PROSPER: Addressing mental health problems and preventing recidivism in the criminal justice system

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

Summary

ID

NL-OMON56141

Source
ToetsingOnline

Brief title
Implementation of PM+ for prisoners detained in Dutch prisons

Condition

- Other condition
- Mood disorders and disturbances NEC

Synonym
anxiety, Common mental health problems, depression, distress

Health condition

Symptomen van angst, (posttraumatische) stress en depressie

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Common mental health problems, Criminal justice system, Implementation and evaluation, Psychological intervention

Outcome measures

Primary outcome

The main study parameter will be the feasibility and acceptability of PM+

intervention. Factors relevant to that include:

1. PM+ fidelity

2. Perceptions about PM+ from RCT participants, professionals and helpers

3. Indicators of intervention delivery: implementation process, adaptation, and

dose

4. Retention rate PM+ sessions

5. Recruitment and consent rates

Secondary outcome

To assess the preliminary indications of pre to post-effects: 1) Symptoms of

depression and anxiety (PHQ9 and GAD-7), 2) Self-identified problems

(PSYCHLOPS), 3) Daily functioning (WHOQOL-BREF), 4) Symptoms of trauma (PCL-5),

and 5) suicidality vulnerability (SCOPE-2)

Study description

Background summary

Each year between 20 and 30 thousand individuals are newly incarcerated in Dutch prisons. Common mental disorders, such as depression and anxiety, are overrepresented in prison populations. As such, mental health problems are an important target for intervention, since they have been found to be associated with re-offending. The prison period may provide opportunities for addressing mental health problems, but there may be important obstacles and barriers to the actual delivery of interventions, such as a lack of mental health care specialists in prisons due to staff shortages.

Within the PROSPER study, we will evaluate the feasibility and acceptability of implementing the brief, scalable Problem Management Plus (PM+) intervention in Dutch prisons. The PM+ intervention is designed to address common mental health problems, is delivered by trained non-specialists, and will be specifically adapted for the prison setting.

Study objective

The primary aim of this study is to investigate the feasibility, acceptability and user-friendliness of implementing PM+ in Dutch prisons. This is a version of PM+ that is specifically adapted to the prisoner population and prison context. The secondary goal is to get a first view of the possible pre- to post effect of PM+ on common mental health symptoms, while taking the sample size into account.

Study design

The PROSPER study consists of three phases: two qualitative studies (study phases 1 and 3) and a pilot randomised controlled trial (RCT) (study phase 2). This proposal concerns study phases 2 and 3. The protocol of phase 1 has already been approved by the ethics review committee of the Vrije Universiteit - faculty of behavioural and movements sciences (VCWE) and received a niet-WMO waiver (reference number: 2022.0393).

Intervention

PM+ is a brief, psychological intervention program based on cognitive behavioural therapy (CBT) techniques that are empirically supported and formally recommended by the WHO (Dua et al., 2011; Tol et al., 2013). The full protocol was developed by the WHO and the University of New South Wales, Australia. The manual involves the following empirically supported elements: problem-solving, stress management, behavioural activation, and accessing social support.

Study burden and risks

The risks associated with participation are estimated to be minimal, as PM+

reduced common psychological complaints in previous studies in Pakistan, Kenya and the Netherlands (Bryant et al., 2017; Rahman et al., 2016; de Graaff et al., 2023), and no significant negative reactions were noted. Participants in the PM+ intervention group may benefit from their participation through the potential reduction of psychological symptoms. Also, participants of the intervention and control group both have access to normal care (CAU).

It is possible that participants experience increased stress during the PM+ sessions (e.g. by talking about stressful events). However, the helpers are trained, supervised and supervised by experienced psychologists. This allows them to be able to guide participants during a more difficult moment and to scale up the care if necessary.

If a participant's mental health does deteriorate during the intervention period, he can be referred to a specialist in the prison (eg the prison doctor, psychologist or psychiatrist). The exact procedure will be determined with the prison in question. The situation of this person will be followed up by the research team.

Contacts

Public
Vrije Universiteit

Van der Boechorststraat 9
Amsterdam 1081BT
NL
Scientific
Vrije Universiteit

Van der Boechorststraat 9
Amsterdam 1081BT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

To be eligible to participate in study phase 2, a subject must meet all of the following criteria: - 18 years old or above; - Imprisoned in a Dutch prison; - Held on remand; - Dutch-speaking; - Elevated levels of psychological distress (K10 higher than15). An individual will be eligible to participate in study phase 3 if: - They were a RCT participant; or - Professionals knowledgeable about (the mental health of) prisoners; or - Helpers, supervisors or trainers of the PM+ intervention; or - Family members or friends of RCT participants.

Exclusion criteria

Study phase 2
- Enclosed in a penitentiary psychiatric centre;
- Presents a potential security risk to the research team (PM+ helper and/or research team)
- Acute medical condition;
- Imminent suicide risk or expressed acute needs/protection risks (e.g., someone who expresses that they are at acute risk of being assaulted or killed);
- Severe mental disorder (psychotic disorders, substance dependence) ;
- Severe cognitive impairment (e.g., severe intellectual disability or dementia);
- Currently enrolled in a specialised psychological treatment program (e.g., EMDR, CBT);
- Less than two months on a stable dose of psychotropic medication (if applicable).

Study phase 3:
- Presents a potential security risk to the research team
- Acute medical condition;
- Imminent suicide risk or expressed acute needs/protection risks.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2023
Enrollment:	85
Type:	Anticipated

Ethics review

Approved WMO

Date:	11-12-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
ClinicalTrials.gov	NCT05927987
CCMO	NL84617.018.23