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Violence risk management in a psychiatric ward

Submission date
01/07/2026

Recruitment status
No longer recruiting

Registration date
03/07/2026

Overall study status
Completed

Last Edited
02/07/2026

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Violent behaviours frequently appear among schizophrenia inpatients in psychiatric wards, threatening the safety of patients and nurses and damaging therapeutic nurse–patient relationships. Traditional violence management mainly responds to crises after events rather than adopting systematic proactive prevention. The PDCA (Plan-Do-Check-Act) cycle is a mature quality improvement framework, yet few controlled studies verify its efficacy for violence risk management in schizophrenia wards. This study intends to test whether adding PDCA cycle management to routine nursing can reduce patients' violent behaviours and raise their satisfaction with nursing services.

Who can participate?
Inpatients aged 18–65 years with schizophrenia

What does the study involve?
Participants are divided into two groups based on different wards without random assignment. All patients receive standard psychiatric nursing for 8 weeks. The research group additionally receives a full set of PDCA violence prevention management, including nurse training, environmental safety renovation, unified emergency protocols and weekly quality inspections. Researchers assess patients' aggression scores and care satisfaction at admission and at the end of 8 weeks and continuously record all violent incidents during hospitalisation.

What are the possible benefits and risks of participating?
Patients in the intervention group obtain more targeted safety protection, personalised communication and early intervention before violent outbursts and may experience a safer ward environment and better nursing experience. No extra invasive examinations or experimental drugs are used; all adopted nursing measures are clinical routine quality improvement strategies with no additional physical risks. Individual patients may feel uncomfortable with regular safety inspections and repeated psychological assessments.

Where is the study run from?
Tianshui Third People's Hospital (China)

When is the study starting and how long is it expected to run for?
April 2021 to June 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Yalan Wang, yalan_wang701@163.com

Contact information

Type(s)
Scientific, Public, Principal investigator

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Study information

Scientific Title
Application of the plan-do-check-act management model to violence risk management in a psychiatric ward: impact on patient safety and nurse–patient relationships

Study objectives
This quasi-experimental parallel controlled study fills the research gap of limited evidence on PDCA violence risk management for schizophrenia patients. It aims to evaluate whether systematic PDCA cycle management can reduce the incidence and severity of violent behaviors via optimized risk identification, proactive intervention and continuous quality improvement. This study also explores whether PDCA-based violence risk management improves nurse–patient therapeutic relationships reflected by higher patient satisfaction with nursing care, so as to provide evidence-based operable management models for psychiatric nursing wards.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 24/06/2026, Medical Ethics Committee of Tianshui Third People’s Hospital (No. 17, Jingbiao Road, Qinzhou District, Tianshui, 741020, China; +86 (0)938-8365207; ts3ybgs@163.com), ref: N/A

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Prevention and management of violent risk behaviors among adult inpatients diagnosed with schizophrenia in psychiatric inpatient wards

Interventions
The study sets two parallel groups without random allocation by ward division.

The control group receives routine standard psychiatric nursing care, including admission assessment, regular mental monitoring, daily medication delivery, basic safety precautions and emergency de-escalation/restraint when violent incidents occur, with standardized incident handover records.

The research group receives identical standard care plus a comprehensive 8-week PDCA cycle violence risk management framework covering four phases: Plan (retrospective violent incident root-cause analysis and multi-dimensional risk factor classification), Do (systematic nurse training, standardized ward violence prevention manual, SBAR shift communication, high-risk area safety management, daily safety inspection and person-centred de-escalation nursing), Check (weekly quality control meetings to analyse aggression scale scores and near-miss incidents), and Act (standardise effective prevention strategies and incorporate unresolved risks into next improvement cycles). All nurses in both groups receive balanced staffing allocation with comparable age, working years and educational background to minimise staff confounding bias. The whole intervention lasts 8 weeks after patient enrolment.

Intervention Type
Mixed

Primary outcome(s)
1. Severity of violent aggressive behaviours measured using the Modified Overt Aggression Scale (MOAS) at baseline (week 1) and week 8

2. Frequency of four subtypes of violent incidents measured using standardised violence behaviour recording forms at continuously throughout the 8-week intervention period

3. Patient satisfaction with nursing care measured using self-developed and validated patient satisfaction questionnaire at baseline (week 1) and week 8

Key secondary outcome(s)

Completion date
30/06/2022

Eligibility

Key inclusion criteria
1. Diagnosis of schizophrenia according to the International Classification of Diseases, 10th Revision diagnostic criteria for mental and behavioural disorders
2. Aged 18–65 years
3. Education level of primary school or above
4. Presence of a family caregiver or guardian with a relatively stable social support system
5. Willingness to participate and provision of written informed consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
400

Key exclusion criteria
1. Comorbid organic brain disorders or severe physical illnesses
2. Alcohol or substance dependence
3. Other psychiatric disorders not meeting schizophrenia diagnostic criteria

Date of first enrolment
01/04/2021

Date of final enrolment
30/04/2022

Locations

Countries of recruitment

China

Sponsor information

Organisation
Tian Shui City Third People's Hospital

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Yalan Wang (yalan_wang701@163.com)

IPD sharing plan summary
Available on request