Effectiveness of routine Risk Assessment and Care Evaluation (RACE) in violence prevention in outpatient forensic psychiatry; a randomized clinical trial

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Ethical review	Approved WMO
Status	Pending
Health condition type	Psychiatric disorders NEC
Study type	Interventional

Summary

ID

NL-OMON30556

Source
ToetsingOnline

Brief title
RACE (Risk Assessment and Care Evaluation) study

Condition

- Psychiatric disorders NEC

Synonym
behavioral disorders, mental disorders

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Drenthe (Assen)

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: forensic psychiatry, patient care planning, randomized clinical trial, risk assessment

Outcome measures

Primary outcome

Primary outcome is the proportion of clients showing *violent behaviour* (including criminal behaviour, physical violence, and verbal aggression) in the six moths prior to follow-up (at 18 months or end or treatment). Information on violent behaviour is gathered in two ways. First, by continuous registration of violent incidents by the case manager, as part of the medical record of clients in both research conditions. And second, by self-report in the follow-up interview. Any reports of a violent incident is judged by a panel of forensic psychiatric experts, who will be *blind* about the research condition of the client, as will be the interviewers.

Secondary outcome

Secondary outcomes are *risk enhancing behaviour* (e.g. breaking of agreements, stopping necessary medication, drug abuse), quality of life, psychiatric and social functioning, aggression, impulsivity, and satisfaction with care and the therapeutic relation.

Study description

Background summary

The goal of risk assessment is violence prevention. Nevertheless, nearly all

risk assessment research is aimed at violence prediction, and there is no evidence that risk assessment actually prevents violence. Recent developments in risk assessment research emphasize the dynamic nature of violence risk and focus on the implications of the assessment for patient care, that is for risk management. We developed a risk assessment procedure for outpatient forensic psychiatry, that is integrated with routine care evaluation by the case manager in discussion with the client. In a pilot study we showed that this procedure is feasible in outpatient forensic psychiatry, and predictive of violent behaviour.

Study objective

The study seeks to answer whether routine risk assessment and care evaluation reduces the frequency of violent behaviour (primary outcome) in outpatient forensic psychiatric clients, and increases their quality of life, psychiatric and social functioning, and satisfaction with care.

Study design

The study is a cluster Randomized Clinical Trial (RCT), where case managers (with their whole caseloads) are randomized to Intervention or Care-As-Usual, and outcome is assessed at the client level. Clients are interviewed at baseline and 18 months (or end of treatment) follow-up.

Intervention

In the experimental group routine risk assessment and care evaluation is carried out at every formal evaluation of the care plan, but at least once every six months. This consists of (1) an assessment of the violence risk of the client by the case manager on the instrument START (Short-Term Assessment of Risk and Treatability), and (2) a standardized evaluation by the case manager and client of the needs for care of the client and the care offered (covering a.o. the view of the client, the view of the case manager or care team, and discussion of adjustments to care). In the control condition no formal method of risk assessment or care evaluation is used, and Care-As-Usual is offered.

Study burden and risks

The intervention formalizes regular elements of care, of which no risk is anticipated for the client. The intervention is incorporated in routine care. Only the baseline and follow-up interviews provide an additional burden by study participation. Benefits to the clients consist of enhanced opportunities for shared decision making in care planning, and the anticipated effects of the intervention on client functioning.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Clients of outpatient forensic psychiatric services, who are expected to remain in care for another six months or more

Exclusion criteria

Less than one contact a month with the outpatient forensic psychiatric service, on average

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2007
Enrollment:	680
Type:	Anticipated

Ethics review

Approved WMO

Date:	21-08-2007
Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL16215.097.07