ISRCTN71467851 https://doi.org/10.1186/ISRCTN71467851

Reducing force in mental health care with the help of guidelines

Submission date
28/10/2019

Recruitment status
No longer recruiting

Registration date
02/12/2019

Overall study status
Completed

Last Edited
17/02/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Coercive measures in psychiatry are discussed controversially. On the one hand, they are a violation of the human rights of people with mental health problems. On the other hand, they are often used as measures of the last resort to restore safety for patients and staff on psychiatric wards. This study aims to find out whether the use of coercive measures on psychiatric wards can be reduced by implementing the German Clinical Practice Guidelines "Avoidance of Coercion-Prevention and Treatment of Aggressive Behavior in Adults" (2018).

Who can participate?
52 psychiatric wards (26 from Southern Germany and 26 from Berlin) selected by the ward's staff according to their needs and possibilities, supported by an implementation consultant (nurse, psychologist).

What does the study involve?
The participating wards are randomly allocated to either an intervention group or a control group. The intervention group receive the intervention (implementation of clinical practice guidelines) straight away for 12 months. The control group also receive the intervention after 12 months. The level of implementation, number of coercive measures, and the duration of coercive measures are recorded before and after the intervention and are compared between the intervention and control wards.

What are the possible benefits and risks of participating?
Staff on the wards might worry that aggressive incidents become more frequent when restrictive measures are reduced and that they might become victims of assaults. Therefore, the number and severity of aggressive incidents is also measured.

Where is the study run from?
1. Ulm University (Germany)
2. Vivantes Klinikum Am Urban, Clinic for Psychiatry, Psychotherapie und Psychosomatic Charite Berlin (Germany)
3. St. Hedwig Hospital, Psychiatric University Clinic, Charité Berlin (Germany)

When is the study starting and how long is it expected to run for?
January 2019 to January 2023

Who is funding the study?
Innovationsausschuss beim Gemeinsamen Bundesausschuss

Who is the main contact?
Dr Sophie Hirsch
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Study website
https://prevco.de/

Contact information

Type(s)
Public

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IVZ S3

Study information

Scientific Title
Implementation of the German Clinical Practice Guidelines on Prevention of Coercion and Violence (PreVCo) in psychiatry: a 2-year multicenter randomized matched-pair waiting list control trial (RCT) with complementary qualitative interviews

Acronym
PreVCo

Study objectives
Current study hypothesis as of 06/04/2023:
H1: The number of coercive measures per bed and year can be reduced by the intervention.
H1a: The guideline adherence can be enhanced by the intervention.
H2: The cumulative duration of seclusion and restraint per bed and year can be reduced by the intervention.
H3: Wards with high fidelity to the clinical practice guidelines have less coercive measures and less aggressive incidents.
H4: There is a correlation between the level of implementation in the intervention phase and the reduction of coercive measures.
H5: Various successful strategies can be identified due to the variety of interventions applied on the different participating wards.

Previous study hypothesis:
H1: The number of coercive measures per bed and year can be reduced by the intervention.
H2: The cumulative duration of seclusion and restraint per bed and year can be reduced by the intervention.
H3: Wards with high fidelity to the clinical practice guidelines have less coercive measures and less aggressive incidents.
H4: There is a correlation between the level of implementation in the intervention phase and the reduction of coercive measures.
H5: Various successful strategies can be identified due to the variety of interventions applied on the different participating wards.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 04/09/2019, ethics committee of Ulm University (Ulm HelmholtzstraBe 20 (Oberer Eselsberg) 89081 Ulm, Germany; Tel: +49 (0)731 500 22050/22052; Email: ethik-kommission@uni-ulm.de), ref: 55/19

Study design
Multicenter randomized matched-pair waiting list control trial (RCT) with complementary qualitative interviews

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Psychiatric wards treating patients with severe mental illness, including the option of involuntary treatment

Interventions
Participating wards choose 2-3 interventions from the following list:
1. Implementation of standardised recording of coercive measures and aggressive incidents allowing analysis on a ward level
2. Implementation of internal standards in accordance with the Clinical Practice Guidelines concerning indication, conduct, review, documentation and debriefing of coercive measures or review existing standards.
3. Establish monthly team meetings were the data on coercive measures are discussed together with the ward manager and the head of the department
4. Establish a schedule for staff training in de-escalation techniques and aggression management and make sure that every employee who has contact with patients is trained at least once every two years
5. Ensure that patients who are secluded or restrained receive continuous personal 1:1 support by trained staff
6. Guarantee that after coercive measures debriefings with involved patients are done regularly and that these debriefings are documented properly
7. Employ peers on the wards
8. Install a plan of action to enhance the physical environment to avoid aggression and coercion on the ward and review this plan annually
9. Implementation of risk assessment tools e.g. the Brøset Violence Checklist (BVC) or another instrument in all patients at risk. Ensure that patients with high scorings will get appropriate interventions, e. g. talking down a patient by two staff members
10. Advise the patients who experienced coercive measures to prepare a patient advance

directive or offer to develop joint crisis plans together with their treating physicians
11. Realize pharmacotherapy in accordance with current clinical guidelines, evaluate the quality of the pharmacotherapy in regular intervals, e. g. once a month
12. Implementation of Safewards or another complex intervention consisting of different modules (e. g. Weddinger Modell, Six Core Strategies)

52 psychiatric wards (26 from Southern Germany and 26 from Berlin) are recruited to implement some of these interventions, selected by the ward's staff according to their needs and possibilities, supported by an implementation consultant (nurse, psychologist). The wards are randomised to an intervention and a control group. The control group will also get the intervention after 12 months.

The level of implementation, number of coercive measures, the duration of coercive measures and the number and severity of aggressive incidents are recorded before and after the intervention and are compared between intervention and control wards. In T0 the intervention wards will have their baseline assessment and their 1-day kick-off workshop. The intervention period will last 12 months. The wards will have 2 further half-day-workshops and telephone and email support by experts during this year. In T1 (after 12 months) follow-up assessment will be performed on the intervention wards and baseline assessment will be performed on the waiting list wards. Then the waiting list wards will have the intervention. In T2 (after 24 months) the waiting list wards will have their follow-up measurement. The study contains also a qualitative part. The interviews will start in month 2 on the intervention wards and in month 14 on the waiting list wards.

Intervention Type
Behavioural

Primary outcome measure
Number of coercive measures, measured per bed and year in the year before the intervention and in the intervention year. These are routine data available in all the clinics as prescribed by law. Coercive measures are forced medication, physical and mechanical restraint and seclusion.

Added 06/04/2023:
Due to the COVID-19 pandemic some wards were closed for several months and could not provide data at 12 months. Therefore the researchers decided to analyse the last 3 months provided by every ward. The intention to analyse all months (9-12 months were available) was also followed and used as a sensitive analysis.

Secondary outcome measures
Current secondary outcome measures as of 17/01/2023:

1. Level of implementation of the Clinical Practice Guidelines measured using a Likert scale graduated in ten steps (0-9) with standard examples covering the 12 interventions (derived from the guidelines recommendations) that can be implemented by the wards. Change will be measured by a pre-post-comparison calculating the difference between post- and pre-scoring (baseline and after 12 months)
2. Cumulative duration of coercive measures (physical and mechanical restraint and seclusion), measured using routine data in the year before the intervention and in the intervention year
3. Number of aggressive incidents measured using patient records during the year of the intervention

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Previous secondary outcome measures:

1. Level of implementation of the Clinical Practice Guidelines measured using a Likert scale graduated in ten steps (0-9) with standard examples covering the 12 interventions (derived from the guidelines recommendations) that can be implemented by the wards. Change will be measured by a pre-post-comparison calculating the difference between post- and pre-scoring (baseline and after 12 months)
2. Cumulative duration of coercive measures (physical and mechanical restraint and seclusion), measured using routine data in the year before the intervention and in the intervention year
3. Number of aggressive incidents measured using the SOAS-R scale during the year of the intervention. Events with >= 10 points on the SOAS-R scale will be counted as assaults

Overall study start date
30/01/2019

Completion date
31/01/2023

Eligibility

Key inclusion criteria
Psychiatric wards with the option to realize involuntary treatment

Participant type(s)
Other

Age group
Adult

Sex
Both

Target number of participants
52 wards

Total final enrolment
55

Key exclusion criteria
1. Forensic wards
2. Wards for children and adolescents
3. Wards where mainly people with dementia are treated

Date of first enrolment
01/02/2020

Date of final enrolment
29/07/2020

Locations

Countries of recruitment
Germany

Study participating centre
Ulm University
ZfP Suedwuerttemberg, CLinic for Psychiatry and Psychotherapie I
Weingartshofer Strasse 2
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Study participating centre
Vivantes Klinikum Am Urban, Clinic for Psychiatry, Psychotherapie und Psychosomatic Charite Berlin,
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Study participating centre
St. Hedwig Hospital, Psychiatric University Clinic, Charité Berlin
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Sponsor information

Organisation
Ulm University

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Sponsor type
Hospital/treatment centre

Website
https://www.zfp-web.de

ROR
https://ror.org/032000t02

Funder(s)

Funder type
Government

Funder Name
Innovationsausschuss beim Gemeinsamen Bundesausschuss

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 17/01/2023:
The study design was published in 2020, the pilot study was published in 2022. In 2023 the quantitative and qualitative analysis will be published.

Previous publication and dissemination plan:
The study design will be published at the end of 2019. In 2023 the quantitative and qualitative analysis will be published.

Intention to publish date
31/07/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	15/09/2020	27/10/2020	Yes	No
Interim results article	Pilot study results	01/05/2022	17/01/2023	Yes	No
Participant information sheet	Brief PIS. In German.	31/08/2019	17/01/2023	No	Yes

Participant information sheet	In German		17/01/2023	No	Yes
Interim results article	baseline survey data	11/05/2023	31/05/2023	Yes	No
Dataset		22/11/2023	16/01/2024	No	No
Results article		01/12/2023	16/01/2024	Yes	No
Other publications	Barriers and facilitators	14/02/2025	17/02/2025	Yes	No