

Randomised controlled trial on seclusion and mechanical restraint

Submission date 06/06/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 25/08/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/05/2010	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title

Acronym
Isofix

Study objectives

There is a difference in the subjective assessment of patients regarding the restriction of human rights after seclusion or mechanical restraint was being conducted.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Ethical Committee of University of Ulm on the 11th November 2002 (amendment approved 20th October 2005) (ref: 136/2002).

Study design

Cohort design with optional randomisation

Primary study design

Observational

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Aggressive behaviour or self-directed aggression

Interventions

Seclusion and mechanical restraint

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Subjective assessment of patients' restrictions of a human rights score composed of human dignity, autonomy, freedom of movement, interpersonal contact and perceived coercion during conducting the measure.

Key secondary outcome(s)

Duration of measure, complications and safety.

Completion date

05/03/2006

Eligibility

Key inclusion criteria

1. Patients for whom coercive measures are indicated
2. Diagnosis F2, F3 or F6 in International Classification of Diseases (ICD-10)
3. Informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Severe intellectual deficits
2. Continuously severely disturbed mental state
3. Poor German
4. Inclusion into study during a former admission
5. Missing informed consent
6. Exclusion Criteria to randomisation:
 - a. definite wish of the patient not to receive one but the other measure
 - b. contraindication to one measure by the psychiatrist

Date of first enrolment

05/03/2004

Date of final enrolment

05/03/2006

Locations

Countries of recruitment

Germany

Study participating centre

ZfP Weissenau

Ravensburg

Germany

88214

Sponsor information

Organisation

University of Ulm (Germany)

ROR

<https://ror.org/032000t02>

Funder(s)

Funder type

University/education

Funder Name

University of Ulm (Germany) - Department of Psychiatric Health Care Research

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/01/2010		Yes	No