Individual health trainers to support health and well-being for people under community supervision in the criminal justice system: the STRENGTHEN pilot RCT

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Scientific summary

The STRENGTHEN pilot RCT

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Scientific summary

Background

People with experience of the criminal justice system typically have poorer physical and mental health, have lower levels of mental well-being and have less healthy lifestyles than the general population. Health trainers have worked with a range of groups, including offenders in the community, to provide support for healthy lifestyle changes and enhancing mental well-being, and to signpost to appropriate services. To date, there has been no rigorous evaluation of the effectiveness and cost-effectiveness of providing such community support; therefore, there is a lack of evidence on which to commission appropriate services. Public services to support those with the greatest need are severely stretched and tend to focus only on acute care needs, so it is important to only invest in support that is effective and cost-effective. The absence of rigorous studies is partly because of difficulties in recruiting participants, completing follow-up assessments and engaging participants in support to improve well-being and healthy lifestyles. The present pilot trial therefore focuses on assessing any trial uncertainties and making recommendations on how to deliver an efficient full trial to determine the effectiveness and cost-effectiveness of health trainer support for improving well-being and healthy lifestyles among people receiving community supervision, as part of the criminal justice system in the UK.

Objectives

The aim of this pilot randomised controlled trial was to explore uncertainties about the acceptability and feasibility of the trial methods and the health trainer-led intervention to inform the design of a full randomised controlled trial.

The objectives were to:

- assess the acceptability and feasibility of the STRENGTHEN intervention, alongside routine engagement with community supervision services, for the key stakeholders, including participants receiving community supervision, Community Rehabilitation Companies, the National Probation Service and health trainers
- assess the acceptability of recruitment, randomisation and assessment procedures within a pragmatic pilot randomised controlled trial
- determine, from the pilot randomised controlled trial, descriptive summary data for proposed outcome measurements to assess well-being (e.g. the Warwick–Edinburgh Mental Well-being Scale) and behavioural measures (e.g. self-reported alcohol consumption, smoking status, diet, physical activity, substance use) and quality of life (e.g. the Short Form questionnaire-36 items and the EuroQol-5 Dimensions, five-level version) at baseline and at the 3- and 6-month follow-ups
- provide data to contribute to sample size calculations for a fully powered randomised controlled trial, with subjective well-being (measured using the Warwick–Edinburgh Mental Well-being Scale) as the primary outcome
- use a mixed-methods process evaluation to reflect on the acceptability and feasibility of the intervention and trial methods to propose further refinements
- 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.

Methods

The STRENGTHEN pilot trial was a parallel two-group randomised pilot trial with 1 : 1 individual participant randomisation to either the intervention plus standard care (intervention) or standard care alone (control), with a parallel process evaluation. Participants were recruited through Community Rehabilitation Companies in the south-west and north-west of England, and through the National Probation Service in the south-west only. Follow-up assessments were carried out at 3 and 6 months post baseline data collection. Ethics approval for the trial was granted by the Health and Care Research Wales Ethics Committee and the former National Offender Management Service, now known as Her Majesty's Prison and Probation Service (Research Ethics Committee reference number 16/WA/0171 and National Offender Management Service reference number 2016-192).

A key aim of this study was to collect data on the following acceptability and feasibility outcomes:

- the proportion of trial-eligible participants among those routinely passing through offender management services, and reasons for exclusions
- recruitment rates
- rates of 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 trial participation to participants.

Inclusion and exclusion criteria

Inclusion criteria were as follows:

- male or female and aged $\geq$ 18 years
- currently receiving community supervision
- having a minimum of 7 months left of community sentence/supervision
- having been in the community for at least 2 months following any custodial sentence
- willing and able to receive support to improve one or more of the four target health behaviours and/or mental well-being
- willing and able to take part in a pilot randomised controlled trial with follow-up assessments at 3 and 6 months
- residing in the geographical areas of the study.

Exclusion criteria were as follows:

- presenting a serious risk of harm to the researchers or health trainers
- unable to provide informed consent
- having disrupted/chaotic lifestyles that may have made engagement in the intervention too difficult.

Primary outcome

The proposed primary outcome for a definitive trial was the Warwick–Edinburgh Mental Well-being Scale, to measure subjective mental well-being, which has good psychometric properties. The short Warwick–Edinburgh Mental Well-being Scale was also calculated for the purposes of possible future interest.

Secondary outcomes

- Self-reported smoking (number of cigarettes smoked per day).
- Fagerström Test for Nicotine Dependence.
- Alcohol use (measured using the Alcohol Use Disorders Identification Test).
- Diet (measured using the Dietary Instrument for Nutrition Education).

- Physical activity (measured using the 7-day Physical Activity Recall questionnaire).
- Substance use (measured using the Treatment Outcomes Profile).
- Confidence, importance (i.e. an individual's perception of the importance of changing the target behaviour), access to social support, action-planning and self-monitoring measures relating to health behaviours.
- Health-related quality of life (measured using the EuroQol-5 Dimensions, five-level version, and the Short Form questionnaire-6 Dimensions, which is derived from the Short Form questionnaire-36 items).
- Cost-effectiveness (related to health trainer time, training, supervision, travel, consumables).
- Health care, social care and other resource use data were collected using a participant self-report resource use questionnaire.

Process evaluation

The aims of the process evaluation were to:

- assess whether or not the intervention was being delivered as per manual and training
- ascertain components of the intervention that were critical to delivery
- explore reasons for divergence from delivery of the intervention as manualised
- understand when context was moderating delivery
- understand the experience and motivation of participants in the control arm of the pilot in order to maximise retention in a full trial
- explore reasons for declining to participate in the trial
- explore reasons for disengaging in the intervention before an agreed end
- understand, from a participant perspective, the benefits and disadvantages of taking part in the intervention.

One-to-one semistructured interviews were conducted with the following participant groups:

- participants randomised to the intervention arm of the pilot ($n = 11$)
- participants randomised to the control arm of the pilot ($n = 5$)
- health trainers across both geographic regions ($n = 6$)
- offender managers/probation workers across both geographic regions ($n = 6$).

Results

It was originally anticipated that approximately 10 participants per month (for 4 months) per offender management service would be recruited from September 2016. In the first 7 months after the first participant was recruited, we had recruited only 22 participants because of delays in opening a second recruitment site (in Manchester instead of Southampton) and challenges within the services themselves in supporting the trial. Once recruitment processes were established across the three offender management services, it took 9 months to recruit the remaining 90 participants (i.e. 3.3 per offender management service per month) before the planned 120 participants were recruited. Reasons for excluding participants were described at three steps in the recruitment process. We are now in a strong position to estimate the resources required to recruit participants.

Trial attrition was initially around 50%, but with improved processes throughout the pilot trial this was improved to 60% overall, which partly met the progression criteria. There was no clear influence of trial arm or recruitment service on retention. An acceptable level of retention was achieved without financial incentives.

It was not an aim of the trial to detect statistical significance in between-group differences, but the reported values for the main outcome variable, the Warwick–Edinburgh Mental Well-being Scale, at the 3- and 6-month follow-ups indicated some differences in favour of the intervention arm, from which to provide estimates for a sample size calculation for a definitive trial. There were also some encouraging signs that there was lower tobacco and alcohol consumption at follow-up in the intervention arm than in the control group. Data for all measures were generally complete because assessments were mainly conducted face to face.

Overall, 28% of participants did not attend any health trainer-led intervention sessions, and 62% had at least two sessions, which partly met the progression criteria. The overall mean number of sessions attended was 3.7 (standard deviation 3.4), with a median of 3. Those who had moderate engagement (2–5 intervention sessions) appeared to have higher Warwick–Edinburgh Mental Well-being Scale scores at follow-up than those who had lower and higher engagement.

We estimated the mean cost of the STRENGTHEN intervention to be approximately £348 (standard deviation £128) per participant. The main cost drivers for the intervention, determined by data prospectively collected using health trainer/participant contact sheets, activity logs of the health trainer co-ordinator and a questionnaire for completion by the intervention providers, were (1) staff time of the health trainers and the health trainer co-ordinator and (2) supervision of the health trainers.

A number of recommendations arose for conducting a full trial concerned with recruitment and trial retention, intervention engagement and blinding.

In terms of recruitment, recommendations included exploring ways to increase the number of female participants, providing clear training for researchers to implement recruitment procedures in the 16 offender management services needed to recruit 900 participants across eight cities, providing routine regular virtual supervision sessions for researchers, offering food vouchers to participants for involvement in the trial (i.e. for completing follow-up assessments), dropping the inefficient recruitment efforts in the community (outside offender management services) and establishing strong working relationships with each offender management service through good communication.

Recommendations to improve trial retention included providing food vouchers as noted in the previous paragraph; optimising working relationships with each offender management service to co-ordinate supervision sessions with follow-up assessments; reflecting on our own processes and other research to optimise ways to stay in touch with participants outside the offender management service, especially among those under Community Rehabilitation Company supervision; and further assessing reasons (and associated participant characteristics) for loss to follow-up from the pilot trial's quantitative and qualitative data collection.

Recommendations to improve intervention engagement included further exploration of quantitative and qualitative reasons (and associated participant characteristics) for engagement to inform the health trainer manual and training; drawing on another of our health trainer trials involving 450 intervention participants to inform our understanding of how to enhance engagement; and delivering a 3-day training course for health trainers initially and maintaining regular supervisory sessions to build a sense of shared learning and personal development for health trainers. The training should focus on helping the health trainers to demonstrate delivery of the core competencies, as manualised.

A recommendation was made to further reduce the risk of bias from the unblinding of participants by training researchers to reinforce to participants and offender managers the need to not discuss intervention involvement (or not) until after any assessment is completed. We will also conduct sensitivity analysis in the main analysis to determine the possible effects of unblinding.

Conclusions

Following a detailed pilot trial to address uncertainties in conducting a full randomised controlled trial, a number of recommendations have been made to improve the efficiency of conducting a full trial to assess the effectiveness and cost-effectiveness of a health trainer intervention on well-being and health behaviours. We have used between-group differences at follow-up in this pilot trial to estimate the probable sample sizes needed for a full trial.

The successful completion of this pilot implies the feasibility of conducting a larger definitive trial with a full cost-effectiveness analysis. Piloting the framework for a future economic evaluation via the collection of intervention resource use and cost data; data on health, social care and broader societal resource use; data on the potential primary outcome measure for the trial; and policy-relevant quality-adjusted life-year outcome measures has led to a number of specific indications for how to structure and conduct such a cost-effectiveness analysis of the STRENGTHEN intervention. The pilot trial has provided a platform on which to develop a multicentred randomised trial to rigorously assess the effectiveness and cost-effectiveness of health trainer support for people under community supervision.

Trial registration

This trial is registered as ISRCTN80475744.

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