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Individual Health Trainers to support health and wellbeing for people under community supervision in the criminal justice system: the STRENGTHEN pilot RCT

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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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Competing interests:

Siobhan Creanor reports grants from NIHR PHR, during the conduct of the study, and various other grants from NIHR and UK charities, outside the submitted work. Siobhan Creanor is Director of the Peninsula Clinical Trials Unit which is in receipt of NIHR CTU Support Funding (current award ends 31/08/21)

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Keywords: Health Trainers, Criminal Justice System, Offender health, Health behaviour change, Wellbeing

Abstract

Background

Little is known about the effectiveness and cost-effectiveness of interventions, such as Health Trainer support, to improve the health and wellbeing of people recently released from prison or serving a community sentence, due to the challenges in recruiting participants and following them up.

Objectives

This pilot study aimed to assess the acceptability and feasibility of the trial methods and intervention (and associated costs) for a randomised trial to assess the effectiveness and cost-effectiveness of Health Trainer support versus usual care.

Design

This involved a pilot multicentre parallel two group randomised controlled trial recruiting 120 participants with 1:1 individual allocation to receive support from a Health Trainer and usual care or usual care alone, with mixed methods process evaluation, in 2017-2018.

Setting

Participants were identified, screened and recruited in Community Rehabilitation Companies in Plymouth and Manchester or National Probation Service in Plymouth. The intervention was delivered in the community.

Participants

We invited those who had been out of prison for at least 2 months (to allow community stabilisation) with at least 7 months of a community sentence remaining, and excluded those who may have posed an unacceptable risk to the researchers and Health Trainers, or weren't interested in the trial or intervention support.

Interventions

The intervention group received, in addition to usual care, our person-centred Health Trainer support in one-to-one sessions for up to 14 weeks, either in person or via telephone.

Health Trainers aimed to empower participants to make healthy lifestyle changes (particularly in alcohol use, smoking, diet and physical activity), take on the 5 Ways to Wellbeing, and signpost to other options for support.

The control group received treatment as usual, defined by available community and public service options for improving health and wellbeing.

Main outcome measures

The measures included the Warwick and Edinburgh Mental Well-being Scale (WEMWBS), alcohol use, smoking, dietary behaviour, physical activity, substance use, resource use, quality of life, intervention costs, quality of life, intervention engagement, and feasibility and acceptability of trial methods and the intervention.

Results

We learned a great deal about recruitment and achieved our target of 120 participants. We met our minimum trial retention target at 6 months (60%). Among those offered Health Trainer support, 62% had at least two sessions. Our mixed-methods process evaluation generally supported the trial methods and intervention acceptability and feasibility. Data from the proposed primary outcome, the WEMWBS, provided us with valuable data to estimate the sample size for a full trial in which to test the effectiveness and cost-effectiveness of the intervention.

Limitations

We identified and discussed several limitations concerned with recruitment, retention, intervention engagement and blinding.

Conclusions

Based on the findings from this pilot trial, a full trial (with some modifications) seems justified with a sample size of around 900 participants to detect between-group differences in the WEMWBS scores at 6-month follow-up.

Future work

We identified a number of recruitment, trial retention, intervention engagement and blinding issues in this pilot and make recommendations in preparation of and within a full trial.

Trial registration

ISRCTN80475744

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All data requests should be submitted to the corresponding author for consideration. Access to anonymised data may be granted following reviews and necessary agreements being in place.

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List of Abbreviations/Glossary

CJS	Criminal Justice Service
CRC	Community Rehabilitation Centre
CRF	Case Report Form
HT	Health Trainer
ITT	Intention to Treat
NPS	National Probation Service
OM	Offender Manager
OMS	Offender Management Service
PE	Process Evaluation
PenCTU	Peninsula Clinical Trials Unit
PPI	Patient Public Involvement
RCT	Randomised Controlled Trial
SPOA	Single Point of Access
SWEMWBS	Short Warwick and Edinburgh Mental Wellbeing Scale
WEMWBS	Warwick and Edinburgh Mental Wellbeing Scale

Plain English summary

Little is known about the effectiveness and cost-effectiveness of interventions to improve the health and wellbeing of people recently released from prison or serving community sentences, due to the challenges in recruitment and study retention. Health Trainers can support healthy lifestyle change without telling clients directly what they should or shouldn't do, and offer direction to other options for support, but the interest in receiving support is not well understood.

This pilot study aimed to find out whether 120 participants could be recruited into a study, from Offender Management Services, in which they may or may not receive Health Trainer-led support, and how many would provide follow-up information about their wellbeing and lifestyles after 3 and 6 months. We also wanted to know the average score and variation in scores in a self-reported measure of wellbeing after 6 months to estimate the number of participants needed to detect better wellbeing after Health Trainer support, compared with usual care, in a full trial. We assessed the participant's interest in the intervention by recording the number of sessions they took part in and interviewed them about their experiences.

We learnt how to improve efficiency of recruitment for a full trial within Community Rehabilitation Companies and the National Probation Service, increase the 60% of participants who completed follow-up assessments, and encourage more than the 62% who saw the Health Trainer at least twice from interviews and observations. Those who received the intervention seemed to be more likely to have higher wellbeing after 6 months than those who didn't, and this information was used to estimate that we would need about 900 participants to fully assess if the differences were due to more than chance. Interviews and data analysis informed us on making a few changes ahead of a full trial.

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Scientific Summary

Some text throughout this report has been reproduced from Thompson TP, Callaghan L, Hazeldine E, et al. Health trainer-led motivational intervention plus usual care for people under community supervision compared with usual care alone: a study protocol for a parallel-group pilot randomised controlled trial (STRENGTHEN). BMJ Open 2018;8:e023123. doi:10.1136/ bmjopen-2018-023123

Background

People with experience of the Criminal Justice System typically have poorer physical and mental health, lower levels of mental wellbeing, 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, enhancing mental wellbeing and signposting to appropriate services. To date, there has been no rigorous evaluation of the effectiveness and cost-effectiveness of providing such community support, and hence the evidence upon which to commission appropriate services is lacking. 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 due to difficulties in recruiting participants and completing follow-up assessments, and engaging participants in support to improve wellbeing 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 wellbeing 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 Health Trainer-led intervention, in order to inform the design of a full randomised controlled trial.

Objectives were as follows:

1. 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 themselves.

2. To assess the acceptability of recruitment, randomisation and assessment procedures within a pragmatic pilot randomised controlled trial.

3. To determine, from the pilot randomised controlled trial, descriptive summary data for proposed outcome measurements to assess wellbeing (WEMWBS) and behavioural measures (e.g. self-reported alcohol consumption, smoking, diet, physical activity, substance use), and quality of life (SF36 and EQ-5D-5L) at baseline and 3- and 6-month follow-up.

4. To provide data to contribute to sample size calculations for a fully-powered randomised controlled trial with subjective wellbeing (WEMWBS) being the primary outcome.

5. To use a mixed-methods process evaluation to reflect on the acceptability and feasibility of the intervention and trial methods to propose further refinements.

6. 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.

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 Southwest and Northwest of England, and through the National Probation Service in the Southwest only. Follow-up assessments were carried out at 3- and 6-months post-baseline data collection. Ethical approval for the study was granted by the Health and Care Research Wales Ethics Committee and the former National Offender Management Service, now Her Majesty's Prison and Probation Service (REC Ref: 16/WA/0171 NOMS Ref: 2016-192).

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

- **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 study participation to participants.**

Inclusion criteria were as follows:

- Males and females aged 18 years or older
- Currently receiving community supervision
- Have a minimum of 7 months left of community sentence/supervision
- Have 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 wellbeing
- Willing and able to take part in a pilot randomised controlled trial with follow-up assessments at 3 and 6 months
- Residing within the geographical areas of the study.

Exclusion criteria were as follows:

- Present a serious risk of harm to the researchers or Health Trainers
- Unable to provide informed consent
- 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 and Edinburgh Mental Wellbeing Scale, to measure subjective mental wellbeing, which has good psychometric properties. The short Warwick and Edinburgh Mental Wellbeing Scale was also calculated for the purposes of possible future interest.

Secondary outcomes:

- Self-reported smoking (n cigarettes smoked per day)
- Fagerström Test for Cigarette Dependence
- Alcohol use (AUDIT)
- Diet (Dietary Instrument for Nutrition Education [DINE])
- Physical Activity (7-day recall physical activity questionnaire)
- Substance use (Treatment Outcomes Profile [TOPS])

- Confidence, importance, access to social support, action-planning, and self-monitoring measures relating to health behaviours
- Health related quality of life (EQ-5D-5L, SF-6D (derived from the SF36))
- Cost-effectiveness (Related to Health Trainer time, training, supervision, travel, consumables)
- Health care, social care, and other resource use data was collected using a participant self-report resource use questionnaire (RUQ)

The aims of the process evaluation were to:

- Assess whether the intervention was being delivered as per manual and training
- Ascertain components of intervention which were critical to delivery
- Explore reasons for divergence from delivery of 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.

Process evaluation:

1:1 semi-structured 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 only recruited 22 participants due to delays in opening a second recruitment site (in Manchester instead of Southampton) and challenges within the services themselves to support the trial. Once recruitment processes were

established across the 3 offender management services, it took 9 months to recruit 90 participants (i.e. 3.3 per offender management service per month), and the planned 120 participants were recruited. Reasons for excluding participants were described at three steps within the recruitment process. We are now in a strong position to estimate the resources required to recruit participants.

Study attrition was initially around 50% but with improved processes throughout the pilot trial this was improved to 60% overall, which partly met our 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 study to detect statistical significance between group differences but the reported values for the main outcome variable, WEMWBS, at 3- and 6-month follow-up 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 compared with the control group. Data for all measures was generally complete because assessments were mainly conducted in face-to-face mode.

Overall, 28% of participants did not attend any Health Trainer-led intervention sessions, and 62% had at least 2 sessions, which partly met our progression criteria. The overall mean (SD) number of sessions attended was 3.7 (3.4), with a median of 3. Those who had moderate engagement (2-5 intervention sessions) appeared to have higher WEMWBS scores at follow-up, compared with those who had lower and higher engagement.

We estimated the mean (SD) cost of the STRENGTHEN intervention to be approximately £348 (£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 HT co-ordinator, and a questionnaire for completion by the intervention providers, were: i) staff time of the Health Trainers and the Health Trainer co-ordinator and; ii) 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

8 cities; provide routine regular virtual supervision sessions for researchers; offer food vouchers to participants for involvement in the study (i.e. for completing follow-up assessments); drop the inefficient recruitment efforts in the community (outside offender management services); and establish strong working relationships with each offender management service through good communication.

Recommendations to improve trial retention included: providing food vouchers as noted above; optimise working relationships with each offender management service to coordinate supervision sessions with follow-up assessments; reflect on our own processes and other research to optimise ways to stay in touch with participants outside of the offender management service, especially among those under Community Rehabilitation Company supervision; and further assess 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; draw on another of our Health Trainer trials involving 450 intervention participants to inform our understanding of how to enhance engagement; and deliver a 3-day training course for Health Trainers initially and maintain 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 the training of 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 wellbeing and health behaviours. We have used between-group differences at follow-up in this pilot trial to estimate likely sample sizes need for a full trial.

The successful completion of this pilot implies the feasibility of conducting a larger definitive trial with 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 upon which to develop a multi-centred randomised trial to rigorously assess the effectiveness and cost-effectiveness of Health Trainer support for people under community supervision.

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Chapter 1: Introduction

Scientific Background

Individuals in the Criminal Justice System (CJS) have a high prevalence of physical and mental healthcare needs, lower psychological wellbeing[1] and experience significant problems in accessing health and social care services.[2] Services for those with multi-morbidities and who are under community supervision often appear fragmented.[3] Key barriers to access of healthcare services include GP registration, long waiting times for appointments and a perception of not being supported by services to make contact, such as probation.[4] Further, a lack of trust in health services and health professionals (e.g. in primary care) causes many offenders to avoid medical help despite a high prevalence of emotional problems.[5]

Unhealthy behaviours such as problematic alcohol use and smoking are much higher in the offender population than the general population.[6] For example, 60-80% of the offender population report problematic alcohol use compared to 20-30% in the general population and c. 80% of offenders smoke compared to c. 20% in the general population.[7] In addition, prevalence data from a rapid systematic review reported 53-69% of adults in the probation setting scored positively for an alcohol use disorder.[8] Both these behaviours (often co-existing) lead to several health problems, and possibly low mental wellbeing, through a number of plausible processes (e.g. economic, social, psychological).[9] Likewise, substance misuse is particularly prevalent, and is also linked to mental health problems. However, services in the substance misuse field are already very well developed for offenders.[10]

In 2004, the Government's White Paper 'Choosing health: making healthy choices easier'[11] introduced a new workforce called Health Trainers (HTs), often drawn from the communities in which they operate. The introduction of HTs signalled a shifting focus in the UK, towards self-management of health, and on reducing the demands placed on formal care (Visram, 2017).[12] A HT's main role is to provide one-to-one support to people in disadvantaged areas to facilitate health behaviour change and access health services. A handbook for HTs was developed in 2008 outlining the approach and evidence-based techniques (e.g. goal-setting, self-monitoring, creating action plans) that HTs can use to help people change behaviour.[13] The core work of HTs includes the support of behaviour changes such as healthy eating, stopping/reducing smoking, increasing physical activity, reducing alcohol and improving mental wellbeing. Their work has been positively rated but there is still a lack of robust evaluation.[14,15]

Our rapid review of published and grey literature, and contact with local probation service leads, revealed that the scope of HTs has been extended to prison and probation settings with

promising findings,[16] especially when the HT has experience of the CJS. While HTs have typically focused on supporting health behaviour change, there is increasing interest in their role being extended to facilitate improvements in mental wellbeing. Further, where enhancing wellbeing has been the main focus, individuals are more likely to attain their planned goals.[16] In parallel work, a screening and brief intervention for reducing alcohol use in individuals in the criminal justice settings[17-19] indicated no additional benefit in comparison with feedback on screening and a client information sheet,[20] suggesting a more client-centred intervention with longer engagement may be needed. A recent systematic review[21] identified 95 studies working with offenders both in and out of prison (42 studies based in the community) on improving health outcomes, of which 59 led to improved mental health, substance use, infectious disease or health service utilisation outcomes, suggesting interventions can be successful. However, 91 of the studies had an unclear or high risk of bias and the review highlighted the lack of high quality rigorous research with a population which is comparatively under-researched. Further rigorous research is therefore needed to evaluate the effectiveness and cost-effectiveness of a HT-led intervention aimed at improving mental wellbeing and health behaviour among people under community supervision, and to understand the change processes involved.

The recent reorganisation of community supervision, as part of the 'Transforming Rehabilitation' agenda, saw the split of services into Community Rehabilitation Companies (CRCs) and the National Probation Service (NPS). CRCs manage the majority of offenders, particularly those who are classified as low to medium risk, whilst the NPS supervises high-risk offenders. The reforms presented an opportunity to engage those released from prison with sentences under one year (who previously would not have received supervision), as well as those serving community sentences. Providing HT support within this context could improve engagement with existing health promotion services,[22] stimulate greater ownership and control over health behaviour change and involvement in activities to foster mental wellbeing.[23]

There has been increasing interest in subjective wellbeing, distinct from lack of mental illness, as an important concept. The following five behaviours to increase mental capacity and wellbeing were recommended in the Foresight Report:[23] *Connect* with others; keep *Learning*; be physically *Active*; take *Notice* of things around you; and *Give* (CLANG). Subjective wellbeing is an important outcome in its own right and has the potential to change relatively quickly.

Wellbeing potentially impacts on physical health (e.g. hypertension, heart disease) and mental health (e.g. depression, self-harm, substance misuse); health behaviours (e.g. smoking, alcohol); employment and productivity; crime; and society in other ways.[23] While

the role of exercise for improving wellbeing is clear, changing other specific health-related behaviours such as smoking can also improve subjective feelings of wellbeing for some individuals.[24,25] Individuals' patterns of current behaviour, motivation to change and potential benefits will be idiosyncratic and require a personal analysis. Assessing the benefit of health promotion interventions is rarely easy and wellbeing poses particular problems. One method of assessing subjective wellbeing is through the Warwick and Edinburgh Mental Wellbeing Scale (WEMWBS). The WEMWBS captures the two perspectives of mental wellbeing: (1) the subjective experience of happiness (affect) and life satisfaction (the hedonic perspective); and (2) positive psychological functioning, good relationships with others, and self-realisation (the eudaimonic perspective). The latter, based on Self-Determination Theory, includes the capacity for self-development, positive relations with others, autonomy, self-acceptance and competence[26] and, therefore, the potential to positively enhance further health-promoting behaviours.

The WEMWBS has been widely used at a population level to assess mental wellbeing, as well as with individuals in specific groups.[27-31] Original data we obtained from the Scottish Prisoner Service showed a mean (SD) WEMWBS score of 43.2 (12.3) (range 14 to 70), compared with a general population score of 51.6 (8.71) for England[29] and 49.9 (8.5) for Scotland.[32] Lower scores are associated with smoking, lower consumption of fruit and vegetables, high alcohol use and lower socio-economic status.[31] While these associations are likely to involve reciprocal causal effects, this does highlight the need for interventions to improve the mental wellbeing among groups with the lowest scores.

People who receive community supervision from the new NPS and CRC services are particularly suitable for a high intensity health promotion intervention for four reasons: (1) they are often excluded from 'usual' health care and health and wellbeing-promoting interventions due to a combination of access arrangements, lifestyle factors and distrust of authority; (2) they often have low levels of mental wellbeing and poor health-related behaviours and thus the gains of the proposed intervention are potentially high; (3) while under supervision, and therefore in a period of sustained mandated contact with a service, there is an opportunity to both engage such individuals in an intervention and capture follow-up data within the context of a rigorous evaluation; (4) being subject to justice supervision can often be a time when individuals wish to improve their life circumstances, particularly towards the start of sentences.

The current research aimed to develop and test the feasibility and acceptability of a client-centred intervention for individuals receiving community supervision, to support them to change one or more health-related behaviours, enhance their wellbeing and to reduce the risk

of long-term conditions. The HT role has been adapted for specific populations, including offenders[16] and smokers,[33] with early signs that the support is acceptable and feasible. However, further intervention development and piloting was required to integrate a focus on promoting wellbeing and multiple health behaviour changes in offenders in the new NPS/CRCs context, and to understand the interactions between wellbeing and health behaviour changes. These uncertainties will be explored, and reduced, in a process evaluation (PE), working with the peer researchers who will have lived experience of the CJS. The pilot trial and PE will further test our assumptions, the intervention and cost-effectiveness.

Aims and objectives of the pilot trial

The aim of this pilot randomised controlled trial (RCT) was to develop and implement a HT-led intervention to support health and wellbeing improvements for those under community supervision within the CJS. Further, the pilot study seeks to explore uncertainties about the acceptability and feasibility of the trial methods and intervention, in order to inform the design of a full RCT.

Specific objectives:

1. 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 themselves.

2. To assess the acceptability of recruitment, randomisation and assessment procedures within a pilot pragmatic randomised controlled trial.

3. 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, substance use), and quality of life (SF36 and EQ-5D-5L) at baseline and 3- and 6-month follow-up.

4. 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.

5. To use a mixed-methods process evaluation to further refine and understand the acceptability and feasibility of the intervention, its delivery and the trial procedures.

6. 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.

Chapter 2: Intervention development

Development of the STRENGTHEN intervention

Through original research and literature reviews, we developed an extensive understanding of what are likely to be the effective components of an intervention targeted at health behaviours and improvement of health and mental wellbeing in this population. A clear starting point logic model of intervention components and aims underpins the intervention, based on the HT role in a previous trial of smoking cessation in disadvantaged groups[32] and the development of a collaborative care model for prison leavers with multiple health problems.[33]

The HT role has been adapted for specific populations, including offenders[16] and smokers, [32] with early signs that the support is acceptable and feasible. However, further intervention development and piloting was required to integrate a focus on promoting mental wellbeing and multiple health behaviours and to understand the interactions between mental wellbeing and health behaviour changes. As with our previous research, we used the original HT Manual with its focus on smoking, alcohol, physical activity and diet as a starting point for possible content and structure, adapting and developing where necessary to meet our specific aims (i.e. a stronger focus on mental wellbeing).

Through engaging with PPI groups to understand what and how 'mental wellbeing' may be interpreted and understood alongside the target behaviours, we integrated mental wellbeing and the four target behaviours within the logic model in such a way that they exist independently from, and are interwoven with, each other. It was felt that for some people, their mental wellbeing may be so low that it would need to be addressed directly before other changes could be considered. For others, addressing the four behaviours could implicitly lead to improvements in mental wellbeing. As such, the training manual was developed in a way that HTs were trained to support people with improving their wellbeing as a target in and of itself, as well as being able to support change in the four behaviours. In creating the STRENGTHEN training manual (see supplementary material 1) extensive work was given to adapting the way the behaviours can be supported in such a way to implicitly and explicitly maximise the benefit for people's mental wellbeing.

Incorporating the Five Ways to Wellbeing

The framework chosen for promoting mental wellbeing was the Five Ways to Wellbeing (5WWB) (see supplementary material 2). The 5WWB were developed as an accessible public health message based on evidence-based practices people can perform easily every day

which could lead to improvements in mental wellbeing.[22] PPI work supported the 5WWB as being an acceptable and useful framework which could be applied with the target population.

In order to incorporate the 5WWB, the research team took part in a one-hour training session where they were trained to understand and focus on their own wellbeing to ensure familiarity and understanding of the framework. Following from this, the 5WWB were incorporated into the training manual as a standalone section for supporting people who want to improve their wellbeing. A section was also developed which embedded ways to promote the four health behaviours of the original HT manual in ways that would maximise their impact on wellbeing. For example, supporting alcohol reduction could also link to exploring how this might help a client to *connect* with others (who may be trying to do likewise), *learn* about the physical and mental health consequences of alcohol use and guidance on safer levels of use, discover how *physical activity* can help deal with alcohol cravings, *notice* the effects of alcohol on financial, social, emotional and cognitive functioning, and *give* support to others to manage their alcohol consumption. A similar set of examples can be developed for each of the health behaviours.

Adapting the HT role and intervention

Content from the original HT manual that was considered appropriate was adapted for the STRENGTHEN intervention; the central ethos of being client-centred and embedded within the community was carried forward into the STRENGTHEN intervention, as were components such as action-planning, problem-solving, self-monitoring, and signposting. The intervention included:

- Heavy focus on engagement, trust/rapport building
- Focus on reduction rather than stopping smoking, or pushing guidelines (5 a day, 14 units, etc.) as this would be seen as threatening
- Flexibility of timing, frequency and duration

The core competencies

As with our previous work adapting the HT role,[34] a set of six core competencies were developed which were designed to underpin the work of the HT (see appendix 1). They reflected elements that were considered to be crucial to successful delivery of the intervention, and were reinforced throughout the manual, HT training, and the supervision process. They were: (1) active participant involvement, (2) motivation-building for changing a behaviour and improving wellbeing, (3) set goals and discuss strategies to make changes, (4) review efforts to make changes/problem-solving, (5) integration of concepts: building an association between wellbeing and behaviour, and (6) engage social support and manage social influence.

These competencies not only served as a guide for what the HTs should be mindful of in their delivery, but also for assessing intervention delivery fidelity (as discussed in Chapter 6).

PPI and stakeholder input into intervention development

In order to ensure that the intervention was acceptable and tailored to the needs of the target population, intervention development work was undertaken in the form of the establishment of Public and Patient Involvement (PPI) groups and a stakeholder consultation. A summary of the findings that were used to shape the intervention manual and HT training is provided below.

STRENGTHEN peer researcher input into intervention development

The research team have established a collaborative relationship with a local day service for substance use and alcohol rehabilitation which supports people with multiple and complex needs. The service had recently collaborated in extensive PPI activities for a trial of an intervention to support prison leavers with common mental health problems to achieve their goals (ENGAGER 2).[35] The research team attended the regular Monday morning group session in order to provide service users with information about the STRENGTHEN pilot trial and invite them to an introductory session to help them decide if they would like to be involved in advising about the development of both the intervention and the trial. It was at this stage that service users advised the research team that, due to the potentially sensitive nature of the topic, there should be separate groups for men and women. It was also seen as beneficial to the development of the intervention as potential gender specific aspects of content, implementation and delivery could be teased out in order to maximise acceptability for both women and men.

Group members were keen to adopt the title of ‘peer researcher’ that was used in the ENGAGER 2 PPI groups.[35] This helped them to both define their role within the project and put them on an equal footing within the team, with their expertise being their lived experience and understanding of the context within which the intervention would be delivered. The groups met on a bi-weekly basis for four months (with 2-3 missed sessions to take account of school holidays due to parenting responsibilities of some group members). Although there was some fluctuation in the attendance of both the men’s and women’s groups, a ‘core group’ of attendees emerged who attended the majority of peer researcher meetings (approximately 5 in the men’s group and 6 in the women’s group). This continuity allowed peer researchers to follow the development of the study and to witness how the outcomes of the previous meeting were implemented. Each meeting was two hours long, with a 15-minute mid-point break, and was facilitated by two members of the research team. Each meeting followed a schedule of activities to address issues regarding the design of the intervention and/or the research, with

flexibility to discuss other topics that peer researchers raised as relevant to the intervention/research. The start of each group involved a catch-up on progress with the pilot trial and, as the groups progressed, how the advice that the group had provided during the last meeting had been used and implemented. It was clear that these updates of how the work of the group had been utilised were key to maintaining engagement by showing the changes and progress with the study to which the peer researchers contributed.

The PPI groups contributed to the intervention in terms of its conceptualisation, content and practicalities of delivery. Each of these will be dealt with in turn with reference to the contribution and changes made by the groups and illustrative quotes from group meetings where appropriate.

Conceptualisation:

Title and logo: peer researchers saw it as important that the title of the intervention was one which both attracted potential participants and encapsulated the meaning of the intervention. Both the men's and women's groups discussed the aims of the intervention and what these meant to them. Both the men's and women's groups were keen to capture the notion of building futures on firm foundations. The men's group generally used building analogies ('firm foundations'; 'scaffolding') and the women's group used more analogies from the natural world ('trees'; 'strong roots'). Both groups posited that the intervention title should provide the feeling that it would support participants to build their own strength, laying down firm foundations for a healthier future.

> *"It's about strengthening people so they can take control."*

> *"For some reason in my mind I've got a picture of a tree. You've gotta start with your roots, haven't you? So you get your group going, your roots. Then a few sessions, the trunk will get stronger and stronger and stronger and then the ideas come and branch out and hopefully if it works, it will bear fruit."*

The outcomes of the peer researcher discussions were delivered to the wider team and an art and photography student from a local school who was on work experience in the Community and Primary Care research team. A range of title options were developed and presented to the peer researchers, who decided that the intervention would be best represented by the word 'strengthen', with the tagline, 'Firm foundations for health and wellbeing'. The work experience student was provided with anonymised quotes from the peer researcher discussions and provided two draft logos: the first, an outline of a human head with a tree-like structure formed of dendrites within the head, with roots at what would be the brain stem,

representing growth and change, and the second, a version of a human figure in the yoga 'tree' pose, to represent strength and wellbeing. Both the peer researcher groups and the research team chose the former logo as that to be used on all trial, intervention and promotional/dissemination materials for the course of the pilot trial.

Practicalities of delivery:

Peer researchers discussed a range of practical issues and potential solutions that could encourage both initial participation and intervention engagement that were included in the HT training.

Location: It was put to the groups that, where risk assessment outcomes allowed and at the preference of intervention participants, that HT sessions could be held in locations other than the NPS or CRC offices where participants were initially recruited. Peer researchers provided a range of options for suitable locations in the local area which provided a basis from which to work on for the Plymouth HTs and categories of location types (cafes, rooms linked to key services, etc.) to locate for the Manchester HTs during intervention set-up. It was considered by both groups that the option of attending sessions at a location that was local to participants or somewhere 'friendlier' than the probation offices may remove a potential barrier to participation and engagement. It was therefore decided that following the initial HT session in the probation offices and confirmation of risk level with the OM that participants would be given the option of meeting at another agreed location. The women's group also stated the importance of provision for children at session locations. One woman who had experience of prison sentences advised that some women who have recently been released from prison could be subject to orders stating that other people are unable to take care of their children, which would necessitate children being present during sessions.

Mode of delivery: Peer researchers felt that in-person sessions would be more personal than sessions delivered over the phone, talking about the more personal aspect of meeting face-to-face, developing empathy and picking up on body language. They also saw it as important for participants to have human contact and not, as they put it, 'talking to another machine'. Peer researchers were clear that all first intervention sessions should be in person, with participants being able to choose if subsequent sessions were delivered in person or by phone.

Contact: Peer researchers agreed that phone was generally the best way to contact people. Peer researchers suggested that informal, between-session contact via phone call or text, for example, providing information linked to a goal or enquiring after them following an appointment/event, to be important in terms of developing trust. Members of the women's

group said that they would not answer a telephone call if it was from a number that they didn't know and so suggested that HTs and researchers should send a text first saying who they are first. Female peer researchers also suggested that some women in abusive relationships would have their text messages read and phone calls monitored and that HTs should be mindful of this when sending messages and making phone calls (not to leave messages with anyone else answering the phone/asking if they can talk when making calls).

Building trust

Building trust and rapport with participants was seen by peer researchers as essential in ensuring effective delivery of the intervention. Peer researchers discussed their own and others' negative interactions with a range of services and also, the type and impact of positive interactions with services with whom they had worked well. The groups were clear that HTs should make building trust a priority and not launch straight in to supporting participants to identify target health behaviour(s). It was viewed as important that HTs were non-judgemental and understand the difficulties and barriers faced by participants in their interactions with other services. The groups described balancing being professional with being a friend. The women's group in particular talked at length about the importance of HTs showing that they care and provided a range of ways in which they could do this, for example, by taking the time to listen; following participants up in a non-judgemental way if they do not attend an appointment; in-between session texts during difficult periods/trigger times. They also suggested that rather than immediately asking how participants had got on with their goals at the start of a session, the HT should ensure that they spend some time asking how the participant has been, to ensure that it is clear that the session is focussed on them as a person.

The importance of trust and ways in which HTs could achieve this was included in both the intervention manual and the training. It was made clear that the first 2-3 sessions should be focussed on developing trust and getting to know the participant before moving on to focus on identifying and working towards goals.

Stakeholder input into intervention development

LC interviewed eight stakeholders from a range of related HTs and CJSs in order to identify any changes/adaptations that needed to be made to the intervention in order to meet the needs of the population and deliver the intervention in the current context. Roles included management and delivery of a similar HT intervention in probation services; practitioners with a remit of providing wellbeing and housing services with a particular focus on women; a court advice and support service; a community-based support worker working alongside custody liaison and diversion workers and a signposting and support service that worked in

collaboration with the CRC and other key services. Most of these services were located in the Southwest of England, with two participants located in the South Central region. As the second site had not yet been identified and secured at this stage, it was not possible to include services from this area. Interviews had a focus on understanding the facilitators and barriers to working with men and women in the CJS, and in particular, under community supervision; experiences of supporting clients to change health behaviours and mental wellbeing; the process of goal-setting used with clients; mode and frequency of contact and how they worked with clients to support initial and ongoing engagement; what works well and what does not work so well in supporting clients to change their health behaviours and improve mental wellbeing.

Interviews were transcribed verbatim and analysed using thematic analysis. A summary of emergent themes is included below:

Challenges to behaviour change:

Some of the challenges to health behaviour change included, managing concurrent mental health needs of clients with little support available, low confidence to make changes, and difficulties of taking ownership. A large proportion of services to which HTs can signpost a client in order to support behaviour change are delivered in a group format which it was perceived is often not acceptable to clients. It was also viewed that clients perceive activities to support behaviour change as expensive. Returning to prison was seen as a particular challenge with working with this client group, as well as returning to old patterns of behaviour.

Behaviour change facilitators:

- Trust and rapport with clients seen as key to effectively supporting behaviour change; achieving something for the client (no matter how small) so *'they feel quite positive about what you can do'*;
- Focussing on the positive during sessions, *'I mean, the more that we turn things into a positive the better with this client group…because they're always, you know, talked at in a condescending way'*;
- Helping clients to see the relationship between their goals, *'allowing them to see how kind of they can build a pathway really for themselves.'*
- Setting simple, achievable goals: '*and we do a lot around making sure that people achieve and that actually something that seems really, really simple is actually quite a challenge to some people. So they have very simple goals.'*
- Support to access free/inexpensive activities to support behaviour change, for example: '*I used to try and promote the outdoor gym…which is the cheapest gym I know, if you've got a dog, go for a walk, if you've got a pushbike, go and*

ride your pushbike…you know it's cheaper than the gym. Cause a lot of people I worked with were on a very low income.'

- Clients supported to set their own goals, not goals decided by the HT*: "It's better to get people to set their own goals…because they're more powerful if it's your own goal."*

Challenges to conducting the role:

- Location of the service and perceived oppressive environment of CJS premises: *"But a lot of people say, oh, I'm not going in there, I'm not…you know, yeah, you might be lovely and all the rest of it, and give me what I want, but I'm not walking through that door."*
- Limited time within sessions to build trust and rapport: *"just everything from really getting to know people well. Erm, and that takes time. Erm, and that suffers when we have, you know, a very busy session."*
- Being seen as part of the probation service: *"So working for a charity we've worked alongside probation very closely and then we get seen as probation by the client, and so we get kind of lumped as oh yeah, just part of the authorities…I've been told, you know, you're just one of them."*
- Difficulties in keeping in contact via mobile phone: "even the ones I work with now, um, don't have mobile phones cause they've probably sold it to buy drugs or more alcohol."

Facilitators to conducting the role:

- Getting to know the client: *"so before we did anything about what they actually wanted me to help them with, we'll have a chat about the footy at the weekend…but then you, you get to meet people…and people come in just for a chat…and then I think you're broken most of the barriers then…"*
- Networking with other services for effective signposting/advice: *"and they're much more likely to help you I think than if it's sort of, someone random that they don't know."*
- In-person contact is important for the client: *"I just think when you've met somebody and you've seen their face and you kind of, I meant they're quite short visits, you know, those initial ones, but you get, probably get a sense, a better sense of what the person can support you with."*
- Sharing with colleagues and team problem-solving: *"but it's also good to throw things around with people. People give you ideas, and people give you sort of advice and, and it's always good to have those conversations."*
- Reimbursement of travel expenses

- Building and maintaining a directory of organisations and resources

Findings from the thematic analysis supported writing of the manual and preparation of the training materials and structure. Direct quotes from both stakeholder interviews and PPI sessions were used as reflection points and to exemplify specific points throughout the manual and by doing so 'bringing the manual to life' by showing the practical application of key points.

The STRENGTHEN intervention

The STRENGTHEN training manual (see supplementary material 1) provides a detailed insight into the structure, delivery style, components, and content of the intervention.

The key components of the piloted intervention are:

1. A HT was available for one-to-one sessions over 14 weeks, in face-to-face or telephone format (frequency and length of sessions was negotiated with each participant). The face-to-face intervention sessions took place in a variety of settings, including probation services and other local community locations.

2. An initial invitation to engage with the HT was described as an 'open and flexible' opportunity to receive support for one or more of the target health behaviours and/or improving overall health and mental wellbeing through other activities including Connecting, keeping Learning, being Active, taking Notice and Giving (i.e. CLANG as part of the 5WWB).

3. HTs were trained to help participants understand the inter-relationship between health behaviours such as smoking, alcohol use, diet, physical activity and their relationship to mental wellbeing and other positive and negative behaviours, including substance use. Each participant was encouraged to develop a personal plan based on individual behaviour-change goals and motivation to improve mental wellbeing. Some participants had positive perceived mental wellbeing but engaged in risky behaviours, others were concerned about emotional distress. The intervention was intended to be flexible enough to support both these extremes.

4. The support was described as 'open' to reflect the planned underpinning and overlapping influence of Self-Determination Theory and the client-centred principles of Motivational Interviewing[36] central to the intervention. HTs avoided giving 'advice' and empowered clients to confirm the desire for change, and develop self-regulatory skills such as self-monitoring, setting action plans and reviewing progress. The intervention was tailored and led by the participants' needs.

5. The HT, informed by the 5WWB, helped clients to build positive behaviours (e.g. initiating and maintaining activities (physical, creative etc.)) and find opportunities for gaining core human needs (i.e. sense of competence, autonomy and relatedness), as well as learn and notice, to enhance mental wellbeing.

6. Any reductions in alcohol consumption (as units per week, alcohol-free days, or avoidance of trigger events, smoking (using different strategies)), [33, 37-38] and increases in physical activity and healthy eating were supported, with the underlying aim (not necessarily explicitly discussed with the participant) to build confidence to meet guidelines for safe alcohol consumption, to quit/reduce smoking, engage in daily/weekly physical activity, and healthy eating.

7. Participants were actively supported to gain help from friends and family, link with other community resources (parks, leisure centres) and services (e.g. Stop Smoking Services, Drug and Alcohol Treatment Service) as a part of achieving their personal plan, and exploring options for continued support after the intervention as appropriate.

Training the Health Trainers

Following the development of the HT manual, a training plan was developed which the training manual supported. The training consisted of various sections covering the key components of the intervention (see appendix 1). The training was delivered over three days at both sites, led by the intervention lead (TT) with input from key members of staff (LC, AHT) to support delivery. The training included multiple opportunities for feedback and discussion, as well as skills practice with staff and PPI representatives. Following the training, HTs were allocated up to three practice participants, who were recruited from the peer researcher groups as a way to develop real world experience of delivering the intervention.

Supervision of the Health Trainers

A supervision contract was drawn up (see training manual in supplementary material 1) outlining expectations of supervision sessions. Supervision sessions were led by the intervention lead (TT) and took place biweekly with both sites simultaneously via Skype. The supervision sessions began following the delivery of the intervention with practice participants. Supervision sessions followed a standing agenda, which allowed for discussion and feedback on specific cases, resolution of any difficulties HTs may have been facing, and allowed HTs to feed back any issues which they felt needed to be resolved. Issues included elements they felt were not working, or elements they felt would be a useful addition; these were fed back by

the intervention lead to the project management group who would decide if any changes were necessary as part of the formative process evaluation. Audio recordings of sessions were also reviewed within some supervision sessions and linked back to the core competencies.

Chapter 3: Trial design and methods

Study design

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 CRCs in the Southwest and Northwest of England, and through the NPS in the Southwest only. Participants were only recruited through the NPS at one site to test the feasibility and acceptability of recruitment and engagement of those classified as presenting a high risk of serious harm to researchers or HTs. Follow-up assessments were carried out at 3- and 6-months post-baseline data collection. Ethical approval for the study was granted by the Health and Care Research Wales Ethics Committee and the former National Offender Management Service (OMS), now Her Majesty's Prison and Probation Service (REC Ref: 16/WA/0171 NOMS Ref: 2016-192.

Eligibility criteria

Participants had to satisfy the following criteria to be enrolled on the study:

- Males and females aged 18 years or older
- Currently receiving community supervision
- Have a minimum of 7 months left of community sentence/supervision
- Have 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 wellbeing
- Willing and able to take part in a pilot randomised controlled trial with follow-up assessments at 3 and 6 months
- Residing within the geographical areas of the study.

Exclusion criteria were as follows:

- Present a serious risk of harm to the researchers or HTs
- Unable to provide informed consent
- Disrupted/chaotic lifestyles that may have made engagement in the intervention too difficult.

Sample size

A recruitment target of 120 participants was set, across the two geographical regions (with the aim of recruiting 60 participants per region). Following consultation with the Trial Steering Committee, the decision was made for a 60:40 men to women purposive sample, to inform understanding of the experience of women in the CJS. Women make up a smaller proportion of those under community supervision, and represent a small number of the total prison population (Ministry of Justice, 2016).[39] However, the aim was to over-recruit for women in attempt to avoid losing that understanding of experience through proportional sampling.

This pilot study was not powered to detect between-group clinically meaningful differences in the proposed primary outcome. Therefore, the target sample was primarily set to assess the feasibility objectives of the study, and to inform sample size calculations for a planned definitive trial. When data from a pilot study are required to estimate the standard deviation of a continuous outcome, to maximise efficiency in terms of the total sample size across pilot and main trials, the recommendation is that a two-group pilot study should have follow-up data from at least 70 participants (i.e. 35 per group).[40] As most participants would remain engaged with the probation service for the length of the trial, it was anticipated that retention would be reasonably high. A recruitment target of 120 participants, based on an assumed non-differential retention rate of 75% at 6 months, in an aim to obtain follow-up outcome data on a minimum of 45 participants in each of the allocated groups, across both regions. A retention rate of 60% would still provide sufficient data for planning the future trial.[40] Local services suggested that over a 3-month window, there may be 20-30 ex-offenders entering each of the two local community supervision systems per week. It was estimated that around 10% would decline to participate in a baseline assessment[10, 16, 41] and a further 20% would be found to be ineligible following the baseline assessment. Based on recruitment rates from other probation trials,[10] it was estimated that around 50% of eligible subjects would consent to participate.

Recruitment

Recruitment for the study was over a 14-month period between October 2016 and December 2017; initially the planned recruitment period was a 3-month period from October-December 2016. This is discussed in more depth in the Results chapter. There were two pathways to participant recruitment: (1) via the CRCs and NPS; and (2) via community organisations including drug and alcohol rehabilitation centres, homeless hostels and day centres (in the Plymouth site only) (see figure 1 below). Recruitment via community organisations was introduced as an attempt to reach those not engaging regularly with the CRC or NPS services.

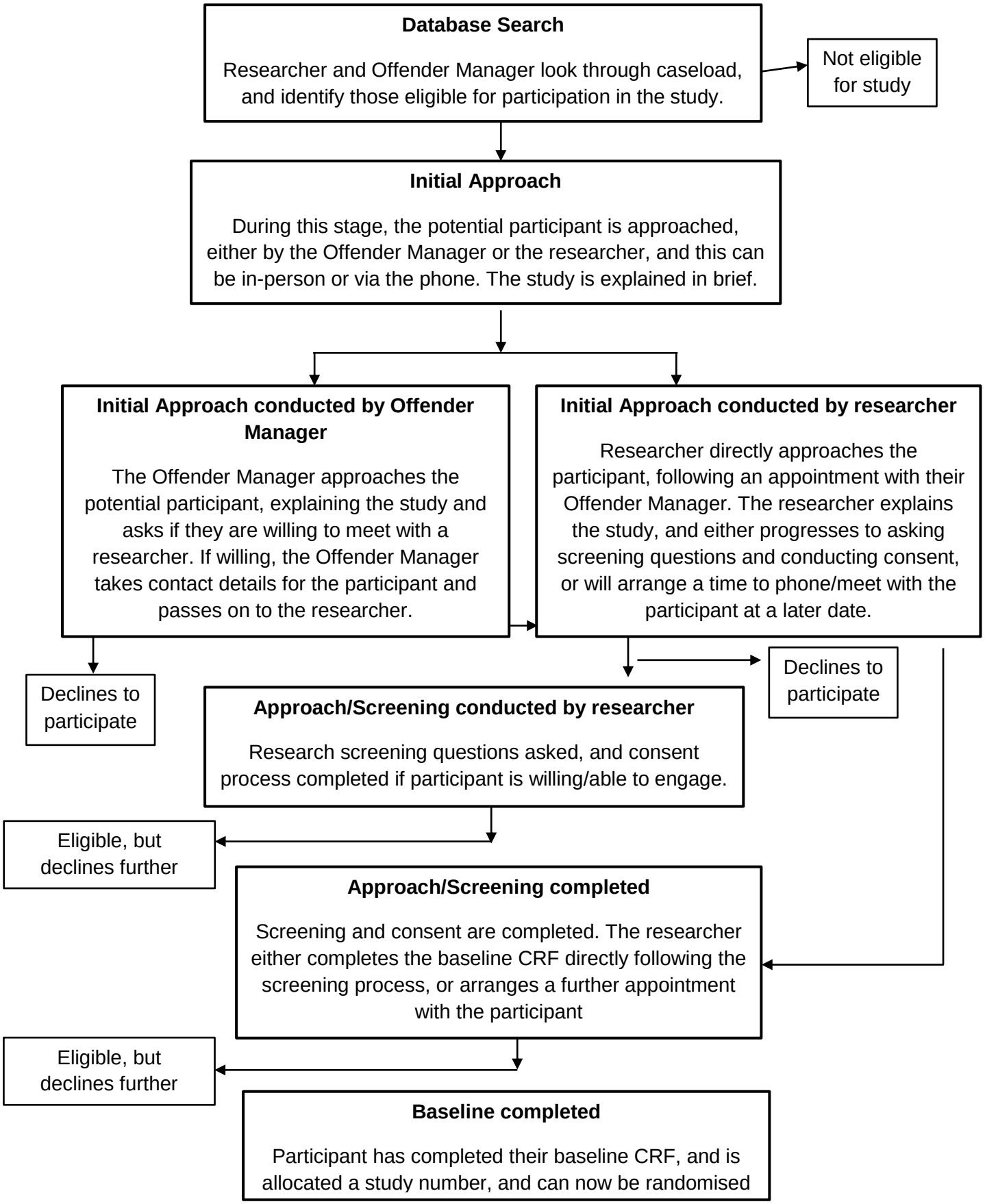


Figure 1: Participant pathway to recruitment

Initially, a single point of access (SPOA) administrator was identified for both the CRC and NPS. The SPOA administrator identified potential participants using the nDelius record system for both services. The Offender Managers (OMs) of identified individuals were then consulted by the researchers for screening for inclusion/exclusion criteria and assessment of risk. Further into the study, a decision was made to alter this process, with researchers helping the OMs to screen caseloads (i.e., sitting alongside them but without visibility of personal information), to maximise efficiency and reduce overall staff demand (see supplementary materials 3 for documents related to the screening process).

Those individuals who were assessed as eligible for participation in the research were initially approached by their OM, who explained the study, and asked if clients would be interested in speaking to the researcher, either: directly after their appointment (when researchers were available), at their next scheduled appointment, or via the telephone. On receiving verbal agreement to approach the client, the OM facilitated this meeting, providing an introduction. All participants were given the opportunity to meet the researchers for the initial appointment at the CRC/NPS offices.

Recruitment via community organisations

Identification of participants through community organisations involved key staff (e.g. Day Centre managers) initially approaching potential participants and inviting them to talk to a researcher about the study. On receiving verbal agreement to approach, the researcher made a time and date for a meeting, to explain the project in more detail. The consent form (see recruitment documents in supplementary materials 4) for potential participants identified through the community organisations requested consent for the researcher to make contact with their OM, to establish whether the individual met criteria for participation in the study. Following positive assessment by the OM, the researcher made contact with potential participants to arrange a time to conduct baseline data collection. If the OM assessed the potential participant as not meeting the inclusion criteria, the researcher made a time to explain to the individual why they were unable to proceed with the study.

Participant approach by researcher

During approaches, at both the CRC/NPS and community organisations, the researcher explained the study, presenting information from the participant information sheet (see supplementary materials 4), including the potential time burden for the participant. Emphasis was placed on ensuring the potential participant fully understood the concept and implications of randomisation, the voluntary nature of the research, and their right to withdraw without detriment to their care or legal rights. Confidentiality (including reasons for a breach of

confidentiality) and data protection were also presented at this stage. Potential participants were given the opportunity to ask questions, and discuss their involvement in the study. All participants were asked if:

- they were willing and able to receive support to improve one or more of the target health behaviours and/or improve mental wellbeing if randomised to the intervention;
- they were willing and able to take part in a pilot RCT with follow-up assessments at 3 and 6 months.

If the individual expressed further interest in taking part in the study, the researcher progressed with the informed consent process, in which both the participant and researcher signed two copies of the consent form (see supplementary materials 4) (one retained by the participant and one by the researcher). If the participant expressed a need for time to think about their involvement, the researcher arranged a later date and time to contact the individual, to discuss whether they wanted to continue with the study. Individuals who were unwilling or unable to proceed were thanked for their time and reminded that there were no negative consequences for not taking part.

When the consent form was completed, the researcher continued with the baseline data collection during the same appointment, if the participant was happy to proceed, or made a further appointment for baseline data collection. In addition to the baseline data assessment, the researcher completed a contact form (see supplementary materials 4) for each participant, noting contact numbers and addresses, as well as any key services they were engaging with. The participant signed this form, to confirm their permission for the research team to contact the participant via relevant services.

In regards to the consent process and data collection, individuals who lacked capacity on a particular day (potentially through intoxication), were given additional opportunities to complete assessments, before being deemed to be ineligible to proceed. Given the often challenging and chaotic lives that this population can present with, this flexibility was particularly important.

Randomisation and concealment

Allocation to intervention or control group was 1:1 and used a minimisation algorithm with a random element, to ensure balance between allocated groups with respect to age, gender and recruitment region.

On completion of the screening interview and baseline data collection, the researcher entered participant details, and confirmed they had completed the baseline case report form (CRF), onto a password-protected web-based randomisation system set up and managed by the Peninsula Clinical Trials Unit (PenCTU). The participant would then be allocated a unique randomisation number, and the participant's allocated group (STRENGTHEN Intervention or Control) was then sent to the trial administrator via email. To maintain blinding of the RAs, the website would confirm that the allocation process had been successful, but would not display the participant's allocated group. HTs would contact participants (via telephone) who had been allocated to the intervention arm of the study, and arrange an initial date/time to meet. Participants allocated to the control group were contacted by telephone or in person at CRC/NPS offices by either a HT or a research administrator, to maintain RA blinding. The conversation included a discussion of the randomisation process, to ensure the participant had understood what group they had been allocated to.

Blinding of the researchers was tested for feasibility, to see whether it would be possible in a definitive trial. Researchers were asked to record instances where they believed they had been unblinded within the baseline, 3- and 6-month CRFs. We recognised from pilot work in our ENGAGER trial that concealment of trial arm may be very difficult since the RA mostly conducted the follow-up assessments within the offender management service (OMS) and OMs or participants themselves may mention their involvement in the intervention in passing.

Data collection

Proposed outcome measures were collected at baseline (at or shortly following recruitment) and 3- and 6-months post-baseline. Six months is the proposed primary assessment point for the future definitive trial (see supplementary materials 5 for documents related to data collection).

Baseline data collection

The researcher typically continued with the baseline data collection following screening; however, additional sessions were arranged to meet the needs of individual participants. Detail of demographic data, as well as primary and secondary outcome measures collected at baseline is provided below. Baseline data collection was delivered using a narrative conversational format developed in previous studies.[10] For the proposed primary outcome, the WEMWBS, participants were given the option to complete it themselves or have the researcher read responses aloud (method of completion was recorded). Questions from other measures were incorporated into a constructed, flexible script that avoids duplication to minimise disengagement.

On completion of the baseline assessment, the researchers discussed the 3- and 6-month follow-ups with participants, and agreed the best way to contact the participant for that appointment, depending on a range of scenarios, and changes to modes of follow-up, including any new mobile telephone numbers.

3- and 6-month data collection

Researchers contacted participants to arrange a time and date to complete the 3- and 6-month follow-ups. Contact ranged from initial text messages, to phone calls and letters (where consent had been given). Where researchers struggled to re-contact participants, OMs were approached for information, and to engage participants at appointments, asking if they were willing to meet with the researcher. Researchers arranged to meet with participants either in the CRC/NPS offices, or at a suitable location in the community. Where possible, assessments were conducted in the premises of services that participants were engaging with, in order to minimise risk to researcher. Where this was not possible, researchers adhered to the project Lone Working policy (see safety documents in supplementary materials 6), and used buddies as an additional safeguard if required. Data collection could be completed via a phone call, but preference was for face-to-face appointments, to support continued engagement with the study.

Prior to the follow-up assessment being conducted, the researcher reminded the participant of the contents of the information sheet and consent process, drawing attention to data confidentiality and instances of disclosure where the researcher would need to breach confidentiality. Identical measures to baseline were collected for 3- and 6-month assessments, with the exception of ethnicity, to avoid unnecessary duplication/participant burden.

Feasibility and acceptability questions

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

- proportion of eligible participants
- 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 study procedures (e.g. blinding, randomisation) to participants.

Proposed primary and secondary outcomes

The proposed primary outcome for the definitive trial was the WEMWBS, to measure subjective mental wellbeing, which has good psychometric properties.[42] The short Warwick and Edinburgh Mental Wellbeing Scale (SWEMWBS) was subsequently calculated for the purposes of possible future interest.[42]

Secondary outcomes were:

- Self-reported smoking (n cigarettes smoked per day)
- Fagerström Test for Cigarette Dependence
- Alcohol use (AUDIT)
- Diet (Dietary Instrument for Nutrition Education [DINE])
- Physical Activity (7-day recall physical activity questionnaire)
- Substance use (Treatment Outcomes Profile [TOPS])
- Confidence, importance, access to social support, action-planning, and self-monitoring measures relating to health behaviours
- Health related quality of life (EQ-5D-5L, SF-6D (derived from the SF36))
- Intervention costs (related to HT time, training, supervision, travel, consumables)
- Health care, social care, and other resource use data was collected using a participant self-report resource use questionnaire (RUQ)

The above secondary outcome measures were selected as they link on to the four health behaviours, and were rated as acceptable to participants during the PPI consultation stage.

Summary of process evaluation methods

The aims of the process evaluation were to:

- assess whether the intervention was delivered as per manual and training;
- ascertain components of intervention which are critical to delivery;
- explore reasons for divergence from delivery of intervention as manualised;
- understand when context is moderating delivery;
- understand the experience and motivation of participants in Control arm of pilot in order to maximise retention in a full trial;
- explore reasons for declining to participate in the trial;
- explore reasons for disengaging in intervention before an agreed end;
- understand, from a participant perspective, the benefits and disadvantages of taking part in the intervention.

Data collection:

Semi-structured 1:1 interviews

1:1 semi-structured 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)
- HTs across both geographic regions (n=6)
- OMs/Probation workers across both geographic regions (n=6)

Interviews were guided by semi-structured interviews schedule (see supplementary materials 7). All interviews were digitally audio-recorded and transcribed verbatim.

Discussions with decliners

Researchers asked up to four potential participants who declined to take part following screening as to their reasons for not continuing with their participation. The researcher was sensitive to the right to withdraw from the study without providing a reason and did not question the potential participant further should they decline to divulge their reason for discontinuation. These discussions were not recorded but notes were taken to inform the PE.

Digital audio recordings of HT sessions (n=20)

HTs were asked to record sessions with participants. Choice of sessions to record were a collaborative decision between the HT and the research team based on appropriateness (assessed by the HT) and data required (assessed by the research team and guided by their knowledge of each case through HT session report forms). All participants were asked for their consent for sessions to be recorded at the start of the intervention. However, HTs were requested to seek verbal consent to record each session prior to recording.

HT session report forms

HTs kept an electronic record of each session on the bespoke intervention section of the data management system. Each contact and session was recorded including information on: date, location, duration, type (face-to-face or by telephone), subsidies taken up by participant, primary and secondary goals of participant, goals met (if applicable), and any particular difficulties encountered for discussion in supervision.

Analysis

Intervention fidelity was assessed through the scoring of audio recordings of HT sessions against a developed list of key intervention processes, or the six core competencies detailed in chapter one ((1) active participant involvement; (2) motivation-building; (3) goal-setting; (4)

reviewing efforts to make changes & problem-solving; (5) integration of concepts and (6) engaging social support an managing social influences). These were scored on two domains: practitioner adherence to the core competencies outlined in the intervention manual, and competence of delivery. Recordings were scored independently by two researchers.

Quantitative data were summarised descriptively, with confidence intervals as appropriate.

Any factors which are identified as possibly contributing to participants' intervention engagement, and trial recruitment and retention will be explored in more detail in the qualitative data. All data were organised using NVivo 11 software.[43] Data related to feasibility and acceptability of trial method and the intervention were analysed using thematic analysis. Interview data and session notes were synthesised into a Framework Analysis grid to understand the experience of participants in receiving the intervention in order to understand how the intervention works in practice and the components of the intervention that are critical to delivery. This will allow the feasibility and acceptability of the intervention, the intervention delivery and the research data collection to be assessed. Any procedures which need to be adapted will be identified and, potentially, improvements and solutions will be suggested.

Statistical analysis

A detailed statistical analysis plan (SAP) was written by the trial statisticians and approved by the Chair/Independent Statistician on the Trial Steering Committee (SAP version 1.0 dated 8 June 2018) prior to trial database lock.

Analytical approach

Analyses were undertaken in accordance with the CONSORT extension for randomised pilot and feasibility trials.[44] Primary analysis (in the form of summary statistics, not formal/inferential analysis) was undertaken on an Intention To Treat (ITT) basis, where participants were analysed according to their allocated group, regardless of adherence to the protocol or lack of participation/engagement if allocated to the intervention group.

Statistical significance levels

As this was a feasibility trial, no inferential between-group comparisons were undertaken (i.e. there was no between-group hypothesis testing). Where presented, confidence intervals are at the 95% level, unless otherwise stated.

Interim analysis

There was no planned interim analysis for this trial.

Time points of statistical analysis

Statistical analysis was undertaken once the final group of participants completed the final assessment and the database was locked following final approval and sign-off of the statistical analysis plan by the Trial Steering Committee.

Missing data

One of the objectives of this feasibility trial was to assess the completeness of potential outcome measures for the definitive trial, at the level of both item and outcome measure. Missing outcome data were noted and used to inform the likely pattern of missing data in a full scale trial.

Imputation methods

No imputation of missing values was undertaken with the exception of missing values in the proposed primary outcome, WEMWBS: the established method for imputing missing item-level data was implemented, when participants were missing between one and three items on this scale.[42]

Statistical software

The statistical analyses were undertaken using StataSE version 14, supplemented where required by R.

Trial population

Data from the screening process through to the completion of the trial was recorded and presented in a CONSORT-style flow diagram.

Participants who discontinued, withdrew or were lost to follow-up

It was possible that participants would withdraw consent part-way through the trial. Participants who discontinued were categorised as follows:

- Continued to consent for follow-up and data collection
- Consented to use pre-collected data only

Reasons for withdrawal or loss to follow-up were summarised where reported, at each stage of the process, including withdrawal prior to randomisation and lost to follow-up.

Participants who withdrew from the trial were not replaced. The extent of discontinuation, withdrawal and loss to follow-up will be used to inform the design of the anticipated fully-powered trial, predominantly to ensure a sufficiently powered trial after allowing for losses to follow-up.

Statistical analyses

As this was a pilot trial, it was not powered to be able to support or justify any conclusions regarding intervention effectiveness realised from hypothesis testing,[45] and indeed that was not the purpose of the trial. As such, the analysis of the results did not involve formal/inferential statistical comparisons between groups, but rather was descriptive with the view to informing the design of a fully powered definitive trial.

Continuous measures were summarised as means, standard deviations, ranges, medians and inter-quartile ranges. Categorical data were summarised by frequencies and percentages. Where appropriate, parameter estimates (e.g. between-group differences) are presented with 95% confidence intervals.

Baseline characteristics and measures, collected prior to randomisation, were summarised by allocated group to informally check for balance between groups and provide an exploratory overview of the trial sample. Analysis of randomised groups at baseline is not good practice[41] and so was not undertaken, but we considered imbalances to assess the efficiency of the randomisation procedures.

Analyses of quantitative data were conducted to summarise feasibility outcomes, evaluate engagement with the STRENGTHEN intervention, and the completion of the planned primary and secondary outcome measures. Summary statistics were calculated for each of the outcome measures at each time-point. Between-group differences in WEMWBS at 3- and 6-month follow-ups were calculated, together with 95% confidence intervals (no p-values are presented). The correlation between baseline and follow-up WEMWBS scores was calculated across all participants with available data, with corresponding confidence intervals, together with upper confidence limits for the standard deviation of WEMWBS, to inform sample size calculations for future trials.

Cost-effectiveness and data collection

The pilot study aimed to estimate the resource use and costs associated with the delivery of the intervention, and develop a framework for estimating the cost-effectiveness of the STRENGTHEN intervention plus usual care, versus usual care alone, in a future economic evaluation alongside a fully powered RCT. We aimed to develop and test economic evaluation methods for the collection of resource use data, for estimating related costs, and also the collection of outcome data appropriate for economic evaluation. Full details of the methods used are presented in Chapter 5.

PPI input to trial methods

The peer researcher groups introduced in Chapter 2 reviewed and discussed trial methods including the following:

- Participant information sheets and consent forms
- Semi-structured interview schedules
- CRFs and associated data collection

Both peer researcher groups reviewed the information sheets and consent forms for both the pilot trial and process evaluation. The first drafts reviewed were adapted from ENGAGER 2 information sheets and consent forms that themselves had been reviewed by the ENGAGER 2 peer researchers. Peer researchers provided guidance to adapt wording and order of text to aid comprehension and to ensure that the main points of the study and requirements for participation were clear.

The first draft of the CRF was given to each of the peer researchers (literacy levels had already been assessed by researchers). Over three weeks, peer and trial researchers role-played each of the measures in pairs or threes as appropriate. It was made clear that peer researchers did not need to answer honestly but could play a role in order that they did not have to disclose any confidential or sensitive information. Peer researchers both discussed the measures in turn and/or annotated drafts and gave them to the trial researchers. Each of the issues raised by the peer researchers in relation to the CRF are detailed below, with reference to the changes made, where applicable.

- Removal of the PHQ-9: The original STRENGTHEN CRF contained the PHQ-9 (measure of depression). Peer researchers questioned the use of the PHQ-9 for a study whose primary outcome was mental wellbeing as opposed to mental illness. They were particularly concerned about the impact that some of the items may have on participants who may be experiencing challenging life circumstances and potentially have mental health needs when it was not in a therapeutic context. As one of the peer researchers stated, "*if someone was just starting a recovery journey, they may not be in a stable headspace and question 6 could be triggering*." The trial researchers took this issue back to the project team meeting who supported the PHQ-9's removal from the CRF as the collection of this outcome was not critical to the aims of the pilot trial.
- Simplification of response format: There was some concern among peer researchers that some of the formats by which participants could respond to items were complex and in some instances provided too nuanced a set of choices. It was explained to the

peer researchers that in the case of validated measures that the responses could not be amended. However, for the measures included to capture confidence, control and connectedness in relation to changing each of the target health behaviours, where there was originally a 9-point scale, this was amended to a 7-point scale on the advice of the peer researchers. Also on the advice of the peer researchers, in order to assist participants in making the appropriate response to the items contained within the validated measures, the researchers produced laminated A4 ‘answer cards’ that contained the options required for each item.

- Understanding of item choice: Peer researchers noted that some of the items could be perceived as sensitive by participants and that it was not always clear as to the rationale for including all of the measures. It was therefore agreed that the research team would add a short paragraph or script for researchers at the start of each measure to explain why they were asking the items contained within each measure.
- Wording of items: Similar to response format above, peer researchers were aware that the wording of validated measures could not be amended. Concerns were particularly raised about what were considered Americanisms in the SF36, e.g. ‘blocks’ and ‘pep’. For items such as this, the peer researchers provided alternatives to aid participants’ comprehension that researchers could use.
- Order of measures: in the first draft of the CRF, the WEMWBS and the items related to offence history were at the start of the booklet. Peer researchers felt that it would be best to start with generic questions before asking those that could be considered more personal. They understood the need to order the WEMWBS near to the start of the CRF to ensure that this was collected if a follow-up appointment was unexpectedly cut short. It was therefore agreed between the peer researchers and the research team that this would be presented after demographic measures and that offence data (considered particularly sensitive) would be collected after measures of target health behaviours.

Chapter 4: Results

This chapter reports on:

- Participant recruitment
- Study attrition and associated factors
- Baseline participant characteristics for the total sample and by allocated group
- Outcomes (e.g., WEMWBS, health behaviours) over time, by allocated group
- WEMWBS descriptive data at follow-up, by allocated arm and CRC/NPS
- Intervention engagement
- Association between intervention engagement and WEMWBS at follow-up
- Factors associated with intervention engagement
- Other methodological considerations
- Indicative sample size calculation for definitive trial

Brief overview

A number of barriers to recruitment were overcome, such as taking on Manchester instead of Southampton as a second site at a late stage (and putting the resources and governance processes in place), and working with OMSs while they were becoming established and overcoming their own challenges. A great deal was learnt about participant flow into the trial and the reasons for excluding those in the service and after having been approached. Having recruited our target of 120 participants, we are now in a strong position to estimate the resources required to recruit participants.

Study attrition was initially around 50% but with improved processes throughout the pilot trial this was improved to 60% overall, which partly met our 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.

The characteristics of sample were described and overall had low levels of wellbeing, unhealthy lifestyles, particularly with respect to diet, alcohol and smoking, and were from low socio-economic backgrounds.

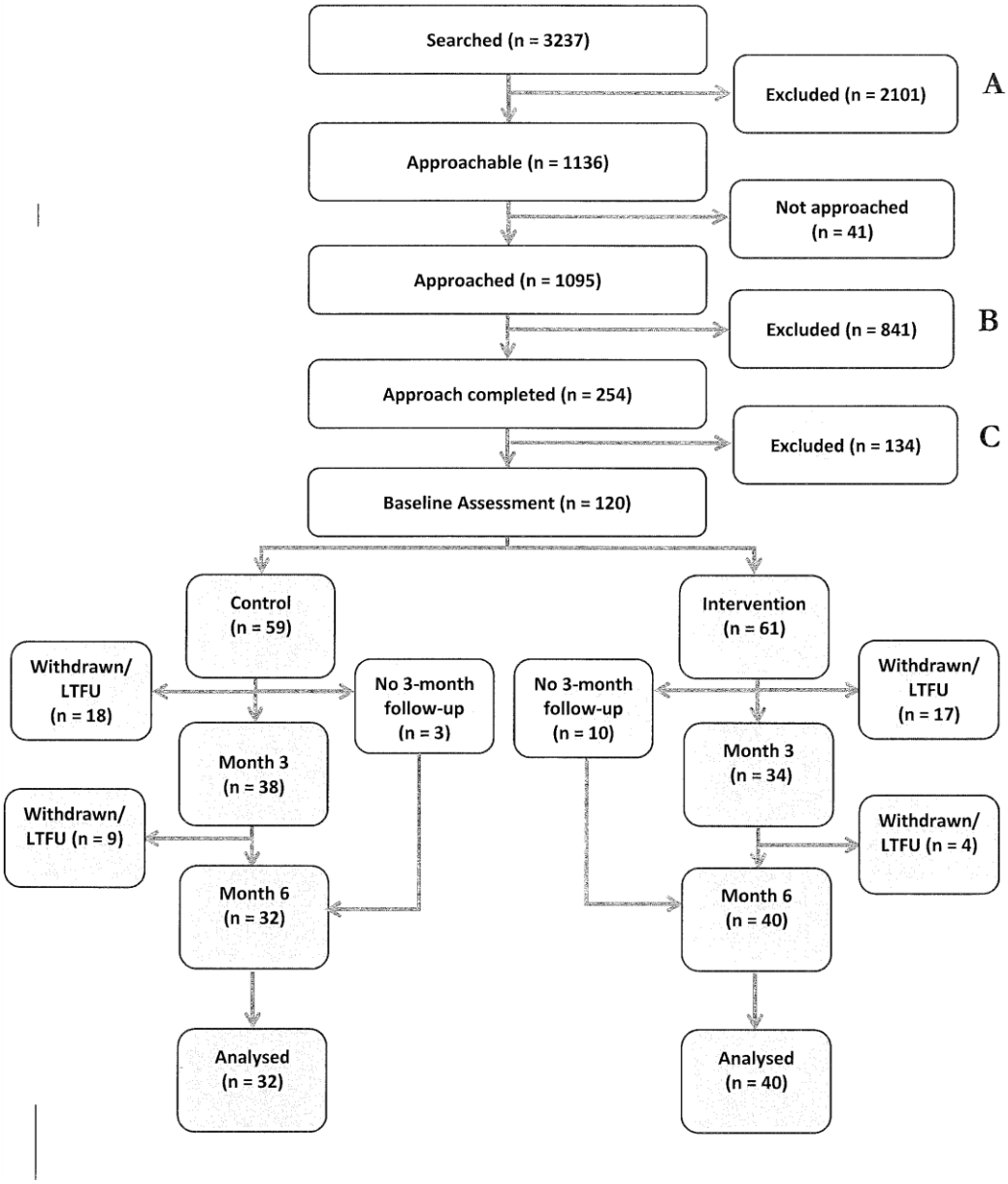
It was not an aim of the study to detect statistical significance between group differences but the reported values for the main outcome variable, WEMWBS, at 3- and 6-month follow-up indicated some differences in favour of the intervention arm from which to provide estimates for a sample size calculation 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 compared with the control group. Data for all measures was generally complete because assessments were mainly conducted in face-to-face mode. Those who had moderate (2-5) intervention sessions appeared to have higher WEMWBS scores at follow-up, compared with those who had lower and higher engagement.

Overall, 28% of participants did not attend any sessions, and 62% had at least 2 sessions, which partly met our progression criteria. The overall mean (SD) number of sessions attended was 3.7 (3.4), with a median of 3.

Recruitment and retention of participants

The flow of participants through the pilot trial is shown in the CONSORT chart (Figure 2) for the whole sample recruited (i.e., N = 120) from identification to recruitment and randomisation through to completion of follow-ups at 3 and 6 months. Additional data on participant flow through the trial for each OMS are shown in Appendix 2 (Figures 5, 6, & 7).



Note: Reasons for exclusions (depicted by A, B and C) are listed in tables
LTFU = Lost To Follow-Up

Figure 2: Flow of participants through the trial (CONSORT)

Table 1 shows reasons for exclusion at Step A (determined by the service), B (from initial screening by the researcher), and C (from further screening or events prior to randomisation by the researcher). Appendix 3 shows the flow of participants through the study for the respective services/sites (i.e. Plymouth NPS and CRC, and Manchester CRC).

Chapter 3 provided details on the processes for recruitment from the OMSs, including the inclusion and exclusion criteria.

At Step A, OMs excluded those who clearly did not meet our inclusion criteria. As Figure 2 shows, of the 3237 people considered in the initial search, 2101 were excluded at Step A. Table 1 shows the reasons for excluding participants across all sites at Step A. In some cases, researchers included multiple exclusion reasons for individual potential participants, hence there being a greater number of exclusions detailed in table one (n= 2,127). Most (77%) of the exclusions (n=1,620) were related to 'risk', 'inability to engage', and timing and duration of the sentence. The remaining 23% (n= 481) were excluded for other reasons as shown. "Unable to engage" includes the following: Doesn't see OM (e.g. because they are doing unpaid work); next appointment would be after trial recruitment ends; warrant out for person's arrest; person in a care home. "Mental health barriers" includes those who were considered inappropriate to approach due to fragile emotional states.

Table 1: Reasons for exclusion and related number of participants at Step A

Reason	Number excluded
Risk	55
Inability to engage	43
Less than 7 months to serve after search	883
Release date 2 months before search	665
Other reasons	481
- **Back in custody/court**	279
- **Repeat screen**	113
- **Unable to engage**	37
- **Moved out of area**	35
- **Missing person**	7
- **Mental health barriers**	5
- **Passed away**	1
- **Unknown**	4

At Step B, the OM and researcher made contact (or not) with the potential participant, and excluded those who did not meet our inclusion criteria (e.g. level of risk, timing and duration of community sentence, not interested in being in the study). Across all sites, of the 1095 approached, 841 were excluded for the reasons shown in Table 2. In a full trial, we would

make minor changes to the way these were recorded as it took many hours trawling through records for reasons which had not been recorded on the CRF or were complex due to delays which subsequently meant a person was no longer eligible due to having less than 7 months remaining of their community sentence. Among the 'other reasons', "Conflicting commitments" includes those who worked full-time or unsociable shifts, those studying or those with other significant service engagement. "Inability to engage" includes those who did not have face-to-face visits with their OM, those who were having their order appealed, or those who could not engage on top of demands of their order. Reasons for "Mental health barriers" are described above in Step A. "Unavailability of OM" refers to case managers who were either too busy to engage with the RA or were not physically present due to annual leave or sickness. "Physical Health Barriers" refers to those who were too physically unwell to take part, and those struggling to engage with other services due to physical health needs. "Stressful life events" includes those who had recently suffered a bereavement, or another event, that would make it difficult for them to engage.

Table 2: Reasons for exclusion and related number of participants and at Step B

Reason	Number excluded
Declined/Withdrew	85
Disruptive lifestyle making intervention engagement too difficult	92
Less than 7 months left to serve after search	138
Limited English	14
Not interested in being supported one-to-one by a Health Trainer	13
Not interested in changing one of four target health behaviours or improving mental wellbeing	14
Unable to provide informed consent	15
Unable to contact	30
Transferred to another area	23
Returned to custody	29
Resides outside of target geographical area	8
Study already closed	192
Previously randomised	3
Risk	14
Other reasons (total)	171
- **Not engaging with CJS services**	74
- **Conflicting commitments**	25
- **Not engaging with researcher**	16
- **Inability to engage**	14
- **Mental health barriers**	9
- **Back in court**	7
- **Repeat screen**	6
- **Unavailability of OM**	6
- **Physical health barriers**	5

- **Stressful life events**	4
- **Missing person**	4
- **Passed away**	1

At Step C, some participants were excluded after they had already been approached and were awaiting completion of the baseline. Table 3 shows the reasons why 134 people did not enter the study. Once again, it was sometimes difficult to ascertain the reason for exclusion and we will make minor changes to the way recording takes place in a full trial. The large number of people (n = 62) who declined/withdrew at this stage is indicative of the chaotic lives some potential participants had. Any delay between screen and gaining consent and completing the baseline assessment increased the likelihood of a potential participant not being recruited.

Table 3: Reasons for exclusion and related number of participants and at Step C.

Reason	**Number excluded**
Declined/withdrew	62
Disruptive lifestyle making intervention engagement too difficult	1
Less than 7 months left to serve after search	14
Limited English	1
Not interested in being supported one-to-one by a Health Trainer	5
Not interested in changing one of the four target health behaviours or improving mental wellbeing	20
Unable to contact	6
Recruitment completed	1
Returned to custody	1
Other reasons (total)	23
- **Conflicting commitments**	13
- **Not engaging with the researcher**	6
- **Inability to engage**	2
- **Stressful life events**	2

In Steps B and C, it was not always easy to determine the precise reason for an eligible participant not entering the study. For example, ‘not being able to contact’, ‘an inability to engage’ and ‘lack of interest’ in being in the study were not always distinct. Assuming a total of 199 potentially eligible participants were recorded as ‘declined/withdrew’ or not interested in the intervention (changing lifestyle or wellbeing) at Stage B or C, and 120 eligible participants did enter the study, we recruited over 30% of eligible participants, suggesting a promising degree of interest and acceptability.

In addition to our attempts above to quantify why the target population within the OMS did not enter the trial, our process evaluation in Chapter 5 qualitatively describes the challenges in the recruitment pathway.

The conversion rates for participants initially identified in searches, through each Step to ultimately being randomised, are shown in Table 4. The percentages indicate the amount of work completed to achieve randomisation, with the cooperation of the OMSs; the greater the percentage moving from one Step to another indicates a more efficient process. Across all sites, 4% of those initially checked by the offender service ended up being randomised, varying from 2-7%. While conversion rates from initial offender service search to the researcher approaching the potential participant for a face-to-face screen was similar across sites and averaged 34%, there was greater variation across sites from the initial researcher approaching the potential participant to successful randomisation averaging 7% across all services and varying from 7-24% between services. Similarly, the Plymouth NPS converted the greatest proportion (80%) from completing the approach to actual randomisation, with only 30% in the Manchester CRC being randomised after completing the approach.

Table 4: Efficiency of recruitment overall and across offender manager service

Recruitment source	**Number of participants recruited**	**Conversion rate (from initial offender service search to randomisation)**	**Conversion rate (from initial service search to researcher approach for initial screen)**	**Conversion rate (from initial approach by RA to randomisation)**	**Conversion rate (from approach completed by RA to randomisation)**
Plymouth CRC	47	5%	38%	12%	60%
Plymouth NPS	33	7%	31%	24%	80%
Manchester CRC	40	2%	32%	7%	30%
All sites	120	4%	34%	11%	47%

Retention of participants:

Overall, as Figure 2 (i.e. CONSORT) shows, of the 120 participants recruited and randomised, 60% (n=72) completed follow-up assessment at 3 months and 60% completed the 6-month follow-up assessment.

As Table 5 shows, there was no consistent difference in retention at 3- and 6-month follow-ups between the intervention and control groups across all sites. Retention varied across recruitment site from 48-70% at 3 months, and 48-88% at 6 months. Observed differences in retention rates between allocated treatment groups were not consistent at each follow-up assessment, suggesting no systematic bias in retention, but it is something to be wary of in a larger trial. Retention rates were higher among those recruited through the NPS than the CRCs at both the 3- and 6-month follow-ups, and again this is something to be wary of in a full trial. Our process evaluation (see Chapter 6) further considers this.

Table 5: N (%) of sample randomised that completed 3- and 6-month follow-up

Recruitment source	**Number recruited/ randomised**	**n (%) completing 3-month follow-up by allocated group and overall**		**n (%) completing 6-month follow-up by allocated group and overall**	
Plymouth CRC	47	Intervention	12 (52%)	Intervention	15 (65%)
		Control	11 (48%)	Control	9 (38%)
		Total	23 (49%)	Total	24 (51%)
Plymouth NPS	33	Intervention	12 (67%)	Intervention	16 (89%)
		Control	11 (73%)	Control	13 (87%)
		Total	23 (70%)	Total	29 (88%)
Manchester CRC	40	Intervention	10 (50%)	Intervention	9 (45%)
		Control	16 (80%)	Control	10 (50%)
		Total	26 (65%)	Total	19 (48%)
All sites	120	Intervention	34 (56%)	Intervention	40 (66%)
		Control	38 (64%)	Control	32 (54%)
		Total	72 (60%)	Total	72 (60%)

Further qualitative information about the factors influencing retention is reported in Chapter 6 (process evaluation).

Participant characteristics

Participant demographic characteristics for the total sample and by allocated group are shown in Table 6 below. The sample as a whole were 91% male, had a mean age of 40.5 years, were

predominantly white British, had few qualifications above GCSE/O Levels, and had little paid employment. The median number of convictions for the sample overall was 6.

Table 6: Demographic characteristics of participants

	Intervention (N=61)	**Control (N=59)**	**All Participants (N=120)**
Gender - male, n (%):	55 (90.2)	54 (91.5)	109 (90.8)
Age in years, mean (SD) [range]	41.3 (12.9) [20.2, 77.9]	39.6 (10.2) [20.6, 63.9]	40.5 (11.7) [20.2, 77.9]
Ethnic group, n (%):			
• White English, Scottish, Welsh or Irish	48 (78.7)	51 (86.4)	99 (82.5)
• White other	2 (3.3)	0 (0.0)	2 (1.7)
• Black British	2 (3.3)	1 (1.6)	3 (2.5)
• Black Caribbean	4 (6.6)	2 (3.3)	6 (5.0)
• Other (including Indian, Pakistani, other Asian background, Chinese and 'mixed background)	5 (8.0)	5 (8.0)	10 (8.0)
Living situation, n (%):			
• Own your own property	2 (3.3)	3 (5.1)	5 (4.2)
• Renting through the housing association/local authority	10 (16.7)	13 (22.0)	23 (19.3)
• Living in a hostel	4 (6.7)	7 (11.9)	11 (9.2)
• Living in supported accommodation	5 (8.3)	4 (6.8)	9 (7.6)
• Sleeping rough	1 (1.7)	0 (0.0)	1 (0.8)
• Renting a property privately	17 (28.3)	15 (25.4)	32 (26.9)
• Living with parents (or other care giver)	15 (25.0)	7 (11.9)	22 (18.5)
• Other (including B&B, sheltered accommodation, sofa surfing)	6 (10.0)	10 (17)	16 (13.3)
Have children aged <18 years:	27 (44.3)	33 (55.9)	60 (50.0)

Have a partner now, n (%):	19 (31.7)	22 (39.3)	41 (35.3)
Whom normally live with, n (%):			
• Husband/wife/partner	12 (19.7)	16 (27.1)	28 (23.3)
• Child or children aged under 18 years	10 (16.4)	9 (15.3)	19 (15.8)
• Parents/parents-in-law/step-parents	15 (24.6)	6 (10.2)	21 (17.5)
• Other family or friends	2 (3.3)	7 (11.9)	9 (7.5)
• On own	22 (36.1)	20 (33.9)	42 (35.0)
• Other	7 (11.5)	11 (18.6)	18 (15.0)
Highest qualification, n (%):			
• University degree or equivalent	5 (8.6)	1 (1.8)	6 (5.3)
• Higher Education qualification (below degree level)	11 (18.7)	10 (18.2)	21 (18.6)
• GCE/GCSE, A-Levels or equivalent	0 (0.0)	5 (9.1)	5 (4.4)
• GCE/GCSE, O-Levels or equivalent	17 (29.3)	17 (30.9)	34 (30.1)
• Other qualifications at NVQ level 1 or below	14 (24.1)	10 (18.2)	24 (21.2)
• No formal qualifications	11 (19.0)	12 (21.8)	23 (20.4)
Previous prison sentence, n (%)	36 (59.0)	38 (64.4)	74 (61.7)
Best description of work situation, n (%):			
• Paid employment	16 (26.2)	14 (23.7)	30 (25.0)
• Voluntary work	2 (3.3)	3 (5.1)	5 (4.2)
• Unpaid care work (not childcare)	1 (1.6)	0 (0.0)	1 (0.8)
• Child care	1 (1.6)	1 (1.7)	2 (1.7)
• Student	0 (0.0)	1 (1.7)	1 (0.8)
• Unemployed	41 (67.2)	39 (66.1)	80 (66.7)
Number of hours per week, mean (SD) [range]			

• Paid employment	N=15 35.1 (11.2) [14, 60]	N=13 37.0 (15.5) [15, 60]	N=28 36.0 (13.2) [14, 60]
• Voluntary work	N=2 18.5 (3.5) [16, 21]	N=3 28.0 (36.4) [6, 70]	N=5 24.2 (26.3) [6, 70]
• Unpaid care work (not childcare)	N=1 40	N = 0	N = 1 40
• Child care	N=1 84	N=1 37	N=2 60.5 (33.2) [37, 84]
• Student	N=0	N=1 20	N= 1 20

Summary of outcome measures at baseline

Table 7 shows baseline summary data, by trial arm and for the whole sample for the WEMWBS scores (long and short version), quality of life measures and behavioural measures (alcohol use, dietary intake, smoking, substance use, and physical activity). The WEMWBS scores were low compared with national data, but similar to a Scottish sample of prisoners. Similarly, the EQ-5D and SF-6D indicated that the sample had low quality of life. Lifestyle measures indicated a poor diet in terms of diet and fat consumption, high risk of alcohol dependence (73%) among the 64% who reported drinking alcohol, a high proportion of smokers (72%) (with 75% having at least moderate cigarette dependency), but also a very physically active sample with the sample averaging 572.5 minutes of moderate-vigorous physical activity over the past seven days. Overall, of the 69 participants (58% of the total sample) who reported some substance use, the most frequent substances reportedly used were cannabis (57%), prescription drugs (40%), non-prescription drugs (15%), Benzodiazepam (7%), opiates (6%), cocaine (7%), and crack (6%).

Data for the demographic variables and proposed primary and secondary outcomes at baseline suggest that the allocated groups were comparable on most measures i.e. the minimisation algorithm (with random element) was generally successful. There were some apparent differences observed between allocated groups in the physical activity measures, with greater amounts of moderate and vigorous activity in participants allocated to the control group compared to those allocated to the intervention group.

Table 7: Baseline measures for wellbeing and health behaviours by allocated group and overall

	Intervention		Control		Overall	
	N	**Summary statistics**	**N**	**Summary statistics**	**N**	**Summary statistics**
WEMWBS: mean (SD), [range]	61	43.6 (12.0) [19,63]	59	44.9 (11.6) [15,68]	120	44.2 (11.8) [15,68]
SWEMWBS: mean (SD), [range]	61	20.9 (4.8) [9.5,32.5]	59	21.2 (4.4) [9.5,30.7]	120	21.1 (4.6) [9.5,32.5]
SF-6D: mean (SD), [range]	59	0.681 (0.138) [0.355 to 0.943]	58	0.654 (0.152) [0.362 to 1]	117	0.668 (0.145) [0.355 to 1]
EQ-5D: mean (SD), [range]	60	0.667 (0.288) [-0.158 to 1]	59	0.685 (0.243) [0.007 to 1]	119	0.677 (0.266) [-0.158 to 1]
Self-reported drinker: n (%)	61	42 (68.9)	59	35 (59.3)	120	77 (64.2)
Total units of alcohol in previous 4 weeks: median (IQR), [range]	39	36 (16,108) [0,1120]	31	36 (9,120) [0,448]	70	36 (14,108) [0,1120]
AUDIT Score: mean (SD), [range]	42	13.5 (9.6) [1,36]	35	14.1 (9.3) [2,35]	77	13.8 (9.4) [1,36]
AUDIT Score indicating higher risk or possible dependence (>7), n (%)	42	30 (71.4)	35	26 (74.3)	77	56 (72.7)

Self-reported Smoker: n (%)	61	43 (70.5)	59	43 (72.9)	120	86 (71.7)
Cigarettes per day: median (IQR), [range]	42	17.2 (11,31.1) [1,126]	41	12 (6.7,15.6) [0,166.7]	83	13.3 (8.9,26.7) [0,166.7]
Fagerström Test for Cigarette Dependence (FTCD): n (%)						
- Low to moderate (score 3-4)	42	10 (23.8)	40	10 (25.0)	82	20 (24.4)
- Moderate (score 5-7)		21 (50.0)		24 (60.0)		45 (54.9)
- High (score ≥8)		11 (26.2)		6 (15.0)		17 (20.7)
Self-reported substance user: n (%)	61	34 (55.7)	59	35 (55.3)	120	69 (57.5)
Minutes of moderate activity: median (IQR), [range]	56	370 (210,750) [30,4200]	50	580 (360,1080) [30,3780]	106	420 (225,840) [30,4200]
Minutes of vigorous activity: median (IQR), [range]	21	210 (60,300) [5,3480]	22	375 (190,720) [0,2520]	43	270 (105,630) [0,3480]
Total minutes of moderate and vigorous physical activity: median (IQR), [range]	56	442.5 (215,1020) [30,4350]	50	795 (420,1440) [30,5880]	106	572.5 (315,1175) [30,5880]

n (%) who reported doing at least 150 mins of moderate and vigorous physical activity per week.	56	49 (87.5)	50	48 (96.0)	106	(91.5)

Outcome measures over time, by allocated group

Tables 8 and 9 show the summary data for the WEMWBS (and SWEMWBS) and lifestyle behaviours, respectively, at baseline, 3 and 6 months, by trial arm, from participants completing assessments. The mean (95% confidence interval) between-group difference (intervention minus control) in WEMWBS was 4.6 (-1.7 to 10.8) at 3 months, and 1.9 (-4.6 to 8.4) at 6 months. We provide similar data for the short version of the SWEMWBS in the interests of completeness for other researchers who may be interested in using this version.

Table 10 shows the summary data for the process outcome measures (i.e. perceived importance, confidence, use of support, action-planning and self-monitoring) at baseline, and 3- and 6-month follow-ups, are summarised by allocated group in Table 10. Only those reporting use of alcohol (64% of total sample) and tobacco (72% of total sample) completed the questionnaire items on beliefs about for alcohol and smoking, respectively. We have not undertaken exploratory factor analysis to confirm the merits of creating a composite score by adding the four items for each behaviour concerned with action-planning, and the two items concerned with self-monitoring; the data presented is for reference only.

Table 8: Summary statistics for proposed primary outcome (WEMWBS) and shortened form (SWEMWBS)

Outcome measure	Time Point	Intervention (N=61) Number (%) completed [95% CI]	Intervention (N=61) Mean (SD) [Range]	Intervention (N=61) Median (Q1,Q3)	Control (N=59) Number (%) completed [95% CI]	Control (N=59) Mean (SD) [Range]	Control (N=59) Median (Q1,Q3)	Mean difference (95% CI) between intervention and control groups
WEMWBS	**Baseline**	61 (100.0) *	43.6 (12.0) [19, 63]	45.0 (34, 53)	59 (100.0) *	44.9 (11.6) [15, 68]	45.0 (37, 55)	NA
	3-month follow-up	34 (55.7) [42.4, 68.5]	50.5 (13.1) [16, 68]	53.5 (47, 59)	38 (64.4) [50.9, 76.4]	45.9 (13.3) [17, 70]	45.5 (38, 56)	4.6 (-1.7, 10.8)
	6-month follow-up	40 (65.6) [52.3, 77.3]	49.6 (13.6) [14, 68]	54.5 (41.5, 60)	32 (54.2) [40.8, 67.3]	47.7 (13.9) [18, 70]	48.5 (37, 61)	1.9 (-4.6, 8.4)
SWEMWBS	**Baseline**	61 (100.0) *	20.9 (4.8) [9.5, 32.6]	20.7 (17.4, 24.1)	59 (100.0) *	21.2 (4.4) [9.5, 30.7]	20.7 (18.0, 23.2)	NA
	3-month follow-up	34 (55.7) [42.4, 68.5]	23.7 (5.4) [9.5, 32.6]	24.1 (21.5, 27.0)	38 (64.4) [50.9, 76.4]	21.9 (5.0) [12.4, 35.0]	21.1 (18.6, 26.0)	1.7 (-0.7, 4.2)
	6-month follow-up	40 (65.6) [52.3, 77.3]	23.1 (6.2) [7.0, 35.0]	25.0 (19.3,27.0)	32 (54.2) [40.8, 67.3]	22.9 (6.4) [7.0, 35.0]	23.2 (18.0, 28.1)	0.1 (-2.9, 3.1)

**100% completion rate, and hence CI not applicable. Q1: First Quartile; Q3: Third Quartile*

Table 9: Summary statistics for health behaviour measures, by trial arm and across all assessments

	Intervention						Usual care					
	Baseline		3-month follow-up		6-month follow-up		Baseline		3-month follow-up		6-month follow-up	
Outcome variable	**N**	**Summary statistics**	**N**	**Summary statistics**	**N**	**Summary statistics**	**N**	**Summary statistics**	**N**	**Summary statistics**	**N**	**Summary statistics**
ALCOHOL												
Drinks alcohol: n (%)	61	42 (68.9)	34	19 (55.9)	40	22 (55.0)	59	35 (59.3)	38	23 (60.5)	32	20 (62.5)
Number of units in previous four weeks for those who drank: median (Q1,Q3) [range]	39	36 (0, 64) [0, 1120]	19	21 (4, 36) [3, 672]	21	12 (4, 24) [0, 120]	31	36 (9, 120) [0, 448]	19	42 (15, 200) [3, 400]	20	36 (8, 129) [0, 240]
AUDIT Score indicating higher risk or possible dependence (>7), n (%)	42	30 (71.4)	18	10 (55.6)	22	12 (54.5)	35	26 (74.3)	23	15 (65.2)	20	11 (55.0)
Overall AUDIT Score for those who drink: mean (SD) [range]	42	13.5 (9.6) [1, 36]	18	10.4 (8.5) [2, 35]	22	8.1 (6.2) [1, 30]	35	14.1 (9.3) [2, 35]	23	12.1 (8.6) [2, 32]	20	11.0 (8.8) [1, 33]
DIET												

DINE Fibre total score: mean (SD) [range]	60	31.7 (16.4) [2, 84]	34	29.2 (13.1) [6, 70]	39	29.8 (14.0) [7, 58]	59	30.6 (14.2) [11, 83]	38	29.4 (10.8) [12, 57]	31	29.7 (12.7) [11, 61]
Dine Fibre category: n (%)												
- Low intake (<30)		31 (51.7)		14 (41.2)		19 (48.7)		32 (54.2)		20 (52.6)		17 (54.8)
- Medium intake (30-40)	60	12 (20.0)	34	15 (44.1)	39	12 (30.8)	59	14 (23.7)	38	12 (31.6)	31	8 (25.8)
- High intake (>40)		17 (28.3)		5 (14.7)		8 (20.5)		13 (22.0)		6 (15.8)		6 (19.4)
DINE Fat total score: mean (SD) [range]	60	36.9 (14) [14, 74]		29.2 (14.6) [13, 69]	40	32.0 (15.4) [13, 75]	58	38.2 (15.8) [11, 80]	38	38.2 (16.8) [10, 75]	31	36.1 (16.8) [10, 76]
Dine Fat category: n (%)												
- Low intake (<30)		23 (38.3)		22 (68.8)		23 (57.5)		19 (32.8)		13 (34.2)		14 (45.2)
- Medium intake (30-40)	60	13 (21.7)	32	5 (15.6)	40	8 (20.0)	58	13 (22.4)	38	13 (34.2)	31	6 (19.4)
- High intake (>40)		24 (40.0)		5 (15.6)		9 (22.5)		26 (44.8)		12 (31.6)		11 (35.5)

DINE Unsaturated Fat total score, mean (SD) [range]	39	8.9 (2.3) [3, 12]	22	8.7 (2.0) [6, 12]	35	9.0 (2.1) [3, 12]	38	9.3 (2.3) [3, 12]	31	9.2 (2.4) [3, 12]	28	8.8 (2.1) [3, 12]
Dine Unsaturated Fat category: n (%)												
- Low intake (<30)		2 (5.1)		15 (68.2)		2 (5.7)		1 (2.6)		3 (9.7)		2 (7.1)
- Medium intake (30-40)	39	23 (59.0)	22	7 (31.8)	35	20 (57.1)	38	21 (55.3)	31	12 (38.7)	28	17 (60.7)
- High intake (>40)		14 (35.9)		0 (0.0)		13 (37.1)		16 (42.1)		16 (51.6)		9 (32.1)
SMOKING												
Smoker: n (%)	61	43 (70.5)	34	15 (44.1)	40	23 (57.5)	59	43 (72.9)	38	22 (57.9)	32	17 (53.1)
Number of cigarettes per day*: median (Q1, Q3) [range]	42	17.2 (11.0, 31.1) [1, 126]	14	14.4 (4.4, 20.0) [4, 66.7]	22	11.1 (8.0, 20.0) [2, 76.7]	41	12 (6.7, 15.6) [0, 166.7]	22	12.1 (8.9, 20.0) [4.4, 33.3]	17	15.6 (8.9, 22.2) [4.4, 66.7]
Fagerström Test of Cigarette Dependence (FTCD) category: n (%)												

- Low to Moderate (score 3-4)		10 (23.8)		4 (28.6)		7 (31.8)		10 (25.0)		6 (27.3)		7 (41.2)
- Moderate (score 5-7)	42	21 (50.0)	14	6 (42.9)	22	8 (36.4)	40	24 (60.0)	22	14 (63.6)	17	5 (29.4)
- High (score ≥8)		11 (26.2)		4 (28.6)		7 (31.8)		6 (15.0)		2 (9.1)		5 (29.4)
PHYSICAL ACTIVITY: 7-day Physical Activity recall												
Done vigorous activities in last 7 days: n (%)	61	21 (34.4)	34	14 (41.2)	40	17 (42.5)	58	22 (37.9)	38	17 (44.7)	31	11 (35.5)
Total number of minutes of vigorous activity: median (Q1, Q3) [range]	21	210 (60, 300) [5, 3480]	14	175 (90, 360) [0, 3090]	17	180 (90, 315) [60, 3600]	22	375 (190, 720) [0, 2520]	17	300 (180, 420) [20, 3600]	11	180 (110, 1105) [60, 1680]
Done moderate activities in last 7 days: n (%)	61	56 (91.8)	34	30 (88.2)	40	36 (90.0)	59	50 (84.7)	38	35 (92.1)	32	30 (93.8)
Total number of minutes of moderate activity: median (Q1, Q3) [range]	56	370 (210, 750) [30, 4200]	30	622.5 (300, 1660) [20, 3360]	36	332.5 (140, 630) [20, 2520]	50	580 (360, 1080) [30, 3780]	35	570 (400, 1440) [0, 2700]	30	540 (210, 1020) [20, 3600]
Total minutes of moderate and vigorous	56	442.5	31	685	37	600	50	795	36	795	30	640

activity: median (Q1, Q3) [range]		(215, 1020) [30, 4350]		(330, 1800) [20, 4140]		(220, 1020) [20, 3720]		(420, 1440) [30, 5580]		(470, 1680) [60, 3600]		(260, 1560) [70, 3900]
Number of hours sleeping each day: mean (SD) [range]	61	6.1 (1.6) [2, 10.5]	34	6.0 (1.4) [2, 8]	40	6.2 (2.2) [0, 12]	56	6.5 (2.3) [1.5, 13]	38	6.9 (2.1) [3, 12]	32	6.6 (3.1) [0, 18]
SUBSTANCE USE in the last 4 weeks**												
Opiates: n (%)		6 (17.6)		1 (12.5)		1 (10.0)		2 (5.7)		1 (6.7)		1 (10.0)
Crack: n (%)		3 (8.8)		0 (0.0)		0 (0.0)		1 (2.9)		1 (6.7)		1 (10.0)
Cocaine: n (%)		2 (5.9)		2 (25.0)		1 (10.0)		3 (8.6)		0 (0.0)		0 (0.0)
Amphetamines: n (%)		1 (2.9)		0 (0.0)		0 (0.0)		0 (0.0)		1 (6.7)		2 (20.0)
Cannabis: n (%)		19 (55.9)		4 (50.0)		7 (70.0)		20 (57.1)		11 (73.3)		7 (70.0)
Legal Highs: n (%)	34	0 (0.0)	8	0 (0.0)	10	0 (0.0)	35	1 (2.9)	15	0 (0.0)	10	0 (0.0)
Benzodiazepam: n (%)		5 (14.7)		2 (25.0)		2 (20.0)		0 (0.0)		0 (0.0)		0 (0.0)
Prescription drugs: n (%)		15 (44.1)		4 (50.0)		2 (20.0)		13 (37.1)		7 (46.7)		4 (40.0)
Non-prescription drugs: n (%)		5 (14.7)		1 (12.5)		1 (10.0)		6 (17.1)		4 (26.7)		2 (20.0)
Other substance(s): n (%)		0 (0.0)		0 (0.0)		0 (0.0)		4 (11.4)		1 (6.7)		1 (10.0)

* Number of self-reported cigarettes based on adding self-reported number of cigarettes smoked plus loose tobacco used (0.45 gram = 1 cigarette)

** Percentages based on the numbers self-reporting the named substance in the last 4 weeks, amongst those participants who have self-reported using at least one substance in the last 4 weeks

Table 10: Summary statistics **(**Mean (SD) [Range] unless otherwise specified) for process measures at baseline, 3 and 6 months by trial arm

	Intervention			**Control**		
Process measure	**Baseline** (N=61)	**3-month follow-up** (N=34)	**6-month follow-up** (N=40)	**Baseline** (N=59)	**3-month follow-up** (N=38)	**6-month follow-up** (N=32)
Self-reported drinker: n (%)	42 (68.9)	19 (55.9)	22 (55.0)	35 (59.3)	23 (60.5)	20 (62.5)
ALCOHOL	**(42 responses)**	**(19 responses)**	**(22 responses)**	**(35 responses)**	**(23 responses)**	**(20 responses)**
Important to reduce alcohol consumption	3.05 (1.59) [1, 5]	2.74 (1.28) [1, 5]	2.82 (1.14) [1, 5]	3.00 (1.71) [1, 5]	3.17 (1.67) [1, 5]	3.10 (1.45) [1, 5]
Confidence in reducing alcohol consumption	4.40 (0.91) [1, 5]	4.42 (0.69) [3, 5]	4.32 (0.84) [3, 5]	4.51 (0.70) [3, 5]	4.57 (0.73) [3, 5]	4.45 (0.69) [3, 5]
People close for support	4.10 (0.98) [2, 5]	3.95 (1.18) [1, 5]	4.05 (0.95) [2, 5]	4.00 (1.21) [1, 5]	4.13 (1.01) [2, 5]	4.00 (1.26) [1, 5]
Made plans for amount when drinking	*2.56 (1.48) [1, 5]	2.95 (1.39) [1, 5]	2.59 (1.14) [1, 4]	2.74 (1.44) [1, 5]	3.17 (1.56) [1, 5]	2.85 (1.31) [1, 5]
Made plans for days not drinking	*3.05 (1.40) [1, 5]	3.05 (1.31) [1, 5]	3.00 (1.20) [1, 5]	2.69 (1.32) [1, 5]	2.87 (1.49) [1, 5]	2.70 (1.22) [1, 5]
Made plans for interferences	*2.46 (1.23)	2.53 (1.22)	2.59 (1.05)	2.26 (1.04)	2.39 (1.16)	2.65 (1.35)

	[1, 5]	[1, 5]	[1, 4]	[1, 5]	[1, 5]	[1, 5]
Made plans for setbacks	*2.34 (1.11)	2.53 (1.31)	2.64 (1.09)	2.49 (1.15)	2.52 (1.20)	2.65 (1.35)
	[1, 5]	[1, 5]	[1, 4]	[1, 5]	[1, 5]	[1, 5]
Monitored amount drinking	*2.51 (1.47)	2.79 (1.47)	2.82 (1.33)	2.66 (1.49)	2.70 (1.66)	3.00 (1.45)
	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]
Thought about amount drinking	*2.95 (1.52)	2.84 (1.46)	2.73 (1.35)	2.91 (1.52)	2.83 (1.67)	3.05 (1.50)
	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]
DIET	**(61 responses)**	**(34 responses)**	**(40 responses)**	**(59 responses)**	**(38 responses)**	**(32 responses)**
Important to eat a healthy diet	3.79 (1.11)	4.35 (0.92)	4.18 (0.87)	4.02 (0.99)	4.11 (1.01)	4.00 (1.16)
	[1, 5]	[2, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]
Confident in eating a healthy diet	3.77 (1.07)	4.18 (1.00)	3.88 (1.22)	3.86 (1.15)	4.05 (0.77)	3.75 (0.95)
	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[2, 5]	[2, 5]
People close for support	3.48 (1.26)	3.94 (1.10)	3.95 (0.93)	3.49 (1.19)	3.55 (1.08)	3.69 (1.00)
	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[2, 5]
Plans for what/how much food to eat	2.85 (1.49)	3.47 (1.56)	3.38 (1.23)	2.73 (1.30)	3.05 (1.25)	3.06 (1.16)
	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]
Plans for replacing things with healthier options	3.10 (1.39)	3.62 (1.44)	3.65 (1.23)	3.00 (1.34)	3.45 (1.27)	3.59 (1.24)

	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]
Made plans for interferences	2.34 (1.01)	2.59 (1.33)	2.98 (1.17)	2.44 (1.04)	2.55 (0.95)	2.75 (0.98)
	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]
Made plans to cope with setbacks	2.39 (1.02)	2.68 (1.34)	2.95 (1.15)	2.39 (1.02)	2.55 (0.86)	2.81 (1.03)
	[1, 4]	[1, 5]	[1, 5]	[1, 4]	[1, 4]	[1, 5]
Monitored amount of food eaten	2.25 (1.21)	3.24 (1.50)	3.25 (1.260	2.29 (1.29)	2.76 (1.24)	2.75 (1.16)
	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]
Regularly thought about what eating	2.92 (1.38)	3.68 (1.34)	3.50 (1.20)	3.10 (1.34)	3.32 (1.30)	3.22 (1.18)
	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]
5 portions of fruit/veg most days	2.52 (1.35)	3.06 (1.39)	2.98 (1.39)	2.64 (1.39)	2.79 (1.23)	2.53 (1.02)
	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]
5 portions of fruit/veg single day	2.57 (1.42)	3.15 (1.64)	3.23 (1.42)	2.86 (1.43)	3.08 (1.32)	3.06 (1.16)
	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]
Self-reported smoker: n (%)	43 (70.5)	15 (44.1)	23 (57.5)	43 (72.9)	22 (57.9)	17 (53.1)
SMOKING	**(43 responses)**	**(15 responses)**	**(23 responses)**	**(43 responses)**	**(22 responses)**	**(17 responses)**
	3.74 (1.29)	3.73 (1.62)	3.78 (1.41)	4.37 (0.79)	4.27 (1.16)	4.53 (0.87)
Important to reduce smoking	[1, 5]	[1, 5]	[1, 5]	[2, 5]	[1, 5]	[2, 5]

Important to quit smoking	3.35 (1.34)	3.53 (1.64)	3.87 (1.39)	4.05 (1.15)	3.82 (1.26)	4.24 (1.15)
	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[2, 5]
Confident in reducing smoking	3.47 (1.40)	3.53 (1.06)	3.22 (1.35)	3.49 (1.37)	3.23 (1.41)	3.41 (1.18)
	[1, 5]	[2, 5]	[1, 5]	[1, 5]	[1, 5]	[2, 5]
Confident in quitting smoking	2.86 (1.44)	3.20 (1.21)	*3.27 (1.16)	3.16 (1.29)	2.82 (1.37)	3.00 (1.37)
	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]
People close for support	3.28 (1.52)	3.40 (1.35)	3.39 (1.31)	3.35 (1.57)	3.50 (1.14)	3.71 (1.05)
	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[2, 5]
Plans for how much smoking	2.40 (1.43)	3.00 (1.77)	2.96 (1.26)	2.77 (1.49)	2.91 (1.31)	3.12 (1.17)
	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[2, 5]
Plans for strategies to reduce smoking	2.67 (1.36)	3.20 (1.57)	3.26 (1.25)	2.86 (1.39)	2.86 (1.25)	3.12 (1.22)
	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[2, 5]
Plans for interferences with plans	2.09 (0.87)	2.20 (1.32)	2.52 (1.04)	2.63 (1.07)	2.45 (1.18)	2.59 (1.00)
	[1, 4]	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]
Plans for coping with setbacks	2.12 (0.88)	2.40 (1.40)	2.52 (1.12)	2.58 (1.10)	2.50 (1.14)	2.65 (1.06)
	[1, 4]	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]
Plans for quitting smoking	2.37 (1.36)	2.93 (1.62)	2.91 (1.31)	2.28 (1.42)	2.45 (1.18)	3.18 (1.24)

	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[2, 5]
Monitored amount of smoking	2.84 (1.51)	2.87 (1.73)	2.91 (1.35)	2.74 (1.43)	2.95 (1.40)	3.18 (1.13)
	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[2, 5]
Thought about amount of smoking	3.35 (1.48)	3.53 (1.55)	3.09 (1.24)	3.56 (1.33)	3.64 (1.14)	3.82 (1.01)
	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[2, 5]
PHYSICAL ACTIVITY	**(61 responses)**	**(34 responses)**	**(40 responses)**	**(59 responses)**	**(38 responses)**	**(32 responses)**
Important to be physically active	*3.97 (1.18)	4.56 (0.66)	4.35 (0.89)	4.29 (0.93)	4.39 (0.86)	4.19 (1.15)
	[1, 5]	[2, 5]	[1, 5]	[1, 5]	[2, 5]	[1, 5]
Confidence in being physically active	*4.17 (0.98)	4.32 (0.77)	4.23 (0.92)	4.05 (1.12)	3.89 (1.25)	4.09 (1.12)
	[1, 5]	[2, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]
People close for support	*3.47 (1.24)	3.94 (1.10)	3.88 (1.14)	3.75 (1.11)	3.89 (1.06)	3.78 (1.04)
	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]
Made plans for when to be physically active	3.23 (1.41)	3.85 (1.21)	3.68 (1.25)	3.19 (1.46)	3.29 (1.33)	3.44 (1.32)
	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]
Made plans for where to be physically active	3.23 (1.41)	4.06 (1.13)	3.73 (1.22)	3.25 (1.37)	3.24 (1.34)	3.50 (1.30)
	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]	[1, 5]

* one missing response; All scores derived from responses on a Likert scale (1 = strongly disagree, 5 = strongly agree)

WEMWBS descriptive data by time, by allocated arm and CRC/NPS

Based on fairly small numbers of participants, we explored if there were noticeable differences in WEMWBS scores at each time-point by trial arm and overall, for participants recruited via the CRC and NPS. As shown in Table 11, baseline scores were slightly lower for the CRC participants. Differences in WEMWBS scores between trial arms was most noticeable at follow-up among the NPS participants.

Table 11: Descriptive data for the WEMWBS by recruitment service, time and allocated group

	Time Point	Intervention (N=61)			Control (N=59)			Overall (N=120)		
		N	Mean (SD) [Range]	Median (IQR)	N	Mean (SD) [Range]	Median (IQR)	N	Mean (SD) [Range]	Median (IQR)
CRC	Baseline	43	42.2 (12.5) [19,63]	43 (33,53)	44	45.6 (11.9) [15,68]	45 (37.8,55.0)	87	43.9 (12.2) [15,68]	44 (36,55)
CRC	3-month follow-up	22	49.0 (14.7) [16,66]	52.5 (43,59)	27	46.3 (14.4) [17,70]	44 (38,59)	49	47.5 (14.4) [16,70]	51 (39,59)
CRC	6-month follow-up	24	47.7 (14.3) [14,65]	49 (40.5,59.5)	19	48.3 (16.1) [18,70]	47 (37,63)	43	48.0 (15.0) [14,70]	48 (37,61)
NPS	Baseline	18	46.9 (10.3) [31,63]	48 (37,54)	15	42.8 (10.9) [20,58]	47 (36,50)	33	45.1 (10.6) [20,63]	48 (37,51)
NPS	3-month follow-up	12	53.3 (9.3) [35,68]	54.5 (50.5,58.5)	11	45.1 (10.8) [23,61]	46 (36,56)	23	49.4 (10.7) [23,68]	53 (44,56)
NPS	6-month follow-up	16	52.3 (12.4) [22,68]	55 (45,62)	13	46.7 (10.6) [28,61]	51 (39,53)	29	49.8 (11.8) [22,68]	53 (41,57)

Intervention engagement

This section describes the level of engagement with the intervention. Further exploration of the views of participants and HTs are described in Chapter 5 (process evaluation).

Table 12 shows the number (%) of sessions with a HT that participants in the intervention group had in Plymouth, Manchester and overall. Overall, only 28% of participants did not attend any sessions, with a slightly higher proportion in Manchester. Our progression criteria for the trial was to achieve a target of at least 70% of participants who attended at least 2 sessions for automatic progression. Overall, 63% attended at least 2 sessions, varying from 50% in Manchester (albeit with small numbers) to 68% in Plymouth. Drawing on the process evaluation, we are seeking to understand these small differences and whether they may be due to chance. The overall mean (SD) number of sessions attended was 3.7 (3.4), with median of 3. Very few participants had more than 9 sessions.

Table 12: Number (%) of sessions that participants allocated to the intervention group had with a Health Trainer

Number of HT-led sessions attended	**Number of participants (%)**		
	Plymouth (N=41)	**Manchester (N=20)**	**Total (N=61)**
0	10 (24.4%)	7 (35.0%)	17 (27.9%)
1	3 (7.3%)	3 (15.0%)	6 (9.8%)
2-5	14 (34%)	6 (30%)	20 (33%)
6-9	12 (29%)	3 (15%)	15 (25%)
10-12	2 (5%)	1 (5%)	3 (5%)

Association between intervention engagement and change in WEMWBS

Table 13 shows the WEMWBS score over time for those who had low (up to one session), moderate (two to five sessions), and high (six or more sessions) intervention engagement, among those completing the WEMWBS assessments. It is noticeable that a smaller proportion

of those assessed at baseline in the ‘low engagement’ group provided data at 3 and 6 months compared with in the moderate and high engagement groups. It would appear that those with moderate engagement had higher WEMWBS scores at 3- and 6-month follow-up compared with the lowest and highest engagers.

Factors associated with intervention engagement

Table 13 below shows the WEMWBS scores at baseline for those with different levels of intervention engagement. The scores were lowest for those who went on to have no more than 1 session with the HT.

Table 13: Summary statistics of WEMWBS scores over time for participants allocated to the intervention group by level of engagement

	Baseline			3-month follow-up			6-month follow-up		
Level of engagement	**N**	**Mean (SD) [range]**	**Median (IQR)**	**N**	**Mean (SD) [range]**	**Median (IQR)**	**N**	**Mean (SD) [range]**	**Median (IQR)**
High engagement (≥6 sessions)	18	44.7 (13.3) [19,63]	47.5 (33,54)	16	48.9 (13.2) [16,66]	53.0 (43.5,55.5)	16	46.7 (15.6) [14,68]	51.5 (37,57.5)
Moderate engagement (2-5 sessions)	20	45.2 (10.9) [21,63]	44.5 (37,54.5)	12	53.9 (14.7) [16,68]	58.0 (51,63.5)	15	53.9 (10.3) [35,68]	55.0 (43,63)
Low engagement (0-1 sessions)	23	41.3 (11.9) [20,59]	44.0 (32,52)	6	48 (9.2) [33,59]	49.5 (43,54)	9	47.4 (14.5) [14,62]	49.0 (45,59)

Other methodological considerations

Recruitment issues

Table 14 presents the planned and actual recruitment into the trial. We originally anticipated, based on expected numbers of likely eligible participants coming through the OMSs, that we would recruit approximately 10 per month (for 4 months) per OMS from September 2016. In the first 7 months after the first participant was recruited, we had only recruited 22 participants. Once recruitment processes were established across the 3 OMSs, it took 9 months to recruit 90 participants (i.e. 3.3 per OMS per month).

Given that the CRCs were still being established at the time of the original bid, the target was somewhat speculative. Our original bid included plans to recruit from offender services in Plymouth and Southampton. During trial set-up in Southampton, we discovered that HTs had been commissioned to support offenders in the community, and we decided against comparing the STRENGTHEN HT intervention with the local HT support. Plymouth and Manchester were already collaborating on another trial involving support for offenders leaving prison, so we set Manchester up as a second site. This caused a delay in recruitment until contracts and excess treatment costs were confirmed, and researchers and HTs were appointed. The first recruitment took place in April 2017 in Manchester. In Plymouth, the first recruitment in the CRC took place in October 2016, just a few weeks after intended. Recruitment via the Plymouth NPS eventually began in April 2017.

The conversion of potential participants from being approached and then randomised was more efficient in the NPS. One explanation for the NPS service having such efficient recruitment processes is that clients had less chaotic lives and once a Step had been completed there were fewer interruptions. It is not clear why the Plymouth CRC was more efficient at recruiting than the Manchester CRC, but we will seek to better understand this ahead of a full trial to maximise our resource efficiency in all CRCs.

The importance of the cooperation of the OMS for recruitment was very evident in December 2016 and January 2017 when the Plymouth CRC was unable to support us due to corporate and staffing difficulties. Several staff were on sick leave and others resigned, which meant searching through services records of potential participants stopped. Later dips in recruitment were due to researcher sick leave.

Retention issues

We originally defined our longest follow-up assessment to coincide with when we expected participants to have a 6-month follow-up with their OM, and in many cases to end their community sentence. As the study evolved, it became clear that the OMSs had not found it

easy to ensure a formal (face-to-face) 6-month session took place, and we therefore attempted to remain in contact with our sample and complete follow-up assessments around 6 months wherever they could be arranged. In three cases, this extended to 6 weeks after the assessment was scheduled to take place. Given it was our aim to demonstrate we could assess participants after at least 6 months this is not seen as a major issue, but did delay database cleaning and lockdown. No participant who withdrew from the trial requested that their previously collected data be removed from the trial database.

The slightly higher 6-month follow-up rate for the intervention group for the whole sample was particularly influenced by the large difference between the two trial arms among participants recruited within the SW CRC as shown in Appendix 2 (Figure 5). Among the 47 SW CRC participants randomised, 65% and 38% were followed up in the intervention and control groups, respectively. It is not clear why there was a between-trial arm difference in the SW CRC participants, but not in the NW CRC. As Figures 5, 6 and 7 show in Appendix 2, follow-up rates were, overall, considerably lower in the two CRCs (51% in the SW, and 48% in the NW) than in the NPS participants (88%).

Data completeness

The completeness of data collection for all variables at baseline and follow-up assessments is shown in Appendix 6. Researchers reported few difficulties with data collection that was mostly administered by the RA in face-to-face format. For the administration of the WEMWBS, almost all participants completed the measure themselves. As one might expect, our researchers reported that sensitive questions about substance use were probably incomplete. Throughout the rest of this chapter, summary statistics (including percentages) are based on the number of participants responding to the given questions; the number of respondents is therefore also given.

Table 14: Planned and actual rate of recruitment into the trial

Project month	Month of recruitment	Planned accumulated recruitment target	Actual recruitment per month	Actual accumulative recruitment
9	Sept 2016	30	0	0
10	Oct 2016	60	3	3
11	Nov 2016	90	9	12
12	Dec 2016	120	2	14
13	Jan 2017		1	15
14	Feb 2017		3	18
15	March 2017		4	22
16	April 2017		8	30

17	May 2017		17	47
18	June 2017		13	60
19	July 2017		5	65
20	Aug 2017		18	83
21	Sept 2017		10	93
22	Oct 2017		7	100
23	Nov 2017		19	119
24	Dec 2017		1	120

Blinding of researchers at follow-up assessments

Table 15 shows the extent of possible bias in capturing follow-up data. As is common in studies involving complex interventions such as a HT intervention, participants may mention something associated with the intervention they have or have not received to a researcher when collecting follow-up data. Researchers were more likely to become aware of the assigned trial arm if a participant had been allocated to the intervention group compared with participants allocated to the control group. The data indicates that it will be very challenging to ensure outcome measures are assessed by blinded researchers in a full definitive trial.

Table 15: The extent to which Research Assistants self-reported being unblinded

	Intervention	**Control**	**Overall**
3-month follow-up	29/34 (85.3%)	14/38 (36.8%)	43/72 (59.7%)
6-month follow-up	34/40 (85.0%)	20/32 (62.5%)	54/72 (75.0%)

Data were analysed to determine how well the protocol was followed in terms of screening and randomisation processes, and completing follow-up assessments in a timely manner, given the challenges in working with a considerable proportion of the sample. Table 16 shows the number of days it took between screening and completing the baseline assessment, and between completing the baseline assessment and randomisation. Together, from the point of satisfactory screening and gaining informed consent to being assigned to the trial group was approximately 9 days.

The mean time between completing the baseline and 3- and 6-month follow-up was 14 and 28 weeks, respectively, suggesting some slippage but this may not be surprising given the challenges of keeping in contact with the participants in this trial. There was no noteworthy difference between trial groups in terms of the times between key events (data not shown).

Table 16: Differences between key events during STRENGTHEN pilot study

Event Time (days)	N	Mean (SD) [range]	Median (IQR)
Screening and baseline (days)	120	8.7 (25.4) [0,237]	0 (0,9.5)
Baseline and randomisation (days)	120	0.6 (2.8) [0,28]	0 (0, 0)
Randomisation and 3-month follow-up (days)	72	99.5 (16.9) [74,169]	96 (89, 111)
Randomisation and 6-month follow-up (days)	72	196.4 (36.6) [152,407]	188.5 (178, 206.5)

Data to inform future sample size calculations

One of the key objectives of the STRENGTHEN pilot study was to collect data to contribute to indicative sample size calculations for a definitive trial to assess the effectiveness (and cost-effectiveness) of the STRENGTHEN intervention in terms of the proposed primary outcome, WEMWBS, at the primary endpoint of 6-months post-baseline.

As the planned primary analyses would include adjustment for baseline WEMWBS, the pilot data have been used to estimate the correlation between baseline and 6-month WEMWBS scores, as well as estimating the standard deviation of the 6-month WEMWBS. Table 17 below shows both the point estimates for these two parameters, together with the lower one-sided 80% confidence bound for the estimated correlation and the upper one-sided 80% bound for the estimated standard deviation.[47] For reference, estimates are shown for the intervention and control groups separately, as well as for the pooled groups (i.e. pooled across all participants) for both WEMWBS and SWEMWBS, with estimates also presented for 3 months for completeness.

Indicative sample size for definitive trial of STRENGTHEN

As specified in the agreed SAP, indicative sample size calculations are based on estimates from the STRENGTHEN pilot data of the required parameters. The data in Table 18 have been used to produce potential target sample sizes for a definitive trial of the STRENGTHEN intervention, to detect a between-group difference of three units[42, 48-49] for the proposed primary outcome of WEMWBS at the primary endpoint of 6-months post-baseline, under a range of plausible assumptions.

The base case for the sample size calculation below conservatively assumes an SD of 14.8 units (i.e. the upper one-sided confidence bound from the pilot data), with calculations also shown for SDs ranging from 12 to 16 units.

As the planned analyses would include adjustment for baseline WEMWBS, the effect of allowing for the correlation between baseline and 6-month WEMWBS scores has also been considered.[50] From the STRENGTHEN pilot trial, the point estimate of the correlation between baseline and 6 months across all participants was 0.68, with the one-sided 80% lower bound being 0.63. The base case for the sample size calculation below assumes a correlation of 0.63, with calculations also shown for correlations of 0.5 to 0.7.

Finally, an allowance is made for the estimated follow-up rate at 6 months. In the STRENGTHEN pilot study, the overall retention rate at 6 months was 60%. However, a recent NIHR PGfAR-funded trial in the CJS has observed an increase in retention rate from 50% to 67% at 3-month follow-up following the introduction of a small financial incentive for completing the trial. Therefore, the target sample size in the base case below assumes a retention rate of 70%.

In summary, the base case assumes detecting a between-group difference of 3 units; SD of 14.8 units; correlation between baseline and 6-month WEMWBS of 0.63; follow-up rate of 70%, and with two-sided 5% alpha and 90% power.

Based on Table 18, the number of participants required to be followed up at the 6-month primary endpoint ranges from ~970 to ~2060, before allowing for the correlation between baseline and follow-up. After including adjustment for this correlation, the number of participants required to be recruited reduces to a range of 580 to 1240.

Table 17: Estimated standard deviations and correlation coefficients between baseline and follow-up for WEMWBS, with appropriate one-sided 80% confidence limits

		Intervention		Control		Pooled Groups	
	Time Point	**Standard Deviation (80% Upper Confidence Limit)**	**Correlation with baseline (80% Lower Confidence Limit)**	**Standard Deviation (80% Upper Confidence Limit)**	**Correlation with baseline (80% Lower Confidence Limit)**	**Standard Deviation (80% Upper Confidence Limit)**	**Correlation* with baseline (80% Lower Confidence Limit)**
WEMWBS	3-month follow-up	13.1 (14.72)	0.72 (0.64)	13.3 (14.89)	0.47 (0.36)	13.3 (14.38)	0.58 (0.51)
	6-month follow-up	13.6 (15.19)	0.61 (0.51)	13.9 (15.76)	0.77 (0.70)	13.7 (14.81)	0.68 (0.63)
SWEMWBS	3-month follow-up	5.4 (6.08)	0.70 (0.62)	5.0 (5.63)	0.36 (0.23)	5.2 (5.67)	0.52 (0.45)
	6-month follow-up	6.2 (6.93)	0.53 (0.43)	6.4 (7.24)	0.73 (0.66)	6.3 (6.76)	0.61 (0.54)

* NB partial correlations were also produced but were near identical to those based on simply pooling the data and so are not show

Table 18: Indicative sample size calculations for a definitive trial of STRENGTHEN

	Between-group difference at 6 months	Standard deviation	Unadjusted total sample size required to be followed up	Total sample size required to be recruited - adjusted for LTF only	Total sample size required to be followed up - adjusted for correlation only	Total sample size required to be recruited - adjusted for correlation and LTF
Base case	3	14.8	1028	1470	620	886
Vary standard deviation	3	12	676	966	408	582
	3	13	792	1132	478	682
	3	14	918	1312	554	792
	3	15	1054	1506	636	908
	3	16	1200	1714	724	1034
Vary correlation	3	0.5	1028	1470	772	1102
	3	0.6	1028	1470	658	940
	3	0.7	1028	1470	524	750
Vary LTF	3	50%	1028	2056	620	1240
	3	60%	1028	1714	620	1033
	3	70%	1028	1470	620	886
	3	80%	1028	1286	620	776

LTF: Loss to follow-up

Chapter 5: Economic Analysis

Research question

A full economic evaluation of the STRENGTHEN intervention would address the following research question:
Is the HT-led motivational intervention plus usual care cost-effective, versus usual care alone in a UK setting, for people under community supervision?

The purpose of this pilot study was to estimate the resource use and costs associated with the delivery of the intervention and to develop a framework for estimating the cost-effectiveness of the STRENGTHEN intervention plus usual care, versus usual care alone, in a future economic evaluation alongside a fully-powered randomised controlled trial. This involved developing and testing economic evaluation methods for the collection of resource use data and the estimation of related costs, and piloting the collection of outcome data appropriate for economic evaluation.

Methods

Design

The economic analysis was conducted concurrently with the pilot randomised controlled trial, using within-trial intervention, resource use, and outcome data, over a 6-month time horizon.

The incremental cost for the delivery of the STRENGTHEN intervention was considered when provided in addition to usual care, and costs associated with health/social care service use and quality-adjusted life-years (QALYs) were estimated for the intervention and control groups.

Intervention and comparator

The intervention arm (see Chapter 2) compromised STRENGTHEN plus usual care and the control arm received usual care alone.

Perspective

We adopted a primary perspective of the UK NHS and Personal Social Services (PSS), with broader aspects of care also reported from a societal perspective.

Time horizon

The pilot trial time horizon of 6-month follow-up was employed in the economic analysis, with outcome assessments at both 3- and 6-month follow-up.

Intervention resource use and costs

The additional (incremental) costs associated with delivery of the STRENGTHEN intervention, when added to usual care, were estimated using resource use data collected within-trial.

The HTs who delivered the intervention kept a record of participant contact on the intervention section of the data management system on which they collated details of face-to-face, telephone, text, email and letter contacts. These were grouped according to whether the contact was a pre-designated intervention session, a planned contact, or other form of contact. The HT also recorded the time spent travelling in relation to these contacts (whether or not the participant attended the appointment) and documented any additional time spent unsuccessfully attempting to contact participants.

Other resources required for the delivery of the intervention were identified via a questionnaire and discussion with the intervention developers after the intervention had been delivered. Such resources included the HTs' handbook, worksheets and folders for participants, training and supervision of the HTs, and additional administrative and management activities undertaken by the HTs and the HT co-ordinator. The HT co-ordinator prospectively recorded their time involved in intervention-related activities.

Costs were applied to the intervention resources in British pounds sterling (£) at 2017 costs. Unit cost estimates were drawn from nationally recognised, published sources, 'Unit Costs of Health and Social Care'[51,52] and NHS Reference Costs,[53,54] with the supplementation of data provided by the intervention providers. These unit costs are set out in Table 19.

Table 19: STRENGTHEN intervention unit costs

Resource item	Unit cost (£, 2017)	Source of cost estimate	Basis of cost estimate
Health Trainer time	£28 per working hour	PSSRU 2017 p.154. Agenda for Change (AfC), Band 4, annual salary £21,579*.	HTs are expected to be employed on AfC Band 4.
HT Co-ordinator time	£33 per working hour	PSSRU 2017 p.154. AfC Band 5, annual salary £23,439.	HTs co-ordinators are expected to be employed on AfC Band 5.
Health Trainer handbook	£18 per handbook	Intervention providers.	Production costs.
Participants' worksheets and folders	£5.00 per set	Intervention providers.	Printing costs.
Training	£13 per participant	PSSRU, 2017 p.154. Intervention providers.	Please see Table 21
Supervision	£94 per participant	PSSRU, 2017 p.154 & 155. Intervention providers.	Please see p.101.

*The PSSRU reference is not specific to the HT role, but the salary structure is similar and other costs are assumed to be appropriate. The cost estimate also includes allowance for salary on-costs, overheads for management, administration and estates staff, travel costs, non-staff overheads, and capital overheads. It does not include qualification costs.

Health, social care and broader societal resource use and costs

Self-report resource use was collected via interviewer-administered questionnaires at baseline, 3-month follow-up and 6-month follow-up (covering the prior two-month, three-month and three-month periods, respectively). (The first reporting time period was two months as, in line with the study inclusion criteria, participants may have only been in the community for 2 months following a custodial sentence). The questions enquired about healthcare, social care and other services that participants may have used such as criminal justice and education resources, in addition to assistance provided by relatives or friends (see supplementary materials 6).

We combined health and social care follow-up resource use data with nationally-recognised, published unit costs[51-54] to estimate the mean (SD) resource costs per participant. Costs were in British pounds sterling (£) at 2017 costs or adjusted for inflation where costs for 2017 were not available (Table 20).

Table 20: Unit costs of health and social care resource use

Resource item	Unit cost (£, 2017)	Source of cost estimate	Basis of cost estimate
Primary care			
GP contacts (surgery)	£31.00 per contact	PSSRU 2017, p.162	Surgery consultation, 9.22 minutes.
GP contacts (home)	£38.76 per contact	PSSRU 2017, p.145 PSSRU 2015, p.176	Per minute of patient contact = £3.40 (allows for average of 12 minutes travel time per visit). Home visit, 11.4 minutes.
GP telephone calls	£24.14 per contact	PSSRU 2017, p.145 PSSRU 2015, p.176	Per minute of patient contact = £3.40 Telephone call, 7.1 minutes.
Practice nurse contacts (surgery)	£9.30 per contact	PSSRU 2017, p.160 PSSRU 2015, p.174	£36 per hour. 15.5 minute consultation.
Practice nurse contacts (phone)	£7.90 per contact	PSSRU 2017, p.164	£36 per hour. 6.6 minute consultation.
Community nurse contacts (home)	£37.00 per contact	NHS Reference costs 2016/2017	Community Health Services, District Nurse, Adult face to face.
Community mental health nurse contacts (home)	£36.00 per contact	PSSRU 2017, p.159	£36 per hour. 1 hour visit
Community psychiatric nurse contacts (home)	£36.00 per contact	PSSRU 2017, p.159	£36 per hour. 1 hour visit
Counsellor contacts	£43.00 per contact	PSSRU 2017, p.155	Band 6 Scientific and Professional staff, £43 per hour. 1 hour consultation.
Physiotherapist contacts	£53.00 per contact	NHS Reference costs 2016/2017	Community Health Services, Physiotherapist, Adult, one to one.
Occupational therapist contacts	£77.00 per contact	NHS Reference costs 2016/2017	Community Health Services, Occupational Therapist, Adult, one to one.
Dietician contacts	£33.00 per contact	PSSRU 2017, p.155	Band 5 Scientific and Professional staff, £33 per hour. 1 hour consultation.
NHS Stop smoking service	£129.67 per intervention	PSSRU 2017, p.115	Mean cost of therapies for smoking cessation.
Alcohol services contacts	£45.00	PSSRU 2017, p.63	Alcohol health worker. 1 hour consultation.
Drug services contacts	£134.00	PSSRU 2017, p.59	Community contact (adult) for drug services.
Walk-in centre attendances	£42.80	NHS Reference costs 2011/2012 HCHS Pay and Prices Index	Average cost for Accident and Emergency Services: Walk In Centres: Leading to Admitted Accident and Emergency Services: Walk In Centres: Not Leading to

			Admitted ([£42 + £38]/2 = £40 at 2011/12 prices Inflation to 2016/17 cost using HCHS pay and prices index: £40 * (302.3/282.5) = £42.80
Secondary care			
Accident & Emergency visits			
General A&E visits	£147.80	NHS Reference costs 2016/2017	Outpatient attendances data, Accident and Emergency.
Mental health A&E visits	£193.00	NHS Reference costs 2016/2017	Mental Health Specialist Teams, A&E Mental Health Liaison Services, Adult and Elderly.
Day cases	£727.00	PSSRU 2017, p.110	Weighted average of all Day Case stays.
Hospital admissions			
General medical admissions (nights)	£324.99	NHS Reference costs 2016/2017	Regular day or night admissions.
Outpatient appointments			
General	£137.00	PSSRU 2017, p.110	Weighted average of all outpatient attendances.
Psychologist	£55.00	PSSRU 2017, p.203.	Band 7 Scientific and Professional staff, £55 per hour. 1 hour consultation.
Psychiatrist	£108.00	PSSRU 2017, p.211.	Psychiatric consultant. £108 per hour. 1 hour consultation.
Alcohol appointments	£45.00	PSSRU 2017, p.63	Alcohol health worker. 1 hour consultation.
Social care			
Home help/care worker contacts	£6.90	PSSRU 2017, p.160	Mean hourly cost of all home care. £18 per hour. 23 minute visit.
Social worker contacts	£59.00	PSSRU 2017, p.174	Per hour of client-related work.

Outcomes

Our primary economic endpoints were costs and QALYs at 6-month follow-up. QALYs are a commonly-used summary measure of health-related quality-of-life, taking account of both quality and quantity of life[55,56] and are the metric used by the National Institute of Health and Care Excellence (NICE) when considering the cost-effectiveness of interventions across a broad range of health and social care contexts.[57] We estimated QALYs over the 6-month trial follow-up, using the EQ-5D-5L trial data and applying the internationally recognised 'cross-walk' algorithm[58] to provide QALY weights from a UK general population survey to value the EQ-5D health states.[59] This methodological approach adheres to the current 'position statement' of NICE regarding use of the EQ-5D.[60]

Given the uncertainty of the appropriateness of the EQ-5D for this population, we additionally used trial data from the SF-36 to estimate QALYs using the SF-6D,[61]

Analysis

Intervention resource use and costs

We calculated quantities (mean and SD) of each component of resource use, applied unit costs to this data (mean and SD), and estimated the mean (SD) cost per participant for the intervention.

Health, social care and broader societal resource use and costs

We calculated mean (SD) resource use, by item, at baseline and for resource use reported at 3- and 6-month assessments. Unit costs were applied to the disaggregated health/social care data over the period of 6-month follow-up, and mean (SD) costs for each of these items were calculated, by treatment arm. Costs of resource use were then calculated for the following sub-categories by treatment group: primary care, secondary care and social care.

Outcome data

We derived QALY estimates, for both the EQ-5D and the SF-6D, using data from baseline, 3-month and 6-month assessments, applying the area-under-the-curve approach, a recognised method for assessing repeated measures data, and specifically recommended for cost-effectiveness analyses.[55]

Results

Resource requirements and cost of the STRENGTHEN intervention

Sixty-one people were provided with the STRENGTHEN intervention. This included 20 from the centre in Manchester, 23 from Plymouth CRC and 18 from Plymouth NPS. The resources used to provide the intervention, and their quantities and costs, are detailed in Tables 21, 22 and 23.

Table 21: STRENGTHEN intervention training costs

Resource item	**Unit cost (£, 2017)**	**Source of cost estimate**	**Cost (£, 2017)**
Trainer's time 1 experienced HT for 3 days	£33 per working hour	PSSRU 2017 p.154. Agenda for Change (AfC), Band 5, annual salary £23,439.	£693
Service user consultant Half a day	£10 per hour	Intervention providers	£35
Trainer and service user consultant travel expenses	£10 each, per day	Intervention providers	£40
Approximate cost to train a HT			**£384**
Approximate cost per participant		(£384 to train a HT who is retained for approximately 2 years, during which time they work with approximately 30 people = £384/30 = £12.80)	**£13**

Table 22: STRENGTHEN intervention resource use per participant

Resource item	**Basis of resource use estimate**				
Health Trainer handbook	1 per 8 participants (1 handbook per HT, 7 HTs, 61 participants).				
Participant worksheets and folder	1 set per participant				
Training	As described in Table 21.				
Supervision	As described on p.101.				
Additional HT co-ordinator time	Administration: 0.5 hours per week. Meetings/discussions with HTs other than supervision: 0.5 hours per week. Meetings/discussions with others (not HTs) on intervention-related matters): 0.25 hours per week. Total: 1.25 hours per week. Assume caseload of 30 per centre, per year and working time of 42.6 weeks per year (PSSRU, 2017 p. 155) = 1.78 hours per participant. (1.25 hours per week x 42.6 weeks = 53.25 hours per year/30 participants).				
Additional HT time	Meetings/discussions with HT co-ordinator other than supervision: 0.25 hours per week, per HT. Assume 2 HTs per centre. Assume caseload of 30 per centre, per year and working time of 42.6 weeks per year (PSSRU, 2017 p.155) = 0.71 hours per participant. (0.25 hours per HT per week x 42.6 weeks x 2 HTs = 21.3 hours per year/30 participants).				
Health Trainer time	***n (%)***	***Number of contacts***			
		Mean	***SD***	***Min***	***Max***
Intervention sessions:	61				
Face-to-face	41 (72.1)	2.90	2.81	0	11
Telephone	15 (24.6)	0.82	1.74	0	8
Contacts:	61				
Face-to-face	7 (11.5)	0.11	0.32	0	1
Telephone	60 (98.4)	7.80	6.24	0	32
Text	57 (93.4)	15.39	11.58	0	56
Email	15 (24.6)	0.90	2.99	0	21
Letter	16 (26.2)	0.28	0.49	0	2
Unsuccessful contact attempts	7 (11.5)	0.21	0.76	0	5
Other:	61				
Face-to-face	5 (8.2)	0.08	0.28	0	1
Telephone	21 (34.4)	0.70	1.19	0	5
Text	6 (9.8)	0.11	0.37	0	2
Email	23 (37.7)	1.34	2.39	0	9
Unsuccessful contact attempts	31 (50.8)	3.28	5.82	0	23
Health Trainer time	***Total time per participant (minutes) (n=61)***				
	Mean		***SD***	***Min***	***Max***

Intervention sessions:				
Face-to-face	136.21	153.17	0	855
Telephone	26.28	71.67	0	445
Contacts:				
Face-to-face	0.69	2.62	0	15
Telephone	14.20	17.83	0	101
Text	12.31	12.73	0	51
Email	1.92	6.56	0	45
Letter	3.13	7.31	0	30
Unsuccessful contact attempts	0.16	0.76	0	5
Other:				
Face-to-face	2.23	15.37	0	120
Telephone	2.11	4.77	0	25
Text	0.18	0.81	0	6
Email	1.97	4.02	0	22
Unsuccessful contact attempts	8.39	20.94	0	120
Health Trainer travel time	***Total travel time per participant (minutes) (n=61)***			
	Mean	***SD***	***Min***	***Max***
Intervention sessions:				
Face-to-face	94.67	104.21	0	420
Planned face-to-face, but participant did not attend*	0.33	2.56	0	20
Contacts:				
Face-to-face	1.31	5.91	0	30
Planned face-to-face, but participant did not attend*	24.39	47.73	0	215
Other:				
Face-to-face	1.80	9.92	0	60
Planned face-to-face, but participant did not attend*	1.20	5.51	0	30

*This travel time refers to instances where the HT travelled to see a participant who did not attend the appointment.

Table 23: STRENGTHEN intervention mean cost per participant

Resource item	**Cost per participant (£, 2017)**			
Health Trainer handbook	2.25			
Worksheets and folders	5.00			
HT training	12.80			
HT supervision	93.72			
Additional HT co-ordinator time	58.58			
Additional HT time	19.88			
Health Trainer time	***Mean***	***SD***	***Min***	***Max***
Intervention sessions:				
Face-to-face	63.57	71.48	0	399.00
Telephone	12.26	33.45	0	207.67
Contacts:				
Face-to-face	0.32	1.22	0	7.00
Telephone	6.63	8.32	0	47.13
Text	5.75	5.94	0	23.80
Email	0.90	3.06	0	21.00
Letter	1.46	3.41	0	14.00
Unsuccessful contact attempts	0.08	0.35	0	2.33
Other:				
Face-to-face	1.04	7.17	0	56.00
Telephone	0.99	2.23	0	11.67
Text	0.08	0.38	0	2.80
Email	0.92	1.87	0	10.27
Unsuccessful contact attempts	3.92	9.77	0	56.00
Total costs of HT time	*97.90*	*88.72*	*0.47*	*417.67*
Health Trainer travel time	***Mean***	***SD***	***Min***	***Max***
Intervention sessions:				
Face-to-face	44.18	48.63	0	196.00
Planned face-to-face, but participant did not attend*	0.15	1.20	0	9.33
Contacts:				
Face-to-face	0.61	2.76	0	14.00
Planned face-to-face, but participant did not attend*	11.38	22.27	0	100.33
Other:				
Face-to-face	0.84	4.63	0	28.00
Planned face-to-face, but participant did not attend*	0.56	2.57	0	14.00
Total costs of HT travel time	*57.73*	*52.34*	*0*	*196.00*
Total mean cost per participant	**347.86**	**128.44**	**192.70**	**805.90**

*This travel time refers to instances where the HT travelled to see a participant who did not attend the appointment, thus the HT spoke to them on the telephone, or contacted them by text or email.

The estimated mean (SD) cost per participant for the delivery of the intervention was £348 (£128). The main requirements for the delivery of the intervention and its cost drivers were HT time and the time of a HT co-ordinator.

HT time

The mean (SD) cost for HTs' time in contact and non-contact activities in relation to participants was £98 (£89). They spent a mean (SD) of 136 (153) minutes providing face-to-face intervention sessions per participant, and a mean (SD) of 26 (71) minutes providing telephone sessions. They spent an additional mean (SD) of 14 (18) minutes and 12 (13) minutes contacting participants by telephone and text, respectively. HTs spent an average of 9 minutes per participant making unsuccessful contact attempts.

HTs travel time cost a mean (SD) of £58 (£52) per participant. This was mainly accounted for by the mean (SD) cost of £44 (£49) to travel to meet participants for face-to-face intervention sessions, although it is of note that the estimated average cost of HTs travelling to meet participants who did not attend the appointment was £12 per participant. HT mileage rates were not included in the estimate of the cost of the intervention as they are included in the overhead costs of the unit cost of HT time.

Training

Based on data provided by the intervention developers, and the future potential implementation of the intervention in practice, we assumed the following resource requirements for training HTs: a HT co-ordinator for three days; a service user consultant for half a day; travel expenses; venue costs for the provision of the training; consumables e.g. handouts.

The estimated costs associated with these resources were £693, £35 and £40, respectively, with venue and consumable costs being covered in the overhead costs of the HT co-ordinator's hourly rate. In addition, we did not include HTs' time in the training costs, assuming this would be included in the overhead costs component of their hourly rate, as described in the 'Unit Costs of Health and Social Care'.[51]

These figures equated to approximately £768 for a training 'block' (Table 21). We assumed that at least two people would be trained concurrently, resulting in a cost to train each HT of approximately £384. The model used in the pilot suggests that pairs of HTs would manage a caseload of

approximately 30 people per centre, per year. Assuming that HTs were retained in post for two years, this implied a training cost attributable to each participant of approximately £12.80.

Supervision

Supervision was provided by a HT co-ordinator and, if implemented in practice, would be expected to take a form similar to approximately one hour's contact per HT per week, to include check-in, debriefing, and any group supervision. This equated to approximately two hours of the HT co-ordinator's time per week (assuming two HTs per centre). Based on an approximate caseload of 30 people per centre, per year, and an estimated working time for the HT co-ordinator of 42.6 weeks per year[51] this implied a supervision cost attributable to each participant of approximately £93.72. The costs of HTs' time were not included in the supervision costs as these were included in the overhead costs of their hourly rate.

Additional intervention costs

Additional intervention costs were the HT co-ordinator's time spent in other administrative/management activities (approximately £59 per participant), HTs' time in other discussions with the co-ordinator (£20 per participant), HT handbooks (£2.25 per participant) and participant worksheets/folders (£5).

Health and social care resource use and costs

Table 24 presents quantities of resources used from the primary economic perspective of the NHS/PSS, across the 6-month follow-up, described by treatment arm. These resources are disaggregated by item and grouped as primary care, secondary care and social care services. Table 25 presents the costs associated with this disaggregated resource use. Total NHS/PSS costs were £773 in the control group and £585 in the intervention group. The largest contributors to overall costs were GP surgery appointments, counselling sessions, community drug or alcohol services, hospital day cases and social worker contacts. Tables 35-37 in Appendix 4 present health and social care resource of intervention and control groups.

Table 24: Health/social care resource use of intervention and control groups, number of contacts over 6-month follow-up

Resource item	**Intervention**		**Control**	
	Number (percent)	**Mean (SD) [range]**	**Number (percent)**	**Mean (SD) [range]**
Primary care services	***29***		***29***	
GP at surgery/health centre	18 (62.07%)	2.44 (3.11) [0-12]	22 (75.86%)	2.75 (2.32) [0-8]
GP via telephone	8 (27.59%)	1.00 (2.47) [0-10]	9 (31.03%)	1.17 (2.40) [0-9]
GP at home	0	0	0	0
Practice nurse at surgery/health centre	9 (31.03%)	0.51 (0.98) [0-4]	9 (31.03%)	0.89 (1.63) [0-5]
Practice nurse via telephone	1 (3.45%)	0.03 (0.18) [0-1]	1 (3.45%)	0.03 (0.18) [0-1]
Practice nurse at home	0	0	1 (3.45%)	0.06 (0.37) [0-2]
Community mental health nurse	3 (10.34%)	0.55 (2.59) [0-14]	3 (10.34%)	0.34 (1.07) [0-4]
Community psychiatric nurse	3 (10.34%)	0.17 (0.53) [0-2]	6 (20.69%)	0.37 (0.94) [0-4]
Physiotherapist at surgery/health centre	0	0	2 (6.9%)	0.20 (0.81) [0-4]
Physiotherapist at home	0	0	0	0
Occupational therapist at surgery/health centre	0	0	0	0
Occupational therapist at home	0	0	0	0
Dietician	0	0	1 (3.45%)	0.03 (0.18) [0-1]
Counsellor	7 (24.14%)	1.65 (4.22) [0-19]	7 (24.14%)	1.75 (4.01) [0-14]
NHS Stop smoking services*	1 (3.57%)	0.13 (0.74) [0-4]	3 (10.34%)	0.31 (1.16) [0-6]
Alcohol services - community	2 (6.9%)	0.51 (1.97) [0-9]	5 (17.24%)	1.65 (4.32) [0-18]
Drug services - community	4 (13.79%)	0.72 (2.37) [0-12]	2 (6.9%)	0.34 (1.31) [0-6]
Walk-in-centre	0	0	1 (3.45%)	0.03 (0.18) [0-1]
Secondary care services	***30***		***29***	
Accident and Emergency visits				
General A&E visits	3 (10%)	0.10 (0.31) [0-1]	3 (10.34%)	0.13 (0.44) [0-2]
Mental health A&E visits	1 (3.33%)	0.03 (0.18) [0-1]	1 (3.45%)	0.06 (0.37) [0-2]
Day Cases	2 (6.67%)	0.1 (0.40) [0-2]	4 (13.79%)	0.34 (1.04) [0-4]

Hospital admissions				
General medical admissions	2 (6.67%)	0.16 (0.74) [0-4]	0	0
ICU admissions	0	0	0	0
Alcohol services admissions	0	0	0	0
Drug services admissions	0	0	0	0
Outpatient appointments				
General appointments	7 (23.33%)	0.3 (0.59) [0-2]	5 (17.24%)	0.31 (0.84) [0-4]
Psychologist appointments	0	0	0	0
Psychiatrist appointments	0	0	2 (6.9%)	0.13 (0.58) [0-3]
Talking therapy appointments	0	0	0	0
Mental health clinic appointments	0	0	0	0
Alcohol appointments	0	0	0	0
Drug services appointments	0	0	0	0
Criminal Justice liaison appointments	0	0	0	0
Social care services	***29***		***29***	
Social worker	7 (24.14%)	0.93 (2.56) [0-12]	4 (13.79%)	0.93 (3.21) [0-13]
Home help/care worker	1 (3.45%)	0.03 (0.18) [0-1]	1 (3.45%)	0.34 (1.85) [0-10]
* n=28				

Table 25: Costs of health/social care resource use, over 6-month follow-up

Resource item	**Intervention**		**Control**	
	n	**Mean (SD) [range] cost (£, 2017)**	**n**	**Mean (SD) [range] cost (£, 2017)**
Primary care services				
GP at surgery/health centre	29	75.90 (96.47) [0-372]	29	85.52 (72.06) [0-248]
GP via telephone	29	24.14 (59.83) [0-241]	29	28.3 (58.09) [0-217]
GP at home	29	0	29	0
Practice nurse at surgery/health centre	29	4.81 (9.17) [0-37]	29	8.34 (15.19) [0-47]
Practice nurse via telephone	29	0.27 (1.47) [0-8]	29	0.27 (1.47) [0-8]
Practice nurse at home	29	0	29	2.55 (13.74) [0-74]
Community mental health nurse	29	19.86 (93.57) [0-504]	29	12.41 (38.82) [0-144]
Community psychiatric nurse	29	6.21 (19.41) [0-72]	29	13.66 (33.9) [0-144]
Physiotherapist at surgery/health centre	29	0	29	10.97 (43.38) [0-212]
Physiotherapist at home	29	0	29	0
Occupational therapist at surgery/health centre	29	0	29	0
Occupational therapist at home	29	0	29	0
Dietician	29	0	29	1.14 (6.13) [0-33]
Counsellor	29	71.17 (181.81) [0-817]	29	75.62 (172.63) [0-602]
NHS Stop smoking services	28	4.63 (24.51) [0-130]	29	13.41 (40.19) [0-130]
Alcohol services - community	29	23.28 (88.88) [0-405]	29	74.48 (194.4) [0-810]
Drug services - community	29	97.03 (318.1) [0-1,608]	29	46.21 (176.45) [0-804]
Walk-in-centre	29	0	29	1.48 (7.95) [0-43]
Primary care subtotal	*28*	*334.64 (526.06) [0-2,124]*	*29*	*374.35 (402.95) [0-1,353]*
Secondary care				
General appointments	30	41.10 (81.65) [0-274]	29	42.52 (116.38) [0-548]
Psychologist appointments	30	0	29	0
Psychiatrist appointments	30	0	29	14.9 (62.74) [0-324]
Alcohol appointments	30	0	29	0

Resource item	Intervention		Comparator	
General medical admissions	30	54.17 (242.65) [0-1,300]	29	0
Day cases	30	72.7 (292.67) [0-1,454]	29	250.69 (759.4) [0-2,908]
General A&E visits	30	14.78 (45.1) [0-147.8]	29	20.39 (65.2) [0-296]
Mental health A&E visits	30	6.43 (35.24) [0-193]	29	13.31 (71.68) [0-386]
Secondary care subtotal	*30*	*189.18 (445.48) [0-1,728]*	*29*	*341.8 (877.56) [0-3,456]*
Social care services				
Social worker	29	54.93 (151.19) [0-708]	29	54.93 (189.83) [0-767]
Home help/care worker	29	0.24 (1.28) [0-7]	29	2.38 (12.81) [0-69]
Social care subtotal	29	55.17 (151.68) [0-708]	29	57.31 (199.27) [0-836]
Total cost to NHS and PSS (excluding intervention cost)	**28**	**584.69 (774.66) [0-2,832]**	**29**	**773.46 (995.74) [0-3,707]**

Details of NHS and social care resource use and costs for the two months prior to baseline, and separately at 3-month follow-up and at 6-month follow-up assessments, for the intervention and control groups, are given in Appendix 5 (tables 38-40) and Appendix 6 (tables 41-43).

Broader societal resource use

Table 26 gives details of broader societal resources that intervention and control group participants reported using over the six months of follow-up. These items are disaggregated and grouped by education services, other services and informal care. Appendix 9 provides additional details of use of these resources in the two months prior to baseline assessment, and separately for 3- and 6-month follow-ups. Similar patterns of resource use were apparent in the intervention and control groups at baseline and at follow-up.

Table 26: Broader societal resource use of intervention and control groups, number of contacts over 6-month follow-up

Resource item	Intervention		Control	
	Number (percent)	**Mean (SD) [range]**	**Number (percent)**	**Mean (SD) [range]**
Other service providers e.g. Criminal Justice, Employment, Education services	***30***		***29***	
Probation worker	26 (86.67%)	5.56 (4.44) [0-19]	25 (86.21%)	6.93 (6.12) [0-27]

Community rehabilitation worker	8 (26.67%)	0.93 (1.68) [0-6]	6 (20.69%)	1.17 (3.21) [0-16]
Employment worker/officer	2 (6.67%)	0.16 (0.74) [0-4]	0	0
Citizen's Advice Bureau	0	0	1 (3.45%)	0.03 (0.18) [0-1]
Job centre	12 (40%)	2.83 (5.33) [0-20]	11 (37.93%)	2.06 (3.65) [0-12]
Enhanced Thinking Skills (ETS)	0	0	0	0
Cognitive Skills Booster (CSB)	0	0	0	0
Cognitive Self Change Programme (CSCP)	0	0	0	0
Police custody	3 (10%)	0.20 (0.66) [0-3]	1 (3.45%)	0.03 (0.18) [0-1]
Focus on Resettlement (FOR)	0	0	0	0
Solicitor/Lawyer	4 (13.33%)	0.33 (0.95) [0-4]	4 (13.79%)	0.20 (0.61) [0-3]
Barrister	1 (3.33%)	0.06 (0.36) [0-2]	0	0
Legal advocate	1 (3.33%)	0.03 (0.18) [0-1]	0	0
Informal care from relatives and friends	***30***		***29***	
Hours per week	10 (33.33%)	1.75 (3.79) [0-16]	10 (34.48%)	1.82 (4.80) [0-24]
Days taken off work	2 (6.67%)	0.20 (0.80) [0-4]	2 (6.9%)	0.06 (0.37) [0-2]

Outcomes

Quality-adjusted life-years

Table 27 reports EQ-5D health state values at baseline, 3-month follow-up and 6-month follow-up, and QALYs based on the EQ-5D, for the intervention and control groups. The intervention group had slightly lower mean EQ-5D health state values at baseline, with an increase in values at 3- and 6-month follow-ups. The EQ-5D data showed a minimal difference in QALYs in favour of the intervention group over the six months of follow-up.

Table 27: EQ-5D and SF-6D health state values and quality-adjusted life-years, by group

Measure: time point	**Intervention**		**Control**	
	n	**Mean (SD) [range]**	**n**	**Mean (SD) [range]**
EQ-5D: baseline	60	0.667 (0.288) [-0.158 to 1]	59	0.685 (0.243) [0.007 to 1]
EQ-5D: month 3	34	0.760 (0.267) [0.083 to 1]	38	0.743 (0.284) [-0.087 to 1]
EQ-5D: month 6	39	0.768 (0.255)	32	0.765 (0.238)

		[-0.162 to 1]		[0.088 to 1]
EQ-5D QALYs (6 months)	29	0.358 (0.121) [0.116 to 0.5]	29	0.354 (0.122) [0.015 to 0.5]
SF-6D: baseline	59	0.681 (0.138) [0.355 to 0.943]	58	0.654 (0.152) [0.362 to 1]
SF-6D: month 3	32	0.753 (0.156) [0.473 to 1]	37	0.719 (0.155) [0.37 to 1]
SF-6D: month 6	39	0.753 (0.158) [0.491 to 1]	30	0.696 (0.186) [0.301 to 1]
SF-6D QALYs (6 months)	26	0.376 (0.065) [0.262 to 0.475]	26	0.345 (0.078) [0.175 to 0.494]

When the SF-6D was used to estimate QALYs, a greater difference was found in favour of the intervention group, but the groups differed in their SF-6D scores at baseline.

Data completeness

Follow-up rates

Table 28 presents the numbers and proportions of participants who provided follow-up data, grouped by intervention and control groups. The proportion of participants who provided data at baseline, 3- and 6-month follow-up points (49%) was the same in the two groups. But overall, 60% of participants completed baseline and 3 months, and 60% completed baseline and 6-months. (Refer to Table 34 in Appendix 3 for completion rates for a selection of secondary outcomes, with 95% Confidence Intervals).

Table 28: Follow-up rates in intervention and control groups

Group	**n**	**Follow-up behaviour**	**n**	**%**
Intervention group	61	Both follow-ups completed	30	49%
		Month 3 only completed	4	7%
		Month 6 only completed	10	16%
		No follow-up data	17	28%
Control group	59	Both follow-ups completed	29	49%
		Month 3 only completed	9	15%
		Month 6 only completed	3	5%
		No follow-up data	18	31%
All participants	120	Both follow-ups completed	59	49%
		Month 3 only completed	13	11%
		Month 6 only completed	13	11%
		No follow-up data	35	29%

Missing resource use data

Among those who provided data at baseline and 3-month follow-up, rates of missing data for individual resource use items were very low. There was no missing data among those who provided data at 6-month follow-up.

The largest amount of missing data was among primary care and social care services. One participant in the intervention group did not complete this section of the CRF for 3-month follow-up; other than this, primary and social care data for this period was complete. Missing primary care resource use data at baseline is presented in Table 29. This suggests that some participants and/or interviewers were not clear about “walk-in centres”.

Table 29: Missing data for primary and social care services and outcomes

Resource item	**Intervention**	**Control**
Primary care services - baseline		
GP at surgery/health centre	Complete	Complete
GP via telephone	Complete	Complete
GP at home	1	Complete
Practice nurse at surgery/health centre	1	Complete
Practice nurse via telephone	2	Complete
Practice nurse at home	1	Complete
Community mental health nurse	1	Complete
Community psychiatric nurse	1	Complete
Physiotherapist at surgery/health centre	1	Complete
Physiotherapist at home	1	Complete
Occupational therapist at surgery/health centre	1	Complete
Occupational therapist at home	1	Complete
Dietician	1	Complete
Counsellor	1	Complete
NHS Stop smoking services	1	Complete
Alcohol services - community	1	Complete
Drug services - community	1	1
Walk-in-centre	2	3
Other	Complete	Complete
Social care services - baseline		
Social worker	1	Complete
Home help/care worker	1	1
Outcome data		
EQ-5D: baseline	1	Complete
EQ-5D: month 3	Complete	Complete

EQ-5D: month 6	1	Complete
EQ-5D QALYs (6 months)	1	Complete
SF-6D: baseline	2	1
SF-6D: month 3	2	1
SF-6D: month 6	1	2
SF-6D QALYs (6 months)	4	3

All secondary care data was complete for baseline and both follow-up periods, with the exception of one missing data point in the intervention and one in the control group at baseline for day cases. All data on education and other services was complete at baseline and follow-up. All data on help from relatives and friends was complete, with the exception of one missing data item in the intervention group at 3-month follow-up, for days taken off work.

Missing outcome data

Table 29 also shows the extent of missing data for the EQ-5D and SF-6D. We might expect a higher rate of missing data for the EQ-5D and SF-6D as compared to the resource use items, because these instruments require respondents to answer a number of questions in order to produce a health state value. Missing data for any one of these constituent questions will result in a missing health state value. Missing data for the EQ-5D, however, was no different to the resource use data, with only one missing value for the intervention group at baseline and 6-month follow-up; data for the control group and for the intervention group at 3-month follow-up were complete. There was slightly more missing data for the SF-6D, although there were only one or two observations missing from each group at each time point.

Discussion

To the best of our knowledge, this is the first report of a pilot trial of the effectiveness and cost-effectiveness of a HT-led motivational intervention for people under community supervision in the UK. As part of this pilot, we have estimated the resource use and costs associated with the delivery of the STRENGTHEN intervention, and considered, developed and tested economic evaluation methods for the collection of resource use, cost and outcome data for a future, policy-relevant, full cost-effectiveness analysis alongside a definitive RCT.

The cost of the STRENGTHEN intervention

We estimated the mean (SD) cost of the STRENGTHEN intervention to be approximately £348 (£128) per participant. The main cost drivers for the intervention, determined by data prospectively collected

using HT/participant contact sheets, activity logs of the HT co-ordinator, and a questionnaire for completion by the intervention providers, were: i) staff time of the HTs and the HT co-ordinator and; ii) supervision of the HTs.

Supervision of the HTs cost approximately £94 per participant, and involved approximately one hour's contact between the HT co-ordinator and each HT per week. This degree of supervision and support is considered imperative for the nature of the intervention, working with this population under community supervision, and would likely be replicated in a definitive trial and if, longer-term, the intervention is implemented more widely. In other work involving HT support for reducing smoking, we have managed to create a more cost-effective supervision process with shared virtual sessions involving up to 8 HT across four sites. In a full STRENGTHEN study, we would expect to therefore reduce supervision costs with an economy of scale.

Costs for training the HTs amounted to approximately £13 per participant, but there were significant uncertainties regarding the resource requirements for training and the allocation of costs across caseload, given the high staff turnover in the pilot. The cost of training would be anticipated to be reduced in a larger trial, and if the intervention is shown to be effective and cost-effective and put into practice across the UK. Economies of scale might mean that more HTs could be trained simultaneously. With implementation a more formalised training programme might be established e.g. in relation to a City and Guilds qualification. A further developed training approach would impact on resource requirements and costs of the intervention, and would warrant additional consideration and investigation in the context of a definitive trial.

It is notable that it cost approximately £12 per participant in HTs' time travelling to meet participants who did not attend appointments. It may be that this is a realistic component of providing an intervention to this population. The tenacity of HTs in repeated attempts to contact and support participants may be an important feature in contributing to the potential effectiveness and cost-effectiveness of the intervention.

The estimated cost of the STRENGTHEN intervention is greater than that of the HT intervention provided in the EARS pilot study (£192).[33] This difference in cost appears largely attributable to more time spent training, supervising and supporting HTs in the STRENGTHEN study. This is a necessary requirement for the HTs to be appropriately skilled and supported given the focus in STRENGTHEN on a broader range of health behaviours and wellbeing and the greater need to build trust and rapport in the first session before moving on to behaviour change.

A future full trial and cost-effectiveness analysis could usefully consider other aspects of the structure of the intervention that might alter if it were to be implemented in practice, and how this might impact on resource requirements and their costs. Such differences could be planned for in sensitivity analyses in a definitive cost-effectiveness analysis. For example, it appeared in examining the association between intervention engagement and WEMWBS scores at follow-up (see chapter 4), that the scores were greater for those who did 2-5 sessions rather than more (or less). Limiting the number of sessions to no more than 5 may help reduce the intervention cost.

Health/social care resource use and costs

The pilot found a lesser cost of health/social care resource use (excluding the intervention) in the intervention group over the six months of follow-up. When the cost of the intervention was also considered, the incremental cost in the intervention group was greater than that of the control group (over the 6-month follow-up period). However, differences in health/social care resource use were largely accounted for by a small number of costly drivers, e.g. hospital day cases, and the groups also differed in the cost of their resource use in the two months prior to baseline. The groups may therefore have been imbalanced at baseline, and the small sample size susceptible to the effect of a limited number of outliers and costly resource events.

Outcomes

At 6-month follow-up, the intervention group had higher WEMWBS scores, more QALYs based on the SF-6D, and marginally more QALYs based on the EQ-5D, but the pattern of scores at baseline indicated that the intervention group had higher SF-6D health state values, but poorer EQ-5D and WEMWBS scores.

Learning from the pilot for a full cost-effectiveness analysis alongside a definitive trial

There are many learning points from this pilot for a future cost-effectiveness analysis, the most important of which are described below:

Costing the intervention

The prospectively collected data regarding HT contacts with participants required some clarification. Contact information was captured by HTs on the data management system. This included key information on the time that HTs spent in contact and non-contact activities with participants. As the trial progressed, the HTs deviated from this format and collected additional information. This provided further contextual information regarding the intervention, but lacked some specificity. For

example, the distinction between ‘Contacts’ and ‘Other’ was somewhat unclear, and the fact that telephone calls, texts and emails could have travel time attributed to them required explanation (HTs had travelled to meet participants who did not attend the appointment, resulting in the HT contacting them by alternative means). A future economic evaluation should use a brief, straightforward Contact Sheet with unambiguous instructions for its completion.

Resource use

The resource use questionnaire was developed with the involvement of individuals under community supervision. This application of public involvement[63] should have served to have made the resource use questions as relevant and accessible to the population as possible. However, there was a fairly large number of ‘other’ responses in terms of the health and social care resources that people used, and particularly in relation to education, criminal justice and other services, but no consistent groupings for these ‘other’ responses were apparent. Steps might be usefully taken to elucidate any specific other key resources to enquire about in a main trial, particularly if a wider-reaching, broader societal perspective is to be adopted in sensitivity analyses. This said, it may only be possible to ‘cost’ such data if methodologically reliable unit costs for such resources can be identified. Our scoping searches have not identified rigorous, transparently devised unit costs for all the resource items currently included under this broader perspective.

There were issues with the quality of the data collected on participants’ use of medications, which arose in part due to the practice of recording this data as free text (see Table 44, Appendix 7). For the main study, we recommend identifying a manageable number (a maximum of ten) of medications that are frequently used by this population, and collecting data on the use of these drugs in a more structured format. This could also be tied into plans for improving the collection of data on illicit drug use.

QALY measures

The profile of health state values differed for the intervention and control groups across the three assessment points dependent on whether the EQ-5D or the SF-6D was used for the estimation of QALYs. This may imply the relevance and/or responsiveness of one of the measures over the other for use with this population. The EQ-5D is the QALY measure preferred by NICE for use in cost-effectiveness analyses,[57] but given the different pattern of responses compared to the SF-6D, we would continue to use the SF-36 in a definitive trial, and analyse SF-6D QALY data in a sensitivity analysis.

The WEMWBS had excellent data quality, with no missing data points. As research plans are underway to produce QALY weights for the WEMWBS,[64] this would indicate including the measure in a definitive trial of the effectiveness and cost-effectiveness of the intervention.

Baseline assessments and covariates

The differences between the groups in resource use costs and outcome scores at baseline highlight the importance of following the recommendation for full cost-effectiveness analyses of adjusting for baseline costs/outcome scores with the use of regression analyses.[56] In addition, key baseline covariates would be accounted for, with good practice being to account for covariates consistent with those used for the effectiveness analyses.

Data completeness

The follow-up rates were higher for the economic outcome measures than for the resource use questionnaire, a finding not usual in the collection of economic evaluation data.[65] Of specific note is that the pilot data was characterised by very little 'missingness', i.e. the measures relevant to the economic evaluation that were completed at follow-up, were comprehensively completed with very few missing data points. This was particularly significant for the responses to the resource use questionnaire given that such questionnaires often suffer from poor response rates and patchy completion.[65] The mode of interviewer administration is very likely to be a contributing factor to this provision of 'complete' data.[66] We would strongly advise retaining this mode of administration for a future definitive trial, particularly given the difficulties of retaining contact and response with this population.

Development of an economic evaluation framework for a definitive trial

In addition to our learning described above, for a future full economic evaluation and cost-effectiveness analysis we would follow good practice guidelines[67] and national policy guidance.[57] Our base case approach of an NHS/PSS perspective follows the methodological guidance for cost-effectiveness analyses set-out by the NICE,[57] and a broader societal perspective will be further explored in future sensitivity analyses, as recommended by the 'Second Panel on Cost-Effectiveness'.[68]

For the full trial, we will assess the cost-effectiveness of the STRENGTHEN intervention in relation to the threshold of £20,000 to £30,000 per QALY used by NICE for recommending treatments or interventions for funding on the NHS.[57] Our primary economic analysis will estimate mean costs and

mean QALYs by treatment allocation, and estimate differences between groups over the follow-up period. We will calculate incremental costs and incremental effects, and combine these to present incremental cost-effectiveness ratios (ICERs), to enable decision-makers to assess value for money using cost per QALY estimates (ICER = [$Cost_{STRENGTHEN}$ –$Cost_{usual\ care}$]/[$QALY_{STRENGTHEN}$ – $QALY_{usual\ care}$]).

To present the level of uncertainty regarding the cost-effectiveness estimates, we will use the cost-effectiveness plane to present combinations of incremental costs and incremental QALYs from bootstrap replicates. We will also use the cost-effectiveness acceptability curve (CEAC),[69] with the net benefit statistic ([incremental QALYs*willingness to pay per QALY] – incremental cost),[56] to present the probability that the STRENGTHEN intervention is cost-effective (i.e. incremental net benefit statistic is >0), against a range of potential cost-effectiveness thresholds.

We will analyse the data on an intention-to-treat basis and, as the follow-up period will not be longer than 12 months, no discounting of future costs or outcomes will be undertaken. We will explore the extent of missing data, with the intention of using regression-based multiple imputation as required in sensitivity analyses.

Conclusion

The successful completion of this pilot implies the feasibility of conducting a larger definitive trial with 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 QALY 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.

Chapter 6: Process Evaluation

Introduction

This chapter focuses on the assessment of the acceptability and feasibility of the intervention, the trial methods and any potential adaptations indicated. We have included the perspectives of the participants (control and intervention), STRENGTHEN HTs, and the OMs who worked with the researchers. The findings are presented for each method of data collection, brought together in a case study and then summarised with regards to our stated aims.

Aims

The aims of the process evaluation were to:

- assess whether the intervention is being delivered as per manual and training;
- ascertain components of the intervention which are critical to delivery;
- explore reasons for divergence from delivery of the intervention as manualised;
- understand when context is 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.

Assessment of fidelity of delivery of the STRENGTHEN intervention

Delivery (treatment) fidelity[70] was assessed within the trial to examine the extent to which the intervention was delivered as intended. This allows greater confidence that any changes in the dependent variables can be reasonably attributed to the intervention[70] and allows planning for future improvements to intervention delivery by identifying areas which may have been delivered below an expected standard.

The HT training, manual, and supervision were designed to equip the HTs with the skills to effectively deliver and engage the participant in six core competencies across the duration of the intervention. In summary, these were:

CC1: Active participant involvement;

CC2: Motivation-building for changing a behaviour and improving wellbeing;

CC3: Set goals and discuss strategies to make changes;

CC4: Review efforts to make changes/problem-solving;

CC5: Integration of concepts: building an association between wellbeing and behaviours;

CC6: Engaging social support and managing social influence.

These core competencies were intended to be transient across sessions, with acknowledgement that not all of them may necessarily be applicable in every session (except for CC1 which was considered fundamental to the intervention in terms of being client-centred and building trust and rapport). All competencies were intended to be delivered in a client-centred approach drawing on motivational interviewing techniques and principles (see appendix 1 for a detailed description).

Methods

Audio recordings of HT delivered sessions (N=18) were purposively sampled across participants who had also taken part in a process evaluation interview to allow for the potential to triangulate process evaluation data. Methods employed were those used in previous research conducted by members of the research team for assessing treatment fidelity,[71] albeit to assess the competence of 3 health trainers in supporting change in two health behaviours, physical activity and smoking. The health trainers in the present study had the opportunity to support change in four health behaviours and wellbeing, but we were interested in the generic competencies, irrespective of the behaviour(s) that the participant wished to work on. In this pilot trial we also aimed to test the methods for assessing intervention fidelity, given the difference in aims of the STRENGTHEN intervention.

Participants sampled (N=9) had a minimum of a first session and a subsequent audio recorded session. The first session and a later session for each participant were listened to and scored as a whole, independently by two researchers, in order to capture competencies which may not have been present in the first session (e.g. CC4 review efforts to make changes/problem-solving). The Dreyfus system for skill acquisition[72] was used to assign a score for each of the six core competencies on a seven-point Likert scale (0-6) reflecting six levels of competence (from incompetent to expert). Written guidance was provided to the researchers to inform their scoring (see appendix 1, Figure 4 for rating criteria for delivery fidelity). A score for each participant was generated based on the HTs performance across two sessions to attempt to reflect their experience of the intervention delivery as designed around the six core competencies. Due to the comparatively large number of HTs (N=6) across the two sites, no comparison between individual HTs was planned.

As part of an initial standardisation procedure, a recorded session was listened to simultaneously by both researchers who independently scored the HT's levels of competence. The scores were then

discussed and agreement reached over interpretation of the scoring scales. A further three sessions were scored independently and subsequently discussed between researchers to ensure both employed similar interpretations before independently reviewing and scoring the remaining sessions.

Scores classed as 'competent delivery' were considered acceptable delivery, those as 'advanced beginner' may need further development in future training, and any below 'novice' may represent problematic performance and warrant further investigation.

Results

Table 30 shows the mean scores for each of the six core competencies, overall and for each coder.

Table 30: Mean (SD) scores for intervention delivery across the six core competencies as scored by two researchers

	CC1	CC2	CC3	CC4	CC5	CC6	**Overall**
Researcher 1, mean (SD)	3.94 (0.81)	3.00 (0.66)	2.72 (0.57)	2.78 (0.57)	2.89 (0.49)	2.39 (1.02)	**2.95 (0.83)**
Researcher 2, mean (SD)	3.67 (0.83)	3.06 (0.77)	3.00 (0.75)	2.89 (0.86)	2.83 (0.75)	2.67 (1.00)	**3.02 (0.85)**
Overall mean (SD)	**3.81 (0.81)**	**3.03 (0.70)**	**2.86 (0.66)**	**2.83 (0.71)**	**2.86 (0.61)**	**2.53 (0.99)**	**2.99 (0.84)**

CC1: Active participant involvement; CC2: Motivation building for changing a behaviour and improving wellbeing; CC3: Set goals and discuss strategies to make changes; CC4: Review efforts to make changes/problem solving; CC5: Integration of concepts: building an association between wellbeing and behaviours; CC6: Engaging social support and managing social influence.

Inter-rater reliability was assessed across all items using a two-way mixed, consistency, average measures intra-class correlation coefficient (ICC). The resulting ICC was in the excellent range, *ICC=0.84*, suggesting coders had a high level of agreement indicating the ratings scales were employed consistently. Overall, the total mean scores for intervention delivery differed by 0.07 between coders, and the mean (SD) for overall delivery was scored at 2.99 (0.84) suggesting overall competent delivery.

Active participant involvement (CC1) scored highest approaching the proficient level of delivery, while engaging social support and managing social influence (CC6) scored the lowest. All other items were rated as approaching the mid-point of the scale for competent delivery (see Figure 3).

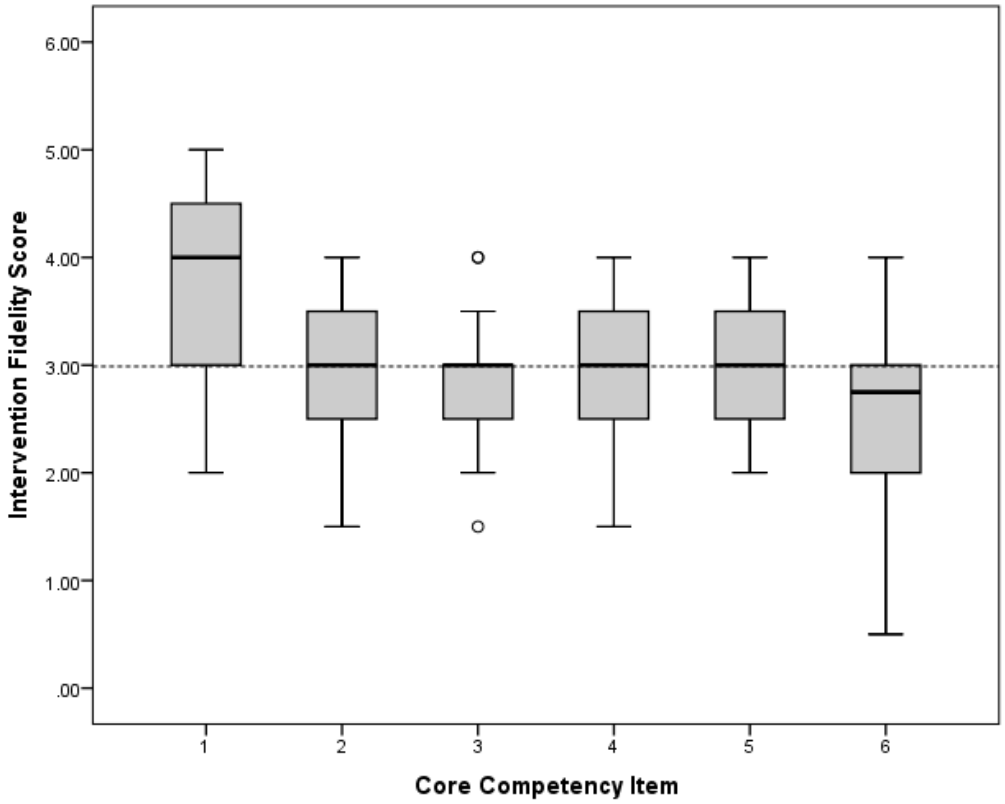


Figure 3: Overall mean (SD) fidelity scores by competency item

Discussion

Overall intervention delivery fidelity was judged to be acceptable, with some areas for improvement. The overall score for competence of delivery was judged to sit between 'advanced beginner' and 'competent'. Given that this was a novel intervention being delivered with a complex target population, delivery can be deemed to be acceptable within the context of a pilot trial, albeit limited by the small number of sessions analysed.

Active participant involvement scored notably higher than the other competencies, and this is likely due to the importance placed upon it during intervention development and HT training. The population were acknowledged as being potentially very distrustful of services, and as such rapport- and trust-building (a key component in CC1) were a key aim emphasised throughout training and supervision. It was particularly evident as an aim of the first session, and through a function of the sampling procedure, more opportunity to demonstrate CC1 was observed due to 50% of the sessions sampled being a first session.

Engaging social support and managing social influence (CC6) showed a trend to be the least well-delivered competence. Anecdotally, this may be due to the difficulties the population faces in ether

feeling trapped by their social circles and influences within a community of offending, unable to relocate, and perceived barriers to what are considered new socially acceptable activities due to their status as a convicted criminal and the attached stigma. Conversely, some participants had consciously isolated themselves in attempt to move away from a culture of offending. Future training and intervention development would benefit from increased understanding of how the population perceive their social influences and identify acceptable ways to help participants to positively manage negative social influence and engage positive social support.

Whilst the other four competencies scored reasonably well, they were all slightly below the threshold for competent delivery. It is possible this occurred as a result of over-emphasis on actively engaging the participant which occurred at the expense of the other competencies, and also possibly as a result of the sampling procedure. Additional scoring of sessions other than the first sessions may have uncovered more examples of proficient delivery of the other competencies. These issues should be considered in more detail in future research and HT training.

Participant experience of the STRENGTHEN intervention

Methods

Recruitment and sampling

Participants were purposefully sampled to take part in a semi-structured one-to-one interview with LC on completion of the 6-month follow-up assessment. Given the challenges of retention and participant burden, the sampling focused on participants who engaged well with the intervention; identified by the HTs and TT. We also aimed to recruit up to six participants who disengaged before an agreed end. Recruiting people who have disengaged from services into research studies is particularly challenging.[73] It was only possible to interview one person who had disengaged due to challenges in making contact and reluctance to participate. This participant's data has been used to inform our understanding of why participants might disengage.

Participants

Eleven intervention and five control participants took part in one-to-one semi structured interviews with LC (broken down by site in Table 31 below). Characteristics of interview participants are presented in table 32 below.

Table 31: Number of participant interviews by site

Service	Control participants (N)	Intervention participants (N)
CRC SW	2	2
CRC NW	1	5

NPS	2	4

Table 32: Characteristics of participants who were interviewed at the end of the study

Characteristics	Control (n=5)	Intervention (n=11)
Age, mean (SD)	45.8 (12.5) years	41.1 (12.4) years
Sex (male/female)	5/0	9/2
Baseline data		
WEMWBS Mean (SD)	42.8 (12.5)	49.6 (11.1)

The two female intervention participants who took part in interviews were from SW CRC (1) and the NW CRC (1).

Interviews

Most interviews were conducted in person in CRC/NPS offices; one participant (CRC) chose to meet in a café. Interviews were between 20-90 minutes; intervention participant interviews took longer. Interviews were guided by a semi-structured interview schedule (see supplementary materials 6) developed for control and intervention (engaged and disengaged) participants. Questions focussed broadly on the acceptability of trial methods (both groups) and the intervention (intervention group). All participants were asked about their experience of being approached to take part in the study, their motivation to participate, their understanding of randomisation and the acceptability of data collection methods. Control participants were asked about their experience of being allocated to the control group and any support that they had accessed to support change in any of the target health behaviours and wellbeing. Intervention participants were asked about their experience of being allocated to the intervention group, acceptability of the intervention, procedures and style of delivery, behaviour/wellbeing focus, experience of goal-setting, own behaviour change (single and multiple) and perceived benefits.

Findings

Acceptability and feasibility of methods used to recruit, randomise and assess participants

Process used to recruit participants to the trial

Participants were initially approached by their OM during routine appointments or, if necessary, by phone. We asked them about their experiences of recruitment. Given participants' mandated

requirements to attend CRC/NPS appointments, it was important that they understood the voluntary nature of their participation.

> I: *Yeah and was it your erm, probation officer that introduced you to [name] and, and the research? How did that all happen? Can you remember?*
> P: *Ah, so I had, yeah I had a er, a normal meeting with [name]*
> I: *Yep*
> P: *And erm, she put it to me that there was somebody that was doing a course of some kind and if I was interested would I like to listen about it and make a decision. Made it clear that I didn't have to and it wouldn't be coming back on me if I said no, so*
> I: *Okay, that's good*
> P*: I wasn't forced into it.*

The research team worked closely with OMs to ensure that participation was not counted toward an enforceable component of their order, although one participant thought that it did. Some OMs allowed their clients to forgo a probation appointment if they attended a STRENGTHEN appointment. Participants in both groups found the initial introduction process acceptable, and the study information sufficient to make a decision regarding participation.

Motivations for taking part

Participants in both groups talked about making a contribution to research as their initial motivation for participation and clearly understood that this was a research study, not an offer simply to receive an intervention. Participants were keen to contribute to help people in a similar situation and to knowledge building.

> *"Erm, after I heard about it I thought yeh, why not? It didn't seem to require a huge amount for me. But I am all for statistical research to back up information, or to discover things."*
> **[Participant 10, SW NPS, control, male]**

Intervention participants in particular spoke about wanting to make a change in their lives, although this was not always obviously linked to the target health behaviours; for example, using the intervention to provide occupation to fill their day and support them in developing a routine.

Others were motivated by concerns about health.

> *"I chose to take part because erm, I realised that perhaps my health isn't at it's great and erm, over the course of the last few years it's deteriorated quite rapidly really."*

[Participant 8, SW NPS, intervention, male]

Randomisation: understanding the process and acceptability

Participants were generally accepting of the process and necessity for randomisation.

> *"Er, and then when she did the initial interview erm, she said she'd phone back and let me know what group I was in. But I could still er, doing like erm, interviews, every three month, erm, without intervention so erm, they could work out, erm, the difference between those that have had intervention and those that haven't."*
>
> **[Participant 16, NW CRC, control, male]**

Although there was some disappointment expressed by control participants interviewed that they were not allocated to the intervention group, it did not reduce their motivation to participate in the study and engage in follow-up appointments. Two of the control participants could not remember being told which group they were in but it was not clear if this was due to difficulty of recollection or failure in communication. There was some confusion about whether the decision was random or based on their responses to outcome measures.

> *"Get a Health Trainer or not so…Erm, yous a, obviously analysed, I don't how it, how is it marked? The questionnaires that I did were assessed and then I got allocated a Health Trainer."*
>
> **[Participant 7, SW NPS, intervention, male]**

Acceptability and feasibility of data collection methods

As described in Chapter 3, the researcher read aloud a script to introduce each measure and completed each item, to support engagement and literacy difficulties. Participants were given the opportunity to self-complete the WEMWBS if preferred, as this measure is validated for self-completion or telephone administration. Participants were generally happy to complete outcome measures at baseline and follow-up. Interview participants questioned the wording of the CRF, particularly the SF36. The STRENGTHEN PPI groups had raised the issue of potentially confusing Americanisms within this measure, which was supported by the interview participants. The RAs were therefore trained to offer alternative words to clarify the meaning of any unfamiliar words or expressions if needed. Although most participants found the length of the CRF and the time taken for completion acceptable, some found a proportion of the items repetitive. Most participants found the experience positive in terms of the interaction and the researcher explaining terms, although one questioned how the presence of a researcher would affect participant's honesty. Some participants

experienced their positive interaction with the researcher as a motivator for completing follow-up interviews.

> *"[researcher]'s been nice, so, you know, that does, that does help your motivation to come back."*
> **[Participant 8, SW NPS, intervention, male]**

There were some frustrations expressed that the measures did not cover areas of participants' lives that they felt were important to understanding their responses to the outcome measures. One participant expressed difficulty responding to items regarding physical health due to their disability which was not covered by the CRF. Other participants experienced difficulties in providing appropriate responses as the 'restrictive' scales did not allow them to respond in a way which represented their situation.

Acceptability and feasibility of the intervention

Intensity of support

The frequency, duration, and mode of support provided by the HTs was flexible and participant-led. Participants were informed at the start of the intervention that they could have up to 12 one-to-one sessions over a 14-week period. The HTs noted, in the early stages, a gap between randomisation and the participants' initial contact with HTs; it was agreed that the 14 weeks would commence from the date of the first session. All first sessions were in person within the building in which participants met with their OMs. However, after this, the frequency, mode (in person or telephone) and length of sessions were guided by the participant in conjunction with the HT. CRC participants were also given the choice to meet with their allocated HT in another location.

Participants were able to make changes to the frequency of sessions according to their needs. Therefore the intensity of HT support could be increased or reduced to support behaviour change goals, due to changes in circumstances or other commitments, or as participants took increased control over health and/or wellbeing and relied less on the support of the HT.

> *"There was a greater, you know, at the beginning I was seeing [name] once a week, then went to fortnightly and then three weekly and then monthly."*
> **[Participant 7, SW NPS, intervention, male]**

The duration of HT sessions was acceptable to participants, with most recalling sessions lasting approximately 30-90 minutes. Participants reported enjoying the sessions and that the time seemed

to go past quickly. Participants also appreciated the flexibility of being able to increase sessions when required, appreciating the chance to talk beyond the suggested hour.

> *"Mmm, erm, I sup, I don't know, I think everything was sort of, for me, you know, [name], I just, you know, she gave up a lot of time, you know, extra time, you know. I know obviously it was an hour and like I said at the beginning sometimes an hour and a half."*
> **[Participant 7, SW NPS, intervention, male]**

No participant felt that the duration of the intervention was too long for them, some felt that the intervention was the right length for them, others would have liked to have received the intervention over a longer period due to changes in circumstances. Examination of dates of sessions showed that 23 participants had gaps of 3 weeks or more during their engagement with the intervention. The flexibility of the duration of the intervention meant that participants could fit the intervention around often very challenging situations in their lives within the 14-week time frame.

Mode of delivery

Participants chose in-person, or telephone sessions, or both. Participants found the modes in which the HT sessions were delivered to them were acceptable.

> *"Definitely. The first Trainer, I feel terrible that I don't remember their name, was very helpful, I got a lot more phone calls. They chose to do this and I chose as a mutual agreement, to do them on the phone."*
> **[Participant 14, NW CRC, intervention, male]**

Participants described how HTs also communicated with them via mobile phones to maintain contact between sessions. This extra communication enabled participants to receive information related to supporting their behaviour-change goals and reminders for intervention appointments. Participants found this to be acceptable.

> *"Erm, I had, you know, texts and erm, and erm, phone calls and stuff, you know. Not overbearing but, you know, just, just enough to you know, remind me and stuff, so yeah."*
> **[Participant 8, SW NPS, intervention, male]**

Location

CRC participants were given the opportunity to meet with their HT at an agreed public place following the initial meeting. This option was not available to NPS participants due to their higher category of risk. As both CRC offices were in busy city centres and in areas where parking charges were enforced, being able to meet in an area that was local to residences or work places facilitated attendance.

> *"Yeah, like a café that was close to me commute, cos I've, it was, I was pushed for time each time, it was, cos of obviously working and two kids and stuff so it was closer to home. It was really handy."*
> **[Participant 12, NW CRC, intervention, male]**

NPS participants were aware of their assessed level of risk and understood that their HT sessions would be held in the probation service offices. One NPS participant stated that although he would have preferred to have attended sessions in another location, the flexibility of delivery meant that he was able to arrange sessions to take place immediately after a mandated course. This flexibility and further strategies for managing his anxiety when in the waiting room meant that he could maintain his engagement.

Suggested adaptations

Participants in both arms of the pilot trial found their participation in the research and, where relevant, the intervention, to be acceptable. Participants suggested potential improvements including:

- Researchers should explain, potentially, hard to understand words within the CRF without the participant having to ask or show that they did not understand.
- Worksheets could be used more systematically to review overall progress.
- A participant with a diagnosis of ADHD suggested that the intervention could be offered alongside activities which could facilitate people with a similar diagnosis to make the most of the support being offered.
- Signposting to other services.
- Providing literature and information about events linked to target behaviours.
- Offering more sessions to follow up their progress or extend the intervention.

Health Trainer experience of delivering the STRENGTHEN intervention

The 6 HTs (3 in NW, 3 in SW) who delivered the intervention took part in one-to-one semi-structured interviews with LC in person (SW) or by telephone (NW). Interviews were guided by a semi-structured interview schedule (see supplementary materials 6) which asked questions in relation to training, supervision, intervention manual, their experience of delivery, including barriers and facilitators and MI techniques.

Findings

Key themes from HT interviews are presented below with example quotes to support each theme.

Training

Seven HTs were trained across both sites (three in the North West and four in the South West, refer to chapter 2, Intervention development). One was not available for an interview at the time of leaving the role.

Practical application

HTs spoke about the chance to practice elements of what they had learned during the training sessions. In particular, the MI techniques with the opportunity to practice one-to-one with one of the STRENGTHEN PPI representatives was valued.

> *"Um, so just having that actual practical experience for me, um, was really useful 'cause, um, you know, we learnt all about the theory and everything but I think it's really important to actually then do that."*
>
> **[HT1]**

Training structure

During the course of the pilot study, we had to find and train some replacement HTs quite quickly. We experimented with offering the HT training over two days instead of three for Health Trainers brought into the study later on, in one-to-one format with subsequent additional remote training and supervision. The HTs were generally positive about the structure of the training in a group, but one of those completing it over 3 days did find that a great deal of information was covered within that timeframe.

> *"Um, no, it was all relevant really, um, I think, I think the three days was difficult but then it was probably even more difficult for H 'cause she's done it in two."*
>
> **[HT3]**

The value of group training was highlighted by a HT who joined the NW site at a later stage. The existing part-time HT was able to join the training, which she felt made a positive difference to her

experience:

> *so I think it was quite useful for him to do it again, but it also meant that both of us kind of with [line manager] just y'know, it was just a bit better having like a three-way chat for sessions* [HT4]

Motivational interviewing

HTs talked about their experiences of receiving MI informed training. They valued the opportunities to watch videos of the techniques being applied by experts and then to practice the techniques live.

> *"And I'd thought about it before in the last project as well, it's one thing to watch a video, and you watch what's-his-face do the motivational interviewing, and he's brilliant at it, and he makes it look really easy, and it's a totally different thing when you're the person, and you don't know what people are going to present with."*
>
> **[HT6]**

The coverage of MI within the training sessions also supported HT training and direction in the delivery of the intervention to the population. Using examples in the manual and those provided by the trainers, they were able to gain an understanding of both the specific needs and characteristics of the population and how the MI techniques and principles could be applied to successfully deliver the intervention in the probation/CRC context.

> *"Through descriptions with people and you had to write things with the strength lenses in mind, and then as a weakness. It was just really good to see. I think the whole idea was talking about you might come across an offender manager who speaks really negatively about like a participant and it's like "oh they're rubbish and …" but if you just get the basic facts about them you can spin it any way. You can make them sound as if they are working really hard to improve themselves, or you can make them sound as the y'know, just stuff about and do nothing."*
>
> **[HT4]**

Manual

HTs described a range of ways in which they used the manual following training and during intervention delivery. Revision of key information was one of the most common ways in which the HTs perceived the manual was supporting them to deliver the intervention. HTs talked about the manual supporting general revision of the intervention, for example:

> *"it's quite a tool to just…just keep the knowledge kind of ticking over."*

[HT4]

It was also used by HTs for specific revision of MI techniques to give confidence and enable them to retain information that they would require during an intervention session.

> *"Just, um, so I did, like before I saw the first person I read through the MI techniques,…and sort of wrote some key points, um, down in my notebook and just like read them through a bit before the appointment just so they're sort of in there*."
> **[HT1]**

Using the manual to prepare for sessions was seen as particularly useful by one HT who used the manual to review and revise the more complex techniques or those that she felt less confident in using prior to delivering a session.

> *"There's one that's in there that I'm stronger at than others naturally, so erm I like to look at y'know like, I think I'm quite good at reflecting…but, it…it's the more complex one and I like to think beforehand if…if those things are fresh in my mind before I go into a session."*
> **[HT4]**

HTs also used the manual to keep in mind the range of tools available to them to deliver the intervention, including behaviour change and MI techniques and supplementary materials including worksheets and diaries. This supported them to be both flexible and responsive to participants' goals and circumstances.

> *"Yeah very much so, I mean I think with, with a lot of work that I've done in the past, obviously I want to make sure that I'm using a range of different techniques as well so I can sort of make sure that I'm doing a good job basically…yeah…re-reading over…over stuff as well, and it is useful because you can just figure it out and you can just look at a section that [you don't know] and yeah, I find it useful, but that's me."*
> **[HT4]**

HTs reported the content and format of the manual as acceptable and accessible. In particular, quotes used to demonstrate and illustrate specific points in the manual were viewed as useful in emphasising what is useful in terms of delivery.

"I can't remember specifically what section it was under – but there was a PPI group saying, um, er, 'it's just nice to feel that you're not being judged, it's nice to have someone be genuinely interested and care'. Um, it's all little things like that to do with the delivery and with the techniques that are being used so you can actually see whether those, whether those techniques are actually working."

[HT2]

Supervision

Overall, HTs found supervision to be acceptable and useful. Group supervision was attended every fortnight with Southwest HTs attending in person with the supervisor (TT) and the Northwest HTs attending virtually by Skype. HTs discussed the ways in which they made use of supervision. Stated uses varied from sharing key issues from HT sessions, consolidating learning of core competencies, confirmation of practice (e.g. appropriateness of signposting), and receiving support to maintain the person-centred approach of the intervention.

At the start of intervention delivery, time was taken during each supervision session to listen to session recordings, to review practice in terms of both delivery of the core competencies and use of MI techniques. As delivery progressed, HTs listened to pre-selected sessions in order to discuss a broader range of practice. All HTs found listening to recordings useful, to review interactions with participants and improve their application of the MI techniques by listening to both their own practice and the suggestions of the supervisor and fellow HTs.

"Good to practise that and again just checking if there are ways that you can improve the techniques or, you know, seeking advice or suggestions from the others and ways to maybe approach things differently if you get like a similar problem with something that comes up or…just, yeah, using it as like a discussion point, um, for how to deal with things really that come up and, so that was useful."

[HT1]

HTs also spoke about the utility of listening to session recordings to reflect on their own practice.

"you know quite difficult listening back to your own voice…but it is really useful because you…you can kind of reflect on what you've done and then go back to your [memory] and think actually I probably could've done more if I'd done that or used that technique. So yeah so far I think it's been…it's been a good experience yeah."

[HT4]

Group supervision was supplemented by short (3-5 minute) one to one phone calls following every HT session. Although these phone calls were primarily to provide a safety check in, they were also perceived by HTs as facilitating a vehicle for brief one-to-one supervision.

> *"Yeah, we had a bit of a chat, and a bit of a debrief and, so that kind of acts as a bit of one to one supervision as well."*
> **[HT5]**

Further, HTs felt that they were able to download their experience of their most recent sessions while it was fresh in their minds, and additionally, the call enabled them to feel supported and connected to the intervention team when working at a distance.

> *"Does make you feel like you're supported, you're part of a team. Your welfare is important and you get to...get to have an immediate debrief. It's quite useful to kind of articulate out loud, that if you go away from your appointment and you just churn it over in your head."*
> **[HT4]**

Formal supervision was conducted as a group, with short post-session telephone calls perceived by HTs as providing one-to-one supervision as described above. Additionally, one-to-one supervision and support was also available at other times when required by the HTs. The focus on group supervision was viewed as acceptable to the HTs in supporting them to share their practice and develop their learning in order to enhance their delivery of the intervention.

> *"Um, but I think the advantage of having joint is that you're learning from each other and, you know, one person might have come, um, had an experience and the other person is like 'oh, I've had that too actually and this is what I did' you know, and it's just, it's really useful for sharing ideas and because, particularly when there's two of you doing, you know, delivering the same intervention, you know, um, you can learn lots from each other."*
> **[HT1]**

The supervision structure and agenda was also flexible to take account of the needs and priorities of the HTs. Additionally, the supervisor facilitated a supportive and responsive approach to promote discussion of key issues.

"No, I don't think so, [name] always gives us lots of opportunities to bring up, it's not like he dictates everything, and goes, right that's it, it's all over. He always gives us plenty of opportunities to ask questions, and bring up any issues that we're having and things."
[HT5]

Barriers to delivery

The main barriers to delivery stated by HTs related to non-attendance of participants and difficulty with contact. Reasons for non-attendance perceived by HTs ranged from caring responsibilities to difficulties with both organisation and ability to attend appointments due to perceived chaotic life circumstances.

"when they've got chaotic lives, things going on, it's actually quite a high rate of, you know, cancellation and that's where you've got to be so flexible but, you know, they tend to always do want to actually then just re-arrange."
[HT1]

HTs spoke about dealing with non-attendance and encouraging attendance by being flexible and non-judgemental when participants cancel and/or make contact to rearrange (in some instances multiple times). They also talked about strategies, such as working alongside OMs so that they were able to assertively contact participants by coordinating with routine appointments in order to make contact. Communication with OMs also enabled HTs to understand participants' needs and that their challenges in attending were not specific to their HT sessions.

"When I got that email from the offender manager, I was almost quite relieved to be honest, that I was like "right it's not me". I was a bit like "oh god no one really" y'know "no one wants to meet me" it's just difficult clients."
[HT4]

Location at probation/CRC offices was perceived as a barrier by two HTs. Only one viewed this as a barrier due to the intervention being delivered in probation per se, due to the negative experiences and associations with the location and the other due to the physical health needs of one of the participants.

"So, that could be a barrier to them engaging with the intervention, if they just don't want to go to the probation."

[HT5]

The final barrier offered by two of the HTs was linked to the person-centred nature of the intervention. Although HTs supported participants to develop and work towards goals that related to health behaviour(s) and/or mental wellbeing that were of the participant's choosing, this was not always viewed by HTs as the optimal decision for the participant in terms of either improving their health or being the most important choice in terms of reducing their risk of ill health.

> *"Yeah I mean I think definitely be able to use the supervision and [unclear] remember after the first one erm…I knew that he would…but…but…I am sure you are going to know exactly what I am saying but you could see what he should probably be focussing on but unless he said he wants to focus on it, he's can't focus on it."*
> **[HT4]**

Suggested adaptations

HTs suggested adaptations to enhance their delivery of the intervention included the following:

Training

- More time to practice MI techniques and receive feedback.
- Wider range of modes of delivery throughout the training sessions to break up time with activities.

Manual

- Add inclusion of a clear definition of the role and remit of the HT.
- Provide guidance regarding the use of the data management system for reference post-training.
- Provide guidelines and suggested wording for telephone calls and text messages to participants to support effective communication.

Supervision

- Allocation of more time for discussion of core competencies and how they are applied in practice to enhance learning.

Two proposed additions to supporting materials were actioned in the early stages of delivery:

1. Development of a working document of local services and schemes to which participants could be signposted. The original HTs in both sites were able to use their time as their

caseloads built up to identify local services to collate a list of signposting options.

2. It was suggested that the participants should be provided with some paperwork to support their engagement with the intervention. This led to the development of a participant pack containing information about the intervention remit, the HT and local services. This was presented in a folder in which any further information and worksheets used by participants during the intervention could be stored.

Offender Managers' experiences of working with the research team

Six OMs who had identified and approached potential participants took part in one-to-one semi-structured interviews, two from each OMS. Interviews were conducted in person by LC during the final phase of intervention delivery and follow-up assessments. Interview participants were purposively sampled with direction and support from site researchers. Interviews were guided by a semi-structured interview schedule (see supplementary materials 6). Questions focussed on caseload characteristics, experience of working with researchers, understanding of the pilot trial, approaching clients to take part in the trial, perceptions of the intervention and their current and recent experience of the impact of Transforming Rehabilitation.

Findings

Key themes from OM interviews are presented below with quotes to support each theme.

Working with women

OMs discussed women both in terms of their needs, and how their service had sought ways of meeting those needs. NPS and CRC OMs who took part in interviews had similar experiences and perceptions of women in terms of both the complexity and level of need. Accentuated areas of need included safeguarding (due to often being past and current victims of abuse); mental health; alcohol and substance use; and childcare.

> *"I suppose their level of need can be higher, I think. I think the ones that tend to come our way do need a lot of support."*
> **[Site 1, OM2]**

There was understanding of the need to offer women alternative locations to the main probation offices in order for them to feel comfortable and safe to access probation support.

> *"I suspect they're better at turning up at those [community organisations] kind of places than they are here, you know it always can be quite daunting for female offenders to come in here."*
> **[Site 1, OM2]**

OMs in both CRC services talked about various ways in which their services worked in order to enhance women's access to and promote engagement with probation support. In both sites, this has involved provision of services in a location separate from the main CRC office. In site 1, this was a drop-in centre with a more relaxed ethos at a community organisation separate from the building and organisation of the CRC.

> *"Well, offering different ways of working, so the drop-in on a Tuesday in [name of service] for women, the women's space, is run differently, it's quite a - I've never been, being a man! - it's much more relaxed and less structured."*
> **[Site 1, OM1]**

Similarly, in site 3, very few women use the main city centre probation offices and are able to see their OMs through more local specialised women's hubs that enable them to attend with children with a more open and flexible approach.

> *"Um, we have specialised women's hubs where it's a little bit more flexible in terms of say half term when they've got the children there, you know, that kind of thing and, um, looking at … there seems to be, especially in Manchester, a lot more kind of support and interventions for females, um, I don't know if that is just the Manchester but that's how it feels. I do think that they have very different needs and there's different crisis when it comes to the male and female."*
> **[Site 3, OM2]**

Sources of community support:

OMs talked about the range of support services in the community and the perceived barriers to accessing these services for their clients. Participants spoke about the need for, and/or provision of, services to meet the varied needs of their clients including the target health behaviours of the STRENGTHEN intervention (including alcohol, physical activity and smoking) and mental wellbeing/mental health, as well as other health and social needs including GPs, housing, probation services, risk, employment and access to dentists. All OMs talked about barriers for their clients in accessing support services to meet these health and social needs in the community. One of the main barriers to access was the lack of service resource to meet the level of need in the community. One OM talked about the lengths that he and his colleagues went to in order to manage a client experiencing mental health crisis and the inability of mental health services to be able to provide timely support due to low resource availability.

"Yeah. I mean we had a guy in reception last week, he'd come in at the beginning of the week and said he was suicidal, he was going to throw himself in front of a car, [name 17:07] managed to talk him out of that and got him down to the housing office and got him some B and B accommodation, he then came back two days later, he did have a mental health appointment but it wasn't til the 7th of March. He came back two days later and said that he'd taken this whole packet of tablets the night before, so we just had to sit with him got an ambulance, just sat with him til the ambulance came. So yeah, that's always-''

[Site 1, OM2]

"But there's just not enough out there, it's not that easy to do it. I know other, the agency that we work with have got a massive waiting list so if somebody turns up and they're homeless it's like, right, okay, you can get seen in six to eight weeks"

[Site 3, OM1]

Some clients are also excluded from being able to access services due to their living circumstances, such as homelessness, which means that they are unable to provide an address. For NPS clients, the nature of their offence and subsequent conviction(s) often resulted in loss of family, employment (and in many cases, chances of future employment), home, and they may have needed to move to another area to live. Further, some services exclude individuals due to the nature of the offence. For example, a local mental health service in one site would not allow sex offenders to access its services despite the arguable need in terms of isolation and loss. Similarly, the same OM identified a need for support services for sexual abuse among her clients which the main local service could not meet due to their exclusion of victims of sexual abuse/violence who had been convicted of sex offences.

"Um, and, you know, I went to [name of service] and said 'will you work with him?', you know, 'you don't need to touch the sexual offending, I am doing that work, but he desperately needs to work on his sense of loss and his identity, his sense of identity' and they just wouldn't touch him. You know, and who else is going to do that work?"

[Site 2, OM2]

Working with the STRENGTHEN pilot trial

OM participants shared their perceptions of the parameters and processes of the trial in terms of their experience of working with the research team to identify and recruit participants.

Inclusion and exclusion criteria

OMs discussed the inclusion and exclusion criteria in terms of their applicability to their clients and their appropriateness, both in enabling a balance of those who might benefit from the intervention

and ensuring, as far as possible, that participants who were recruited would be able to engage in both the research and the intervention if they were allocated to the intervention group. One of the inclusion criterion considered by the OMs was that of potential participants having to be released from prison (where applicable) for at least 2 months before the search was conducted. One CRC OM commented that this might be more appropriate for NPS participants than for those in the CRC.

> *"I suppose it's probably different for us* [CRC] *and the guys upstairs* [NPS] *as well, they probably at the two-month stage would be fairly settled, because probably for those that aren't settled by that time they'd be looking probably to send them back to prison."*
> **[Site 1, OM2]**

Although the other OM participant at the same site concurred that basic needs had not always been met in his client group within this timeframe, he felt that having the two-month limitation was a useful starting point and ensured that they could develop a relationship with him which he believed supported the initial approach to take part in the study.

> *"It also meant that they had a chance to get to know me, cos if they'd just come out of prison and they've not worked with me before, they're perhaps less likely to be interested or willing to consider it."*
> **[Site 1, OM1]**

Other issues stated included the need to exclude potential participants due to the length of time that they had left to serve on their order, which reduced the proportion of the caseload that could be approached.

Conducting the search

OM participants spoke about their involvement in the identification of potential participants in terms of using the inclusion and exclusion criteria to search for potential participants on their caseload. Generally, OMs felt that their involvement in this process was valuable in supporting accurate identification of people who might want to take part in the trial.

> *"I mean, someone can look through a whole caseload and say, on the dates we have, yes, this person's eligible and they're not, but they can't say whether they're motivated, or potentially interested, or there are other thing going on which mean that they're unlikely to be able to take part."*
> **[Site1, OM1]**

OM participants found the process of working with the researchers to be acceptable as they were able to fit this in alongside their routine work. It was also noted that this was facilitated by the flexibility of the researcher both being based in the organisation (or for site 2, within the same building) and flexible about when they were able to meet with the OM. Further, two OMs commented on the minimal burden that this process involved.

> *"It was fine, it was really straightforward and really quick".*
>
> **[Site 2, OM2]**

Recruitment

The co-location and flexibility of researchers was viewed by OMs as helpful for the recruitment process, enhancing communication and maximising opportunities to approach potential participants with perceived chaotic lifestyles. Initial approaches, in most cases, were made by OMs asking their client if they would be willing to talk to a researcher about taking part in the pilot trial. Following a positive response, they were able to immediately invite the researcher into the room to make the approach to participate.

> *"What I normally do is, um, explain that she's here, are they OK to just have a little chat with her and she can explain more about what the study is….um, and then they can either go away and have a think about it or they can let her know if they want to be involved or not. And then introduce [name of researcher] and she'll explain what it's about."*
>
> **[Site 3, OM2]**

It was also important for OMs to feel that they could introduce the study appropriately, either if the researcher was not able to be there at the time of a routine appointment or for some of their clients who may not have responded well to the initial approach being undertaken by the researcher.

> *"Yeah, because some of them, you know my less motivated people, might be very angry, so I will just test the water first, and if they poke it, I won't waste (researcher name) time. Or it might be that no one can make it on the Tuesday, so I will run it through with them, and they can meet the following Tuesday."*
>
> **[Site 2, OM1]**

During this initial introduction made by the OM, they spoke about both what the intervention would involve, in terms of the health behaviour and wellbeing focus, and the research, in particular the voluntary nature of the study and randomisation. OM participants not only emphasised to their clients that taking part in the pilot trial was voluntary, but also believed that the voluntary nature of participation in research was important for successful engagement.

> *"if they're only doing it 'cause they think their probation officer wants them to do it and they think that it's part of a, er, a statutory instrument then … that could undermine the, the study because the study is all about it being voluntary."*
> **[Site 2, OM2]**

This understanding contributed to the decision not to link involvement in the trial and/or intervention as a contribution to Rehabilitation Activity Requirements (RAR); as well as potentially incentivising participation, the enforceable nature of RAR days (i.e. if they did not attend a researcher or HT session, they could be called to see their OM or to court), meant that ongoing participation could not be considered voluntary.

> *"Yeah, endorsement of worth considering about, but making sure that they were aware it was entirely voluntary and that it didn't affect their work with me, that it could fit in with that, but if they didn't want to take part that had no bearing on what I was working on with them."*
> **[Site1, OM1]**

In general, OMs understood both how randomisation worked and that it was necessary for the pilot trial. However, there was some disappointment and frustration for those who were allocated to the control group and did not receive the intervention who were perceived as needing further support.

> *"It's frustrating but I suppose, I don't entirely understand the how and why cos it's like if you've got somebody who does need it, why not give it to them?"*
> **[Site 3, OM1]**

Barriers and facilitators to engagement and retention:

OMs described a range of barriers and facilitators to engagement and retention both in terms of what has worked and not worked in their management of clients and also their views about what would and would not work in terms of engaging and retaining participants in the trial and intervention. Having both busy and chaotic lives was seen as a barrier to engagement. Common challenges

included childcare and other caring-related commitments (particularly for women) which clients may perceive as making them too busy to take on further appointments, and substance/alcohol abuse and homelessness that contributed to perceived chaotic lives.

> *"Cos they're just all over the place, it's like herding cats really, with some of those."*
> **[Site 1, OM1]**
> *"So current homeless people. I think relevant, I mean it would be of use to them, cos you know, really cos a lot of times their health, wellbeing is terrible… but they're also more likely to not turn up."*
> **[Site 3, OM1]**

Related to the perceived chaotic lifestyle of a proportion of (mainly CRC) clients, is the competing priorities of these individuals in terms of accessing interventions when their basic needs have not been met. OMs from both CRC sites cited homelessness as one of the main priority areas for people which needs to be addressed prior to accessing health and wellbeing interventions.

> *"And I suppose, if they're worrying about where they're going to sleep at night, or, how they're gonna pay their bills, what they're going to eat that day, or anything like that, because quite often that's what we're dealing with, and you know, I suppose it's just prioritising."*
> **[Site 1, OM2]**

The association of STRENGTHEN with probation was also viewed as a potential barrier to engagement due to (potential) participants being suspicious and defensive in that context.

> *"Sometimes they associate it with probation sort of thing, even once they're through the door, so people think, they've got their own barriers just because they're here. You know, so they've got their defences up all the time, sometimes."*
> **[Site 3, OM1]**

Lack of motivation to change was also perceived as being a barrier to engagement. Firstly, through not wanting to take part in anything above what they are already doing and second, not having an insight into their current situation and therefore not perceiving a need for support from an intervention designed to help them to make changes. Other practical barriers suggested by OMs included distance required to travel to access the support/intervention and lack of finance to pay for travel.

> *"Their lack of motivation, thinking they haven't got any issues."*

[Site 2, OM1]

A range of facilitators to engagement and retention were provided by OM participants, often in response to the barriers stated above. Accessibility of the researcher and having someone known to the individual who was present in the building was seen as supporting initial engagement, through direct introduction by OMs.

> *"Because their lives are that chaotic and stuff so it's a case of, so we almost need like somebody in house, just here all the time, who can do that. So when they are here it's like, just gonna go and get them, can just be like, yeah."*
>
> **[Site 3, OM1]**

Flexibility of location was also perceived as being facilitative of engagement. As presented above, provision of services in a location other than probation offices was seen as being supportive of women's engagement. This could be extended to individual men, for example meeting in cafes, when they did not want to be seen by others in the building. There were opposing views about the extent to which delivering an intervention in the probation offices, or in partner agencies generally, enhances presentation/engagement, with one OM from one CRC site suggesting that meeting in a neutral location would be beneficial, whereas the other OM from the same service suggested that location in the CRC would support engagement.

> *"You need to be flexible enough. Cos we do it. I see some of my clients in coffee shops and stuff because they've got so much anxiety of coming into the building and being seen by other people, or we've got people in gangs and stuff like that and they're not allowed to cross certain boundaries so you go and see them in local places. As long as it's safe to do so obviously."*
>
> **[Site 3, OM1]**

The nature of sex offenders as 'compliant' was viewed by two OMs (one CRC and one NPS) as making them more likely to engage. However, the NPS OM did offer a note of caution that though they may present, that does not automatically translate into engagement.

> *"plus the fact that they are kind of naturally very compliant in all aspects of the way they work with us…at least, ah, certainly on the surface"*
>
> **[Site 2, OM2]**

It was proposed that a small incentive may support initial engagement. However, it was also recognised not only that doing something that may support changes to health may be sufficient incentive for some but also that the offer of support needs to come at a point in someone's life when they are ready to make a change.

> *"I think that would probably be quite successful, I think you're getting a population of people who are wanting to make a change of some kind, and then if there's an opportunity offered, then, it's kind of a happy accident they'll go, yeah, OK, maybe I'll have a chat with somebody then."*
> **[Site 1, OM2]**

Benefits of the intervention

OMs were not directly collecting information about the trial or intervention, however their feedback is insightful. Two OM (CRC & NPS) participants had received feedback about progress of their clients who received the intervention. The CRC OM recalled that one of his clients had completely stopped using cannabis while he was receiving STRENGTHEN HT support. The NPS OM described the benefits of the intervention for two participants who reported health behaviour changes including healthy eating, reduced alcohol consumption and improved mental wellbeing. Further, she perceived positive experience of the intervention as potentially contributing to reducing re-offending.

> *"But, you know, as he left, you know, his, um, order he was saying that, you know, it had been really positive, he was still eating better, he was drinking less, he was walking more, I think he'd lost some weight and I think he was just generally feeling more in control and more positive about himself and his health, so I think that, you know, if anything to boost self-esteem with that group of offenders is a positive thing 'cause, a lot of time they're, you know, just way down here, um, 'cause they know that, you know, they've thrown away so much of their lives and they know that, you know … they, their offending is part of an incredibly dark part of their lives and anything which can raise their self-esteem and make them feel a little bit better about themselves also will be a bit of a protective factor against going back to that sort of very dark time when they were offending so, you know, it is a positive thing for them to feel a little bit good about themselves."*
> **[Site 2, OM2]**

Probation service context and changes

OMs were asked about the service changes that had occurred due to Transforming Rehabilitation and the impact of the change on the service. Participants spoke about a range of impacts on staff

such as changing to new roles and locations, staff changes and losses due to both redundancy and sickness. One of the main impacts on staff stated by OM participants was that of increased caseloads and associated burden. These issues were compounded by staff shortages due to a perceived under estimation of the number of individuals who would be eligible for support.

> *"In terms of how many, how much staff they would need. And when the sentencing guidelines changed, um, in 2014 I think it was, so when the people who got short sentences who initially, they didn't have probation, they went on licence when they came out so that's created so much more work."*
> **[Site 3, OM2]**

Higher caseloads, and other service changes, were perceived as having changed the role of probation workers due to the restricted time that they are able to spend on one-to-one support necessitating increased signposting to other services, with a shift towards increasing group work. Furthermore, referral processes are not viewed as facilitating timely engagement.

Another way in which the changes have impacted on client support in the CRCs is the development of support by telephone. The 'in-touch' team has been developed for low risk offenders to be supervised via telephone rather than in person on CRC premises. Further, the other CRC site had restructured during the recruitment period of the pilot trial to form specialised teams which focus support on specific need including homelessness and women. There was a sense that the organisations were operating in a state of constant change.

> *"it's just kind of constantly changing in terms of the interventions that we deliver and how those are supposed to operate."*
> **[Site 1, OM1]**

Another major impact on the structural and continuous changes to the services is the implementation and functionality of systems that are required to support the work of the OMs and the service as a whole. This has created difficulty for OMs not only in terms of learning and using new systems following the division of services, but also having the required operational resources to enable functions that now need to be shared across two services that were previously managed by one.

> *"And that just takes time cos it's a bit job and sometimes people will come in and they'll be coming in for an induction and we won't be able to see them on the system because it's not been transferred yet."*

[Site 3, OM1]

The STRENGTHEN intervention at work

HT case notes were used to identify the primary and secondary target behaviours of the intervention participants interviewed for the process evaluation. Table 33 below presents the number of intervention sessions attended by interview participants and their original target behaviours. The majority of participants aimed to change at least two of the target behaviours and/or wellbeing. Of the 10 participants who identified a target behaviour early in intervention delivery, 7 reported how they had changed that behaviour in their process evaluation interview, examples of which are also included in Table 33 below. Of the remaining three participants who identified a target behaviour, one reported changing different behaviours (smoking and alcohol consumption) to the original targets (healthy eating and mental wellbeing), and two did not report change in their behaviour during their interview. One participant who did not identify target behaviours reported change in his diet due to the intervention.

Table 33: Number of intervention sessions and original target behaviours of process evaluation participants

Participant	**Number of sessions attended**	**Primary target**	**Secondary target**	**Participant perspective of benefit of the intervention**
Participant 1 [SW CRC; male]	4	Reducing smoking	n/a	Smoking: *Oh, I was really bad at the time, I was sort of smoking in excess of like 15 fags a day, 20 fags a day…So. And within a few weeks of like speaking to [Health Trainer] and stuff I changed onto the electric fags…And that…* *worked really well, I didn't smoke for about 4 weeks, 5 weeks…And broke my electric fag and went straight back to sort of like smoking, but I've noticed I have really, really, really cut down.*
Participant 2 [SW CRC; female]	8	Increasing physical activity	Healthy eating	Unable to make changes due to personal circumstances: *A few, well I'd say, I'd, because of all the stuff that was going on I didn't keep up with it, if you know what I mean*
Participant 5 [SW NPS; male]	7	Healthy eating	Reducing alcohol	Healthy eating: *When this came along (STRENGTHEN), one of things I said was well okay, I sometimes have a couple of cakes after my lunch, I could cut that down to one cake, and that's 50% off that already.* Alcohol: *With the alcohol I knew I was drinking on at least three occasions, a week and I would drink a whole bottle of wine or a couple of beers or something like that. I tried to get it down, mainly successful to twice a week. ..and I try to keep it down to the 11 units, but I don't worry if it goes a little bit above. But I have certainly been keeping it below 20 units.*

Participant 6 [SW NPS; male]	7	Healthy eating	Increasing physical activity	Healthy eating: *To me I wasn't starving, I just wasn't eating properly* *…I'd only eat biscuits and pasties or whatever but…* *There wasn't, you know I wasn't eating but, I do, I did, certainly start. And I bought myself a little thing to cook some stuff in as well. Cos I've got a little grill, you know, grill. I didn't have an oven because I didn't cook* Physical activity: *now I do it on a regular, I mean, whereas I was a bit lazy and went for a walk once, twice a week, I do it everyday*
Participant 7 [SW NPS; male]	11	Other stated target(return to work)	Reducing alcohol	Alcohol: *You know, so that, and then it was just, it sort of weened itself off. And then I used to sort of, you know, when I seen [name] erm, on a thu, as I say, usually on a Thursday, I used to sort of say, right, okay, treat of the week this, once you've seen [name], you've done your two thing, right, go and have a pint. That's what I did, it was just my little treat*
Participant 8 [SW NPS; male]	2	Increasing physical activity	n/a	Physical activity: *I was thinking about it for a while before, but erm, I never really put anything into action. Erm, but I, I started looking at erm, the unhealthy snacks I'd been eating, erm…binge eating er, and erm, and the reasons as to why I've been doing it. Erm, so erm, a lot of it's food boredom erm, and I've, I've been addressing the, the boredom by er, taking my dog out on lots of walks*
Participant 11 [NW CRC; male]	11	No stated target	n/a	Healthy eating: *the only thing that was helpful to me about was me diet because even though I thought I was eating quite healthy when I actually did the food plans and I wrote it down …I did realise that I was eating too much red meat…erm, and so I did cut, cut back on the red meat er…content, content.*
Participant 12 [NW CRC; male]	5	Healthy eating	Enhancing mental wellbeing	Alcohol: *Give up, stopped drinking. On holiday, went on holiday without having a drink* Smoking: *Yeah, that's what I was doing, cutting down over the sessions and… stuff like that yeah*

Participant 13 [NW CRC; female]	4	Reducing smoking	Enhancing mental wellbeing	Smoking: *so yeah from like 20 a day of pre-packed cigarettes to a couple of hand-rolled, um, cigarettes…So, yeah, I'm almost there*
Participant 14 [NW CRC; male]	5	Increasing physical activity	Healthy eating	Physical activity: *I wasn't great before, rubbish to be honest. I was a bit low at times, not really exercising. So I kind of changed everything.*
Participant 15 [NW CRC; male]	4	Other stated target (own accommodation)	Increasing physical activity	No stated change in behaviour: Felt helpful to kind of talk through stuff and try and sort some positive targets out and stuff.

Case study: Jack's story

This case study presents the experience of an individual who engaged well with the intervention who focused on and changed multiple behaviours. Jack's focus was on healthy eating, physical activity and mental wellbeing. All personal identifiers, including distinguishing features of his presentation were carefully modified or removed to ensure anonymity. The case study was selected as an example of multiple health behaviour change alongside change in mental wellbeing. The case study makes use of transcribed HT session recordings, HT session notes and participant interview to describe Jack's journey through the intervention.

Participant description

Jack is a 50-59 year old male who suffers from social anxiety and finds attending the probation offices very stressful. Jack has a casual job and tends to avoid social contact. During the course of the intervention, he moved from a shared house into a self-contained flat. Jack found the process of arrest, court and sentencing traumatic. He has built up a good working relationship with his OM which he finds supportive.

Early engagement with the intervention

Jack's HT had difficulty in making initial contact to arrange the first session. Through Jack's OM, his HT was able to arrange an initial meeting at a routine probation appointment so that his OM could introduce his HT which helped him to meet her in a way that he was comfortable with.

Through this interaction with Jack's OM, his HT was aware of his social anxiety and mindful of the impact that this may have on building trust. However, she felt that he had relaxed to some extent by the end of the first session.

> *I think it will take some time for Jack and me to develop trust as he is very anxious and wary of people. However he did seem to relax a little in this middle of the session…he has agreed to attend another session, and made a joke on his way out, which suggests he might feel a little more comfortable than at the start of the session.*
>
> **[HT session notes]**

With knowledge of Jack's social anxiety, she adapted her approach in the first session in order to actively involve Jack in the session. This involved the use of one of the worksheets to take the focus away from general conversation. This helped to focus discussion on how he felt about the health behaviours and his mental wellbeing, using MI techniques to support rapport-building.

> *This session was more directive than other sessions, in that I felt the best way to engage with Jack was to focus on the project as he didn't seem like he would find it easy to talk more generally at this stage. Using the pentagon was particularly useful in this session, as it gave us a focus for discussions. I tried to be gentle, e.g. in terms of my tone of voice and taking things at his speed. I was careful about my body language. I used open questions, affirmation and praise and empathy.*
>
> **[HT session notes]**

Jack's use of the pentagon worksheet provided a score out of 10 for each health behaviour and mental wellbeing (0 being the worst it could be and 10 the best it could be). Jack scored his diet at 5, physical activity as 5 and his mental wellbeing as 3. Jack's primary target was healthy eating, with a secondary target of increasing physical activity. Jack lived primarily on take-away foods and did not cook. With a focus on healthy eating in the first session, Jack used this as an opportunity to review his eating and relationship with food and the processes that he needed to engage in to eat food that he prepared himself, i.e. shopping, preparing food and cooking. One of his early observations was about cooking.

> *"I haven't had a cooked meal for about eighteen months."*
> **[Session 1 recording]**

Further, as Jack felt more comfortable opening up to his HT, he spoke about the impact of his social anxiety on his ability to buy healthy foods.

> *"I don't go Tesco's or Sainsbury's and all of that, there's too many people now, I couldn't go there. I'm no good with people at the minute."*
> **[Session one recording]**

Exploring motivation

As the HT supported Jack to review his recent eating behaviours, he revealed that he had recently bought food in his local corner shop to make himself a sandwich. This was a big step for Jack, as he explains.

> *"I bought a loaf of bread and some cheese and made myself a cheese sandwich…I mean, that's how unusual…because I felt it was unusual for me to be doing it."*
> **[Session 1 recording]**

The HT actively explored Jack's motivation for wanting to change his eating habits, and in particular, why this was important to him. She noticed that Jack had talked about being normal or wanting to feel normal and used refection to test this out with him.

> *"You've said normal a couple of times isn't it there's sort of feeling normal seems something that's sort of quite important to you doesn't it*?"
> **[HT session 1]**

Jack agreed with this and went as far as to say that the act of buying food and making a sandwich for him to eat made him feel:

"Bit back to normality"

[Session 1 recording]

While it was clear that his confidence for shopping in supermarkets was low, he felt confident buying food in his local corner shop.

P: *Cos I know the corner shop and they know me…so I can just go there, buy my stuff*

HT: *Feel safe there?*

P: *Yeah, that's it. Then come away*

[Session 1 recording]

By understanding both why it was important for Jack to focus on and change this behaviour, and by exploring his current level of confidence for performing behaviours to support healthy eating, the HT was able to start to offer suggestions related to Jack's review of his current eating and link that to his aim to improve this.

"So maybe think about, maybe it's just next time you're in there buying your kind of, your regular stuff, think, have a little look at what else they've got in there that you might fancy. I'm just thinking you know, what's gonna move you. So you're a four at the moment and I'm you know, wondering what's gonna kind of, what we could do to get, to move it up a little bit."

[HT session 1]

Early goals

Due to the way in which the HT actively engaged Jack from the outset, progress was made in the first session in terms of both identifying target behaviours, and developing goals, both long-term and short-term. By the end of the first session, Jack had explored foods that he enjoyed which formed the basis of a shopping list and made a plan to shop in his local corner shop and prepare simple food.

"But that's an idea, maybe I'll write erm, and I'll go and get some stuff. Maybe at the weekend."

[Session 1 recording]

The HT and Jack also discussed using a food diary following their session. Jack was keen to use this both to review what he was currently eating and to make plans for what he would eat in the week ahead.

"Cos what I might do is, I think I'll write down what I'm eating but try and put a plan. Not every day but for certain days to have certain meals."

[Session 1 recording]

Further, although the majority of the first session was focussed on healthy eating, Jack and his HT discussed physical activity, firstly talking about his past experience.

> *"Played football every week, you know, did training twice a week. Do running (inaudible, 25.24) none of that now but…"*
> **[Session 1 recording]**

Although time was limited to discuss this area due to the focus on healthy eating, as Jack had already stated physical activity as a target, the HT suggested using a pedometer which was available for Jack to take away with him and use following the session. Jack responded positively to this and made a plan to make use of it with a view to increasing his walking.

> *"No, I will use it, you know, to see how much I walk…I might walk just to more, higher, you know."*
> **[Session 1 recording]**

Further progress

Approximately halfway through intervention delivery (session four of the seven sessions Jack attended), Jack had progressed further in attaining his goals around healthy eating and physical activity. Regarding healthy eating, Jack had managed his social anxiety in order to shop in two large supermarkets and buy some food items from a list that he and his HT had written together.

> *"Yes, that's what I took and I had a look at some of the things on there…and yeah and at least I did it…not a drastic amount but…but the thing was I did it."*
> **[Session 4 recording]**

Jack was supported to review and reflect on what had motivated this change in behaviour, which he concluded was due to goal-setting.

> *"I have to set myself a goal to do something…otherwise I don't do it…and the way my life is at the moment it's easier not to do something."*
> **[Session 4 recording]**

Now that Jack was also cooking, he was also supported to reflect on how he felt after he ate a cooked meal.

> P: *But it's my food has got better just slowly but*
> HT: *Do you feel like you've got a bit more energy from eating a bit better?*
> P: *I do, I feel different after I've eaten*

[Session 4 recording]

Further, Jack had also used his pedometer and had increased his physical activity to 35,000 steps in a week.

Reflection

Jack made changes to both his eating and physical activity which impacted on his mental wellbeing. His WEMWBS scores increased from 31 when recruited to the study, to 35 when the 3-month outcome measures were collected and increased again to 41 on the collection of the 6-month outcome measures. In his one-to-one interview with LC, he reflected on the challenges that he faced and overcame to enhance his diet, particularly around shopping.

> *"But I know that I did go into and I have since, not all the time but been into the bigger shops, if you understand. Didn't buy very much but the thing was just going in there with what I knew I wanted to buy and just went in to buy them. Then come out the shop. And to me that was, I hadn't done that for a long time because of my anxiety and stuff like that so."*
> **[Interview recording]**

He also reflected on the impact that his cooking had on the food that he was now eating compared to what he was eating prior to the intervention.

> *"Spaghetti Bolognese, shepherd's pie, that sort of thing, you know, mince and that. And I made, I think I did sausage, peas and potatoes… You know, just generally easy stuff, nothing you know, nothing too much but to me compared to what I was eating before it was a meal."*
> **[Interview recording]**

Jack also increased his physical activity and even found ways to combine healthy eating and physical activity.

> *"Now I do it on a regular, I mean, whereas I was a bit lazy and went for a walk once, twice a week, I do it every day…*
> *And then I used to, like I'd go for a walk out on the moors or down, wherever I'd go for a walk… and I'd stick a bit of fruit in the pocket for the walk. So I was really doing two things…at the same time."*
> **[Interview recording]**

Finally, increasing physical activity also impacted positively on Jack's mental wellbeing by giving him more opportunities to be in the countryside and take notice and connect with his environment.

"I feel, sorry, mentally I go to a calm place now and like, you know, it's erm, it's erm, yeah it calms me down…Even if I'm not stressed I just, I can go in there and I'm calm and I, I just looking at different things that there I'm walking past, you know. It could be animals, it could be the trees, it could be the birds, it could be people just cycling past, you know…But all these little things, they just send me into my own little world… cos, yeah, cos with my anxiety I just, when I'm in me own space there's nobody else there… so, so it's quite cool."
[Interview recording]

Researcher observations on recruitment & follow-up

RAs kept logs on issues of recruitment and follow-up during data collection. The points below summarise the main observations of RAs across both geographic areas that impacted on recruitment and retention:

- Services were observed as being extremely busy. Researchers were aware that they were working with services during a challenging time of restructuring and change. RAs had difficulty in making times to meet with OMs. Meeting OMs one-to-one supported rapport-building, which aided supporting follow-up.
- Some issues with OMs acting as gatekeepers – suggesting that some potential participants would not be suitable despite meeting the inclusion criteria.
- RAs were aware that they, and therefore the pilot trial, might be seen as part of probation. There was a general feeling that this was more of a problem for CRC participants than for those under NPS. For some participants, OMs supporting the project was seen as being in partnership with probation. For others (mainly NPS) it seemed to help that the OM was supportive of their involvement and that it was to some extent endorsed by the organisation. However, being aligned with probation made it difficult to meet with participants for the 6-month follow up if they had finished the terms of their order early.
- Delays in conducting searches and screening potential participants occurred due to the reliance of the RAs on OMS staff to conduct this role as the research team did not have access to the record system. This also impacted on follow-up appointments as RAs were not able to directly access up to date information that would support securing appointments with participants.

Summary of findings against aims

1. Assess whether the intervention is being delivered as per manual and training;

Assessment of delivery fidelity considered delivery of the intervention by HTs to be acceptable within the context of a pilot trial, with the overall score for competence of delivery rated between 'advanced beginner' and 'competent.' Feedback from HTs showed clear use of the manual to support consolidation of learning from training, which was further supplemented through supervision.

2. We have explored the key components of intervention which are critical to delivery;

The core competencies were seen as critical to delivery, with 'active participant involvement' viewed as the foundation on which the remaining core competencies could be delivered. Other components of the intervention critical to delivery include flexibility and person-centeredness in terms of location, time, duration of intervention and behavioural focus of the intervention. A full trial would permit mediation analysis to determine if key components were important for change in the respective outcomes.

3. Explore reasons for divergence from delivery of intervention as manualised;

There were few reports of divergence from manualised delivery, due to the inbuilt flexibility of the intervention and acceptability and feasibility of delivering the intervention core competencies using the vehicle of the motivation interviewing techniques (with the support of training, manual and supervision). The example of divergence in terms of not solely using the first session for rapport-building rather than goal-setting presented in the case study, was supported by the manual in terms of the delivery being participant-led.

4. Understand when context is moderating delivery;

Participants and HTs generally found the location of intervention acceptable. There was some indication from participants that meeting HTs in a location other than the CRC facilitated rapport-building. Further, some NPS participants suggested that they would have preferred to have met HTs away from NPS offices. In a definitive trial, we could explore individual risk assessments for NPS participants to enable those assessed as low-risk to the HT to be seen in another safe location. Although the context, particularly that the CRC was in flux which impacted on recruitment and retention, there was no evidence that this impacted on intervention delivery.

5. Understand the experience and motivation of participants in Control arm of pilot in order to maximise retention in a full trial;

Participants in the control arm found the trial methods to be acceptable and generally understood and accepted the process of randomisation. Initial motivation of control participants was that of wanting to help others in similar circumstances and contribute to the evidence base by taking part in research. Some participants found the engagement with the researcher at recruitment and follow-up to be a motivating factor, impacting on retention. Although some control participants expressed some

disappointment at their group allocation, this did not demotivate them to continue their participation. It should be noted that those control participants who took part in the process evaluation had completed the 6-month follow-up and therefore may have perceived their experience of participation differently from those who were not retained in the study.

6. Explore reasons for declining to participate in the trial;

Researchers noted reasons provided for declining to participate on the data management system and are provided as exclusion reasons (see Chapter 4, Tables 1-3). Where potential participants provided a reason for declining to take part in the study these were:

- Conflicting commitments (unsociable shifts; full-time working)
- Stressful life events which meant they did not want to take part (bereavement; sexual assault)
- Physical health issues that they perceived would be a barrier to engaging with the intervention

7. Explore reasons for disengaging in intervention before an agreed end;

Recruiting participants to take part in a process evaluation interview who disengaged from the intervention before an agreed end was problematic due to difficulty in making contact and a time to participate. One participant who took part in an interview and who had disengaged from the intervention indicated that he disengaged due to a change in life circumstance and would have liked to have returned to the intervention but was only ready to do so following the end of the 14-week timeframe.

8. Understand, from a participant perspective, the benefits and disadvantages of taking part in the intervention.

This chapter has presented a range of perceived benefits of the intervention in terms of health and wellbeing behaviour change and associated impacts. Participants have also benefited from understanding the links between (1) health behaviours in relation to behaviour change, (2) health behaviours and mental wellbeing and (3) emotions, wellbeing and behaviour. Participants spoke little about disadvantages of the intervention, which would need to be explored further in a full trial.

Chapter 7: Discussion and conclusions

Context

This research was conducted as a result of commissioned NIHR (PHR) call to fill a gap in our understanding of the effectiveness and cost-effectiveness of interventions to improve the health of offenders in the community. A proposal was initially submitted to conduct a full trial but given the uncertainties about conducting a randomised trial with the target group, we were funded to conduct a pilot trial. This Report considers those uncertainties and what we have learned to take into a full trial.

Just before the research began, offenders were managed by either an NPS or a CRC. The latter had been introduced in February 2015 and our proposal, in anticipation of this, aimed to recruit through CRCs and NPSs in two sites, Plymouth and Southampton. In the lead-up to the start of the study, HT support became available for offenders in Southampton, and as a result we had to seek another second site. We chose Manchester since The University of Plymouth had an ongoing collaboration within another NIHR trial underway with the University of Manchester, but to avoid delay we only set up recruitment in the CRC.

Building on a previous single site pilot trial to examine the effectiveness and cost-effectiveness of HT support to help promote exercise assisted reduction to stop smoking (EARS), we explored how HTs around the country interacted with offenders. Our PPI work also involved considerable engagement to inform the intervention and study design. A significant adaptation to our EARS intervention took place to accommodate promoting the 5 Ways to Wellbeing and supporting changes in smoking, physical activity, alcohol and diet for the STRENGTHEN study.

The STRENGTHEN pilot RCT was developed to assess the feasibility and acceptability of the HT intervention and trial methods. Criteria were identified upon which to judge recruitment, trial retention and intervention engagement. Data collection involved mixed methods to fully explore how the intervention and study procedures were viewed by stakeholders and areas for improvement.

This chapter will consider issues associated with the following: Trial design and methods; Recruitment ; Study attrition and follow-up data completion; Participant characteristics and reach; Outcomes at follow-up; Intervention content, design, acceptance and feasibility; Describing usual care; Health economics and plans for a full trial; Strengths; Limitations; Implications for health and social care; Implications for future research.

At the end of the chapter we will summarise the strengths and weakness of the study and implications for future research, with a particular focus on conducting a full trial.

Trial design and methods

Based on what we reported in Chapters 4, 5 and 6, this study provides support for the trial design and methods being acceptable and feasible to progress to a full trial, with some minor changes.

Recruitment

We eventually recruited the planned 120 participants, albeit over a longer timescale due to a number of delays beyond our control. The pilot trial has helped us to better understand the recruitment constraints experienced in three different offender services in two cities as well as the resources needed to do this in a timely manner, from both quantitative and qualitative data. Given that the CRCs in both Plymouth and Manchester were only just finding their feet at the beginning of the study, and at times were under extreme operating pressures, it was an extra challenge to build vital relationships with the OMs and the service leads. We are indebted to those working in the services who ran searches for potentially suitable participants, informed us of when appointments were taking place to allow our researchers to make contact, and for their support in many other ways. We have used all our experience of working in the CJS to make it work, and should further changes occur to services, we feel we will be even more equipped to minimise barriers to recruitment, across different services and recruitment sites in a larger trial.

At the start of the trial, there were uncertainties about the conversion rates within the recruitment processes and we largely addressed these. Early experiences of working with the OMS led to more consistent and informative understanding of the numbers of potentially eligible participants and the likely recruitment rates. The main reasons for not including potential participants in the pool to be screened was that that they didn't fit within a pre-defined window of having lived in the community for at least 2 months (following release from prison, if relevant) or they had less than 7 months of community supervision remaining within their court order 'typical' lifestyles and levels of wellbeing. The CRC and NPS data management systems were mostly resource-efficient for completing this pre-screening, though our researchers still had to remove people from our pool of potential participants due to lapses in time between the initial search by the service and further screening.

Many potential participants were also not included in the pool of potential participants or were subsequently excluded due to the risk they posed to the trial researchers and HTs within the community. Making such assessments was understandably resource-intensive, involving both objective and subjective criteria for the OMS, and delayed the recruitment process at times of high pressure on staffing within the services. Due to this screening and subsequent lone-worker policy procedures, there were only a few minor incidents in which researchers and Health Trainers felt uncomfortable and these were efficiently resolved.

We also wanted to ensure a balance between including participants who had appeared to have a chaotic life (e.g. were hard to establish contact with and perhaps often missed OMS appointments) and low levels of wellbeing, who may have the most to gain from the HT intervention, and excluding those who were likely to be lost to follow-up, given we had set a challenging progression criteria for the pilot trial. We also wanted to include only those who were likely to remain in the same geographic area to maximise follow-up rates and intervention engagement. The results provisionally indicate a possible association between baseline WEMWBS scores and intervention engagement; those with the lowest WEMWBS scores at baseline tending to have the lowest levels of intervention engagement, and they tended to be more likely to be lost to follow-up. Leading into a full trial, we would continue to review our processes for including and excluding those with a chaotic life, and ways to maintain intervention engagement and completion of follow-up assessments.

The process evaluation also tried to identify why some participants had chosen not to take part in the study through interviews. The reasons largely mirrored those recorded by researchers during screening, and it wasn't always easy to differentiate between whether they simply didn't want to take part and didn't value what was on offer, or had other conflicts and chaotic lives meaning that even a brief follow-up meeting or intervention session would have been difficult. Interviews with staff in the OMS also identified a tension between the objectives of the pilot trial to assess client-centred health trainer support, and the need for the OMS to provide opportunities for their clients to gain credits for community engagement. The research team agreed to resist this as it would have changed the dynamics of the intervention. We could probably have increased recruitment had the intervention been badged as something to provide 'credits' but we resisted this.

The trial and intervention procedures were generally well-understood, based on our process evaluation. Participants in the control group were occasionally disappointed at not receiving the intervention but in general were happy to feel they were contributing to the research evidence. We had developed participant information sheets with our PPI groups and these seemed to generally be well-understood. The idea of being in an RCT and having a chance of receiving (or not) a complex intervention was not always easy to convey but there were few examples of misunderstanding. Describing a complex intervention, such as HT support to explore change in four health behaviours and wellbeing, with a largely open-ended format in terms of intervention aims, frequency and location of sessions and intervention duration, is not easy. The overall levels of engagement suggest that we had considerable success in recruitment and intervention engagement. Ahead of a full trial, we would seek to explore further ways with our PPI group to improve understanding of the trial methods and nature of the intervention, but anticipate only minor changes would be necessary.

Study attrition and follow-up data completion

As we indicate above, a full trial could have improved follow-up rates by only including those who have less chaotic lives but we have learnt a lot about getting the right balance between selective recruitment and maximising the potential for the intervention supporting those with the greatest need. A full trial will be about producing effectiveness and cost-effectiveness information on the HT intervention and also understanding for whom it is beneficial. It will be important to maximise recruitment and retention from the range of people with community sentences.

Over the course of the pilot trial, we did improve follow-up completion rates in a number of ways, such as making contact directly with participants rather than waiting for planned service offender meetings (which did not always take place), using social media to stay in touch, and by putting more focused staffing resource into the process across sites. We will further explore the socio-economic, demographic and other factors influencing study attrition but propose that in a full trial we will include a financial incentive to improve follow-up rates.

We found only limited evidence that the trial assessment procedures were overly burdensome, and thereby contributed to lower follow-up rates. All follow-up assessments were completed in face-to-face format with our researchers and once a meeting was underway, the level of data completion was very good for most outcomes.

Participant characteristics and reach

We cited information in the Introduction section of this report from other sources that show that the offender population have typically lower levels of wellbeing and poorer lifestyles than the general population. The demographic characteristics, lifestyle behaviours and measures of wellbeing in this pilot study mirror those in the literature, and therefore indicate good reach and generalisability for the findings. For example, original data obtained from the Scottish Prisoner Service showed a mean (SD) WEMWBS score of 43.2 (12.3) (range 14–70), compared with a general population score of 51.6 (8.71) for England[29] and 49.9 (8.5) for Scotland.[32] Our overall sample had a mean (SD) WEMWBS score of 44.2 (11.8). Lower WEMWBS scores are typically associated with smoking, lower consumption of fruit and vegetables, high alcohol intake and lower socioeconomic status. Our data in this pilot trial indicate similarly unhealthy lifestyle behaviours, low levels of educational attainment, and other socio-demographic indices.

Quality of life scores (EQ-5D and SF-6D) for the present sample are also very low compared with the general population.[74-77]

The sample overall were 91% male, and this reflects the overall low proportion of females in the UK CJS. Within the process evaluation, we interviewed OMs who spoke about the gender balance

among the clients they worked with, and the focus of the OMS on risk level, with NPS participants being mainly males on males who had committed sexual offences or serious assault.

Outcomes at follow-up

As we have noted, this pilot trial did not aim to identify the effectiveness of the intervention at follow-up. Our planned sample size of 120 participants was aimed at informing sample size calculations from data collected at follow-up to inform sample sizes for a full trial. The main focus, as the likely primary outcome in a full trial, was on the WEMWBS scores. We reported higher scores in favour of the intervention at 3 and 6 months. There also appeared to be less alcohol consumed at 3 and 6 months, and fewer cigarettes smoked at 6 months in the intervention group compared with the control group. We captured survey data on processes associated with individual behaviour changes and presented the data. This would be used to explore if changes in such processes, aligned closely to our intervention logic model, would mediate changes in health behaviour.

SF-6D scores at 6 months were 0.753 (0.158) in the intervention group and 0.696 (0.186) in the control group; a difference of 0.041 has been described as a meaningful difference.[78]

Intervention content, design, acceptance and feasibility

One of the primary aims of the STRENGTHEN study was to develop an acceptable and feasible intervention. We built on previous work adapting HTs to support changes in physical activity and smoking reduction, through engagement with PPI groups and individuals to develop and manualise the STRENGTHEN intervention addressing physical activity, smoking, alcohol use, diet, and incorporating an exclusive focus on mental wellbeing, with HT training materials and supervision processes established in parallel. Six part-time HTs were trained and involved in delivering the STRENGTHEN intervention in Plymouth and Manchester. Quantitative and qualitative data was captured to help understand the processes and acceptance and feasibility of the intervention for the target population, and identify further ways to improve the intervention.

Both quantitative and qualitative data indicated that the intervention was acceptable and well-received by participants. The flexibility in the number and timing of support sessions received, the way support was offered (by phone or face-to-face), the location where sessions took place, the pace of the intervention (from building trust and rapport to working on changing wellbeing and or lifestyle), and signposting to additional tailored support (e.g. drug and alcohol services, employment agencies) all contributed to the delivery of a client-centred and empowering intervention.

We also recorded 18 HT support sessions with participants and coded these to check intervention delivery fidelity. Provisional analysis (see Process Evaluation chapter) of two sessions with the same participant (n=9) showed acceptable intervention delivery fidelity for all 6 core competencies (i.e.

active participant involvement; motivation-building for changing a behaviour and improving wellbeing; set goals and discuss strategies to make changes; review efforts to make changes/problem-solving; integration of concepts: building an association between wellbeing and behaviours; engaging social support and managing social influence) against a prior agreed level of acceptability. HTs' overall mean (SD) competency was 2.99 (0.84) on our 6-point scale. Given the sometimes challenging nature of the sessions, with a good proportion of the sample with somewhat chaotic lives, the scores for delivery were considered acceptable, and whilst some parts were delivered better than others, no component was delivered to an unacceptable standard suggesting it is feasible for the HTs to deliver the intended intervention.

As in our previous trial,[71] the competence 'engaging social support and managing social influence' was least well-delivered, and ways to further improve this competence will be consider ahead of training staff for future delivery of the intervention with this population. 'Active participant involvement' was the highest-rated competence, which reflects the focus of the intervention on building trust and empowering the participants, and confirms that the HTs offered a client-centred intervention as embedded within the intervention manual and training. There was also consistency across HTs in intervention delivery fidelity in terms of competency ratings. The initial session, always included in the ratings, confirmed that our focus on building trust and respect to empower participants to return for repeat sessions, and then work on changes in lifestyle or wellbeing, was an effective approach leading to mostly good intervention engagement.

We also aimed to empower participants by offering choice around the mode of delivery and where HT sessions to place if in face-to-face mode. Interviews with intervention participants and HTs noted that it was valuable to hold meetings away from the offices of the OMS, to separate the HT support from sentence requirements and the CJS.

A significantly novel aspect of the intervention was how to raise awareness of the 5 Ways to Wellbeing and integrate these with initiating plans for lifestyle change using evidence-based behaviour-change techniques. We have learned a lot about how the intervention was delivered and received from both quantitative and qualitative data. The HTs valued the training and opportunity to build new skills. With further refinement to training and delivery, as a result of the learning experiences in the pilot trial, the acceptability and effectiveness could be further enhanced and fidelity improved.

Describing usual care

Interviews with OMs highlighted how limited the opportunities in the community were for supporting wellbeing and lifestyle change. The services that were available tended to focus on acute needs.

Our resource use survey successfully tested the acceptability of collecting this data, with very high levels of data completeness.

Health economics and plans for a full trial

In this first pilot trial of the cost-effectiveness of a HT-led motivational intervention for people under community supervision in the UK, we have estimated the resource use and costs associated with the delivery of the STRENGTHEN intervention, and considered, developed and tested economic evaluation methods for the collection of resource use, cost and outcome data for a full cost-effectiveness analysis alongside a definitive RCT. Overall, due to all assessments being completed in face-to-face mode, data completeness was very good. Some minor changes in capturing health and social care resource use will be needed to more efficiently capture costs recorded as 'other' for the database in a full trial. The data provide tangible evidence of the resources needed to maintain contact (by a variety of means) between HTs and the participants in an effort to deliver the intervention.

Sample size estimations for a full trial

Assuming the need to detect a between-group difference of 3 units; SD of 14.8 units with a correlation between baseline and 6-month of 0.63 for the WEMWBS and a follow-up rate of 70%, and with two-sided 5% alpha and 90% power, the number of participants required to be recruited for a full trial falls within a range of 580 to 1240. Without that correlation, the range would be between c. 970 to 2060. The pilot trial has enabled us to estimate with greater precision what the required sample size for a full trial would be.

Strengths

- This is the first study to explore the acceptability and feasibility of conducting a rigorous evaluation of the effectiveness and cost-effectiveness of a HT intervention to improve wellbeing and health behaviours among an offender population under community supervision.
- The mixed-methods process evaluation provided valuable information to inform some changes to improve the trial methods.
- The mixed-methods process evaluation provided valuable information to inform some changes to improve the intervention in terms of practitioner training, standard of delivery, and acceptability.
- A bespoke, centralised, secure IT system has allowed us to make a detailed assessment of the resources needed to deliver the STRENGTHEN intervention, provide an opportunity to maintain some degree of intervention delivery fidelity, and subsequently assess the costs of

intervention delivery and what degree of intervention engagement (i.e. dose) would be required to have the desired benefits on wellbeing and lifestyle change.

- The health economic analysis provides a solid basis for designing the economic analysis for a full-scale trial.
- The study provides a rigorous assessment of the resources required to deliver a full trial, with respect to recruitment and follow-up assessments.

Limitations

- Uncertainty about how to engage with more females.
- We only worked with one NPS service so differences in resources needed to recruit and retain participants, and engage them in the intervention, are less well-understood.
- Recruitment: While we attempted to recruit a representative sample of the target population, from both CRCs and NPS, our inclusion/exclusion criteria may have biased the sample, and therefore the generalisability of the findings. Conducting randomised trials with people under community supervision, with long-term follow-up is a challenge and while we tried to accommodate a broad range of participants, inevitably our trial methods inevitably excluded some of the most hard-to-reach. Conversion of participants from the RA approaching a potential participant to randomisation was lower via the Manchester CRC than the two OMS in Plymouth, and especially the NPS. This may suggest that the findings were less generalisable in Manchester, or it may just indicate that the RAs and OMS were more risk-averse in interpreting the exclusion criteria.
- Trial retention: The study was designed to synchronise the capture of follow-up data with scheduled meetings for the participants with OMs. Due to the fluidity of the OMS, especially early in the study, the OMS did not consistently hold these meetings and this contributed to a lower trial retention than would be optimal. We explored if OMS was associated with trial retention, albeit with small numbers of participants in subgroups, and again follow-up rates were higher among participants recruited via the NPS (in Plymouth). It is likely that participants in the NPS had less chaotic lives and were easier to keep in touch with due to the nature of their offences.
- Intervention engagement: We set in our progression rules, based on another HT intervention trial delivered in a disadvantaged community, a goal for 70% of the sample to attend at least 2 intervention sessions. In Plymouth, and especially in the NPS, this target was all but met (68%) but only 50% met this target in Manchester, albeit among only 20 participants randomised to the intervention.

- Intervention delivery: We only coded 18 audio recorded sessions between participants and HTs upon which to assess delivery fidelity (as defined by the core competencies) for this pilot trial Report. Further analysis is planned to ensure we have a robust measure to assess delivery fidelity in the future.
- To ensure high data completion at follow-up assessments, the trial RAs mostly met participants face-to-face and were trained to minimise bias. We also used HTs and an RA to notify participants at baseline of their allocated trial arm, to attempt to keep the RAs blinded. Despite these measures, overall, RAs noted that they had become unblinded in assessing 60% and 75% of participants at 3 at 6 months, respectively, with a higher proportion of intervention participants inadvertently indicating to RAs their trial arm. We cannot therefore we certain that the RA did not introduce bias in the way the survey items in the follow-up assessments were answered, though meetings and supervision with RAs did not suggest this happened.

Implications for health and social care

There is currently little or no evidence available to determine what an effective and cost-effective intervention would look like to support offender populations under community supervision, and what the improvements in wellbeing and health behaviours would be. We have estimated the mean (SD) cost of the STRENGTHEN intervention to be approximately £348 (£128) per participant from the recorded staff time of the HTs and the HT co-ordinator (for training and supervision). The pilot trial has provided valuable information about the implementation of such an intervention in terms acceptability and feasibility. The WEMWBS has undergone extensive psychometric assessment and plans are underway to produce QALY weights for the WEMWBS.[64]

While there is an association between WEMWBS scores and health behaviours (with lower scores linked to poorer diet, alcohol and cigarette use), it is unknown if there is a causal direction. In a full trial, our process evaluation would seek to further explore, through mediation analysis, whether changes in lifestyle influence wellbeing, or vice versa, or if there is a bi-directional effect. This pilot study provides provisional support for improvements in wellbeing and particularly alcohol use among those receiving the intervention. Our logic model suggests that by empowering the target population they can make choices to change behaviour and find ways to improve wellbeing.

The present study did not seek to assess if the intervention had an effect on re-offending. It is possible that changes in alcohol consumption, and feeling more competent, in control, and being connected to others, which are components of wellbeing alongside the feeling and functioning aspects of mental wellbeing captured by the WEMWBS, could have impact on re-offending. A full

trial would seek to determine this with potentially significant implications for the CJS and support options provided alongside the OMS.

Due to the limited rigorous evidence for the effectiveness and cost-effectiveness of providing health training support among disadvantaged populations more broadly, on multiple health behaviours and wellbeing the present study provides some valuable insights into the possible effects of such an intervention compared with usual care.

During the course of the study, we were asked by staff in one of the OMS, if the HT support could be 'badged' as a RAR for which clients could be awarded credits. Because the intervention was underpinned by Self-Determination Theory, and MI principles, it was designed to empower participants to make changes to lifestyle and things that might improve a sense of wellbeing. Our PPI group strongly indicated that the OMS building and personnel were part of the 'controlling' CJS and that linking credits to our intervention would change the interpersonal relationship between HT and participant. We have therefore concluded that the HT support as a future possible intervention would be best delivered outside (physically and organisationally) the CJS, in community settings where the client is more comfortable, with safeguarding processes in place as appropriate.

Implications for future research

We have conducted a detailed pilot trial to address uncertainties in conducting a full randomised controlled trial, and estimated the likely sample size needed for a full trial. We believe that such a full trial involving c. 900 participants (determined from between-group differences at follow-up in this pilot trial), recruited from 16 different OMS (8 NPS and 8 CRC) across the UK would optimise the generalisability of the findings, and inform future health care, public health, and CJS policy. Research is also urgently needed to examine the effects of HT support for disadvantaged groups more broadly, with poor health and wellbeing and the proposed study will make a significant contribution to our understanding of both if and how change occurs, thereby adding value for money. Our proposed full trial has drawn from findings of the reported pilot trial, but overcoming the identified limitations will improve the efficiency of the trial methods and intervention delivery. We therefore propose the following actions to address limitations relating to recruitment, trial retention, intervention engagement, and blinding, to take place before trial recruitment commences:

Recruitment:

- We will seek further PPI input into how to disproportionally over-recruit females within our sample to maximise the generalisability of the findings.
- We have already approached and will work closely with all 16 OMS to identify trial procedures including recruitment processes. The OMS we have already engaged with are very keen to

be involved again, and we are aware that they can be powerful advocates for bringing new OMS into the study. We propose a full trial to recruit from 8 cities, paired into 4 regions, with an NPS and CRC in each city, to maximise researcher efficiency.

- We envisage more efficient recruitment from our NPS partners, and will therefore consider the balance of research resources needed to recruit similar number of participants from each OMS.
- We have found from initial RA training that maintaining RA engagement is essential for recruitment in the challenging OMS environments. We will established bi-weekly virtual RA meetings to share learning about recruitment processes and opportunities, as in the pilot trial and in another NIHR HT trial.
- The addition of a £10 shopping voucher as a reward for completing 3-month follow-up assessment and £20 at 6 months may also provide an extra incentive for potential participants, as identified by our PPI group.
- There is a risk of bias in terms of which participants will be identified as being suitable for the trial by OMs. RAs at each site will be trained to provide each OMS with a clear brief on our inclusion/exclusion criteria and how HTs work with those with more chaotic lives, to try to ensure only the most high-risk clients are excluded. We will build on the procedures used in the pilot trial to monitor and report on risk of bias in the recruitment process. For example, the reasons for exclusion were sometimes done retrospectively in the pilot trial, which was resource-intensive and with revised procedures and RA training this could be done proactively, and linked to the PenCTU database system.
- Given the range of recruitment efficiencies (i.e. conversion rates from approach to randomisation) between Manchester and Plymouth and NPS/CRC, we will review processes at all sites and carefully monitor recruitment rates, with the addition of support as needed.
- We recruited just six participants via the community (i.e. without searching NPS and CRC databases) at a time when we were struggling to recruit into the trial. These few participants were not subjectively different from other participants in the trial but required additional resources. We would not plan to use such an approach in a full trial.
- Finally, there are proposed changes to the organisation of OMS and at the time of writing it is unclear where clients currently being supervised within community rehabilitation companies will be managed. As in the pilot trial, we had to adapt quickly to the emergence of the CRCs which came into existence just 8 months before we began recruitment.

Trial retention:

- To improve trial retention (i.e., increase follow-up assessments to at least 70%) we would introduce the following changes to a full trial protocol: (1) The attendance at follow-up assessments would be incentivised, with participants receiving a shopping voucher on completion of 3-month (£10) and 6-month (£20) visits; (2) We would maintain close working relationships with OMs to facilitate the need for RAs to conduct follow-up assessments in conjunction with 3- and 6-month supervisory visits to the OMS, or elsewhere if needed; (3) We would reflect on pilot trial processes and those in another trial (ENGAGER) to optimise ways to stay in touch with participants outside of the OMS; (4) Special attention would be given by RAs to improve retention rates for those participants under supervision in the CRCs, to limit bias in the findings.
- In a full trial, we would focus process evaluation resources on trying to determine reasons for loss to follow-up using OMS information and participant interviews.
- We will conduct further exploratory analysis from the pilot trial data to describe the characteristics of participants who did/didn't complete follow-up assessments to inform strategies to further boost trial retention.

Intervention engagement:

- We will conduct further exploratory analysis from the pilot trial data to describe the characteristics of participants who completed more/less/no intervention sessions to inform strategies to further boost intervention engagement, especially in CRC participants.
- We will further explore the association between number of intervention sessions attended and WEMWBS scores at follow-up.
- We will further use the data captured in the process evaluation of the intervention in the pilot trial to identify what the HTs found difficult to do and what was well-received by participants, and how the intervention impacted on generating trust and rapport, and changes in wellbeing and lifestyle. This would be used to inform PPI discussion groups and make what we anticipate to be relatively minor changes to the intervention and training materials ahead of a full trial.
- We would also use ongoing data gathering from the delivery of a HT intervention in our 4-site RCT (TARS) with a focus on changing smoking and physical activity, involving 450 participants who are being offered HT support. Within this trial, we have developed training materials for a single training event for 8 HTs over 3 days, with subsequent regular virtual training. All HTs have remained in post over 12 months to date and ongoing process evaluation is helping us to reflect on training and supervision processes, and intervention

content. Leading into a full STRENGTHEN trial, this experience will be added to the learning from the pilot trial to produce more efficient and effective training and delivery of the HT intervention and assessment of intervention fidelity.

Intervention delivery

- The training for the practitioners should be adapted to incorporate more focus on delivering the competencies which were not so well-delivered in the pilot trial (e.g. engaging social support and managing social influence). Whilst active participant is central to the intervention, such a strong focus in training and throughout ongoing supervision possibly came at the expense of the other competencies. This should be accounted for through extra time for training and supervision, particularly early on.

Blinding:

In response to the finding that RAs had become unblinded in assessing 60% and 75% of participants at 3 at 6 months, respectively, with a higher proportion of intervention participants inadvertently indicating to RAs their trial arm, we would explore ways with PPI input into how best to minimise unblinding ahead of a full trial. Unblinding in studies of this kind are notoriously difficult to maintain, as in another NIHR trial involving offenders (ENGAGER). It is possible that blinding would have been even more unlikely without the steps we put into place, i.e. using an administrator to notify participants which arm participants had been allocated to, instead of using the RAs. So we would propose to use a similar system to that in the pilot trial, with some minor changes. Our process evaluation revealed that unblinding resulted from participants mentioning if they had been involved in the intervention, and sometimes the OM (often present at follow-up assessments) mentioning it. We would train RAs 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

The pilot trial has provided a platform upon which to develop a multi-centred randomised trial to rigorously assess the effectiveness and cost-effectiveness of HT support for people under community supervision. We have made recommendations for reviewing some trial methods, with further analysis of the pilot trial findings, engagement with our PPI groups and learning from our NIHR funded ENGAGER trial (due to complete in Spring 2019), and NIHR funded TARS trial moving into the analysis phase in Autumn 2019. The retention rates in this study provided sufficient data for planning a full trial.[40] The research question about improving health and wellbeing among those

under community supervision remains a high priority, irrespective of likely changes to the organisations who deliver community supervision.

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Contribution of authors

Lynne Callaghan (Senior Research Fellow) co-led the drafting and development of the Final Report overall, and particularly Chapters 1, 2, 3 and 6.

Tom P Thompson (Senior Research Fellow) and Jane Horrell (Research Assistant) led the assessment and reporting of intervention fidelity in Chapter 6 and contributed to the overall report-writing.

Siobhan Creanor (Associate Professor in Medical Statistics), Doyo Gragn Enki (Research Fellow in Medical Statistics), and Ben Jones (Research Assistant) led the data analysis and estimation of sample size calculations for a possible full trial and contributed to the overall report writing.

Cath Quinn (Senior Research Fellow) contributed to the overall report writing and particularly Chapter 6.

Jane Senior (Senior Lecturer in Forensic Mental Health) and Jenny Shaw (Professor of Forensic Psychiatry) contributed to the overall report preparation, and led input on trial processes at the Manchester site.

Colin Green (Professor in Health Economics), Annie Hawton (Senior Research fellow in Health Economics) and Elizabeth Goodwin (Research Fellow) contributed to the writing of final report and particularly Chapter 5.

Richard Byng (Professor in Primary Care Research) contributed to the writing of final report.

Gary Wallace (Associate Director of Public Health) contributed to the writing of final report with insight on the future implementation of the intervention.

Julia Sinclair (Associate Professor of Psychiatry) contributed to the writing of final report.

Jill Annison (Associate Professor of Criminology) contributed to the writing of the final report

Amy Kane, Emma Hazeldine, Samantha Walker, Rebecca Crook, Verity Wainwright, (all Research Assistants) contributed to the writing of final report and prepared data on trial methods.

Lucy Cartwright (Professional Services) contributed to the preparation of final report.

Adrian H. Taylor (Professor in Health Services Research) co-led the drafting and development of the Final Report overall, and particularly Chapters 4 and 7.

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Appendices

Appendix 1: Health Trainer core competencies and fidelity scales

CORE COMPETENCY 1: ACTIVE PARTICIPANT INVOLVEMENT

Key features: The HT should encourage the client to be actively involved in the consultation. The idea is to maximise the client's autonomy as the main agent of change, developing intrinsic rather than extrinsic motivation, and encouraging her /him to be the person coming up with ideas for improving the situation. However, the client should not be allowed to ramble excessively in an unstructured way and the consultation should be guided through skilful use of MI techniques. A collaborative/shared decision-making style is appropriate and the HT may share his /her own expertise and ideas, using techniques such as elicit-provide-elicit. Overall, the client should be increasingly empowered to take control of her /his behaviours and decisions. Interactions should be encouraging, respectful and non-judgemental (the opposite of a didactic, telling or persuading style of interaction). The client should ideally talk for at least half of the time. The interaction should also be *individually tailored* to the participant's specific information needs, beliefs, motivations and barriers. The HT should engender a clear sense of warmth, genuineness and empathy (within professional boundaries) to develop trust.

Intervention techniques: OARS (Open questions, Affirmation, Reflective listening, Summaries). Reflective listening may include simple reflections of content but may also be more sophisticated (e.g. amplified reflection; reflection with a twist) and used to direct the conversation or highlight key strengths or barriers. The elicit-provide-elicit technique should be used to exchange information (e.g. to address misconceptions, or offer helpful new information, and provide vicarious experience). The above empathy-building techniques and Individual tailoring should be used throughout the consultations - from the initial consultation through action-planning through to review /maintenance sessions.

CORE COMPETENCY 2: MOTIVATION-BUILDING FOR CHANGING A BEHAVIOUR AND IMPROVING WELLBEING

Key features: The HT should work with the client to explore initial beliefs and motivations about why they want to make any changes. The client's motivation for making change is built up/enhanced through the exchange of information and techniques to assess and enhance motivation – i.e. to enhance the perceived benefits (importance) of making a change and confidence (self-efficacy) to take the actions needed.

Intervention techniques: OARS (Open questions, Affirmation, Reflective listening, Summaries) should be used specifically to explore current and behaviour, the pros and cons of changing and to develop discrepancies between current behaviour and desired behaviour (or outcomes). The decisional balance technique or 0-10 questions may be used to explore importance and confidence. Information should be exchanged on the pros and cons of changing and this and other techniques (exploring possible futures; discussing past attempt) should be used to explore barriers and possible solutions to increase confidence about cutting down /quitting. Motivation-building should ideally happen around the start of the intervention process, although it can be further explored and reinforced at later (action-planning, review and maintenance) stages. Establishing self-rewards or incentives (e.g. saving money in a jar, planning rewards) may be part of the process for maintaining motivation.

CORE COMPETENCY 3: SET GOALS AND DISCUSS STRATEGIES TO MAKE CHANGES

Key features: The HT should work with the client to discuss a range of strategies for making the desired changes. They should agree a verbal plan of action, seeking to make this as specific as possible. They should discuss the use of self-monitoring to keep track of progress. Written goals and self-monitoring can be implemented where appropriate.

Intervention techniques: Goal-setting (with gradual /graded progression), Action Planning, Self-Monitoring, Deconditioning strategies. Any or all of strategies presented in the manual may be presented and discussed. The action plan should normally be made verbally, but the HT should seek to make this as specific as possible in terms of "What, Where, When and Who with" and making the goal as SMART (Specific, Measurable, Achievable, Relevant and Time-related) as possible. The HT should introduce and discuss with the client the usefulness of self-monitoring of behaviours (level of behaviour, pattern of behaviour, how behaviours link). A specific plan for self-

monitoring should be included in the action plan. The HT may also encourage self-monitoring of the contexts (social or environmental or emotional circumstances) in which problems/relapses might occur. Pre-empting and thinking of solutions for possible problems (making a coping plan, if/then plans, barriers/facilitators) is also appropriate here and may involve the use of other recognised behaviour change techniques (e.g. engaging social support, stress-management).

CORE COMPETENCY 4: REVIEW EFFORTS TO MAKE CHANGES / PROBLEM-SOLVING

Key features: The HT should work with the client to reflect on progress with goals. The HT should affirm /reinforce any successes. The client and HT should discuss any setbacks (reframing to normalise them, identifying barriers and exploring ways to overcome them). The HT and client should then set new targets, either progressing from the old one or establishing new ones which help avoid successive failure.

Intervention techniques: Use of OARS (Open questions, Affirmation, Reflective listening, Summaries) specifically to reinforce successes, to discuss setbacks, to identify barriers (including social or environmental contexts which hinder progress) and explore ways to overcome them (problem-solving). Reframing should be used to normalise setbacks. Goals /action plans should then be reviewed. There may also be some reflection on, and reinforcement of the client's skills in avoiding or managing relapse to undesired behaviour (building skills and self-efficacy). Problem-solving may involve the use of other recognised behaviour change techniques (e.g. engaging social support, stress-management).

CORE COMPETENCY 5: INTEGRATION OF CONCEPTS: BUILDING AN ASSOCIATION BETWEEN WELLBEING AND BEHAVIOURS/UNDERSTANDING THE RATIONALE AND HOW BEHAVIOUR, MOOD, AND EMOTIONS LINK.

Key features: The HT should work with the client specifically to help her /him gain an appreciation of the relationship between behaviours and wellbeing. A clear rationale should be presented for how behaviours and feelings/mood are linked and can influence one another. However, both explicit processes (encouraging the client to complete activities to specifically enhance their

wellbeing) and implicit processes (encouraging clients to embrace approaches to changing their behaviour which incorporate the 5WWB) should be facilitated by the HT.

Intervention techniques: Use of OARS (Open questions, Affirmation, Reflective listening, Summaries), Goal-setting (with gradual /graded progression), Action Planning, Self-Monitoring, Deconditioning strategies. HTs should present the rationale to the client in an appropriate way and time (after they client is well engaged) and invite clients to reflect on if/how it relates to their own behaviour and wellbeing. HTs could encourage clients to use self-monitoring approaches and treat it as an experiment, to see how their wellbeing is on a day to day basis in relation to how their other behaviours are. Using MI principles and guiding clients towards plans which incorporate the 5WWB (e.g. connecting with non-drinkers to help reduce their alcohol intake).

CORE COMPETENCY 6: ENGAGING SOCIAL SUPPORT AND MANAGING SOCIAL INFLUENCES

Key features: The HT should encourage the client to engage social support (to assist on making or carrying out plans) or manage social influences on their behaviour. Social support can be informational (helping to make plans, providing ideas), emotional (not putting pressure on the person to perform unwanted behaviour/accepting their decision to change), or practical (e.g. helping to monitor progress). They should also look to support people to engage social support as a way to connect with others where ever possible.

Intervention techniques: Open questions, Affirmation, Reflective listening and Summaries may be used to explore social influences and to identify possible problems and solutions relating to social influences.

Below is some guidance on how these core competencies may be scored as part of the research process when session recordings are being reviewed. If it is helpful, a scoring approach could also be used in supervision sessions.

The rating scale

The present seven-point scale (i.e. a 0-6 Likert scale) extends from (0) where the HT did not deliver the intervention element appropriately - either they didn't do it well or didn't do it sufficiently (low fidelity) to (6) where there is the element is delivered appropriately (high fidelity). Thus the scale assesses a composite of adherence to the intended intervention method and skill of the HT. To aid with the rating of items, an outline of the key features of each item is provided at the top of each section above. A description of the various rating criteria is given in Figure 4. The examples are intended to be used as useful guidelines only, providing illustrative anchor points, rather than prescriptive scoring criteria.

Adjusting for the presence of participant difficulties

Adjustments may be needed when participant difficulties are evident (e.g. excessive avoidance or resistance). In such circumstances, the rater needs to assess the HT's therapeutic skills in the application of the methods. Even though the HT may not facilitate change, credit should be given for demonstrating appropriate skilful interaction.

Competence level		Examples
Incompetent	0	Absence of feature, or highly inappropriate performance
	1	Inappropriate performance, with major problems evident
Novice	2	evidence of competence, but numerous problems and lack of consistency
Advanced Beginner	3	competent, but some problems and/or inconsistencies
Competent	4	good features, but minor problems and/or inconsistencies
Proficient	5	very good features, minimal problems and/or inconsistencies
Expert	6	excellent performance, even in the face of patient difficulties

Figure 4: Rating criteria for delivery fidelity The scale incorporates the Dreyfus system [72] for denoting competence. Please note that the 'top marks (i.e. near the 'expert' end of the continuum) are reserved for those HTs demonstrating highly effective skills, particularly in the face of difficulties (i.e. clients with high resistance to change; high levels of emotional expression; and complex situational barriers). Please note that there are 6 competence levels but 7 potential scores.

When rating the item, you should first identify whether some of the ‘Key Features’ are present. If the HT includes most of the key features and uses them appropriately (i.e. misses few relevant opportunities to use them and delivers them well), the HT should be rated very highly. It is also possible not every item will be applicable in every consultation. It is important to remember that the scoring profile for this scale should approximate to a normal distribution (i.e. mid-point 3), with relatively few scoring at the extremes.

Appendix 2: Flow of participants to recruitment (SW CRC)

Figure 5: Flow of participants to recruitment (SW CRC)

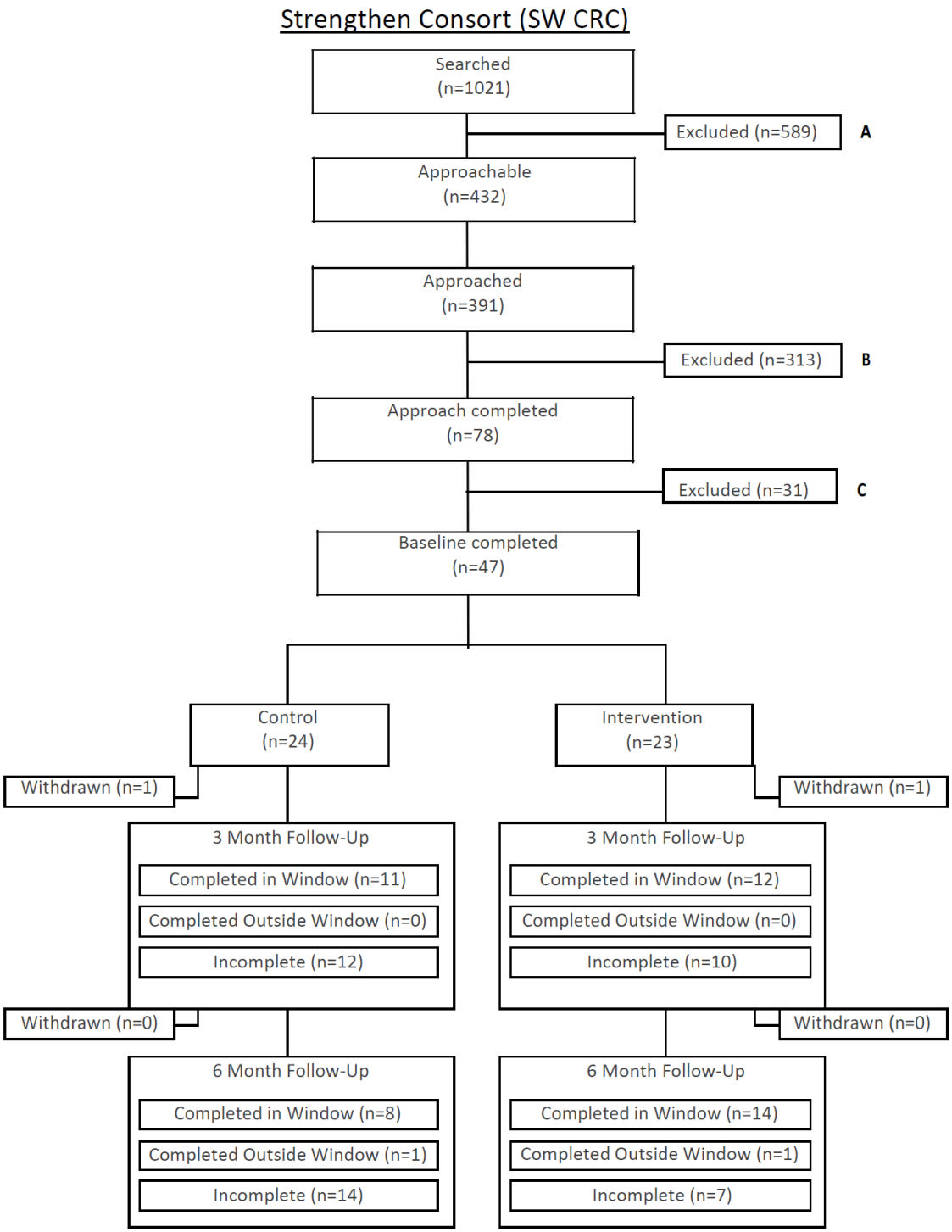


Figure 6: Flow of participants to recruitment (SW NPS)

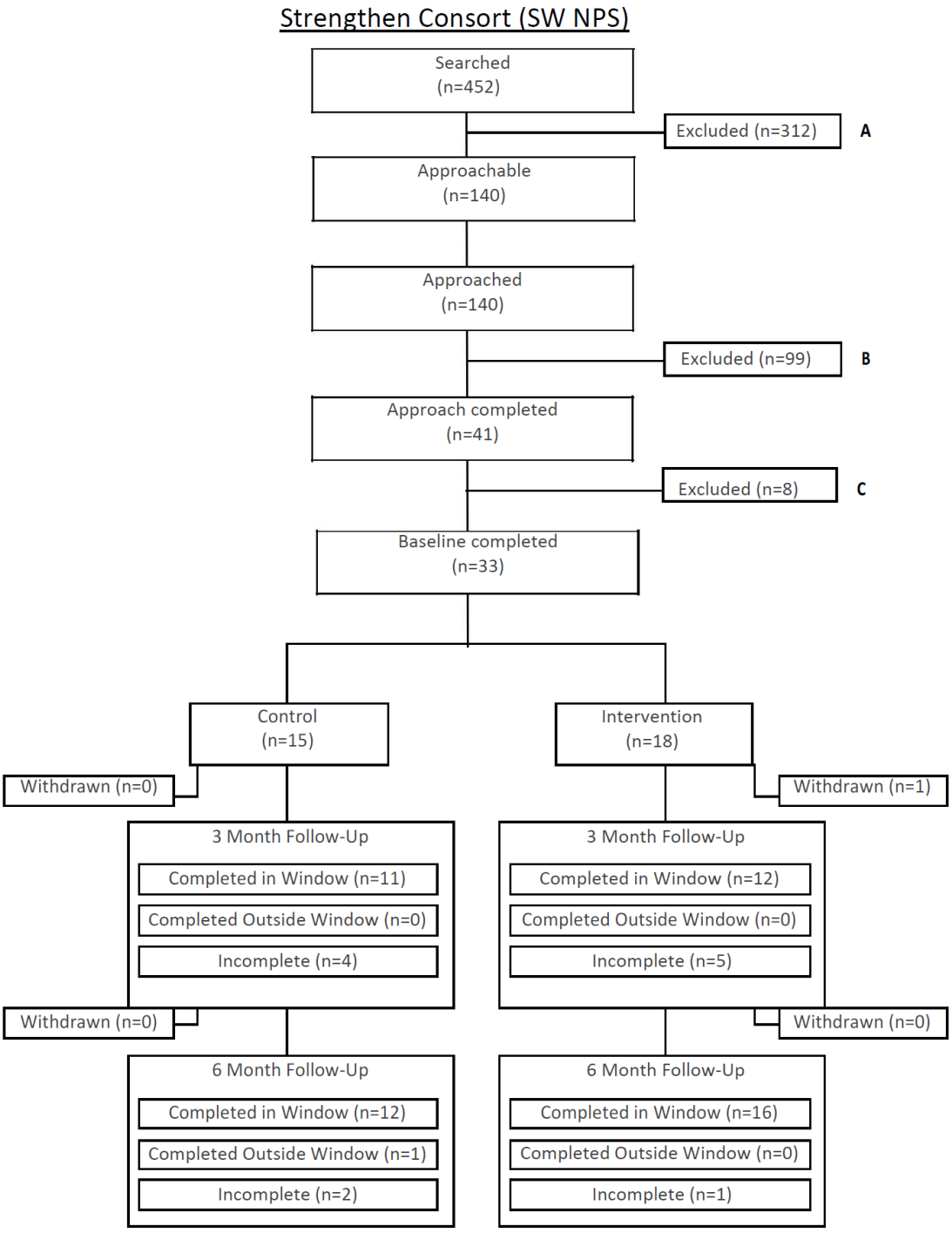
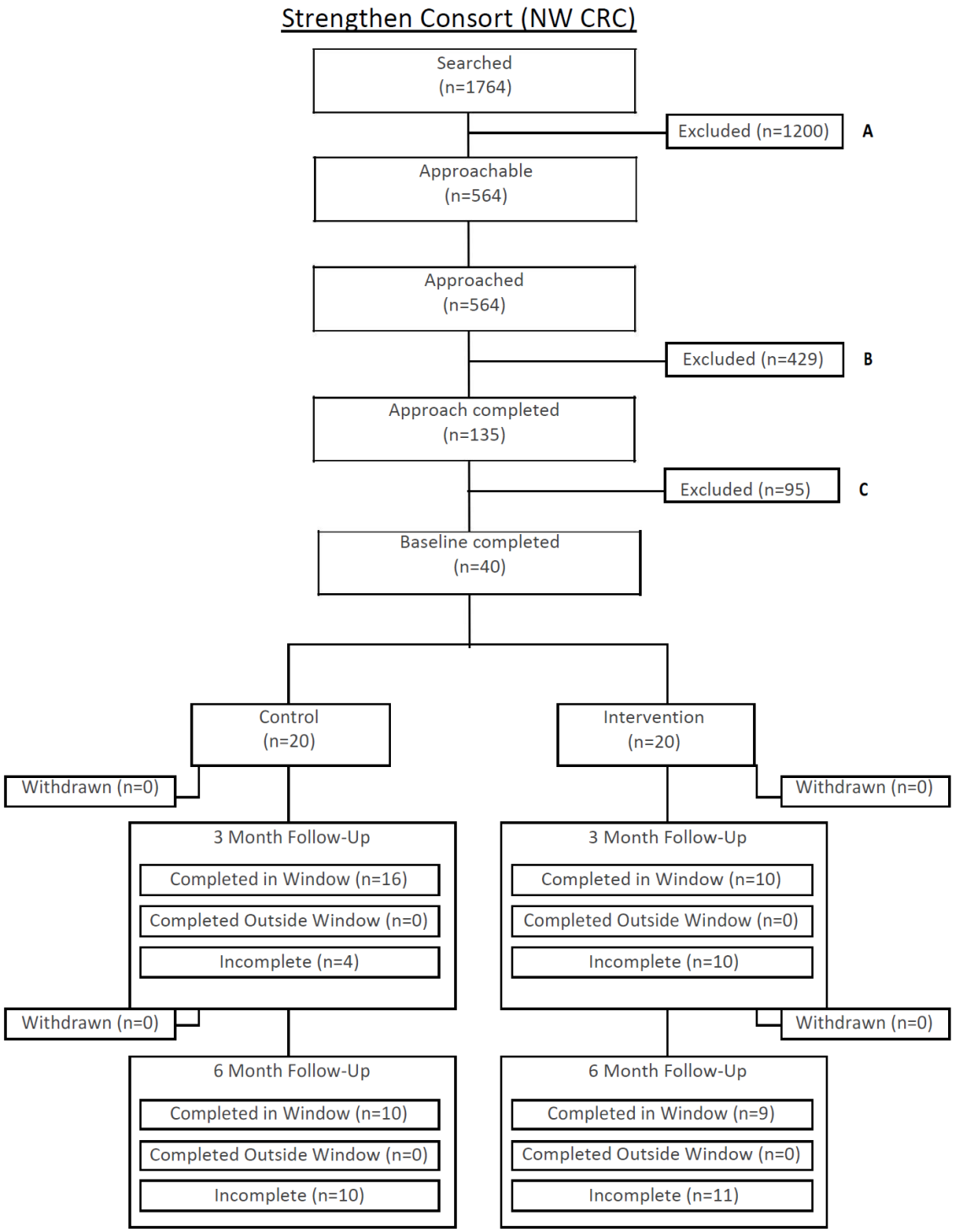


Figure 7: Flow of participants to recruitment (NW CRC)



Appendix 3: Completeness of data collection at baseline and follow-up

Table 34: Completion rates for a selection of secondary outcomes, with 95% Confidence Intervals

	Baseline (N=61)		3-month follow-up (N=34)		6-month follow-up (N=40)		Baseline (N=59)		3-month follow-up (N=38)		6-month follow-up (N=32)	
Outcome variable	**N**	**% (95% CI)**	**N**	**% (95% CI)**	**N**	**% (95% CI)**	**N**	**% (95% CI)**	**N**	**% (95% CI)**	**N**	**% (95% CI)**
Overall Audit Score amongst those who drink	42	100.0 (91.6,100.0)	18	94.7 (74.0,99.9)	22	100.0 (0.85,100.0)	35	100.0 (90.0,100.0)	23	100.0 (85.2,100.0)	20	100.0 (83.2,100.0)
DINE Fibre total score	60	98.4 (91.2,100.0)	34	100 (89.7,100.0)	39	97.5 (86.8,99.9)	59	100.0 (93.9,100.0)	38	100.0 (90.7,100.0)	31	96.9 (83.8,99.9)
DINE Fat total score	60	98.4 (91.2,100.0)	32	94.1 (80.3,99.3)	40	100.0 (91.2,100.0)	58	98.3 (90.9,100.0)	38	100.0 (90.7,100.0)	31	96.9 (83.8,99.9)
DINE Unsaturated Fat total score	39	63.9 (50.6,75.8)	22	64.7 (46.5,80.3)	35	87.5 (73.2,95.8)	38	64.4 (50.9,76.4)	31	81.6 (65.7,92.3)	28	87.5 (71.0,96.5)
Smoker	61	100.0 (94.1,100.0)	34	100.0 (89.7,100.0)	40	100.0 (91.2,100.0)	59	100.0 (93.9,100.0)	38	100.0 (90.7,100.0)	32	100.0 (89.1,100.0)

Fagerström Test of Cigarette Dependence (FTCD)	42	97.7 (87.8,99.9)	14	93.3 (68.1,99.8)	22	95.7 (78.1,99.9)	40	93.0 (80.9,98.5)	22	100.0 (84.6,100.0)	17	100.0 (80.5,100.0)
Substance Use	34	55.7 (42.4,68.5)	8	23.5 (10.7,41.2)	10	25.0 (12.7,41.2)	35	59.3 (45.7,71.9)	15	39.5 (24.0,56.6)	10	31.3 (16.1,50.0)

Appendix 4. Health/social care resource use of intervention and control groups at baseline, 3 month follow-up and 6 month follow-up

Table 35: Health/social care resource use of intervention and control groups at baseline

Resource item	Intervention		Comparator	
	n	Mean (SD) [range]	n	Mean (SD) [range]
Primary care services (number of contacts)				
GP at surgery/health centre	61	1.78 (2.15) [0-10]	59	1.89 (1.90) [0-10]
GP via telephone	61	0.42 (1.47) [0-10]	59	0.83 (1.46) [0-6]
GP at home	60	0	59	0.03 (0.18) [0-1]
Practice nurse at surgery/health centre	60	0.33 (0.75) [0-4]	59	0.62 (2.15) [0-16]
Practice nurse via telephone	59	0.05 (0.22) [0-1]	59	0.05 (0.22) [0-1]
Practice nurse at home	60	0	59	0.33 (2.60) [0-20]
Community mental health nurse	60	0.11 (0.37) [0-2]	59	0.13 (0.39) [0-2]
Community psychiatric nurse	60	0.05 (0.38) [0-3]	59	0.05 (0.28) [0-2]
Physiotherapist at surgery/health centre	60	0	59	0.37 (1.27) [0-8]
Physiotherapist at home	60	0	59	0
Occupational therapist at surgery/health centre	60	0	59	0
Occupational therapist at home	60	0	59	0.01 (0.13) [0-1]
Dietician	60	0.13 (1.03) [0-8]	59	0
Counsellor	60	0.63 (1.72) [0-8]	59	0.66 (3.30) [0-24]
NHS Stop smoking services	60	0.08 (0.53) [0-4]	59	0.03 (0.26) [0-2]
Alcohol services - community	60	0.8 (2.69) [0-16]	59	0.94 (3.37) [0-20]
Drug services - community	60	0.96 (2.64) [0-16]	58	0.37 (1.12) [0-6]
Walk-in-centre	59	0.32 (1.20) [0-8]	56	0.28 (1.38) [0-10]
Other	61	0.11 (0.58) [0-4]	59	0.50 (1.68) [0-10]

Secondary care (number of events)	***Intervention***		***Comparator***	
Accident and Emergency visits				
General A&E visits	61	0.14 (0.44) [0-2]	59	0.22 (0.72) [0-4]
Mental health A&E visits	61	0	59	0
Day Cases	60	0.18 (0.70) [0-4]	58	0.25 (0.98) [0-6]
Hospital admissions				
General medical admissions	61	0.03 (0.17) [0-1]	59	0.10 (0.35) [0-0]
ICU admissions	61	0	59	0
Alcohol services admissions	61	0	59	0
Drug services admissions	61	0	59	0
Other hospital admissions	61	0	59	0.01 (0.13) [0-1]
Outpatient appointments				
General appointments	61	0.19 (0.67) [0-4]	59	0.18 (0.47) [0-2]
Psychologist appointments	61	0	59	0.01 (0.13) [0-1]
Psychiatrist appointments	61	0	59	0.01 (0.13) [0-1]
Talking therapy appointments	61	0	59	0
Mental health clinic appointments	61	0	59	0
Alcohol appointments	61	0	59	0.03 (0.26) [0-2]
Drug services appointments	61	0	59	0
CJ liaison appointments	61	0	59	0
Other outpatient appointments	61	0.04 (0.38) [0-3]	59	0.03 (0.26) [0-2]
Social care services (number of contacts)				
Social worker	60	0.63 (1.89) [0-8]	59	0.35 (1.48) [0-8]
Home help/care worker	60	0.05 (0.38) [0-3]	58	0.13 (1.05) [0-8]

Table 36: Health/social care resource use of intervention and control groups at 3-month follow-up

Resource item	**Intervention**		**Comparator**	
	n	**Mean (SD) [range]**	**n**	**Mean (SD) [range]**
Primary services (number of contacts)				
GP at surgery/health centre	33	1.45 (1.87) [0-6]	38	1.65 (1.68) [0-6]
GP via telephone	33	0.36 (1.14) [0-6]	38	0.55 (1.20) [0-5]
GP at home	33	0	38	0
Practice nurse at surgery/health centre	33	0.27 (0.62) [0-3]	38	0.55 (1.05) [0-4]
Practice nurse via telephone	33	0.03 (0.17) [0-1]	38	0.02 (0.16) [0-1]
Practice nurse at home	33	0	38	0
Community mental health nurse	33	0.12 (0.41) [0-2]	38	0.10 (0.64) [0-4]
Community psychiatric nurse	33	0.06 (0.34) [0-2]	38	0.23 (0.81) [0-4]
Physiotherapist at surgery/health centre	33	0	38	0.18 (0.72) [0-4]
Physiotherapist at home	33	0	38	0
Occupational therapist at surgery/health centre	33	0	38	0.10 (0.64) [0-4]
Occupational therapist at home	33	0	38	0 (0) [0-0]
Dietician	33	0	38	0
Counsellor	33	0.66 (2.32) [0-12]	38	0.52 (1.53) [0-8]
NHS Stop smoking services	33	0.12 (0.69) [0-4]	38	0.15 (0.71) [0-4]
Alcohol services - community	33	0.18 (1.04) [0-6]	38	1.07 (3.07) [0-12]
Drug services - community	33	0.30 (0.84) [0-3]	38	0.13 (0.57) [0-3]
Walk-in-centre	33	0	38	0.02 (0.16) [0-1]
Other	33	0.24 (0.50) [0-2]	38	0.10 (0.38) [0-2]

Secondary care (number of events)	***Intervention***		***Comparator***	
Accident and Emergency visits				
General A&E visits	34	0.06 (0.24) [0-1]	38	0.18 (0.45) [0-2]
Mental health A&E visits	34	0	38	0
Day Cases	34	0.02 (0.17) [0-1]	38	0.15 (0.67) [0-4]
Hospital admissions				
General medical admissions	34	0.08 (0.37) [0-2]	38	0.02 (0.16) [0-1]
ICU admissions	34	0	38	0
Alcohol services admissions	34	0	38	0
Drug services admissions	34	0	38	0
Other hospital admissions	34	0	38	0
Outpatient appointments				
General appointments	34	0.20 (0.47) [0-2]	38	0.15 (0.43) [0-2]
Psychologist appointments	34	0	38	0
Psychiatrist appointments	34	0	38	0.10 (0.50) [0-3]
Talking therapy appointments	34	0	38	0
Mental health clinic appointments	34	0	38	0
Alcohol appointments	34	0	38	0
Drug services appointments	34	0	38	0
CJ liaison appointments	34	0	38	0
Other outpatient appointments	34	0.02 (0.17) [0-1]	38	0.05 (0.32) [0-2]
Social care services (number of contacts)				
Social worker	33	0.18 (0.72) [0-4]	38	0.28 (1.62) [0-10]
Home help/care worker	33	0	38	0.26 (1.62) [0-10]

Table 37: Health/social care resource use of intervention and control groups at 6-month follow-up

Resource item	**Intervention**		**Comparator**	
	n	**Mean (SD) [range]**	**n**	**Mean (SD) [range]**
Primary services (number of contacts)				
GP at surgery/health centre	40	1.22 (1.64) [0-6]	32	1.15 (1.27) [0-5]
GP via telephone	40	0.8 (1.98) [0-10]	32	0.62 (1.56) [0-6]
GP at home	40	0	32	0
Practice nurse at surgery/health centre	40	0.35 (1.14) [0-6]	32	0.31 (0.69) [0-3]
Practice nurse via telephone	40	0.15 (0.94) [0-6]	32	0
Practice nurse at home	40	0	32	0.06 (0.35) [0-2]
Community mental health nurse	40	0.3 (1.89) [0-12]	32	0.18 (0.78) [0-4]
Community psychiatric nurse	40	0.15 (0.48) [0-2]	32	0.06 (0.24) [0-1]
Physiotherapist at surgery/health centre	40	0.17 (0.78) [0-4]	32	0
Physiotherapist at home	40	0	32	0
Occupational therapist at surgery/health centre	40	0	32	0
Occupational therapist at home	40	0	32	0
Dietician	40	0 (0) [0-0]	32	0.03 (0.17) [0-1]
Counsellor	40	0.65 (2.23) [0-12]	32	1.15 (3.12) [0-12]
NHS Stop smoking services	40	0	32	0.18 (0.64) [0-3]
Alcohol services - community	40	0.22 (1.04) [0-6]	32	0.46 (1.54) [0-6]
Drug services - community	40	1.12 (4.26) [0-24]	32	0.5 (1.60) [0-6]
Walk-in-centre	40	0.65 (3.79) [0-24]	32	0
Other	40	0.1 (0.49) [0-3]	32	0.28 (1.11) [0-6]

Secondary care (number of events)	***Intervention***		***Comparator***	
Accident and Emergency visits				
General A&E visits	40	0.05 (0.22) [0-1]	32	0.03 (0.17) [0-1]
Mental health A&E visits	40	0.02 (0.15) [0-1]	32	0.06 (0.35) [0-2]
Day Cases	40	0.05 (0.31) [0-2]	32	0.12 (0.55) [0-3]
Hospital admissions				
General medical admissions	40	0.1 (0.44) [0-2]	32	0
ICU admissions	40	0	32	0
Alcohol services admissions	40	0	32	0
Drug services admissions	40	0	32	0
Other hospital admissions	40	0	32	0
Outpatient appointments				
General appointments	40	0.07 (0.34) [0-2]	32	0.15 (0.57) [0-3]
Psychologist appointments	40	0	32	0
Psychiatrist appointments	40	0.02 (0.15) [0-1]	32	0
Talking therapy appointments	40	0	32	0
Mental health clinic appointments	40	0	32	0
Alcohol appointments	40	0	32	0
Drug services appointments	40	0	32	0
CJ liaison appointments	40	0	32	0
Other outpatient appointments	40	0.07 (0.47) [0-3]	32	0
Social care services (number of contacts)				
Social worker	40	0.52 (2.09) [0-12]	32	0.5 (2.17) [0-12]
Home help/care worker	40	0.02 (0.15) [0-1]	32	0

Appendix 5. Costs of health/social care resource use of intervention and control groups at baseline, 3 month follow-up and 6 month follow-up

Table 38: Costs of health/social care resource use of intervention and control groups at baseline

Resource item	**Health trainer intervention**		**Usual care**	
Costs at baseline	**n**	**Mean (SD) [range]**	**n**	**Mean (SD) [range]**
Primary care services (number of contacts)				
GP at surgery/health centre	61	55.39 (66.76) [0-310]	59	58.85 (59.18) [0-310]
GP via telephone	61	10.29 (35.66) [0-241.4]	59	20.05 (35.34) [0-144.84]
GP at home	60	0	59	1.31 (7.07) [0-38.76]
Practice nurse at surgery/health centre	60	3.1 (6.99) [0-37.2]	59	5.83 (20.06) [0-148.8]
Practice nurse via telephone	59	0.4 (1.75) [0-7.9]	59	0.4 (1.75) [0-7.9]
Practice nurse at home	60	0	59	12.54 (96.34) [0-740]
Community mental health nurse	60	4.2 (13.41) [0-72]	59	4.88 (14.11) [0-72]
Community psychiatric nurse	60	1.8 (13.94) [0-108]	59	1.83 (10.41) [0-72]
Physiotherapist at surgery/health centre	60	0	59	19.76 (67.4) [0-424]
Physiotherapist at home	60	0	59	0
Occupational therapist at surgery/health centre	60	0	59	0
Occupational therapist at home	60	0	59	1.31 (10.02) [0-77]
Dietician	60	4.4 (34.08) [0-264]	59	0
Counsellor	60	27.23 (74.25) [0-344]	59	28.42 (142.3) [0-1032]
NHS Stop smoking services	60	4.32 (23.47) [0-129.67]	59	2.2 (16.88) [0-129.67]
Alcohol services - community	60	36 (121.15) [0-720]	59	42.71 (151.67) [0-900]
Drug services - community	60	129.53 (354.07) [0-2144]	58	50.83 (150.24) [0-804]
Walk-in-centre	59	13.78 (51.78) [0-342.4]	56	12.23 (59.26) [0-428]
Primary care subtotal	58	233.58 (310.32) [0-1494]	56	271.87 (329.15) [0-1503.6]
Secondary care				

(number of events)				
General appointments	61	26.95 (92.98) [0-548]	59	25.54 (64.73) [0-274]
Psychologist appointments	61	0	59	0.93 (7.16) [0-55]
Psychiatrist appointments	61	0	59	1.83 (14.06) [0-108]
Alcohol appointments	61	0	59	1.53 (11.72) [0-90]
General medical admissions	61	10.66 (58.35) [0-324.99]	59	33.05 (116) [0-649.98]
Day cases	60	133.28 (509.55) [0-2908]	58	188.02 (714.91) [0-4362]
General A&E visits	61	21.81 (65.19) [0-295.6]	59	32.57 (106.54) [0-591.2]
Mental health A&E visits	61	0	59	0
Secondary care subtotal	60	193.69 (604.94) [0-3603.8]	58	277.46 (848.56) [0-5285.98]
Social care services (number of contacts)				
Social worker	60	37.37 (111.82) [0-472]	59	21 (87.49) [0-472]
Home help/care worker	60	0.35 (2.67) [0-20.7]	58	0.95 (7.25) [0-55.2]
Social care subtotal	60	37.71 (111.74) [0-472]	58	22.31 (88.27) [0-472]
Total cost to NHS and PSS (excluding intervention cost)	57	480.17 (789.5) [0-4675.8]	54	567.4 (1042.79) [0-6484.78]

Table 39: Costs of health/social care resource use of intervention and control groups at 3-month follow-up

Resource item	**Health trainer intervention**		**Usual care**	
Costs at three month follow-up	**n**	**Mean (SD) [range]**	**n**	**Mean (SD) [range]**
Primary care services (number of contacts)				
GP at surgery/health centre	33	45.09 (58.04) [0-186]	38	51.39 (52.11) [0-186]
GP via telephone	33	8.78 (27.54) [0-144.84]	38	13.34 (29) [0-120.7]
GP at home	33	0	38	0
Practice nurse at surgery/health centre	33	2.54 (5.82) [0-27.9]	38	5.14 (9.84) [0-37.2]
Practice nurse via telephone	33	0.24 (1.38) [0-7.9]	38	0.21 (1.28) [0-7.9]
Practice nurse at home	33	0	38	0
Community mental health nurse	33	4.36 (14.95) [0-72]	38	3.79 (23.36) [0-144]
Community psychiatric nurse	33	2.18 (12.53) [0-72]	38	8.53 (29.51) [0-144]
Physiotherapist at surgery/health centre	33	0	38	9.76 (38.68) [0-212]
Physiotherapist at home	33	0	38	0
Occupational therapist at surgery/health centre	33	0	38	8.11 (49.96) [0-308]
Occupational therapist at home	33	0	38	0
Dietician	33	0	38	0
Counsellor	33	28.67 (100.08) [0-516]	38	22.63 (66.12) [0-344]
NHS Stop smoking services	33	3.93 (22.57) [0-129.67]	38	6.82 (29.34) [0-129.67]
Alcohol services - community	33	8.18 (47) [0-270]	38	48.55 (138.16) [0-540]
Drug services - community	33	40.61 (113.53) [0-402]	38	17.63 (77.39) [0-402]
Walk-in-centre	33	0	38	1.13 (6.94) [0-42.8]
Primary care subtotal	33	144.57 (232.65) [0-1011]	38	197.03 (218.64) [0-799.71]
Secondary care (number of events)				
General appointments	34	28.21 (65.57) [0-274]	38	21.63 (59.81) [0-274]
Psychologist appointments	34	0	38	0
Psychiatrist appointments	34	0	38	11.37 (54.95) [0-324]

Alcohol appointments	34	0	38	0
General medical admissions	34	28.68 (123.11) [0-649.98]	38	8.55 (52.72) [0-324.99]
Day cases	34	21.38 (124.68) [0-727]	38	114.79 (493.55) [0-2908]
General A&E visits	34	8.69 (35.30) [0-147.8]	38	27.23 (67.47) [0-295.6]
Mental health A&E visits	34	0	38	0
Secondary care subtotal	34	86.96 (213.78) [0-797.78]	38	183.57 (557.03) [0-3232]
Social care services (number of contacts)				
Social worker	33	10.73 (42.89) [0-236]	38	17.08 (95.93) [0-590]
Home help/care worker	33	0	38	1.82 (11.19) [0-69]
Social care subtotal	33	10.73 (42.89) [0-236]	38	18.89 (107.07) [0-659]
Total cost to NHS and PSS (excluding intervention cost)	33	244.89 (305.52) [0-1011]	38	399.5 (632.98) [0-3640.88]

Table 40: Costs of health/social care resource use of intervention and control groups at 6-month follow-up

Resource item	**Health trainer intervention**		**Usual care**	
Costs at six month follow-up	**n**	**Mean (SD) [range]**	**n**	**Mean (SD) [range]**
Primary care services (number of contacts)				
GP at surgery/health centre	40	37.98 (50.86) [0-186]	32	35.84 (39.46) [0-155]
GP via telephone	40	19.31 (48.03) [0-241.4]	32	15.09 (37.67) [0-144.84]
GP at home	40	0	32	0
Practice nurse at surgery/health centre	40	3.26 (10.65) [0-55.8]	32	2.91 (6.44) [0-27.9]
Practice nurse via telephone	40	1.19 (7.49) [0-47.4]	32	0
Practice nurse at home	40	0	32	2.31 (13.08) [0-74]
Community mental health nurse	40	10.8 (68.31) [0-432]	32	6.75 (28.09) [0-144]
Community psychiatric nurse	40	5.4 (17.39) [0-72]	32	2.25 (8.85) [0-36]
Physiotherapist at surgery/health centre	40	9.28 (41.38) [0-212]	32	0
Physiotherapist at home	40	0	32	0
Occupational therapist at surgery/health centre	40	0	32	0
Occupational therapist at home	40	0	32	0
Dietician	40	0	32	1.03 (5.83) [0-33]
Counsellor	40	27.95 (96.18) [0-516]	32	49.72 (134.26) [0-516]
NHS Stop smoking services	39	0	32	12.16 (38.4) [0-129.67]
Alcohol services - community	40	10.13 (47.24) [0-270]	32	21.09 (69.51) [0-270]
Drug services - community	40	150.75 (571.9) [0-3216]	32	67 (215.26) [0-804]
Walk-in-centre	40	27.82 (162.63) [0-1027.2]	32	0
Primary care subtotal	39	309.43 (844.61) [0-4872.24]	32	216.15 (287.85) [0-933.67]
Secondary care (number of events)				
General appointments	40	10.28 (47.94) [0-274]	32	21.41 (78.66) [0-411]
Psychologist appointments	40	0	32	0

Psychiatrist appointments	40	2.7 (17.08) [0-108]	32	0
Alcohol appointments	40	0	32	0
General medical admissions	40	32.5 (143.46) [0-649.98]	32	0
Day cases	40	36.35 (229.9) [0-1454]	32	90.88 (402.45) [0-2181]
General A&E visits	40	7.39 (32.62) [0-147.8]	32	4.62 (26.13) [0-147.8]
Mental health A&E visits	40	4.83 (30.52) [0-193]	32	12.06 (68.24) [0-386]
Secondary care subtotal	40	94.04 (321.52) [0-1728]	32	128.96 (492.69) [0-2592]
Social care services (number of contacts)				
Social worker	40	30.98 (123.89) [0-708]	32	29.5 (128.04) [0-708]
Home help/care worker	40	0.17 (1.09) [0-6.9]	32	0
Social care subtotal	40	31.15 (124.36) [0-708]	32	29.5 (128.04) [0-708]
Total cost to NHS and PSS (excluding intervention cost)	39	437.83 (952.49) [0-4980.24]	32	374.61 (590.62) [0-2675.3]

Appendix 6: Broader societal resource use of intervention and control groups at baseline, 3 month follow-up and 6 month follow-up

Table 41: Broader societal resource use of intervention and control groups at baseline

Resource item	Intervention		Comparator	
	n	Mean (SD) [range]	n	Mean (SD) [range]
Education services (number of contacts)				
Education courses	61	0.40 (2.01) [0-14]	59	0.67 (3.47) [0-24]
Employment worker/officer	61	0.26 (2.04) [0-16]	59	0
Citizen's Advice Bureau	61	0	59	0.01 (0.13) [0-1]
Job centre	61	1.81 (6.86) [0-40]	59	0.79 (1.90) [0-8]
Enhanced Thinking Skills (ETS)	61	0.26 (2.04) [0-16]	59	0
Cognitive Skills Booster (CSB)	61	0	59	0
Cognitive Self Change Programme (CSCP)	61	0	59	0
Other	61	2.13 (7.94) [0-58]	59	1.52 (8.05) [0-60]
Other service providers (number of contacts)				
Probation worker	61	3.29 (2.71) [0-8]	59	3.55 (2.40) [0-9]
Social worker	61	0.62 (1.88) [0-8]	59	0.38 (1.52) [0-8]
Community rehabilitation worker	61	0.93 (2.64) [0-16]	59	0.23 (1.17) [0-8]
Police custody	61	0.04 (0.21) [0-1]	59	0.03 (0.18) [0-1]
Focus on Resettlement (FOR)	61	0	59	0
Solicitor/Lawyer	61	0.09 (0.47) [0-3]	59	0.18 (1.05) [0-8]
Barrister	61	0	59	0.05 (0.28) [0-2]
Legal advocate	61	0	59	0
Other	61	1.09 (5.28) [0-40]	59	0
Help from friends and relatives				
Hours per week	61	1.70 (4.66) [0-24]	59	1.16 (4.23) [0-28]
Days off work in the last 2 months	61	0	59	0.05 (0.28) [0-2]

Table 42: Broader societal resource use of intervention and control groups at 3-month follow-up

Resource item	Intervention		Comparator	
	n	Mean (SD) [range]	n	Mean (SD) [range]
Education Services (number of contacts)				
Education courses	34	1.5 (6.55) [0-36]	38	0.52 (2.06) [0-10]
Employment worker/officer	34	0.14 (0.70) [0-4]	38	0.13 (0.81) [0-5]
Citizen's Advice Bureau	34	0	38	0.02 (0.16) [0-1]
Job centre	34	1.55 (3.50) [0-12]	38	1.57 (2.77) [0-10]
Enhanced Thinking Skills (ETS)	34	0	38	0
Cognitive Skills Booster (CSB)	34	0	38	0
Cognitive Self Change Programme (CSCP)	34	0	38	0
Other	34	2.55 (10.8) [0-62]	38	2.71 (10.3) [0-62]
Other service providers (number of contacts)				
Probation worker	34	2.70 (2.55) [0-8]	38	3.39 (3.14) [0-12]
Social worker	34	0.17 (0.71) [0-4]	38	0.28 (1.62) [0-10]
Community rehabilitation worker	34	0.55 (1.18) [0-4]	38	0.68 (2.09) [0-12]
Police custody	34	0.11 (0.40) [0-2]	38	0.05 (0.22) [0-1]
Focus on Resettlement (FOR)	34	0	38	0 (0) [0-0]
Solicitor/Lawyer	34	0.20 (0.68) [0-3]	38	0.15 (0.49) [0-2]
Barrister	34	0	38	0.02 (0.16) [0-1]
Legal advocate	34	0.02 (0.17) [0-1]	38	0
Other	34	0.26 (0.86) [0-4]	38	0.92 (5.67) [0-35]
Help from friends and relatives				
Hours per week	34	1.38 (3.44) [0-14]	38	1.23 (2.81) [0-14]
Days off work in the last 2 months	33	0.12 (0.69) [0-4]	38	0.05 (0.32) [0-2]

Table 43: Broader societal resource use of intervention and control groups at 6-month follow-up

Resource item	**Intervention**		**Comparator**	
	n	**Mean (SD) [range]**	**n**	**Mean (SD) [range]**
Education Services (number of contacts)				
Education courses	40	0.22 (0.91) [0-5]	32	0.71 (2.59) [0-14]
Employment worker/officer	40	0	32	0
Citizen's Advice Bureau	40	0	32	0
Job centre	40	1.15 (2.15) [0-8]	32	0.71 (1.70) [0-6]
Enhanced Thinking Skills (ETS)	40	0	32	0
Cognitive Skills Booster (CSB)	40	0	32	0
Cognitive Self Change Programme (CSCP)	40	0	32	0
Other	40	3.77 (11.7) [0-62]	32	0.21 (0.79) [0-4]
Other service providers (number of contacts)				
Probation worker	40	3.2 (2.61) [0-12]	32	3.71 (4.84) [0-24]
Social worker	40	0.57 (2.13) [0-12]	32	0.03 (0.17) [0-1]
Community rehabilitation worker	40	0.32 (0.85) [0-3]	32	0.40 (1.10) [0-4]
Police custody	40	0.1 (0.44) [0-2]	32	0
Focus on Resettlement (FOR)	40	0	32	0
Solicitor/Lawyer	40	0.12 (0.46) [0-2]	32	0.06 (0.24) [0-1]
Barrister	40	0.07 (0.34) [0-2]	32	0
Legal advocate	40	0	32	0
Other	40	0.05 (0.22) [0-1]	32	0.06 (0.35) [0-2]
Help from friends and relatives				
Hours per week	40	1.62 (5.13) [0-30]	32	2.15 (8.57) [0-48]
Days off work in the last 2 months	40	0.07 (0.34) [0-2]	32	0

Appendix 7: Medications data

Table 43 reports medications used during each reporting period, grouped by the main reported reason for prescription. In total, 60 different drugs were identified by participants as medication that they had used at some point over the baseline and follow-up periods (plus unspecified vitamin supplements). Prescription rates for most individual drugs were very low, with fewer than five users. The medications with more than five users at any assessment point were: citalopram, co-codamol, codeine, ibuprofen, mirtazapine, paracetamol, pregabalin, quetiapine, salbutamol and sertraline. Due to the small numbers, Table 43 reports medication use for the intervention and control groups combined. The drugs listed are grouped according to the main types of health problem for which participants said they were prescribed.

There were issues with the quality of the data collected on participants' use of medications, which arose in part due to the practice of recording this data as free text. This led to considerable data quality issues, with many misspellings across a mixture of brand and generic drug names. As a result, for every data entry, the spelling of the drug name and reason for prescription provided on the case report form was checked against the British National Formulary (BNF) (online access provided by NICE) to ensure that the medication was correctly identified, using consistent naming conventions. This process would not be feasible with a full trial dataset. In a high proportion of cases, the participant was unable to name the medication that they were prescribed. In addition, there were some drug names that we were unable to match to a drug listed in the BNF. Overall, the percentage of drugs reported by participants that were unidentifiable for one of these two reasons was 22% at baseline (18% at three month follow-up, 28% at six month follow-up). Other issues that would cause problems for costing medication use were that the "length of prescription (in days)" was not always completed, and the dose was seldom recorded. In some cases, it was not clear whether the medication had been prescribed or purchased over the counter. These issues prevented us from including the use of medication in the analysis of resource use and costs. For the main study, we recommend identifying a manageable number of (around ten) medications that are frequently used by this population, and collecting data on the use of these drugs in a more structured format. This could also be tied into plans for improving the collection of data on illicit drug use.

Table 44: Reported use of medication by both groups

	Number of participants		
Medication by reported reason for prescription	**Baseline**	**Month 3**	**Month 6**
Mental health (non-psychosis)			
Mirtazapine	22	12	9
Pregabalin	10	1	6
Sertraline	9	4	6
Citalopram	6	3	3
Propranolol hydrochloride	5	2	2
Fluoxetine	4	2	2
Venlafaxine	2	2	4
Amitriptyline hydrochloride	4	1	2
Diazepam	3	0	3
Buprenorphine	3	2	0
Methadone hydrochloride	2	2	1
Methylphenidate hydrochloride	2	2	1
Zopiclone	2	0	2
Temazepam	1	1	0
Duloxetine	0	1	0
Naltrexone hydrochloride	1	0	0
Paroxetine	1	0	0
Promazine hydrochloride	1	0	0
Psychosis			
Quetiapine	7	3	5
Trazodone hydrochloride	1	1	3
Olanzapine	0	1	1
Risperidone	1	1	0
Valproic acid	1	1	0
Amisulpride	1	0	0
Chlorpromazine hydrochloride	0	0	1
Pain			
Paracetamol	9	3	2
Codeine phosphate	9	3	1
Co-codamol	8	2	1
Ibuprofen	6	1	3
Naproxen	2	3	4
Gabapentin	2	2	2
Aspirin	0	0	2
Diclofenac sodium	0	2	0
Tramadol hydrochloride	1	1	1
Morphine (Oramorph)	1	0	0
Pizotifen	1	0	0

Gastric problems			
Omeprazole	1	2	4
Lansoprazol	2	0	0
Peppermint Oil	0	1	1
Osmorol	1	0	0
Asthma			
Salbutamol	7	3	4
Fluticasone with salmeterol inhaler (Seretide)	1	3	2
Beclometasone dipropionate	0	0	1
Other			
Carvedilol	1	0	4
Thiamine	3	2	0
Amoxicillin	0	3	0
Vitamin supplement (unspecified)	2	2	2
Metformin hydrochloride	2	1	1
Insulin (not specified)	2	0	0
Lactulose	1	1	1
Lisinopril	1	1	1
Apixaban	1	1	0
Cetirizine hydrochloride	1	1	0
Folic acid	0	1	1
Ascorbic acid	0	0	1
Co-amoxiclav	1	0	0
Finasteride	0	0	1
Loratadine	0	0	1
Penicillin	0	1	0
Rivaroxaban	1	0	0
Sodium valproate	1	0	0
Non-identifiable medication use			
Participant did not know the name of the drug	42	17	34
Unable to match to British National Formulary	4	2	4