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STUDY PROTOCOL

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Acceptability and feasibility of Problem Management Plus to address mental health problems among remand prisoners in the Netherlands: a pilot randomised controlled trial protocol

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Abstract

Background Worldwide, the prevalence of mental health problems in prison populations is higher than in the general population. While prisons may provide opportunities to address mental health problems, the prison setting can also include obstacles to the actual delivery of interventions, such as mental health care staff deficiencies. A brief scalable psychological intervention such as the World Health Organization's (WHO) Problem Management Plus (PM+) intervention, which is delivered by trained non-specialists, could be valuable in addressing common mental health problems in the prison setting. The primary aim of the study is to evaluate the feasibility and acceptability of PM+, adapted for use in Dutch remand prisons. The secondary aim is to examine barriers and facilitators for scaling up the adapted version of PM+ in the Dutch prison setting.

Method This single-blind pilot randomised controlled trial (RCT) will compare individual PM+ with care-as-usual (PM+/CAU) to CAU only. Dutch-speaking remand prisoners (18 years or older; $N=60$) who report an elevated level of psychological distress (K10 ≥ 16) will be included. The feasibility of the intervention will be reviewed using different measures such as recruitment success, intervention retention, protocol adherence, number of serious adverse events, and stakeholders' views. Participants will be assessed for self-reported anxiety, depression, self-identified problems, vulnerability for suicide and self-harm behaviour and post-traumatic stress disorder (PTSD) symptoms at baseline, one-week post-intervention and three-month follow-up. The pilot RCT will be followed by a process evaluation. For the process evaluation, stakeholders will be interviewed ($N=25$), including 1) RCT participants, 2) PM+ helpers, supervisors and trainers, 3) prison professionals, and 4) family members & friends of RCT participants. Data of the process evaluation will be analysed using reflexive thematic analysis.

Discussion This pilot RCT will be the first to study the potential of WHO-developed scalable interventions aimed at reducing mental health problems within (Dutch) prisons. Results from this study could subsequently inform a potential full-powered RCT.

Trial registration This trial is registered on ClinicalTrials.gov (number NCT05927987) on 13/06/2023.

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Introduction

Worldwide, the prevalence of mental health problems in prison populations is higher than in the general population (Favril et al., 2024; Sirdifield et al., 2009). These problems include, but are not limited to, psychotic illness (3.7%), major depression (11.4%), anxiety disorders (30%), and posttraumatic stress disorder (PTSD; 9.8%) (Bebbington et al., 2017; Favril et al., 2024). Prisoners who are held on remand have a relatively high prevalence of mental health problems. In general, mental health problems seem to peak in the initial weeks after arrival in (pre-trial) detention, gradually decline afterwards, and eventually stabilise at a persistently elevated level (Dirkzwager & Nieuwbeerta, 2018; Jones et al., 2023). Only a minority of prisoners experience complete resolution of their mental health problems (Jones et al., 2023). Mental health problems in prisoners are associated with a decreased quality of life (Skowroński & Talik, 2021; Zwemstra et al., 2009) and an increased risk of victimisation and misconduct in prison (Fazel et al., 2016). Furthermore, while the relationship between mental health and recidivism has been studied extensively in the past, the findings of these studies are mixed and not equivocal. However, more recent and more methodically robust studies seem to support that mental health problems are related to a higher risk of recidivism (Bales et al., 2017; Beaudry et al., 2021; Chang et al., 2015; Ogilvie et al., 2023; Wallace & Wang, 2020).

The prison environment is characterised by confinement and a structured environment. This presents a valuable opportunity to systematically and effectively identify and address mental health problems. However, notable challenges and institutional barriers may impede the recognition of mental health problems and prisoners' access to mental health treatment.

Firstly, the effective identification of mental health problems in prisons may be challenging. For example, in the Netherlands, psychiatric screening upon arrival in prison is not formally standardised (Bulten et al., 2009). As a consequence, the task of recognising prisoners' mental health problems and their needs often lies with prison staff who lack a background in mental health care. The staff may be able to recognise externalising mental health problems with more pronounced behavioural aspects (e.g., attention deficit hyperactivity disorder [ADHD] or psychotic symptoms) more easily than less visible internalising problems such as depression, PTSD, and anxiety. Moreover, like many other countries, Dutch prisons have been affected by executive and healthcare staff shortages. These shortages are so severe that several prison units have temporarily closed down (Dienst Justitiële Inrichtingen, 2019, 2023; Tweede Kamer der Staten-Generaal, 2023-2024). This exerts pressure on the existing staff, which may further affect their recognition of prisoners' common mental health problems.

Secondly, access to mental health treatment may be hampered by prisoners. For example, prisoners' lack of trust in the intentions of health specialists, their fear of stigmatisation due to a mental health diagnosis, and their perceived pressure to not appear vulnerable may prevent them from seeking treatment (Byrne et al., 2024; Howerton et al., 2007). Institutional barriers to receiving help may include a knowledge gap among prisoners about the prisons' available mental health services, high bureaucracy and long waiting times for the help they need (Byrne et al., 2024; Patel et al., 2018). Prisoners who face barriers seeking help are at risk of being undertreated, which could worsen their problems and could potentially increase their risk of re-offending.

One potential solution to overcoming the barriers described above is the implementation of scalable interventions that do not need professionally trained mental health workers. One such intervention is Problem Management Plus (PM +), which was developed by the World Health Organization (WHO). PM + aims to alleviate common mental health symptoms, such as anxiety and depression, by teaching participants how to manage the practical problems they face in their day-to-day lives (Dawson et al., 2015). The strategies taught in PM + are based on cognitive behavioural therapy (CBT) techniques. PM + involves five sessions delivered by trained non-specialists, who are called PM + helpers. Often PM + helpers are peer mentors: individuals who speak the same language, are from the same cultural background or have experienced similar events as the client. PM + has been proven effective in reducing psychological distress (symptoms of depression and anxiety), impaired functioning and daily problems in different vulnerable populations, for example, Syrian refugees and individuals in conflict situations (de Graaff et al., 2023; Schäfer et al., 2023). In short, PM + is brief and affordable, and its delivery does not rely on specialised prison psychologists or other prison health care providers but can be delivered by peer helpers, such as (former) prisoners.

Intervention studies with strong designs, such as RCTs, have only rarely been conducted in prisons

compared to other contexts (Tully et al., 2024). In recent years, there has been a small increase in RCTs evaluating psychological interventions in Europe (Holloway et al., 2021; Jarrett et al., 2012; Kirkpatrick et al., 2018; Kuin et al., 2020; Nathan et al., 2019). However, the feasibility of RCTs can be affected by the intricate setting of the prison itself, which poses significant challenges to conducting research (Lennox et al., 2022). Conducting a pilot RCT, instead of a full-powered RCT, could help to foresee and tackle potential problems upfront. Furthermore, a pilot RCT could mitigate the risk of squandering (public) money by applying ill-fitting protocols (Thabane et al., 2010).

To address common mental health problems and the mentioned obstacles to offering mental health care to remand prisoners, the primary aim of this study is to evaluate the feasibility and acceptability of PM + in Dutch remand prisons with a pilot RCT. The secondary aim is to examine barriers and facilitators for scaling up the adapted version of PM + in the prison setting. A process evaluation will follow after the completion of the pilot RCT.

Method

Design

The PROSPER study is a parallel-group pilot RCT with an allocation ratio of 1:1. The study consists of two arms comparing individual PM + with care-as-usual (PM +/CAU) to CAU only. A flowchart of the study design is shown in Fig. 1 (the CONSORT diagram; Schulz et al., 2010).

Participants

Eligible individuals for inclusion will be detained Dutch-speaking adults (18 years or older) who report elevated levels of psychological distress as measured by the Kessler-10 Psychological Distress Scale (K10 $\geq$16; (Kessler et al., 2002). The individuals will be recruited from remand units in two prisons in the Netherlands, one with adult males only and the other with adult females only.

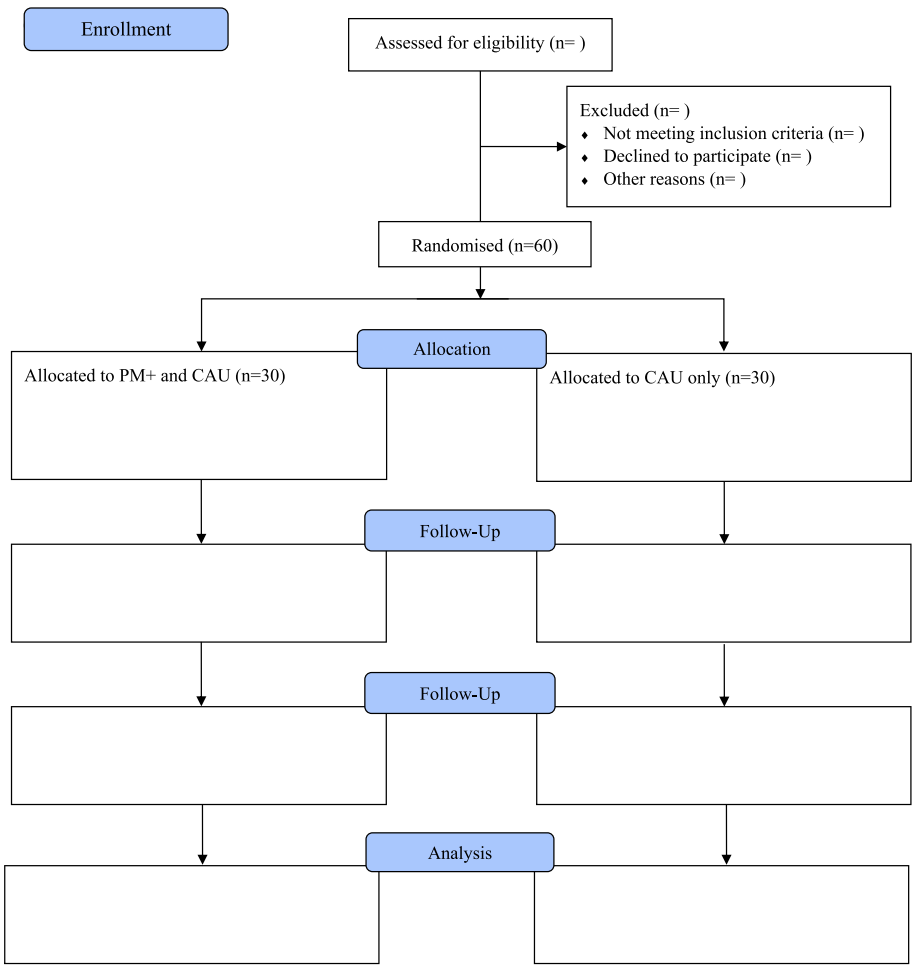

Fig. 1 CONSORT diagram of study

Individuals will be excluded if they are: 1) enclosed in a penitentiary psychiatric centre (PPC), 2) a potential security risk to the research team, 3) having an acute medical condition, imminent suicide risk or acute safety needs, 4) receiving specialised mental health care treatment, 5) severely mentally or cognitively impaired, and, if applicable, 6) not on a stable dose of psychotropic medication for the last two months.

In addition, different stakeholder groups will be invited for an individual interview for the process evaluation following the pilot RCT. The stakeholder groups are 1) participants of pilot RCT, 2) their family members or friends, 3) PM + helpers, trainers and supervisors and 4) prison staff.

Research context

Within the Dutch correctional system, there are different possibilities to receive mental health care depending on the severity of the mental health problems. In regular prison units, prison staff can refer a prisoner to a mental health professional (e.g., a psychologist), or the prisoner can request a consultation themselves. These requests will first be discussed in a psycho-medical meeting, which includes the psychologist, psychiatrist, doctor and the nurse of the institution (in Dutch: psycho-medisch overleg, PMO; Netherlands Institute for Forensic Psychiatry and Psychology, 2024). If indicated, a mental health professional will meet the individual and the care will be in line with current Dutch medical standards (Netherlands Institute for Forensic Psychiatry and Psychology, 2024). However, Dutch prisons only provide the necessary care; if (mental) health care is deemed deferrable until release it will not be provided. Furthermore, prisons in the Netherlands have a ratio of 1 (para)medical staff to 318 prisoners (Fazel et al., 2016). This is considerably higher than in countries with relatively comparable conviction and/or imprisonment rates, such as Austria (1:115), Denmark (1:149), Finland (1:185), and Germany (1:236; Fazel et al., 2016).

For those prisoners who need more structure and care than regular prison units can offer there are extra care units (ECU) within regular prisons. Persons on these units are for instance more vulnerable due to their mental health needs (e.g. autism) or their offence (e.g. sex offence). If the care provided in a regular prison is not sufficient, prisoners can be referred to one of the PPCs. These PPCs accommodate and treat prisoners with severe mental health problems (i.e. psychotic disorders or comorbid psychiatric disorders) whose mental state makes them unable to function in a regular detention regime. Prisoners in both PPCs and ECUs could either be on remand or convicted.

Procedure

Participants will be recruited from remand units within two Dutch prisons. Individuals can express their interest in participating in the study via prison staff, directly contact the researchers face-to-face or via a contact form. The research team contacts the individuals and meets them face-to-face to give them the information letter and verbal information about the study. This meeting will be held at a location where no other persons are present to preserve privacy. Afterwards, they will have seven days to consider their consent to participate in the study. From all those who choose to participate after these seven days, written informed consent will be obtained. In the consent form, participants can also indicate whether they agree to the audio recording of the PM + sessions for fidelity checks.

The participants will be assessed for their eligibility in terms of the in- and exclusion criteria (see 'Participants'). To assess the level of psychological distress, the self-report questionnaire K10 (Kessler et al., 2002) will be used (see 'Screening measures'). In addition, demographic variables such as gender and age will be collected during screening. The estimated completion time of the screening is 20 min.

If eligible, the participant will be invited for a baseline assessment. After the baseline assessment (T0), participants will be randomised into one of the two groups: PM + & CAU ($n = 30$) or CAU only ($n = 30$). Within seven days after baseline, a PM + helper will be assigned to the participant to make an appointment for the first session. Participants will be invited for two post-intervention assessments. Firstly, one week after completion of the last PM + session (T2), which is six weeks after the baseline measurement. Secondly, three months (13 weeks) after baseline measurement (T3) (i.e. 8 weeks after the last PM + session). The baseline and the two post-intervention assessments will take about 50 to 60 min to complete. A small break will be included in the assessment if indicated.

All assessments will be conducted on a tablet without an internet connection using Qualtrics with an assessor present. From the baseline assessment onwards, participants will receive an incentive of 5 euros per completed assessment while imprisoned, and 10 euros for completion of an assessment when released.

Participants who are released from prison or transferred to another facility during the study period will not be required to discontinue their participation. The contact information of all participants will be collected at baseline. For participants that are released, efforts will be made to schedule the remaining PM + sessions remotely (online) and assessments either online or face-to-face at a place of their choosing (e.g. a neutral location

or the respondent's house). In case of a prison transfer, the prison service will be contacted to inquire about the new location of the participant. For these participants, the remaining PM + sessions and/or assessments will take place within the new prison. As not all prisons have a private teleconferencing place available for prisoners, the appointments will be preferably face-to-face. If participants transfer to a higher care prison unit, it will be discussed per case with the psychologist if continuation of the PM + sessions is possible. Assessments will be continued as long as their medical condition allows it.

Assessors

Consent and screening procedures will be conducted by research assistants, who will be recruited via the Clinical/Forensic Neuropsychology master's program and must be fluent in Dutch. The first author MO will train and supervise research assistants, see for more information about the supervision 'Ethics and Trial Monitoring'.

Process evaluation

The process evaluation will follow after the completion of the pilot RCT and will include a document analysis and semi-structured interviews. Relevant documents included in the document analyses are: 1) pseudo-anonymised notes of supervision meetings, 2) a review of PM + helpers' records of PM +, and 3) a fidelity checklist made of audio recordings of PM + sessions.

Semi-structured interviews will be held with relevant stakeholder groups ($N = 25$) (see'Participants' for the stakeholder groups). An interview guide will be made for each stakeholder group separately. The interviews aim to gather information about 1) the experiences of the stakeholders with the intervention and 2) barriers and facilitators for scaling up PM + in the prison setting. The interview guides will cover the following subjects: PM + intervention (i.e., content, format, participant compliance and attendance), development of PM + helpers and participants (i.e., the applicability of PM + strategies in daily life for participants, PM + training and supervision for helpers), the research (i.e., contact with the research team, assessments), and, lastly, scaling up the PM + intervention with the prison system. The interviews will be audio recorded and verbatim transcribed.

At the last post-intervention assessment, RCT participants who gave informed consent to be approached for follow-up research will be asked if they are willing to participate in the process evaluation. PM + helpers, supervisors and trainers will be informed about the possibility of participating in an interview before the start of their participation in this study. Recruitment for this stakeholder group will start after their involvement in the trial. Professionals will be informed of the interviews by their manager. When interested, they can contact us directly or through their manager. Lastly, we will explain to the RCT participants our interest in interviewing a close relation of theirs. The RCT participant will receive a leaflet containing study information if willing. Consequently, the interested close relation can contact the research team directly. Released pilot RCT participants and their close relations will receive an incentive (20 euros). Pilot RCT participants who are still imprisoned at the time of their interview will not receive an incentive.

Sample size

As mentioned earlier, this study focuses on the acceptability and feasibility of PM + in the prison context, rather than the effectiveness of the intervention. The aim is to generate insights into the feasibility of the study procedures (e.g. recruitment and attrition rates), in preparation for a potential full-powered RCT (Moore et al., 2011). Based on recommendations by Viechtbauer et al. (2015), including 59 individuals allows a 95% probability of detecting major feasibility issues. In line with this guidance, we will enrol 60 participants in total. Because one of the study's aims is to assess actual attrition, potential dropout is not factored into the sample size calculation. No formal power analysis was conducted beforehand, in line with guidance discouraging hypothesis testing in pilot trials (Lancaster et al., 2004).

Although not the primary focus, the study may yield exploratory insights into symptom change. For instance, a pilot study of PM + with Syrian refugees in the Netherlands showed promising effects, both in the pilot and in the subsequent full-powered RCT (de Graaff et al., 2020, 2023).

Randomisation

After the baseline assessment, participants will be randomly allocated to one of the groups. The group allocation will be conveyed to the participants via a sealed envelope. In the randomisation, stratified permuted block randomisation will be used: the block numbers will randomly be generated by an electronic program. Consequently, the block numbers and the whole allocation sequence will be unknown to the involved researchers. The trial will stratify on gender to prevent an unequal gender balance between the two arms. The trial will employ a single-blind design, where assessors (research assistants) will be unaware of the arm to which each participant is allocated. However, the PM + helpers, supervisors, and principal researchers will know the participant allocations.

Study measures

In addition to the process evaluation, this study will also gather several other measures relevant to the aims of the pilot. These measures are grouped into three categories. First, screening measures will assess whether participants meet the inclusion criteria. Second, feasibility and acceptability measures will evaluate the study procedures of PM + in Dutch remand prisons. Third, exploratory symptom measures will be used to examine baseline characteristics of the sample, to test whether mental health instruments that are often used in full-powered PM + studies can be used in the prison context, and to gain an exploratory insight into potential changes in symptoms. The exploratory symptom measures will be administered at baseline and at two post-intervention assessments.

Screening measures

To screen for psychological distress over the past thirty days the K10 (Kessler et al., 2002) self-report questionnaire will be used. The K10 consists of 10 items whereby the scoring scale ranges from 1 (none of the time) to 5 (all of the time). The aggregated total score can range from 10 to 50, with a higher score indicating a higher level of psychological distress. The cut-off score of 16 or higher will be used, which represents moderate (16–21), high (22–29), and very high (30 and higher) scores. This cut-off score is in line with earlier PM + studies (Alozkan Sever et al., 2021; de Graaff et al., 2023; Roos et al., 2023). Psychometric studies of the Dutch version of the K10 shows good content validity and reliability (Cronbach's α: 0.94; Donker et al., 2011).

Possible impairment due to cognitive and severe mental disorders will be assessed with the checklist from the PM + manual. Using this observational checklist, the assessor can examine, for example, whether or not the individual seems in contact with reality during the screening.

Suicidal ideation will be assessed with both the module 'suicidality' of the Mini-International Neuropsychiatric Interview (MINI; Lecrubier et al., 1997). The MINI is a diagnostic interview and consists of 17 modules. It measures if diagnostic criteria for 17 disorders – one module for each—according to the Diagnostic Statistical Manual of Mental Disorders IV (DSM-IV) are currently present. The MINI has good psychometric properties (Lecrubier et al., 1997) and a Dutch version is available (Van Vliet & de Beurs, 2007). For this study, only the module suicidality will be used. This module distinguishes the suicide risk between 'low', 'moderate' or 'high'. Individuals who score 'high' on suicide risk on the MINI will be excluded from participating in the study.

Feasibility measures

Operationalisation of feasibility and acceptability of PM + in Dutch remand prisons will help to make decisions about a future full-powered RCT, e.g. about adjustments to the current study protocol. The following indicators are used as measures of feasibility in this study: 1) retention in intervention, 2) retention at assessments, 3) recruitment, 4) protocol adherence, 5) views of stakeholders, and 6) adverse events (see Table 1). An adverse event is defined as an event that has an undesirable medical effect, e.g. in case is it life-threatening, requires hospitalisation, or results in substantial disability or incapacity. These measures and their criteria are based on earlier prison/PM + research (Alozkan Sever et al., 2021; Beaudry et al., 2021; de Graaff et al., 2023; Kirkpatrick et al., 2018).

Symptom measures

Various measures will be administered to examine mental health symptoms and overall functioning to test their use and feasibility in the prison context (see Table 2). Information gathered includes sociodemographic

Table 1 Feasibility measures of the study

Constructs	Outcome measure	Timepoint(s) of monitoring	Criteria
Retention in the intervention	Percentage of participants completing at least four PM + sessions	Every 26 weeks and after the trial ended	≥ 80%
Retention at assessments	Percentage of participants completing post-intervention assessments	Every 26 weeks and after the trial ended	≥ 80%
Recruitment	Average number of successful included individuals within the timeframe	Every 26 weeks and after the trial ended	≥ 1 inclusion per week
Protocol adherence	Percentage of treatment fidelity to PM + elements	Every 26 weeks and after the trial ended	≥ 75%
Views of stakeholders	Acceptability of implementation and intervention	After trial ended	Prominent themes derived from qualitative data
Serious adverse events	Percentage of participants experiencing any serious adverse events (e.g. high suicide risk)	Every 26 weeks and after the trial ended	< 10%

Table 2 Schematic overview of enrolment, interventions, and assessments of the study

	STUDY PERIOD				
	Enrolment	Allocation	Post-allocation		
TIMEPOINT	**-T1**	**T0**	**T1** + 1 week – + 5 weeks	**T2** + 6 weeks	**T3** + 13 weeks
ENROLMENT:					
Eligibility screen	X				
Informed consent	X				
Baseline		X			
Allocation		X			
INTERVENTIONS:			◆——		
PM+ & CAU			X		
CAU			X		
ASSESSMENTS:					
K10	X				
PM+ manual checklist	X				
MINI - suicidality	X				
SCOPE-2	X	(X)		X	X
SCIL		X			
GAD-7		X		X	X
PHQ-9		X		X	X
PSYCHLOPS		X		X	X
CSRI		X		X	X
PCL-5		X		X	X
LEC-5		X		X	X
WHOQOL-BREF		X		X	X

characteristics (e.g. date of birth, gender, education and employment, relationship status, ethnicity), health information (e.g. utilisation, medication), and detention information (e.g. perceived burden of custody, imprisonment history).

The screener for intelligence and learning disabilities (SCIL; Screener voor Intelligentie en Licht verstandelijke beperking) assesses the potential presence of a mild or borderline intellectual disability (Kaal et al., 2015). The questionnaire consists of 14 items and scoring per item ranges from 0 to 2 (range = 0–28). A higher score indicates a higher chance of the presence of a mild or borderline intellectual disability. This Dutch questionnaire has a high predictive validity, good internal consistency, and good test–retest reliability (Nijman et al., 2018).

The Life Events Checklist for the DSM 5 (LEC-5) with criterion A will assess the lifetime occurrence of potential traumatic events (Weathers et al., 2013). In part one, 17 events are listed with a 6-point nominal scale (e.g., "have happened to them", "learned about" and "doesn't apply"). The second part consists of 8 items asking about the worst event they experienced in their lifetime. The LEC-5 has not been validated yet. However, the predecessor of the LEC-5—the LEC—did have good test–retest reliability and good convergence validity (Gray et al., 2004). The PCL-5 and LEC-5 have been translated into the Dutch language by Boeschoten et al. (2014).

The Patient Health Questionnaire – 9 items (PHQ-9) will be used to assess depression symptoms (Kroenke et al., 2001). The PHQ-9 consists of 9 items (range = 0–27), which can be scored from 0 (not at all) to 3 (nearly every day). A higher score indicates a higher severity of current depressive symptoms. The PHQ-9's validation and reliability have been evaluated both within the Netherlands and internationally (Kroenke et al., 2001; Zuithoff et al., 2010).

To assess symptoms of anxiety, the Generalized Anxiety Disorder – 7 item (GAD-7) questionnaire will be used (Spitzer et al., 2006). This questionnaire consists of 7 items (range = 0–21) which can be scored from 0 (not at all) to 3 (nearly every day). A higher score indicates a higher severity of anxiety symptoms. The Dutch version has good convergent validity and good internal consistency (Donker et al., 2011).

Posttraumatic stress symptoms will be assessed using the Posttraumatic Stress Disorder checklist for the

DSM-5 (PCL-5) (Blevins et al., 2015). The self-report questionnaire consists of 20 items and ranges from 0 (Not at all) to 4 (Extremely). The total score ranges from 0 to 80, with a higher score indicating a higher amount of trauma symptoms. A recent systematic review found that the PCL-5 has good to excellent internal consistency for the total score and good construct validity (Forkus et al., 2023).

The Suicide and Self-Harm Prison Environment—2 (SCOPE-2) assesses the vulnerability of prisoners to self-harm and suicide (Perry & Horton, 2020). It consists of 19 items, constituting two subscales 'Optimism' and 'Protective self-worth.' A higher score is related to a higher risk of suicide and non-fatal self-harm behaviour. The SCOPE-2 has a consistent differential item functioning (DIF), and good item and person fit residual. A study on the SCOPE—the predecessor of the SCOPE-2—has also shown good concurrent validity and good internal reliability (Perry & Olason, 2009). A Dutch version of the self-report questionnaire was not available. Thus, the first and second authors, MO and AB, independently translated the SCOPE-2 into Dutch.[1]

Self-identified problems will be assessed with the Psychological Outcome Profiles instrument (PSYCHLOPS) (Ashworth et al., 2004). The Dutch translation of PSYCHLOPS from (Schreuders, 2007) was slightly adapted, to match the PM + PSYCHLOPS adaptions (World Health Organization, 2016) and some grammatical adaptions. The pre-intervention PSYCHLOPS and post-intervention PSYCHLOPS consist of 4 and 6 items, respectively. PSYCHLOPS showed good psychometric properties (Sales et al., 2023).

To measure the experienced quality of life, the World Health Organization Quality of Life Brief (WHOQOL-BREF) questionnaire will be used (The WHOQOL Group, 1998). This self-report questionnaire consists of 4 domains: physical health (7 items), psychological health (6 items), social relations (3 items), and environment (8 items). The items are answered on a 5-point Likert scale. A higher score indicates a higher experienced quality of life in a specific domain. The content validity of the Dutch WHOQOL-BREF is good (Trompenaars et al., 2005). The internal consistency from the Dutch WHOQOL-BREF ranges from questionable (social relations, $\alpha = 0.66$), acceptable (environment, $\alpha = 0.73$ & psychological health, $\alpha = 0.74$) to good (physical health, $\alpha = 0.80$) (Trompenaars et al., 2005).

To measure healthcare utilisation after allocation an adapted version of the Client Service Receipt Inventory (CSRI) will be used (Knapp et al., 1992). The questionnaire was adapted to fit the Dutch prison context. The CSRI asks about medication use, contact with health care facilities, and training that was followed. Follow-up questions are given if someone indicates the usage of one of the services, for example, about the frequency and dosage.

Intervention

Problem Management Plus

PM + can be delivered in an individual or a group format and consists originally of five 90-min sessions once a week. The core of the PM + intervention is based on CBT techniques, including a) stress management, b) problem-solving, c) behavioural activation, and d) strengthening social support (Dawson et al., 2015). Prior to the pilot RCT, PM + was adapted to better suit the specific prison context. Based on this contextual adaption, changes were made in the case examples in the PM + protocol, and in the length and frequency of the PM + sessions. Within this study, participants will receive individual PM + with two 60-min sessions a week. Details of the contextual adaption of PM + to the prison context will be published elsewhere.

Care-as-usual

All participants can receive CAU within the residing prison. Participants' access to prison-provided care will not be withheld or altered during the study, including visits to the psychologist. In the Netherlands, remand prisoners are entitled to 42,5 h of activities per week (Penitentiaire maatregel, 2022). These activities entail, for example, labour, sports, library visits, yard time, spiritual care and re-integration training programs. The availability of re-integration training programs for individuals on remand is limited and differs per prison (Doekhie et al., 2024). Remand prisoners do not have an evening programme and must remain in their cells when there are no programme activities (Dienst Justitiële Inrichtingen, 2020).

PM + helpers

Within this study, the PM + sessions will be given by third-year bachelor's or master's students in psychology or criminology. PM + helpers will receive a 5-day training. As the PM + helpers have, due to their educational background, a higher knowledge of mental health problems the PM + training was shortened from 8 to 5 days. The Training of Helpers will focus on basic helping skills,

[1] After translating, the two authors, MO and AW, discussed the two versions of the translations. If they could not reach consensus on the translation of a word or phrase, it was discussed with all authors. After reaching consensus, that version was subsequently back-translated by two individuals, one of whom is a native English speaker. Adjustments to the Dutch version were then made accordingly to create a final Dutch translation. The translated SCOPE-2 will be made available upon request.

PM + strategies, the behaviour of individuals with a criminal justice background, and how to interact with them (Rahman et al., 2016). Throughout the trial, they will have weekly group supervision from PM + supervisors (for more detailed information about the supervision, see 'Ethics and Trial Monitoring'). PM + supervisors and PM + trainers will be (forensic) mental health professionals who completed a PM + Training of Trainers. The Training of Trainers will include information about the PM + strategies and supervision skills.

Fidelity check

Adherence to the PM + protocol (treatment fidelity) will be measured in two ways. Firstly, PM + helpers will complete a questionnaire after each session. This questionnaire assesses the completion of specific components within each PM + session. Secondly, if participants provide consent, PM + sessions will be audio-recorded. Research assistants will then use a fidelity checklist to check randomly selected sample recordings, stratified by PM + helper. This checklist mirrors the self-report questionnaires used by PM + helpers. These recordings will undergo continuous review throughout the trial. Feedback derived from these assessments will be conveyed in supervision meetings to enhance the quality of the intervention provided during the trial.

Data analysis plan

A mixed-methods approach will be used to assess the feasibility and acceptability of PM + for remand prisoners. The analysis of the feasibility measures, self-report questionnaires of pilot RCT participants and PM + helpers and the qualitative analysis of the documentation and interviews with stakeholders will be combined. The interviews with stakeholders will also be analysed to address our secondary aim, that is to examine the barriers and facilitators of scaling up PM + in the prison population.

Reflexive thematic analysis will be employed as the methodological approach for analysing interviews and documentation. Documents such as PM + helpers' and supervision records are included in these analyses. The analysis will be conducted via ATLAS.ti (ATLAS.ti Scientific Software Development GmbH, 2024) using the method of Braun and Clarke (2021).

The focus for the analysis of the quantitative data will primarily be on descriptive analyses, albeit with confidence interval assessments, as the study is designed as a pilot and is therefore underpowered to determine reliable treatment effects of PM + (Arnold et al., 2009; Lancaster et al., 2004; Moore et al., 2011). Consequently, the quantitative analyses should be interpreted with caution.

Intention-to-treat (ITT) will be employed as a statistical strategy within the analyses. Indication of changes will be assessed by comparing the two groups on PHQ-9, GAD-7, PSYCHLOPS, PCL-5, and SCOPE-2. The two groups will also be compared in terms of lifetime life events and indications for intellectual disability. For normally distributed data, the demographic characteristics of the two groups will be compared using either an independent T-test for continuous data or a chi-square test for categorical data. In the case of continuous non-normally distributed data, the Mann–Whitney U test will be conducted. Analyses will be conducted with SPSS Statistics (IBM Corp, 2024) and/or Jamovi (The Jamovi project, 2024). A significance level of 0.05 will be used. The feasibility measures will only be analysed descriptively.

Ethics and trial monitoring

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2013. The study was approved by the Medical Ethical Committee of Amsterdam UMC (reference number: 2023.0446). Involved researchers (including research assistants) and PM + helpers will convey a certificate of good conduct before offering PM + to participants or completing research tasks.

For adverse events, e.g. any undesirable experience occurring to a study participant while the study is ongoing, protocols were made in collaboration with the prisons. Prison psychologists will receive information about who participates in the trial. This information will only tell them which persons participate in the trial. Information about the assigned condition and information shared during sessions will not be conveyed to the prison psychologists. Only in the case of a serious safety risk—for the participants themselves or others—more detailed information will be shared with prison psychologists. This is communicated to participants upfront in the information letter and informed consent form.

If a participant expresses suicidal ideations towards a PM + helper or an assessor, they will administer the MINI 'suicidality' and take appropriate actions based on the assessment. All (serious) adverse events will be followed up by the research team. Furthermore, all serious adverse events will be recorded and reported to the Medical Ethical Committee of Amsterdam UMC.

To ensure the safety of both the involved PM + helpers and the research team (including the research assistants), they are trained in how to interact with individuals who have a criminal justice background upfront. Furthermore, they will be instructed to always sit closest to the exit and to regularly make a self-assessment of their perceived safety during an appointment. Additionally, to enhance

the feeling of safety, PM + helpers can also provide the PM + sessions with another PM + helper present.

Furthermore, PM + helpers and research assistants will receive regular supervision. For PM + helpers, supervision will be given by a psychologist MO and a clinical psychologist with forensic experience. The supervision will focus on two main subjects. Firstly, on matters concerning providing the PM + intervention to participants in order to enhance the quality of the given intervention during the trial. Helpers can introduce a topic for supervision themselves. Based on the needs of the helpers, helpers will exchange tips or a role-play will be conducted, with a specific case or PM + strategy. Secondly, the supervision will focus on interactions with individuals who have a criminal justice background and the effect it may have on PM + helpers' mental well-being. If needed, notes with tips suggested by PM + supervisors or other PM + helpers will be compiled and shared after supervision with the helpers.

The research assistants will receive supervision by the first author MO if needed after a visit to the prison. These meetings provide an opportunity to reflect on experiences with participants, receive feedback, and discuss any questions. If deemed necessary, additional training or practice will be provided. A security protocol will be followed if a research assistant meets a released participant, for example for an assessment or interview. This protocol stipulates that two assessors must always be present at an appointment. Furthermore, a third person is informed beforehand of the appointment specifics. This person will receive a message from the assessors before and after they enter and leave the appointment's location. In case of no contact, the third person is required to contact the authorities.

Discussion

Worldwide, individuals with mental health problems are overrepresented in prisons, showing an excess of mental health problems behind bars (Favril et al., 2024; Sirdifield et al., 2009). The PROSPER study addresses this important issue and focuses on the potential of the brief and scalable PM + psychological intervention for individuals held in remand prisons in the Netherlands. More specifically, the study aims to improve current knowledge about the feasibility and acceptability of the intervention. Its secondary aim is to examine barriers and facilitators for scaling up the adapted version of PM + in the prison setting. Accordingly, the findings may inform the design and procedures of a potential future full-powered RCT examining the effectiveness and cost-effectiveness of PM + among remand prisoners. Furthermore, insights from this study could inform other researchers in preparing for an RCT within the (Dutch) correctional setting, a context in which rigorous research designs are notably scarce.

The PM + intervention has certain interesting characteristics that could add value to the prison context. PM + is an evidence-based intervention developed by the WHO (Dawson et al., 2015). The intervention is scalable, brief, and there is evidence supporting its transdiagnostic approach and effects in other vulnerable populations (Schäfer et al., 2023). Importantly, PM + may bypass existing staff shortages since it is provided not by professional healthcare providers like psychologists but by non-specialists. As such, the prison environment may offer several possibilities for the delivery of PM +; not only by university students, as in this study, but potentially also by prisoners serving as peer PM + helpers. This could not only prevent further strain on prison staff but may also have a positive impact on the peer PM + helper (Perry et al., 2021). For example, peer mentors in a peer-led mentor scheme in a prison in England experienced improvements in personal and work skills – such as increased self-confidence, a heightened sense of purpose and better communication abilities (Perry et al., 2021).

The high prevalence of mental health problems among prisoners is well known in academia, mental health care and prisons. Reducing mental health problems among prisoners is important, not only because it improves their wellbeing but also because of the potential relationship between mental health and re-offending (Bales et al., 2017; Beaudry et al., 2021; Chang et al., 2015; Ogilvie et al., 2023; Wallace & Wang, 2020). In addition, PM + seems to counter certain challenges that individuals may face when in need of care in prison. Specifically, PM + may hold promise as an accessible intervention for prisoners who struggle with common mental health problems, yet who are reluctant to seek or cannot receive help from a psychologist. PM + could thus serve as an intermediary between receiving no treatment and psychologist-delivered mental health treatment in prison, provided that PM + proves feasible and acceptable, and effective in future full-powered RCTs. The current study is an important step towards more knowledge of the potential value of PM + in the correctional setting.

Authors' contributions
MO drafted the main manuscript text. AW, AD, and MS critically reviewed the manuscript and provided detailed feedback. All authors have approved the manuscript.

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Data availability
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

The study will be conducted in accordance with the ethical standards set forth in the Declaration of Helsinki. The Medical Ethical Review Committee of Amsterdam UMC approved the protocol of this study. Consent will be obtained from all participants.

Competing interests

The authors declare no competing interests.

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