psychiatry

Abstract

Background On 23 July 2018, the German Constitutional Court decided that mechanical restraint in psychiatric patients lasting longer than 30 minutes requires a judge's immediate decision. On the same day, the German Association for Psychiatry and Psychotherapy published its guideline on the prevention of coercion and violence. The registry for coercive measures in the federal state of Baden-Wuerttemberg, available since 2015 and comprising all 32 hospitals licensed to admit involuntary patients, has made it possible to evaluate the effect of the legal change, considered the strongest intervention ever in Germany to reduce coercion.

Methods We analysed the mean percentage of patients subjected to coercive measures and the mean cumulative duration of these interventions in ICD-10 diagnostic groups in psychiatric hospitals from 2017 compared to 2019 among a total of 233,0273 admissions.

Findings The percentage of patients subjected to any kind of freedom-restricting coercion decreased from 6.6% in 2017 to 5.8% in 2019 ($p = 0.000$). Accordingly, the percentage of patients subjected to mechanical restraint decreased from 4.8% to 3.6% in 2019 ($p = 0.000$). At the same time, the percentage of patients subjected to seclusion increased from 2.9% to 3.3% ($p = 0.000$). The median cumulated duration of restraint and seclusion per affected case decreased from 12.5 to 11.9 hrs ($p = 0.001$).

Interpretation There is clear evidence that a strong legal intervention was effective in reducing the use of coercive measures under routine conditions.

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Introduction

The use of coercive measures such as involuntary hospitalisation, seclusion, mechanical and physical restraint, and involuntary treatment is an inherent problem of clinical psychiatry, causing distress, ethical conflicts, and stigma for patients and professionals as well [1,2]. The urgent necessity to reduce the use of coercion has

been emphasised by many national and transnational organisations such as the United Nations and the Council of Europe based on principles of human rights [3]. There is evidence from clinical studies that a variety of single or complex interventions can reduce the use of coercion in clinical settings [4]. However, beyond efficacy in mostly small-scale studies, the effectiveness of

*Corresponding author: Prof Dr Tilman Steinert

E-mail address: tilman.steinert@zfp-zentrum.de (T. Steinert).

^a Dr Erich Flammer, ZfP Südwürttemberg, Weingartshofer Str 2, 88214 Ravensburg

^b Dr Sophie Hirsch, ZfP Südwürttemberg, Pfarrer Leube Str 29, 88427 Bad Schussenried

^c Prof Dr Tilman Steinert, ZfP Südwürttemberg, Weingartshofer Str 2, 88214 Ravensburg

Research in context

Evidence before this study

In the course of the development of German clinical practice guidelines on prevention of coercion, a systematic review on the reduction of freedom-restrictive measures was conducted, searching all journals listed in the MEDLINE and CINAHL databases up to 2017. This review was updated again in 2019. All trials studying interventions to reduce seclusion, physical restraint, and mechanical restraint were included, with legal and other regulatory changes as an additional category that was explicitly investigated. Articles in any language were included (e.g., English, German, Dutch, Danish, and Hebrew). The international literature examining the impact of legislative changes on the development of restraint in psychiatry dates primarily from the 1980s and 1990s.

These studies are subject to a strong risk of bias (e.g., reporting bias).

Added value of this study

Today, by contrast, studies such as ours can draw on routine data collected electronically and reported centrally on a statutory basis. Therefore, legislative changes can be investigated both prospectively and for a whole federal state, and bias can be reduced significantly.

Implications of all available evidence

Legal changes may have an impact on the amount of violence and coercion in psychiatry. A dialogue between the government, the legal system, and experts from the mental health care system is therefore necessary.

most of these measures in routine care has not been demonstrated up to now. Normative interventions seem to have stronger effects than interventions that address attitudes or clinical procedures. For example, precise rules as to when seclusion and restraint may be used can significantly reduce coercive measures, as a study on the S&R Challenge programme shows [5]. Normative standards set by authorities, management, or supervisors were identified as important factors in the evidence-based programme Six Core Strategies ('leadership') [6]. In a programme in which the directors of a clinic personally apologised to patients affected by coercive measures, seclusion was completely avoided for three years [7]. On the other hand, evidence of the influence of staff attitudes on coercive measures was inconclusive in a recent systematic review [8]. Additionally, an attempt to modify staff attitudes was not successful. The presence of more nursing staff with above-average empathy ratings was strongly associated with reduced use of coercion in over 1,000 shifts, but empathy training showed no further benefit [9].

Accordingly, in a longitudinal study of over 14 years, we found evidence for a substantial reduction of coercive measures in old age psychiatry, but not in general psychiatry [10].

On 23 July 2018, after a two-day-hearing of experts, the German Constitutional Court decided that mechanical restraint for over 30 minutes required an immediate decision by a judge. A British expert had explained in the court that physical restraint in the UK was considerably shorter in duration in comparison to mechanical restraint [11]. The court declared that mechanical restraint was the most invasive intervention compared to seclusion and physical restraint, even if seclusion might be more distressing for some patients than restraint. Taking into account these deliberations, the impact of mechanical restraint on human rights was considered so strong that a judge's decision as well as individual 1:1 supervision during the measure would be necessary in each case of mechanical restraint. The latter had previously been mandatory in some but not all mental health laws of the 16 federal states. The new rules did not apply to seclusion. On the same day, the German Association for Psychiatry, Psychotherapy, and Psychosomatics (DGPPN) published its evidence-based Clinical Practice Guidelines on the Prevention of Coercion and Treatment of Aggressive Behaviour [12].

Hence, the Constitutional Court advised that the justification of mechanical restraint be reviewed by a judge; the guidelines, on the other hand, provide clinicians with tools to prevent or replace restraint. Taken together, this was the strongest intervention ever to reduce coercion in psychiatric facilities on a national level. By this normative intervention, the threshold for mechanical restraint was increased not only by the legal examination but also by the requirement to provide staff for 1:1 supervision. In the following months, the German federal states adopted their mental health laws according to the specifications of the Constitutional Court. In practice, a judge on duty must be informed as soon as a measure of mechanical restraint is assumed to endure longer than 30 minutes, with regional variations according to availability at night. Subsequently, a personal assessment by a judge must take place at the patient's bedside within 24 hours.

Based on available data, seclusion or mechanical restraint are used in 3 to 8% of treatment episodes in psychiatric hospitals in Germany [13–15], positioning the country in a middle position in an international comparison [16]. Forced medication is reported to occur in 0.5 to 8% of treatment episodes, which is comparably low compared to most other countries due to legal restrictions [17–22]. Baden-Wuerttemberg has about 11 million inhabitants, is highly industrialised and the standard of living is among the highest in Germany. The mental health system is very well developed and those involved are well networked.

From the registry, data on each coercive measure in the state's 32 psychiatric hospitals required to treat involuntary patients are available [13]. This offers an opportunity to evaluate the effects of the legal change with the following research questions: Is there evidence for a significant change in the use of coercive measures after the introduction of the judge's review i) in the total amount of measures and percentages of affected patients, ii) in the kind of measures applied, and iii) in their respective duration?

Methods

Data sources

In 2015, a new mental health law was introduced in the German federal state of Baden-Wuerttemberg following a Constitutional Court decision. It contained the unique feature of requiring all 32 public psychiatric hospitals to collect data on seclusion, restraint, forced medication in emergency situations or by judicial order.

Raw data on each coercive measure in all hospitals are reported to the registry. This procedure has special requirements for data protection and data security considering the highly sensitive personal data. An online platform was set up after detailed consultation with the state data privacy and data security officer and his final approval. The platform serves for both uploading data by the institutions and downloading data by the evaluation office. Data privacy is ascertained by a double and irreversible pseudonymisation carried out by different institutions and through the use of passwords. Thus, the identification of individual persons is not possible, i.e., the data are anonymised. For each coercive intervention the dataset contains the kind of intervention as defined by a codebook, its legal basis, the duration, the patient's gender, the ICD-10 principal group, and a pseudonymised patient ID. This allows assigning coercive measures with identical pseudonymised case numbers to the same case, which is necessary to determine the outcomes according to the study questions. While the registry contains raw data on coercive measures (not on the numbers of admissions), it does not contain information whether two or more cases represent the same patient across different admissions. For all hospitals, the number of admissions with respect to diagnoses and the number of involuntary admissions according to different laws are available [23]. All hospitals but one have provided data since 2015 and one hospital started doing so in 2016.

Hospitals must deliver data for the previous year before a deadline. The data are then checked for completeness and plausibility. In case of abnormalities, the clinics concerned are consulted and if necessary and possible, the data is corrected. The results of these evaluations are reported to the hospitals and to the Ministry of Social Welfare and Integration of Baden-

Wuerttemberg in a standardised annual report. Once in the legislative period, a report to the state parliament of Baden-Wuerttemberg is made by the Ministry of Social Welfare and Integration.

Definitions of coercive measures and detailed prescriptions for recording them with respect to duration and legal grounds are available in a codebook provided for the hospitals by the Ministry of Health, Social Welfare, and Integration. There have been only very minor changes since 2015. All use of freedom-restricting devices has to be recorded as mechanical restraint, encompassing not only belts in beds, but also (undivided) bedrails, movement-restricting blankets, tables attached to a chair, and other devices in old age psychiatry. Physical restraint (staff holding a person for a period of time by force) is rare in psychiatry in Germany [23] but is recorded separately. Seclusion is defined according to suggestions in the literature [24] as locking a person in a scarcely furnished room (mostly with only a mattress and toilet) without the presence of staff. Chemical restraint is uncommon as a category in Germany. Medication against the patient's will can be administered only in cases of acute emergency or for therapeutic reasons after an independent expert review and a judge's decision.

Outcomes

We have chosen two primary outcomes: The mean percentage of treated cases that were affected by coercive measures and the mean cumulative duration of coercive measures (forced medication not included) of affected cases, each subdivided per diagnostic group and type of measure. Both outcomes are necessary to depict a comprehensive picture of the clinical practice [23,25–27].

Study design

We used an observational prospective design and compared data on coercive measures from 2017 with data from 2019.

Analyses

We compared the percentage of affected cases and the median (inter-quartile range, IQR) cumulative duration of coercive measures per affected case for 2017 with the respective data for the year 2019. Data from 2018 was omitted from analyses because the German Constitutional Court's ruling on the requirement of an immediate judge's decision on the application of mechanical restraint was in July 2018 and practical realisation is supposed to have occurred with some delay in some hospitals. Due to poor data, one hospital was omitted from analyses for the year 2017 but for the year 2019, this hospital could be included. To assess statistical significance of differences we used the chi-square test for the proportion of affected cases and the Mann-Whitney

U test for the duration of coercive measures. We chose the Mann-Whitney U test, as the data were heavily skewed. We also calculated effect sizes. For the differences in the proportions of cases with coercive measures, we calculated risk ratios (RR), and for the differences in the median cumulated duration of coercive measures, we calculated Cohen's d.

Ethics

The Ethics Committee of Ulm University waived the requirement for ethics approval as approval is not required for studies analysing anonymised data, in accordance with national legislation and institutional requirements.

Role of the Funding Source

The authors' department receives funding from the Ministry of Social Welfare and Integration of Baden-Wuerttemberg for the administration of the case registry and presentation of the results in an annual report. The funders of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Table 1 shows the absolute numbers of admissions (cases), of restraint and seclusion measures, of forced

medication and the cumulated duration of restraint and seclusion measures in the year 2017 compared to 2019 as well as the proportion of affected cases.

For the proportion of cases with restraint, there was a significant reduction from 4.8% to 3.6% (RR = 0.75, $p = 0.000$, Table 1), and the proportion of cases with seclusion increased from 2.9% to 3.3% (RR = 1.14, $p = 0.000$, Table 1). The percentage of mechanical restraints not longer than 30 minutes rose from 1.8% to 10.5% ($p = 0.000$, Table 1). The proportion of cases with either restraint or seclusion decreased from 6.6% to 5.8% (RR = 0.88, $p = 0.000$, Table 1). The median cumulated duration of restraint per affected case declined from 11.5 hours to 8.6 hours ($d = 0.2$, $p = 0.000$). The median cumulated duration of seclusion per affected case increased from 10.9 hours to 11.8 hours ($d = 0.1$, $p = 0.009$, Table 1). The median cumulated duration of either restraint or seclusion or both decreased from 12.5 hours to 11.9 hours ($d = 0.1$, $p = 0.001$, Table 1). There was also a significant trade-off between restraint and seclusion measures ($p = 0.000$). In 2017, 63.8% of coercive measures were restraints and 36.2% were seclusions while in 2019, 43.1% of coercive measures were restraints and 56.9% were seclusions. The proportion of cases with forced medication increased from 0.6% to 0.8% (RR = 1.33, $p = 0.000$, Table 1).

A significant reduction of restraint from 2017 to 2019 was found in the diagnostic groups Fo/G30 (organic disorders, mostly delirium and dementia) from 12.6% to 7.4% (RR = 0.59, $p = 0.000$), F1 (mental and

	2017	2019
Cases	115,011	118,016
Restraint measures	17,130	10,923
Restraint measures not longer than 30 minutes	314	1,147
Seclusion measures	9,716	14,448
Forced medications	1,028	1,763
Cases with restraint	5,420	4,202
% cases with restraint	4.7	3.6
Cases with seclusion	9,716	3,877
% cases with seclusion	2.9	3.3
Cases with forced medication	695	911
% cases with forced medication	0.6	0.8
Cases with restraint or seclusion	7,559	6,814
% cases with restraint or seclusion	6.6	5.8
Cases with restraint or seclusion or forced medication	7,695	7,020
% cases with restraint or seclusion or forced medication	6.7	5.9
Cumulated duration of restraint per affected case (median, IQR)	11.5 hrs (4.5–28.3)	8.6 hrs (2.8–24.0)
Cumulated duration of seclusion per affected case (median, IQR)	10.9 hrs (3.8–24.5)	11.8 hrs (4.0–28.2)
Cumulated duration of restraint or seclusion per affected case (median, IQR)	12.5 hrs (5.0–31.5)	11.9 hrs (4.2–31.4)

Table 1: Use of restraint, seclusion, and forced medication in the admitted patients in 2017 compared to the year 2019

behavioural disorders due to psychoactive substance use) from 3.9% to 3.0% (RR = 0.77, $p = 0.000$), F2 (schizophrenic disorders) from 9.9% to 7.9% (RR = 0.80, $p = 0.000$), and F3 (mood disorders) from 1.5% to 1.2% (RR = 0.80, $p = 0.000$). There was no significant increase in restraint from 2017 to 2019 in any other diagnostic group.

The median cumulative duration of restraint decreased significantly in diagnostic groups F1 from 8.1 hours to 6.4 hours ($d = -0.3$, $p = 0.000$), F2 from 15.0 to 10.3 hours ($d = -0.3$, $p = 0.000$), F3 from 12.0 hours to 8.1 hrs ($d = -0.1$, $p = 0.000$), F4 (neurotic, stress-related and somatoform disorders) from 8.9 hours to 5.1 hours ($d = -0.4$, $p = 0.001$), F6 (disorders of adult personality and behaviour) from 12.0 hours to 6.9 hours ($d = -0.3$, $p = 0.001$), and in the group with diagnoses other than F from 14.7 hours to 5.0 hours ($d = -0.6$, $p = 0.0019$).

The percentage of cases affected by seclusion rose significantly in diagnostic groups F1 from 2.0% to 2.3% (RR = 1.15, $p = 0.017$), F2 from 7.1% to 8.8% (RR = 1.24, $p = 0.000$), and F3 from 1.1% to 1.4% ($d = 1.27$, $p = 0.000$). The median cumulative duration of seclusion did not change significantly in any diagnostic group.

Interpretation

In order to assess the effects of a legal change on the use of coercive measures, we compared data before and after a German Constitutional Court decision to require an immediate judicial authorisation of mechanical restraints longer than 30 minutes in all 32 psychiatric hospitals required to treat involuntary patients in a German federal state with 11 million inhabitants.

Compared to 2017, the proportion of cases in 2019 with restraint or seclusion decreased significantly by 12% and the cumulated duration of restraints and seclusion per affected case was reduced significantly by 5%. With respect to the cumulated duration of restraint per affected case, there was a significant reduction by 25%; for seclusion, there was a significant increase of 8%. The proportion of cases with forced medication increased significantly from 0.6% to 0.8%, but remained on a very low level, probably due to the existing strict legal regulations. As in the same time the percentage of mechanical restraints not longer than 30 minutes rose from 2% to 11%, it seems conceivable that forced medication has been applied earlier to prevent mechanical restraints which last more than 30 minutes.

Overall, this shows the very clear effect of a change in the legal framework for the use of coercive measures in psychiatry. This is noteworthy, as evidence of the effectiveness of interventions to reduce the use of coercive measures in large-scale data collections of routine care has been lacking, which is also true for our previous efforts in psychiatric hospitals, except for geriatric

psychiatry [10]. Most of the major legislative changes reported in the literature date from the 1980s and 1990s.

Mental health laws in Denmark and Finland have regulated the use of coercive measures and were evaluated in two studies [28,29]. Norwegian law explicitly prescribes indications and the correct use of mechanical restraint and requires a 1:1 supervision. Finnish law does not contain specific rules on the use of mechanical restraints.

Neither law reduced coercive measures. In Poland, coercive measures during transition from socialism to democracy, which included the implementation of a new mental health law, were investigated. No reduction in coercive measures was achieved [30]. By contrast, legislation restricting seclusion and restraint to predefined situations and linking compliance of these rules to funding of institutions was effective in reducing these measures in the US [31,32].

The results from our study need to be put into context. The baseline data recorded from the year 2017 are in the range of previous data reported from studies in Germany [10,13] and other countries [33] as well. Available data from the same hospitals in the preceding years 2015 and 2016 yielded very similar results compared with our baseline data from 2017 presented here. Hence it seems very probable that the significant reductions observed in 2019 were caused by the changes of legislation, accompanied by the introduction of specific guidelines.

The substantial reduction of restraints along with an increase in seclusion raises the question of what impact this has on patients, in terms of subjective experiences and possible harmful consequences. The Constitutional Court's decision that mechanical restraint has to be considered as the most intrusive coercive technical measure (not weighting the role of forced medication) was explicitly based on evidence of a randomized controlled trial comparing mechanical restraint and seclusion, including comprehensive interviews with patients [34,35]. While assessments during the in-patient stay revealed no significant differences neither in the Coercion Experience Scale (CES) nor in interviews [34], a follow-up study a year after discharge provided significantly more subjective distress and feelings of humiliation for mechanical restraint [35]. Therefore the observed decrease of the use of mechanical restraint in favour of the use of seclusion can be considered as a shift to a less intrusive practice, as intended by the court, and probably continuing further. However, individual patients can consider seclusion, not being accompanied by 1:1 contact by staff, as more fear-inducing, so that the guidelines recommend to provide a choice between different measures and to choose the least intrusive for the individual patient, asking for preferences if possible [12].

A question of some interest is whether the considerable reduction in the use of coercive measures had

unwanted side effects, particularly an increase of incidents of aggression. Such a finding was reported in a previous study from the US [36]. From the hospitals evaluated in our study, data on in-patient violence over several years is available only for one hospital with long-term data over 14 years. As a matter of fact, reported violent incidents were 47% higher in 2019 compared to the year 2017 [37]. Without further analyses, a causal inference cannot be made.

Whether a reduction in the range of about 10% to 15%, as achieved in our evaluation, is impressive or disappointing, considering the enormous strength of the intervention in terms of invested time by psychiatrists, judges, and patients, can be discussed from different perspectives. The complete lack of any measurable effect or insignificant changes would have meant that the use of coercion had been so restricted in relation to the dangers to be managed that a further reduction could not be achieved even with the introduction of strong external control. That was not the case, however. On the other hand, a considerably greater reduction would have meant that the use of coercion had been at an unjustified high level before introducing external control. In this light, the size of the obtained effects can be considered a good outcome.

Another important result was that a shift was observed from the use of mechanical restraint to seclusion.

The proportion of restraints among all coercive measures decreased from 62% to 43% while the proportion of seclusions increased from 38% to 57%. The proportion of restraints not longer than 30 minutes increased significantly from 2% to 11%, contributing to the significant decrease of the cumulated duration of mechanical restraint per affected case. This finding was expected. One reason was that the mental health law as updated since the Constitutional Court's ruling in 2018 requires that the least restrictive alternative has to be applied in each case. As a consequence, some hospitals that had not used seclusion up until then had to install seclusion rooms. The other reason is that secluding a patient as an alternative to mechanical restraint avoids the court procedure and the necessity to provide immediate and continuous 1:1 supervision. Against that background and taking into account that in neighbouring countries such as Switzerland or the Netherlands mechanical restraint is used very rarely [14], a further shift in the direction of seclusion in the future seems probable.

In terms of diagnoses, the use of restraint did not decrease equally across all diagnostic groups. The effect was largest in patients with organic psychiatric disorders, in patients with disorders due to psychoactive substance use, in patients with schizophrenia and in patients with mood disorder, while in patients with an ICD-10 F4, F5, F6, F7, F8, or F9 diagnosis no significant reduction in the use of restraint could be found.

This is possibly due to the fact that among these diagnostic groups the baseline and, hence, the potential to achieve reductions was rather high [10].

Strengths and Limitations

Our study has some strengths. First of all is the complete coverage of a German federal state with respect to coercive measures, which is comparable in magnitude to nationwide case registers in Scandinavia.

Second, there are clear and mandatory definitions of all the variables collected. These definitions had been provided in detail to the reporting hospitals before the registry was launched and have been repeatedly discussed at annual symposia with decision-makers of the hospitals. Moreover, the procedure of data collecting was not introduced for this study but had been well established over previous years and before we formed our study question based on the 2018 Constitutional Court decision.

The study also has some limitations. An important question is whether the data on coercive measures are reliably recorded. Although the data are routinely checked for plausibility by the Department of Research and teaching at the Centres for Psychiatry Suedwuerttemberg, which is the office in charge of the evaluation, statements on the validity must be made cautiously. To insure a standardised and consistent collection of data, together with the registry, a detailed manual with binding definitions and documentation guidelines was introduced in 2015. Although in a first evaluation, the quality of the data provided has shown to be good [13], it cannot simply be concluded from this that the coverage is complete. But there are a few points that speak in favour of reliable recording. Firstly, the detailed instructions are provided with many examples of how and how not to document coercive events. These instructions are permanently discussed in a close contact between hospitals and data evaluation office. In addition, a specialist conference is held once a year with clinics, the evaluation office and the Ministry of Social Welfare and Integration of Baden-Wuerttemberg, at which questions regarding the reduction of coercive measures as well as questions regarding uniform and complete documentation are discussed in detail. Then, due to the clear legal obligation of which all staff is very aware, it seems very unlikely that coercive measures ordered by a physician remain undocumented or that coercive measures would be carried out without informing a physician, which would be absolutely illegal. However, the exact documentation of duration by nursing staff might be inaccurate in a proportion of cases. Underreporting in terms of loss of data can be ruled out with considerable certainty as the dataset is based on raw data drawn directly from the patients' electronic files.

Furthermore, the samples in the two years are not completely independent. As known from other analyses

in the authors' hospital group, about 8.5 % of patients had admissions in 2017 and 2019 as well. While the registry contains raw data on coercive measures (not on the numbers of admissions), it does not contain information whether two or more cases represent the same patient across different time points. Insofar, the used chi-square tests and the Mann-Whitney-U test, which warrant independent samples, must be interpreted with caution. We also do not know, whether the implicit assumption that the populations in 2017 and 2019 have roughly the same underlying risk of restraint or seclusion is true. As the available data contains no information on sociodemographic features and as we do not know whether two or more cases represent the same individual, more elaborate statistical analyses like multi-level models could not be used. It therefore cannot be completely ruled out that the reduction in coercive measures is due to differences in that underlying risk, rather than due to the implementation of the new legislation.

Though our findings with respect to the percentages of cases affected by coercive measures are in line with previous findings for Germany, the generalizability and comparability of our results might be limited. It is unclear whether the findings on the impact of legal changes in the Federal State of Baden-Wuerttemberg can be transferred to the whole country or even other countries with different mental health care systems.

Conclusion

Our study shows an effect of a change in the legal framework for the use of coercive measures in psychiatry. There is clear evidence that a strong legal intervention was effective in reducing the use of coercive measures under routine conditions. Restraints were reduced, and this reduction was not overcompensated by seclusion or by forced medication.

Data sharing statement

The datasets generated for this study cannot be made publicly available. The data stored in the register is classified as confidential by the data protection officer of Baden-Wuerttemberg and is not publicly available due to data privacy.

Contributors

TS and EF designed the study. TS wrote the initial draft of the paper. EF and SH analysed the data. All authors interpreted the data. All authors contributed to reading and approving the final version of the manuscript. EF and

SH had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of data analysis.

Conflicts of Interest

All authors have no conflicting interests to disclose.

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Supplementary materials

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