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Health trainers for people on community supervision

Submission date
21/07/2016

Recruitment status
No longer recruiting

Registration date
24/08/2016

Overall study status
Completed

Last Edited
05/03/2021

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
People receiving Community Supervision (adult probation) have greater healthcare needs, but tend to access healthcare less frequently than the general population. This means that they often suffer from poorer health and wellbeing compared to the general population. Mental health and substance misuse problems are particularly common. People who come into contact with the criminal justice system are also more likely to face homelessness and unemployment, particularly those just released from prison. Uncertainty about basic needs can make it difficult to pay attention to behaviours that may contribute to poorer health -such as smoking, drinking alcohol, poor diet and lack of exercise. Little is known about the effectiveness of support to improve the health and well-being of people serving community sentences, due to a lack of routine data collection and challenges of keeping in touch with people after a period of time. Health Trainers, with an understanding of the client group and basic training in how to change people's behaviour, may be able to support clients by helping to motivate them and make them feel confident about making important changes. This study is testing a Health Trainer-led programme (the intervention) that aims to help people under community supervision to get support to improve their health and wellbeing.

Who can participate?
Adults under community supervision that have been out of prison for at least 2 months and have at least 7 months left to serve on their community supervision.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 have up to 12 one-to-one sessions with a Health Trainer over a period of 14 weeks. The trainers work to gain the participants trust and encourage them to work towards certain health-related goals. These may include reducing the number of cigarettes smoked, reducing the amount of alcohol drunk, increasing the amount of exercise that they do and taking steps to improve their diet and general wellbeing. They also advise the participants of appropriate community based services and organisations that may be able to help them. The participants also have access to the usual services available to people under community service. Participants in group 2 have access to the usual support services only. All participants are followed up for the next 6 months with assessments at 3 and 6 months.

What are the possible benefits and risks of participating?
Participants allocated to group 1 may experience benefits on a range of outcomes including their target health behaviour and/or wellbeing. Group 2 participants will be offered the opportunity of a one-to-one Health Trainer session after the 6-month follow up data collection. Those participants in the control group who take up this opportunity may experience benefits in relation to identifying target behaviour that they would like to work on and/or identifying local support organisations to help them meet their needs.

Where is the study run from?
Plymouth University Peninsula Schools of Medicine and Dentistry (UK)

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

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

Who is the main contact?
1. Dr Lynne Callaghan (public)
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2. Professor Adrian Taylor (scientific)
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
14/54/19

Study information

Scientific Title
Improving health, under community supervision, with the support of a Health Trainer: Evaluating a pilot randomised controlled trial

Acronym
STRENGTHEN

Study objectives
The overall aims of the trial are:
1. To further develop a Health Trainer-led intervention (STRENGTHEN) aimed at helping people under community supervision to receive support to improve mental wellbeing and be empowered to change health behaviours
2. To assess the acceptability and feasibility of such an intervention, alongside routine engagement with community supervision services, for the key stakeholders including CRCs, the NPS, HTs and those receiving community supervision
3. To assess the acceptability of recruitment, assessment and randomisation procedures within a pilot pragmatic, randomised controlled trial of the intervention versus usual care (to be defined by service observation, but likely to be minimal). Determine acceptability and feasibility of the methods in a pilot trial, including: proportion of eligible participants; recruitment rate; attrition and loss to follow-up; completion and completeness of data collection; estimates of the distribution of outcome measures; acceptability of intervention to participants; acceptability of study participation to participants.
4. To determine, from the pilot RCT, completion rates for proposed outcome measurements to assess wellbeing (WEMWBS) and behavioural measures (e.g. self-reported alcohol consumption, smoking, diet, physical activity) and quality of life (SF36 and EQ-5D-5L) at baseline and follow-up
5. To provide data to contribute to sample size calculations for a fully powered RCT to primarily assess subjective wellbeing (WEMWBS) and to ensure that the effect size (intervention vs. usual care) chosen for powering the definitive trial is plausible
6. To use a two-stage, mixed methods, process evaluation to refine and understand the acceptability and feasibility of the intervention, its delivery and the trial procedures. The

findings will be used to refine the intervention and the logic model of the causal assumptions that underpin it
7. To estimate the resource use and costs associated with delivery of the intervention, and to pilot methods for the cost-effectiveness framework in a full trial

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. NHS Health Research Authority Wales REC 3, 09/06/2016, ref: 16/WA/0171
2. National Offender Management National Research Committee, 17/06/2016 (conditional ethics approval), ref: 2016-192

Study design
Parallel two-group randomised pilot trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Mental wellbeing

Interventions
Participants are randomly allocated to one of two groups:

Intervention arm:
Participants in the intervention arm will be offered up to 12 sessions with a Health Trainer over 14 weeks. Health Trainers will spend time developing trust with patients and encourage development of goals in one or more of the following health behaviours: reducing smoking, reducing alcohol consumption, increasing physical activity and improving diet, and/or mental wellbeing. Health Trainers, with basic training in effective behaviour change techniques, will support patients on a one-to-one basis to build motivation and confidence to change the target health behaviour(s). Health Trainers will also signpost patients to appropriate community based services and organisations that may be able to support achievement of their goals. Participants in the intervention arm will also have access to the usual services available to people receiving Community Supervision. Outcome measures will be collected at baseline with 3- and 6- month follow-up.

Treatment As Usual (TAU) arm:
Participants in the Treatment As Usual arm will have access to the usual services available to people receiving Community Supervision which in most cases will be limited to supporting only the most acute needs.

Follow-up:
Outcome measures will be collected at baseline with 3- and 6- month follow-up.

Randomisation process:
Randomisation will be achieved by means of a web-based system created by the Peninsula

Clinical Trials Unit . Following completion of screening and baseline data collection, the researcher/administrator will access the randomisation website using a unique username and password. The website will require entry of the study site, participant initials, participant age and gender, before returning the participant's unique randomisation number and allocation (STRENGTHEN intervention or TAU) to the trial administrator via email. The website will confirm successful randomisation but not allocation at the point of entry to maintain blinding of researchers.

Intervention Type
Behavioural

Primary outcome(s)
Acceptability and feasibility outcomes:
1. Eligibility rate, measured by reviewing patient notes (baseline)
2. Recruitment rate, measured by reviewing patient notes (baseline)
3. Attrition and loss to follow-up, measured by reviewing patient notes (baseline, 3- and 6-month follow ups)
4. Completion and completeness of data collection, measured by reviewing patient questionnaires (baseline, 3- and 6-month follow ups)
5. Estimates of the distribution of outcome measures, measured by reviewing patient questionnaires (baseline, 3- and 6-month follow ups)
6. Acceptability of intervention to participants, measured by patient interviews and reviewing patient notes (baseline, 3- and 6-month follow ups)
7. Acceptability of study participation to participants, measured by patient interviews and reviewing patient notes (baseline, 3- and 6-month follow ups)

Key secondary outcome(s))
Secondary outcome measures/proposed outcomes measures for future definitive RCT:
1. Subjective mental wellbeing is measured using the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) at baseline, 3 and 6 months
2. Self-reported smoking (number of cigarettes smoked per day) is measured using 7-day recall of smoking at baseline, 3 and 6 months
3. Cigarette dependence is measured using the Fagerström Test for Cigarette Dependence (FTCD)29 at baseline, 3 and 6 months
4. Alcohol use is measured using the Alcohol Use Disorders Identification Test (AUDIT-C) at baseline, 3 and 6 months
5. Diet is measured using the Dietary Instrument for Nutrition Education (DINE) at baseline, 3 and 6 months
6. Physical activity is measured through a 7-day recall of physical activity at baseline, 3 and 6 months
7. Substance Use is measured using the Treatment Outcomes Profile (TOP) at baseline, 3 and 6 months
8. Confidence to and importance of behaviour change, access to social support, action planning, and self-monitoring measures relating to health behaviours at baseline, 3 and 6 months – Please separate these outcomes, including the method and timepoints of measurement for each
8.1. Reducing alcohol consumption:
8.1.1. Confidence to reduce alcohol consumption is measured using a 9-point scale at baseline, 3 and 6 months
8.1.2. Importance of reducing alcohol consumption is measured using a 9-point scale at baseline, 3 and 6 months
8.1.3. Access to social support is measured using a 9-point scale at baseline, 3 and 6 months

8.1.4. Action planning to reduce alcohol consumption is measured using 30-day recall at baseline, 3 and 6 months
8.1.5. Self-monitoring of alcohol consumption is measured using 30-day recall at baseline, 3 and 6 months
8.2. Reducing smoking:
8.2.1. Confidence to reduce smoking is measured using a 9-point scale at baseline, 3 and 6 months
8.2.2. Importance of reducing smoking is measured using a 9-point scale at baseline, 3 and 6 months
8.2.3. Access to social support is measured using a 9-point scale at baseline, 3 and 6 months
8.2.4. Action planning to reduce smoking is measured using 30-day recall at baseline, 3 and 6 months
8.2.5. Self-monitoring of smoking is measured using 30-day recall at baseline, 3 and 6 months
8.3. Increasing physical activity:
8.3.1. Confidence to increase physical activity is measured using a 9-point scale at baseline, 3 and 6 months
8.3.2. Importance of increasing physical activity is measured using a 9-point scale at baseline, 3 and 6 months
8.3.3. Access to social support is measured using a 9-point scale at baseline, 3 and 6 months
8.3.4. Action planning to increase physical activity is measured using 30-day recall at baseline, 3 and 6 months
8.3.5. Self-monitoring of physical activity is measured using 30-day recall at baseline, 3 and 6 months
8.4. Improving diet
8.4.1. Confidence to eat a healthy diet is measured using a 9-point scale at baseline, 3 and 6 months
8.4.2. Importance of eating a healthy diet is measured using a 9-point scale at baseline, 3 and 6 months
8.4.3. Access to social support is measured using a 9-point scale at baseline, 3 and 6 months
8.4.4. Action planning to eat a healthy diet is measured using 30-day recall at baseline, 3 and 6 months
8.4.5. Self-monitoring of dietary behaviour is measured using 30-day recall at baseline, 3 and 6 months
9. Health related quality of life is measured using the EQ-5D-5L and SF-36 questionnaires at baseline, 3 and 6 months

Economic Outcomes:
1. Quality-adjusted life-year (QALY) derived from the EQ-5D-5L, with the SF-36 used to derive QALYs (SF6D) in sensitivity analyses at baseline, 3 and 6 months
2. Key areas of intervention resource use and costs (e.g. HT time, training, supervision, travel, consumables) are measured using Health Trainer notes at 3 and 6 months
3. Health care, social care, and other resource use data will be collected using a participant self-report resource use questionnaire (RUQ) at baseline, 3 and 6 months

Completion date
31/12/2017

Eligibility

Key inclusion criteria

1. Males & Females
2. 18 years or older
3. Receiving Community Supervision
4. For prison releases: in the community for at least 2 months
5. Minimum of 7 months of community sentence to serve
6. Willing & able to: receive support in one or more target health behaviours (alcohol reduction; smoking reduction; increased physical activity; improved diet) and/or improve wellbeing
7. Willing and able to: take part in a randomised controlled trial with follow-up at 3 and 6 months
8. Residing within the geographical areas of the study

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
120

Key exclusion criteria
1. Present a serious risk of harm to the researchers or Health Trainers
2. Unable to provide informed consent
3. Those with disrupted lives who may find it difficult from the outset to engage in the intervention.

Date of first enrolment
01/09/2016

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Plymouth University Peninsula Schools of Medicine and Dentistry
John Bull Building
Tamar Science Park
Research Way
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Study participating centre
The University of Manchester
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Sponsor information

Organisation
Plymouth University

ROR
https://ror.org/008n7pv89

Funder(s)

Funder type
Government

Funder Name
National Institute for Health 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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2019	05/03/2021	Yes	No
Protocol article	protocol	04/06/2018	24/10/2019	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes