The added value of an internet-based intervention for treatment of aggression in forensic psychiatric outpatients

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON51418

Source
ToetsingOnline

Brief title
Aggression

Condition

- Other condition

Synonym
aggression, self-efficacy, treatment readiness

Health condition

reactieve agressieregulatie problematiek

Research involving
Human

Sponsors and support

Primary sponsor: Dimence (Deventer)
Source(s) of monetary or material Support: Kwaliteit Forensische Zorg (KFZ)

Intervention

Keyword: Aggression, Forensic psychiatric care, Minddistrict, RCT

Outcome measures

Primary outcome

The primary outcome measure of this study is regulatory emotional self-efficacy. This construct is measured by means of the validated, 12-item Regulatory Emotional Self-efficacy (RESE) scale. The RESE scale assesses self-efficacy in managing negative emotions (8 items) and in expressing positive emotions (4 items). Negative emotional self-efficacy refers to the perceived *capability to ameliorate negative emotional states once they are aroused in response to adversity or frustrating events and to avoid being overcome by emotions such as anger, irritation, despondency, and discouragement*. Positive self-efficacy is defined as the perceived capability *to experience and to allow oneself to express positive emotions such as joy, enthusiasm and pride in response to success or pleasant events*. Earlier research has demonstrated the validity and reliability of the RESE scale. Because the RESE scale consists of only 12 items, it is easy to administer and does not require much effort of participants.

Secondary outcome

The secondary outcomes are treatment readiness, aggression, risk assessment and engagement. Treatment readiness and aggression are measured by the validated

Dutch version of the Corrections Victoria Treatment Readiness Questionnaire (20-items) and the much-used and validated Aggression Questionnaire (12 items).

In treatment of all forensic psychiatric patients, risk assessment has to be conducted by means of evidence-based risk assessment instruments. In forensic psychiatric outpatient care, the Dutch standard is the Forensisch Ambulante Risico Evaluatie (FARE), version 2. The FARE is not only used to estimate the risk on recidivism, but also to monitor changes in dynamic risk factors and risk of recidivism during treatment. Research into inter-reliability and convergent validity has shown promising results. The FARE is part of Dutch guidelines on risk assessment of forensic psychiatric outpatients. According to these guidelines, the FARE is administered twice a year, i.e. once each six months.

In the FARE, 6 static and 11 dynamic risk factors are assessed. Static risk factors refer to *unchangeable* characteristics, such as age of the first offense. While they predict the risk of recidivism, they are not changeable by means of targeted interventions. Dynamic risk factors however are more related to the individual behaviour of the person and their social and living situation. Because these 11 factors are influenceable by interventions, they will be included in the analyses of this study.

Finally, engagement is measured with the TWente Engagement with Ehealth and Technologies Scale (TWEETS). The scale employs a definition of engagement that incorporates behaviour, cognition, and affect, and has been shown to have a good validity and reliability. The TWEETS contains only 9 items - with three items per component of engagement - and has three slightly different versions:

one for expected engagement, to be used when someone starts using an intervention, one for current engagement, to be used during the use of an intervention, and one for past engagement, to be used when a user has completed or stopped using an intervention.

Study description

Background summary

While internet-based interventions have been used for over ten years in Dutch forensic psychiatric outpatient care, no thorough evaluation study has been conducted yet. Studies on internet-based interventions in other mental healthcare sectors show promising results: they can increase the quality and efficiency of care. However, it is not clear if, why and for whom these interventions work in forensic mental healthcare. It is especially important to study whether these interventions are of added value for this complex patient population, known for its low treatment motivation, co-morbidity and low literacy levels.

Study objective

The primary objective of this study is to investigate whether the addition of the internet-based intervention *Aggression* to forensic psychiatric outpatient treatment as usual (TAU) results in better treatment outcomes in terms of self-reported regulatory emotional self-efficacy, treatment readiness, and aggression. Additionally, it is studied whether the experimental group requires fewer treatment sessions and improves more on dynamic risk factors. Furthermore, to gain more insight into for whom these interventions work, it is investigated whether engagement with the internet-based intervention predicts adherence and effectiveness. Finally, this study aims to explore reasons for the (in)effectiveness of the intervention according to patients and therapists.

Study design

To investigate if the use of internet-based interventions is of added value for treatment of forensic psychiatric outpatients, a multicenter, non-blinded, parallel groups, mixed-methods randomized controlled trial design is used. Patients fill out three short self-report questionnaires four times: at baseline, mid-treatment (+6 weeks), post-treatment (+14 weeks) and at follow-up (+26 weeks). Semi-structured interviews with a randomly selected sample of 20 patients from the experimental condition and with all participating therapists

are conducted to explain the results of the RCT.

Intervention

This study investigates the existing internet-based intervention Aggression, which was introduced in forensic mental healthcare over ten years ago. However, as is the case with other internet-based interventions, uptake in practice remains relatively low. *Aggression* is used as an addition to treatment as usual, and thus does not replace any part of treatment in this study. The intervention is developed by the company Minddistrict, in close cooperation with therapists, patients and other stakeholders. The goals of this intervention are to (1) increasing the motivation to change, (2) acquiring skills for dealing with conflict, and (3) breaking the cycle of aggression by providing knowledge on situational, emotional, cognitive and physical triggers. It contains ten lessons, each containing written texts, videos and audio files, and short written assignments on which the therapist can give feedback.

Study burden and risks

Since participants only have to fill out short questionnaires and are compensated for their time, participating in this study is not viewed as a major burden. Furthermore, the interventions of Minddistrict have been used for over ten years in mental healthcare, during which no risks or adverse events have been observed. Because not all forensic psychiatric patients receive internet-based interventions as part of their standard care and because these interventions are not yet evaluated and are thus not evidence-based, participants in the control condition are not deprived of effective treatment. During the entire treatment, experienced therapists monitor the patient*s progress. Finally, multiple precautions are taken to ensure that patients are aware that the decision to participate does not have any effect on their treatment progress. Consequently, the burdens and risks associated with this study are low or even non-existent.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
1) The patient is 18 years or older
2) The patient is treated at an outpatient clinic
3) The patient receives one-on-one treatment
4) During the intake, improvement of aggression regulation has been selected as one of the treatment objectives
5) The patient indicates that they are able to read and write simple texts
6) The therapist responsible for treatment of the patient indicates that participating will not result in any harm for the patient
7) The patient voluntarily consents to participation

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
1) The patient has a current psychosis
2) The patient resides in any type of psychiatric inpatient clinic - this can be a forensic, but also another type of clinic
3) The patient is analphabetic, i.e. being unable to read and write
4) The responsible therapists identifies any other valid reason for exclusion

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-03-2023
Enrollment:	154
Type:	Actual

Ethics review

Approved WMO Date:	15-06-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-02-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL80846.091.22