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

Submission date
23/09/2021

Recruitment status
No longer recruiting

Registration date
24/09/2021

Overall study status
Ongoing

Last Edited
09/12/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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 April 2027

Who is funding the study?
National Institute for Health Research (NIHR) (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
274976

ClinicalTrials.gov (NCT)
Nil known

Grant Code
RP-PG-0218-20006

Central Portfolio Management System (CPMS)
50267

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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
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 as 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
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10. Coping as measured by the Coping Inventory for Stressful Situations at 6 months post randomisation
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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.

Completion date
01/04/2027

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.

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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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

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
United Kingdom

England

Study participating centre
Four prisons in the North of England
-
-
England
-

Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

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

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

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?
Protocol article		18/12/2024	19/12/2024	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes