

Prevention of suicide behaviour in prison (work packages 3 and 4)

Submission date 23/09/2021	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 24/09/2021	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/12/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The rate of suicide in prisons in the UK has doubled in the last ten years and represents a significant problem. Cognitive Behavioural Suicide Prevention (CBSP) is a psychological intervention that aims to address suicidal behaviour. In a small trial of CBSP, the therapy group was found to have engaged in fewer suicidal behaviours compared to controls. However, the study could not provide any definitive comment on efficacy. The pilot trial found that many participants in the treatment arm required substantial 'pre-intervention support' in order for the necessary open, warm therapeutic relationship to develop. The need for further modification to the standard delivery of CBSP therapy was identified. These modifications, including 'pre-intervention support' were addressed in the first two work packages of the research programme (submitted under IRAS ID: 266858) to produce the Prospect Programme.

This application represents the next phase of the research programme and involves assessing the clinical and cost-effectiveness of the new PROSPECT programme in a Randomised Controlled Trial (RCT). This application covers work packages 3 and 4.

Who can participate?

Male adults (aged over 18 years) who are currently detained in prison and are feeling suicidal

What does the study involve?

Work package 3:

We will conduct an RCT in four UK prisons, recruiting 360 participants who are currently detained in prison and are feeling suicidal. We will assess participants at baseline and then again six months later. After baseline assessments, half will be randomised to receive the PROSPECT programme plus treatment as usual and the other half will receive treatment as usual. We will then compare the two groups to determine whether the intervention was clinically and cost-effective. The study will take 27 months to complete.

Work package 4:

Alongside the RCT, we will conduct a process evaluation to assess the extent to which the intervention was delivered to participants in the PROSPECT programme group and to enhance our understanding of how the intervention worked.

What are the possible benefits and risks of participating?

There is no direct benefit for people in prison and staff participants who take part in the study. However, some participants may find it helpful to talk about their experiences and may be satisfied that they are contributing to an important area that aims to improve suicide prevention in prison. There is a risk that some people may find it distressing when answering questions about suicide, but previous studies have found that individuals are more likely to derive benefit from discussing suicide than experience harm.

Where is the study run from?

University of Manchester (UK)

When is the study starting and how long is it expected to run for?

October 2019 to March 2027

Who is funding the study?

National Institute for Health Research (NIHR) (UK).

Who is the main contact?

Dr Daniel Pratt, Daniel.pratt@manchester.ac.uk

Dr Caroline Hendricks, caroline.stevenson@manchester.ac.uk

Study website

<https://sites.manchester.ac.uk/prospect/>

Contact information

Type(s)

Scientific

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Additional identifiers**EudraCT/CTIS number**

Nil known

IRAS number

274976

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 50267, Grant Codes: RP-PG-0218-20006, IRAS 274976

Study information**Scientific Title**

The prevention of suicide behaviour in prison: enhancing access to therapy (PROSPECT) programme (work packages 3 and 4)

Acronym

PROSPECT

Study objectives

The rate of suicide in prisons in the UK has doubled in the last ten years and represents a significant problem. Cognitive Behavioural Suicide Prevention (CBSP) is a psychological intervention that aims to address suicidal behaviour. In a small trial of CBSP, the therapy group was found to have engaged in fewer suicidal behaviours compared to controls. However, the study could not provide any definitive comment on efficacy. The pilot trial found that many participants in the treatment arm required substantial 'pre-intervention support' in order for the necessary open, warm therapeutic relationship to develop. The need for further modification to the standard delivery of CBSP therapy was identified. These modifications, including 'pre-intervention support' were addressed in the first two work packages of the research programme (submitted under IRAS ID: 266858) to produce the Prospect Programme.

This application represents the next phase of the research programme and involves assessing the clinical and cost effectiveness of the new PROSPECT programme in a Randomised Controlled Trial (RCT). This application covers work packages 3 and 4.

Work package 3:

We will conduct an RCT in four UK prisons, recruiting 360 participants who are currently detained in prison and are feeling suicidal. We will assess participants at baseline and then again six months later. After baseline assessments, half will be randomised to receive the PROSPECT programme plus treatment as usual and the other half will receive treatment as usual. We will then compare the two groups to determine whether the intervention was clinically and cost effective. The study will take 27 months to complete.

Work package 4:

Alongside the RCT, we will conduct a process evaluation to assess the extent to which the intervention was delivered to participants in the PROSPECT programme group and to enhance our understanding of how the intervention worked.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 28/10/2021, Wales REC 3 (Health and Care Research Wales Support and Delivery Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0)2920 230457; WALES.REC3@wales.nhs.uk), ref: 21/WA/0273

Study design

Interventional randomized controlled trial with quantitative follow up and parallel process evaluation

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Prison/detention

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Suicidal behaviour

Interventions

WP3:

Intervention Arm [PROSPECT programme plus TAU]: In addition to Treatment As Usual the intervention arm will receive targeted psychological therapy comprising of a preparatory phase which aims to develop the therapeutic relationship between therapist and participant followed by a delivered Cognitive Behavioural Suicide Prevention (CBSP) programme

Control Arm [TAU only]: Treatment As Usual group will receive standard care in accordance with national and local service protocols.

All outcome measures will be collected at baseline and 6 months (+ 3 months) follow-up.

Process Evaluation (WP4):

Process Evaluation interviews: Semi-structured interviews will focus on understanding the mechanisms of action, how the prison context and culture affect implementation, and why those receiving the PROSPECT programme did or did not engage in subsequent suicide behaviours.

Observation study: As with the semi-structured interviews, observations will focus on understanding the mechanisms of action and how the prison context can affect the implementation of the intervention.

Intervention Type

Behavioural

Primary outcome measure

1. Suicidal ideation as measured by the Beck Scale for Suicide Ideation at 6 months post randomisation
2. Number of occurrences of suicidal behaviour during the last 6 months collected via self-report from participants with researchers using an adapted version of the Suicide Attempt – Self-Injury Interview to improve recall and reporting of suicide behaviour

Secondary outcome measures

Current secondary outcome measures as of 07/03/2022:

WP3:

1. Number of days from randomisation to first suicidal behaviour as measured participant self-report at 6 months post randomisation
2. Future suicide potential as measured by the Suicide Probability Scale at 6 months post randomisation
3. Suicide schema as measured by the Brief Suicide Cognitions Scale at 6 months post randomisation
4. Depression as measured by the Beck Depression Inventory II at 6 months post randomisation
5. General psychopathology as measured by the Brief Symptom Inventory at 6 months post randomisation
6. Personality dysfunction as measured by the Standardised Assessment of Personality – Abbreviated Scale at 6 months post randomisation
7. Hopelessness as measured by the Beck Hopelessness Scale at 6 months post randomisation
8. Defeat as measured by the Defeat Scale at 6 months post randomisation
9. Entrapment as measured by the Entrapment Scale at 6 months post randomisation
10. Self-esteem as measured by the Robson Self Concept Questionnaire at 6 months post randomisation
11. Coping as measured by the Coping Inventory for Stressful Situations at 6 months post randomisation
12. Wellbeing as measured by the ICEpop CAPability measure for adults at 6 months post randomisation
13. Therapeutic alliance as measured by the Working Alliance Inventory at regular intervals during the 6 months of intervention delivery

NB: The 6-month follow-up will take place between 6-9 months post randomisation

WP4:

14. Prisoner and staff experiences of receiving the Prospect programme (for prisoner participants), or their experience of managing suicide behaviour in prison (for staff participants) measured using interviews during the trial and after 6 month follow up

Previous secondary outcome measures:

WP3:

1. Future suicide potential as measured by the Suicide Probability Scale at 6 months post randomisation
 2. Depression as measured by the Beck Depression Inventory II at 6 months post randomisation
 3. General psychopathology as measured by the Brief Symptom Inventory at 6 months post randomisation
 4. Personality dysfunction as measured by the Standardised Assessment of Personality – Abbreviated Scale at 6 months post randomisation
 5. Hopelessness as measured by the Beck Hopelessness Scale at 6 months post randomisation
 6. Defeat as measured by the Defeat Scale at 6 months post randomisation
 7. Entrapment as measured by the Entrapment Scale at 6 months post randomisation
 8. Suicide schema as measured by the Suicide Cognitions Scale at 6 months post randomisation
 9. Self-esteem as measured by the Robson Self Concept Questionnaire at 6 months post randomisation
 10. Coping as measured by the Coping Inventory for Stressful Situations at 6 months post randomisation
 11. Wellbeing as measured by the ICEpop CAPability measure for adults at 6 months post randomisation
 12. Therapeutic alliance as measured by the Working Alliance Inventory at regular intervals during the 6 months of intervention delivery
- NB: The 6 month follow-up will take place between 6-9 months post randomisation

WP4:

13. Prisoner and staff experiences of receiving the Prospect programme (for prisoner participants), or their experience of managing suicide behaviour in prison (for staff participants) measured using interviews during the trial and after 6 month follow up.

Overall study start date

01/10/2019

Completion date

31/03/2027

Eligibility

Key inclusion criteria

Current inclusion criteria as of 14/03/2022:

For the RCT (WP3):

1. Male Prisoner (defined as a person sentenced to imprisonment in a male prison)
2. Aged over 18 years - updated 07/03/2022: aged 18 years or over
3. At current risk of suicide behaviour as indicated by currently being on the host prison's ACCT system, or on the ACCT system within the four weeks prior to consent.

4. Able to complete a battery of self-report measures with breaks if needed
5. Willing to consent to being subject to a 'holding order' to require them to remain within the host prison for the duration of their participation in the trial.

For the Process Evaluation Interviews (WP4)

Prison participants:

1. Is a participant on the Prospect RCT randomised to receive the Prospect programme.

Staff participants:

2. Is a member of staff currently working in the prison in a role that involves the care and/or management of prisoners who engage in suicide behaviour.

OR

3. Is a member of staff directly involved in delivering the Prospect programme.

Observation study:

Shadowing of prisoner participants:

1. Is a participant on the Prospect RCT randomised to receive the Prospect programme.

Staff participants:

2. Is a member of staff currently working in the prison in a role that involve the care and/or management of prisoners who engage in suicide behaviour.

3. Has taken part in the process evaluation interviews

But observation could also include:

Any prisoner or member of staff present during an observation session and not having asked to be excluded.

Previous inclusion criteria:

For the RCT (WP3):

1. Male Prisoner (defined as a person sentenced to imprisonment in a male prison)
2. Aged over 18 years - updated 07/03/2022: aged 18 years or over
3. At current risk of suicide behaviour according to the host prison's ACCT system
4. Able to complete a battery of self-report measures with breaks if needed
5. Willing to be placed on a holding order to remain in the host prison for the duration of their participation.

For the Process Evaluation Interviews (WP4)

Prison participants:

1. Is a participant on the Prospect RCT randomised to receive the Prospect programme.

Staff participants:

2. Is a member of staff currently working in the prison in a role that involves the care and/or management of prisoners who engage in suicide behaviour.

OR

3. Is a member of staff directly involved in delivering the Prospect programme.

Observation study:

Shadowing of prisoner participants:

1. Is a participant on the Prospect RCT randomised to receive the Prospect programme.

Staff participants:

2. Is a member of staff currently working in the prison in a role that involve the care and/or management of prisoners who engage in suicide behaviour.

3. Has taken part in the process evaluation interviews

But observation could also include:

Any prisoner or member of staff present during an observation session and not having asked to be excluded.

Participant type(s)

Mixed

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Target number of participants for the RCT is 360. The minimum target sample size for the process evaluation is 36. For the process evaluation we aim to interview between 12-48 prisoner participants who are involved in the RCT and receiving the PROSPPECT intervention, between 8-16 members of staff and the 4 therapists delivering the PROSPECT intervention. For the observation study, we aim to observe between 8-16 members of staff and 4-8 prisoners who are receiving the PROSPECT intervention.

Key exclusion criteria

For the RCT (WP3):

1. Planned release within next 9 months
2. Insufficient knowledge of English to enable adequate participation in the assessment process
3. Deemed by prison staff to be too dangerous/elevated risk of harm to the researcher
4. Lacking capacity to provide informed consent

For the process evaluation (WP4):

Prison participants:

1. Deemed by prison staff to be too dangerous/elevated risk of harm to the researcher

Staff participants:

There are no exclusion criteria for staff participants

Observation study:

1. Any member of staff or prisoner who informs the researcher that they do not wish to be included in the observation study.

Date of first enrolment

17/03/2022

Date of final enrolment

31/12/2025

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre
4 prisons in the North of England
United Kingdom
M13 9PL

Sponsor information

Organisation
University of Manchester

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Sponsor type
University/education

Website
<http://www.manchester.ac.uk/>

ROR
<https://ror.org/027m9bs27>

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Funder Name

National Institute for Health Research (NIHR) (UK)

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

30/09/2027

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author Dr Kerry Gutridge (kerry.gutridge@manchester.ac.uk) on reasonable request

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol article		18/12/2024	19/12/2024	Yes	No