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The feasibility of a prisoner-led intervention to reduce smoking and improve diet and physical activity amongst prisoners

Submission date
09/03/2017

Recruitment status
No longer recruiting

Registration date
03/04/2017

Overall study status
Completed

Last Edited
24/01/2023

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Diseases such as cancers, cardiovascular (heart) disease and diabetes are known as 'non-communicable diseases' (NCDs). Cigarette smoking, unhealthy diets and lack of physical activity contribute to these conditions. NCDs are a health issue for many prisoners. There is increasing evidence that peer-based approaches in prisons can be effective in supporting healthcare delivery and health improvement amongst prisoners, many of whom struggle to trust or engage with mainstream services. The aim of this study is to investigate how a peer-led intervention might help prisoners to lead healthier lifestyles and make them less likely to suffer from NCDs.

Who can participate?
Men aged 21 and over who are in prison

What does the study involve?
The study is made up of two phases. In the first phase, the research team undertook focus groups with prisoners and interviews with staff to develop an appropriate peer-led intervention. The second phase involves delivering the peer-led intervention to test the feasibility and also whether or not the intervention leads to behaviour change (namely reductions in smoking and improvements in diet and physical activity amongst prisoners). Participants are randomly allocated to either the intervention or the control group. The peer-intervention is delivered to intervention group participants over a 6-week period and involves these participants attending weekly group sessions run by trained prisoner facilitators. Control group participants receive standard care. Smoking, diet and physical activity levels and well-being are measured using questionnaires in both groups at the start of the study, immediately after the intervention, and at 1, 3 and 6 months after the intervention. Smoking is also tested with a breath test and body mass index (BMI) is measured for each participant.

What are the possible benefits and risks of participating?
Prisoners may benefit from healthier lifestyles, and ultimately a reduction in NCDs. The research could also lead to improvements in prisoners' general health (e.g. improved emotional well-being). The peer-deliverers may also benefit from the research through gaining knowledge on

health-related issues, increased employment prospects on release due to experience of working in a peer role, and the peer role may also link in with sentence planning goals. In the design of the study, every attempt has been made to minimise the intrusive nature so that it does not impose too much burden upon the participant. However, there may be a time inconvenience that inevitably accompanies participation. Inconvenience is minimised by discussing all information face-to-face so providing ample opportunity for participants to seek clarification through questioning the researcher. The study may encourage participants to undertake more physical activity as increased levels of activity is one of the aims of the intervention. Any exercise comes with risk of injury to participants. However, current health advice is that the benefits of exercise far outweigh the risks. Where appropriate, those who are particularly at risk from exercise are identified and the trialists seek review from a clinician before starting exercise. This is standard practice in research involving exercise.

Where is the study run from?
1. HMP Leeds (UK)
2. HMP Wealstun (UK)

When is the study starting and how long is it expected to run for?
March 2016 to July 2017

Who is funding the study?
Spectrum CIC (UK)

Who is the main contact?
Miss Philippa Hearty

Contact information

Type(s)
Scientific

Contact name
Miss Philippa Hearty

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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
3

Study information

Scientific Title
The feasibility of a prison-based peer-led intervention to reduce non-communicable disease risk-factors amongst prisoners

Study objectives
No hypothesis - a feasibility study exploring the potential of peer-interventions in prisons to reduce non-communicable disease risk factors amongst prisoners

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - South East Research Ethics Committee, 01/07/2016, ref: 16/LO/0815

Study design
Multicentre feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Prison/detention

Study type(s)
Prevention

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
Non-communicable disease risk-factors

Interventions
Using a randomised controlled design participants will be allocated 1:1 to intervention versus control arms.
The peer-intervention will be delivered to intervention arm participants over a 6-week period and will involve these participants attending weekly group sessions run by trained prisoner facilitators. Control participants will receive standard care.

The primary and secondary outcomes will be measured at baseline, immediately post-intervention, 1, 3 and 6 months post-intervention. The outcomes will be measured through self-report via a questionnaire. Self-reported smoking will be validated against participants' objective carbon monoxide readings. BMI will also be measured for each participant.

Intervention Type
Behavioural

Primary outcome measure
Smoking, diet and physical activity levels, measured through self-report via a questionnaire at baseline, immediately post-intervention, 1, 3 and 6 months post-intervention

Secondary outcome measures
Well-being, measured through self-report via a questionnaire at baseline, immediately post-intervention, 1, 3 and 6 months post-intervention

Overall study start date
01/03/2016

Completion date
01/09/2017

Eligibility

Key inclusion criteria
1. 21 years of age and over
2. If sentenced, the research participants must be in prison for the full duration of the intervention delivery
3. If remand, the research participants must be expected to be in prison for the full duration of the intervention delivery.
4. Mental capacity to provide consent to participate

Participant type(s)
Other

Age group
Adult

Sex
Male

Target number of participants
160

Total final enrolment
80

Key exclusion criteria
1. Those who will not be or are not expected to be in prison for the full duration of the intervention delivery

2. Those deemed not to have mental capacity to provide consent to participate
3. Those deemed to be a security risk (either to the researcher or other prisoners due to the group session nature of the intervention - this is because prison security departments will not usually authorise those prisoners deemed high risk to participate in group sessions)
4. Those unable to understand/speak English. This is because the intervention will involve the peer-deliverers communicating with the participants, and participants communicating with each other, on a regular basis through group sessions and one-to-one sessions. Due to the small scale nature of the project and limited funding, whilst the trialists would be able to provide translation facilities throughout the provision of information and consent process, they would be unable to provide appropriate translation facilities throughout the intervention delivery
5. Those with a severe life threatening physical illness that would preclude taking part in physical activity (e.g. bed bound due to terminal illness)

Date of first enrolment
12/12/2016

Date of final enrolment
09/01/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
HMP Leeds
Leeds
United Kingdom
LS12 2TJ

Study participating centre
HMP Wealstun
Wetherby
United Kingdom
LS23 7AZ

Sponsor information

Organisation
Spectrum CIC

Sponsor details

1 Navigation Walk
Hebble Wharf
Wakefield
England
United Kingdom
WF1 5RH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/011af0v55

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Spectrum CIC

Results and Publications

Publication and dissemination plan
The results of the research will be submitted to the journal 'Pilot and Feasibility Studies' for publication.

Intention to publish date
01/12/2018

Individual participant data (IPD) sharing plan
The dataset will not be made available as the trialists didn't seek such approval when obtaining NHS REC approval. Following completion of the research, the dataset will be held for 5 years before being destroyed in a confidential manner.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No