# Assessing the impact of using problem-solving skills with people in custody in Poland

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
18/05/2021		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
25/05/2021	Completed	☐ Results		
Last Edited	Condition category	Individual participant data		
01/06/2021	Mental and Behavioural Disorders	<ul><li>Record updated in last year</li></ul>		

#### Plain English summary of protocol

Background and study aims

Problem-solving skills are important in helping people work out what to do when faced with a problem. A problem might be anything that is on your mind a lot, or something that you worry about. Lots of people have problems in life and sometimes these are made more difficult to address when in prison. We know that ignoring problems can have an impact on how people feel and behave and if left, you may find that they affect your physical and mental health. The aim of our study is to find out whether a brief workshop on the use of problem solving skills can help to support people to feel better, act differently and take an active part in addressing problems you might experience when in prison.

#### Who can participate?

You will be an adult male prisoner with more than three months left to serve in one of two prisons in Poland: zk Plock or Kłodzko.

#### What does the study involve?

Everyone who agrees to take part in the study will be entered into a random draw using a unique study number that is unique to you. Half of those people taking part will be randomly picked to participate in a workshop on problem solving skills and complete some questionnaires. The other half will be asked to complete some questionnaires only.

Everyone will complete some questionnaires before the study starts and again at the end of the project. On each occasion it is likely that these questionnaires will take about 30 minutes to complete. The questionnaires will be used to collect some of your background information, your general health and your mental health and will ask you about how you cope with problems in custody.

The group workshop this will last for up to one and a half hours and will include up to five prisoners. The workshop will be held on the wing and delivered by members of the research team. The workshop will include watching a video clip showing someone in custody describing a problem and using the problem-solving steps. You will also use some workbooks that will show how the skills work. This will help you to learn about how you deal with your own problems now and in the future.

What are the possible benefits and risks of participating?

Everyone taking part in the project will receive a notebook and a calendar as a small token of our appreciation. Participants will be given the opportunity to learn some new problem-solving skills which may help you cope better when faced with problems in custody. It is unlikely that you might feel upset or anxious during the research study, but if you do feel upset you can talk to a member of prison staff or the research team who will support you. Staff members can refer you to the appropriate professional (e.g., psychiatrist, psychologist, wing officer) in accordance with the standard prison procedure.

#### Where is the study run from?

The research project is conducted by the Academy of Justice in Warsaw, Poland. The project is coordinated by the Health Sciences Department and York Trials Unit at University of York in the UK.

When is the study starting and how long is it expected to run for? October 2020 to October 2021

Who is funding the study?

The study is funded by the Centre for Future Health at the University of York in the UK.

Who is the main contact?

Dr Amanda E. Perry, amanda.perry@york.ac.uk

#### Study website

https://www.york.ac.uk/healthsciences/research/mental-health/projects/international-adaptation-poland/

## Contact information

## Type(s)

Scientific

#### Contact name

Dr Amanda Perry

#### **ORCID ID**

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#### Contact details

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## Additional identifiers

#### **EudraCT/CTIS** number

Nil known

#### **IRAS** number

#### ClinicalTrials.gov number

Nil known

#### Secondary identifying numbers

Nil known

# Study information

#### Scientific Title

International Adaptation of Problem-Solving Skills in Poland (IAPPS): A feasibility randomized controlled trial for offenders in custody to improve symptoms of depression, general well-being and coping strategies

#### Acronym

**IAPPS** 

#### **Study objectives**

Problem solving skills reduces symptoms of depression more than usual care

#### Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 13/05/2021, Health Sciences Research Governance Committee (Health Sciences Department, University of York, YO10 5DD, UK; +44 (0)1904 323253; stephen.holland@york.ac. uk), ref: none

## Study design

Multicentred interventional pragmatic feasibility randomized controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

#### Study setting(s)

Other

#### Study type(s)

Prevention

## Participant information sheet

See additional file ISRCTN70138247\_PIS\_v5\_18May2021 (added 01/06/2021) and https://www.york.ac.uk/healthsciences/research/mental-health/projects/international-adaptation-poland/

#### Health condition(s) or problem(s) studied

Prevention of mental health and well-being in offenders in custody with mental health problems

#### **Interventions**

Up to 50 participants will be randomized to receive either a brief problem-solving skills intervention plus usual care versus 50 randomized participants to receive usual care only.

The intervention will be delivered in a group comprising of up to five participants. The intervention will be delivered by a trained psychotherapist. The intervention training will last up to 1.5 hours in length and include digital and paper-based activities.

Participants will be randomized by the York Trials Unit Randomization Service at the University of York. This web-based randomization process will randomize patients to one of the two arms of the trial based on a computer-generated code. The information will be stored on a secure server and access to the sequence will be confined to the Trial Manager. Allocation to the trial arms will be in the ratio of 1:1. The Trial Manager will access the treatment allocation for each patient by remote internet-based randomization. The group allocation will be disclosed to the Trial Manager after baseline data has been collected for each participant. The allocation outcome will be entered into the secure shared database so that all members of the research team can view the allocation.

#### Intervention Type

Behavioural

#### Primary outcome measure

1. Depression measured using the PHQ-9 validated questionnaire at baseline and six weeks post-randomization

#### Secondary outcome measures

- 1. General well-being is measured using the GHQ-28 questionnaire at baseline and six weeks post-randomization
- 2. Coping strategies are measured using the COPE questionnaire at baseline and six weeks post-randomization

#### Overall study start date

15/10/2020

#### Completion date

15/10/2021

## Eligibility

#### Key inclusion criteria

- 1. Male prisoners
- 2. >18 years of age
- 3. Mental health diagnosis and housed on the therapeutic unit

#### Participant type(s)

Other

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Male

#### Target number of participants

100

#### Key exclusion criteria

- 1. Length of sentence or planned duration is less than three months
- 2. Unable to provided informed consent and/or
- 3. Pose a risk to the researchers.

#### Date of first enrolment

01/06/2021

#### Date of final enrolment

28/09/2021

## Locations

#### Countries of recruitment

England

Poland

United Kingdom

## Study participating centre

#### York Trials Unit

Health Sciences Department University of York York United Kingdom YO10 5DD

# Study participating centre

#### The Academy of Justice

Wyższa Szkoła Kryminologii i Penitencjarystyki w Warszawie Ul. Wiśniowa 50 Warsaw Poland 02-520 Warszawa

# Sponsor information

#### Organisation

University of York

#### Sponsor details

ARRC Buildings
Heslington
York
England
United Kingdom
YO10 5DD
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kerry.cipriano@york.ac.uk

#### Sponsor type

University/education

#### Website

https://www.york.ac.uk/future-health/funding/

#### **ROR**

https://ror.org/04m01e293

# Funder(s)

#### Funder type

University/education

#### **Funder Name**

Centre for Future Health (University of York/Wellcome Trust)

## **Results and Publications**

#### Publication and dissemination plan

Planned publication in a high impact peer reviewed journal. Participants will get feedback on the prison wing through a poster that will explain the results in lay person terms.

#### Intention to publish date

01/06/2022

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available as consent has not been obtained to share the data.

## IPD sharing plan summary

Not expected to be made available

## **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v5	18/05/2021	01/06/2021	No	Yes
Protocol file	version V2	18/05/2021	01/06/2021	No	No