1 Project Title

Understanding the Impacts of Care Farms on Health and Well-being: A Pilot study to inform the design of a follow-on study to assess the cost-effectiveness of care farms in improving health and wellbeing and reducing re-offending.

2 Background

2.1 Existing Research

There is a growing body of evidence that points to the positive benefits of green exercise to mood and self-esteem (12; 14; 17). Green exercise refers to exercise that is taken in the natural environment. Studies comparing outdoor with indoor exercise have identified potential positive benefits for health and well being, however small sample sizes and methodology limitations of these studies does not allow firm conclusions to be drawn (13).

The evidence base for the effectiveness and cost effectiveness of care farms (CFs) is even more limited. CFs use farming activities as therapy and often work with disadvantaged groups from the most deprived communities (40). Searches for published literature were conducted using Cochrane, Pub Med and Web of Knowledge using the terms: CF; green care; community farm; and no such studies were found. A review of care farming (3) also identified that while there is a growing body of qualitative evidence of the positive benefits of CFs on their clients' physical and mental health, there are limited quantitative studies. There is also a shortage of economic data assessing the cost effectiveness of CFs, or their utility, for offenders or any other client groups. The only such study conducted by the West Mercia Constabulary and Probation Trusts has been identified by Hine et al (3). This found CFs to be cost effective for the only 2 offenders studied with an estimated total cost saving of £47,471 to the community. However neither the incremental cost effectiveness of CFs compared to other Community Order (CO) settings nor the incremental cost per re-offending event avoided due to CFs have been explored.

A survey by the National Care Farming Initiative in the UK was completed by 76 CFs, however the authors believe this to be an underestimation of the number of CFs in the UK (3) and in 2012, 189 are currently operating (personal communication NCFI). The care farmers surveyed identified that their work improved the quality of life of their clients, often enabling them to become more engaged in society and in many cases to take up paid work (3). Of the farms completing the survey, 30% of clients were referred from Probation Trusts. A before and after survey of 72 CF clients from 7 CFs was also conducted (3). This self-report data showed that 64% of participants felt their self-esteem had improved. Paired samples t-test found a statistically significant decrease in self-esteem scores (representing an increase in self-esteem) between before ($M=21.47$, $SD=5.80$) and after spending time on the farm [$M=19.65$, $SD=6.43$, $t(50) = 3.05$, $p<0.01$] Profile of mood states questionnaires were also conducted before and after attending a care farm. An 18 point drop in mean Total Mood Disturbance scores from 165 to 147 95% CI (-6.163 to -30.697) was found, showing a statistically significant improvement in mood. It should be noted that these findings are from only a small sample of 51 clients (3).

Care farming is a growing movement across Europe, and there have therefore been attempts at assessing effectiveness from Norway and the Netherlands. Non-significant improvements in self-efficacy and quality of life have been found after 6 months among psychiatric patients working with dairy cattle in Norway (18) and improvements in physical and mental health and also social benefits have been found in the Netherlands (19). It is likely that these non significant findings are due to underpowered studies.

Offenders suffer a greater burden of physical and mental ill-health than the general population (7; 8). They are more likely than the general population to have been in care (4; 5), suffered harsh or neglectful parenting, developed early behaviour difficulties (6), be excluded from school (4; 7; 8), have witnessed violence at home and suffered from addiction problems as children (4; 5). The link between poor mental health and reoffending is well-established (9; 10; 11; 20). The evidence of factors associated with desistance, or not re-offending, highlights the importance of building hope (21) and social capital (22; 23), and changes in perceptions of self (24) and the interplay of these factors with improvements in opportunities and social, environmental circumstances (25). The limited evidence base on green care and care farming would suggest that these environments can produce exactly these sort of benefits and may therefore be particularly appropriate for this and similar client groups.

In England, there is a policy emphasis on the use of Community Orders (COs) which have been shown to be more effective than custodial sentences of less than 12 months in reducing reoffending, although this may be in part due to the case mix of offenders (26). The positive impacts of COs have been explained theoretically through concepts of generativity whereby offenders are able to realise personal redemption through positive contributions to the community (24). The use of COs has increased; in 2009 14% of offenders were given a community sentence, 3% more than in 2008 and 29 % more than in 1999. From June 2010 to June 2011 13.3% of magistrates' court sentences, and 18.2% of crown court sentences were COs (4).

A search of the following databases found no systematic reviews or RCTs of interventions to improve the health and/or quality of life of offenders in the community: Cochrane, Web of Knowledge, were searched using the terms: offender; reoffending; recidivism; health; quality of life; community sentence/penalty/payback/order. The evidence available on reoffending is based on Ministry of Justice data which show that the frequency of reoffending for COs has been falling (4).

This study would include a systematic search and analysis of the unpublished grey literature on the effectiveness and cost effectiveness of care farming and community orders in the UK and other high income countries.

The long term aim of the study team is to conduct a natural experiment comparing CFs in England with other CO settings. This would address the gap in the evidence on the cost-effectiveness of CFs in improving health and well being and reoffending rates.

2.2 Risks and Benefits

Once informed consent has been given the participants will be asked to either complete a series of questionnaires or qualitative interviews. It is not expected that these interviews will present a great level of risk to the participants, however if participants do become unduly perturbed by the questions or process, the research staff, who are experienced in interviewing offenders, will be able to make use of the strong links with probation services and care farm staff to refer the participant to further counselling or advisory support.

The successful completion of this pilot and any subsequent definitive trial will allow commissioners to take evidence-based decisions on where best to allocate offenders in order to most benefit their health, well-being and quality of life. This has potential benefits not only for the individual offenders, but their families and the wider community in terms of reductions in reoffending and its subsequent societal costs.

2.3 Rationale

The idea for this study emerged from commissioners both in the NHS and the Probation Trust. Commissioners were concerning that, whilst they had much anecdotal evidence that commissioning services from CFs for disadvantaged population groups was beneficial, there was a lack of evidence for the effectiveness, and particularly cost-effectiveness, of CFs in improving health and well-being. The initial literature search conducted, on which this proposal is based, confirmed these concerns of the lack of evidence of the effectiveness of CFs or even the effectiveness of other settings for serving COs.

This proposal is not for a definitive trial or natural experiment, instead a pilot study is proposed. Given the limited quantitative studies that have been conducted with CF participants and with offenders, there are many methodological questions that require answers before a larger study can be considered. The research questions for this pilot study are:

- How can recruitment of offenders serving COs on CFs and in comparator settings be maximised?
- What are the optimum ways to collect baseline and follow up data (whilst minimising drop-out), cost data from CFs, Probation Trusts and individual reoffending data from the Police National Computer?
- What are the impacts of CFs on offenders' lives and how appropriate are the measures used in the pilot study for identifying changes in quality of life, health and well-being?
- What is the extent of variation between the activities and approaches used on different CFs and the variation in outcomes for offenders at different types of CF?
- What is the influence of seasonality on decisions concerning the allocation of setting to serve a CO, the activities on the CFs and the health and well being of participants?
- What factors may lead to selection bias and what are the potential confounders, particularly in terms of factors influencing allocation to CFs and other CO settings, and how can these best be measured?
- What is the feasibility of conducting a cost-effectiveness analysis of CFs in comparison with other CO settings for offenders?

While NHS commissioners and CFs in particular expressed an interest in understanding the impact of CFs on a wide variety of disadvantaged population groups, such as those with substance misuse issues, young people excluded from school, people with physical and learning disabilities, the research team advocated focusing only on offenders serving COs. The rationale for this is that such diversity in the population being studied, coupled with greater diversity in support and activities at the CF in addition to complexities in identifying comparator populations would make a quantitative approach unfeasible. So the participants for this study are offenders and not other CF users. However, a closer look at the socio-economic background of offenders serving COs also indicates that there are many similarities between offenders and other disadvantaged population groups. Thus, findings from this programme of research can potentially help in understanding the role of CFs in improving the health and wellbeing of other disadvantaged population groups.

3 Socioeconomic Position of Participants and Inequalities

Many CF clients are from disadvantaged backgrounds. Of these clients, offenders are particularly disadvantaged. Offenders are predominantly male and under 30 years. They are more likely than the general population to have been in care (4; 5), suffered harsh or neglectful parenting, developed early behaviour difficulties (6), be excluded from school (4; 7; 8), witnessed violence at

home and suffered from addiction problems as children (4; 5). The link between poor mental health and reoffending is well-established (9; 10; 11). Reaching these individuals with interventions to improve health and well-being is a challenge. Whilst serving COs, there is an opportunity to work with this disadvantaged population. There is growing evidence of the benefits of activity in the natural environment on mental well-being and self esteem (12; 13; 14; 15; 16; 17). An intervention capable of improving health and well being of this disadvantaged group could reduce reoffending and the cycle of deprivation. As offenders share many characteristics with those from deprived backgrounds, particularly young men, CFs are potentially a valuable intervention to address inequities among a broader population.

4 Research Objectives

Aim: This pilot study aims to build knowledge on the mechanisms through which care farms (CFs) may improve the health and well being of adult offenders serving Community Orders (COs) and explore the feasibility of assessing the cost effectiveness of CFs in achieving these outcomes in a subsequent study.

Objectives:

1. Conduct a systematic review of published and grey literature evaluating the impacts and mechanisms within CFs and green care in improving the health and well-being of disadvantaged populations and the impacts of COs and costs of offending to society and health services.

2. Identify factors that drive the decision of CO allocation in order to identify potential selection bias and confounders as well as the most appropriate ways to collect data on these factors.

3. Identify the most appropriate ways to gain informed consent, maximise recruitment and follow up whilst minimising drop out and deliver questionnaires effectively among offenders serving COs in CFs and comparator CO settings.

4. Identify the most appropriate ways to collect cost data, including health care resource use by offenders, cost of reoffending, costs of crime and gains of employability of offenders in CFs and comparator CO settings and explore the feasibility of measuring cost utility.

5. Identify differences in effectiveness in terms of quality of life, mental health, lifestyle behaviours and reoffending rates between the three CFs and between CFs and comparator settings in order to estimate variation and thus determine the intra-cluster correlation coefficient (ICC) and sample size required in the follow on study.

6. To develop a logic model based on offender's experiences of serving their CO on a CF and their perceptions of the impact the CF has on their lives and well-being, taking into consideration seasonal changes, to illustrate the possible mechanisms that lead to changes in health and well being among offenders serving COs on CFs.

Objective	Timing	Methods to Meet Objective
1. Conduct a systematic review of published and grey literature evaluating the impacts of care farming and green care on disadvantaged	To be completed within the first year of the study and updated in the last 6	Two systematic reviews: 1. Impacts and mechanisms of CFs, Green Care and COs on disadvantaged populations over 18 years. An initial logic model will guide this realist review and be developed in light of evidence found, and ultimately the quantitative and qualitative findings of the pilot. Search strategies will be developed by the information

populations and the impacts of COs and costs of offending to society and health services.	months.	specialist in accordance with Cochrane Collaboration guidance for identifying studies and quantitative and qualitative reviews. See section 18 for MeSH terms Databases to be searched will include: MEDLINE (Ovid), EMBASE (Ovid). Global Health (Ovid), CINAHL (EbscoHost), Criminal Justice Abstracts (EbscoHost), GreenFILE (EbscoHost), Dissertations Abstracts (ProQuest), and ASSIA (ProQuest). Further relevant studies will be identified through citation tracking activities and CF networks to identify grey literature. A realist synthesis will be conducted. 2. Costs of offending to society and health services (including mental health) for adults over 18 years. Search strategies will be developed by the information specialist in accordance with the NHS CRD guidance for identifying studies for reviews and economic evaluations. Health, Economic and Social Science databases will be searched including: MEDLINE (Ovid), EMBASE (Ovid), NHSEED (Ovid), EconLit (EbscoHost), Criminal Justice Abstracts (EbscoHost), ASSIA (ProQuest), Sociological Abstracts (ProQuest) and IDEAS (RePeC). See MeSH terms in setion 18. Further relevant studies will be identified through citation tracking activities.
2. Identify factors that drive the decision of CO allocation in order to identify potential selection bias and confounders as well as the most appropriate ways to collect data on these factors.	To be explored in the first 6 months in order to inform data collection	6 Individual interviews with 2 probation officers in each of the 3 Probation Trusts responsible for CO allocation. Analysis of socio-demographic data on CF and comparator participants to identify any significant differences in characteristics of those allocated to CF or comparator setting.
3. Identify the most appropriate ways to gain informed consent, maximise recruitment and follow up whilst minimising drop out and deliver questionnaires effectively among offenders serving COs in CFs and comparator CO settings.	Oct 2013 to April 2015.	6 semi-structured interviews (SSIs) with CF and comparator participants 1 month into recruitment and feedback from RA, CF and probation services on the recruitment, consent and questionnaire process. From the last 3 months of recruitment/ follow up phase: 6 more SSIs (3 CF and 3 comparator) and feedback from RA and CF and probation services on the process of follow up.
4. Identify the most appropriate ways to	Oct 2013 to April	Collection of cost data from CF and Probation Trusts on intervention costs in CF and comparator settings. Health

collect cost data, including health care resource use of offenders, cost of reoffending, crime rates and gains of employability of offenders with COs in CFs and comparators and explore the feasibility of measuring cost utility	2015	and social care resource use questionnaire filled by offender participants in CF and comparators baseline and follow up after CO. Analysis of response rates and ease of completion of health and social service use questionnaire to be filled by all CF and comparator participants. The systematic review will inform the collection of cost data. Dr Tubeuf and the AUHE RA will conduct preliminary and exploratory analysis of the incremental cost-utility of care farms compared to other types of community services for offenders and the incremental cost-effectiveness in the management of re-offending.
5. Identify differences in effectiveness in terms of quality of life, mental health, lifestyle behaviours and reoffending rates between the three CFs and between CFs and comparator settings in order to estimate variation and thus determine the intra-cluster correlation coefficient (ICC) and sample size required in the follow on study.	Main data collection: Oct 2013 to Sept 2014 Analysis to be completed by July 2015 to allow 3 months for final report and publication writing.	Baseline and follow up measures (at end of CO or 6 months from final recruitment) for 90 CF participants and 90 comparators: Clinical Outcome in Routine Evaluation –Outcome Measure (CORE-OM) • Re-offending rates over a max 18 month period • Warwick-Edinburgh Mental Well-being Scale (WEMWBS) • Measures of smoking, alcohol, drug use, diet and physical activity The health and well-being outcomes will be used jointly with costs to offer a preliminary and exploratory analysis of incremental cost-effectiveness and cost-utility. Collection of meteorological data throughout data collection period to allow analysis of impacts of seasonality on outcome measures. Variation in outcome measures between the 3 CFs to be analysed to inform the ICC estimation for follow on study.
6. To develop a logic model based on offender's experiences of serving their CO on a CF and their perceptions of the impact the CF has on their lives and well-being, taking into consideration seasonal changes, to illustrate the possible mechanisms that lead to changes in health and well being among offenders serving COs on CFs.	Qualitative data collection October 2014 to March 2015 with ongoing analysis. Model complete by July 2015	24 In-depth interviews (8 from each of the 3 CFs) with CF participants. If feasible, 1 focus group discussion using participatory methods in each CF (3 FGDs) 6 In-depth interviews with CF staff working with CO participants. Qualitative methods will explore participants' experiences of the CF and their perceptions of their CO setting on their health, well-being and life experience and staff reflections on CF as an intervention for this and other similar disadvantaged client groups. Triangulation of qualitative findings with quantitative results in order to further develop the logic model devised during the realist review (36, 37). Particular emphasis on building better understand the variations between and characteristics of CFs.

5 Research Design

This pilot study will utilise quantitative and qualitative methods in order to address the aims and objectives as shown in the table above. The section below provides more details of the main pilot study design.

5.1 Target Population:

Adult (18 and over) offenders serving COs. Inclusion criteria: Any adult 18 years and over serving a CO in a CF or comparator setting. Exclusion criteria: None. Offenders who have committed severe offences or have severe mental health issues are not sentenced to COs. Resources have been included in the budget for translation services for those who are not comfortable being interviewed in English, thus no one will be excluded based on their ethnicity or language abilities.

5.2 The Intervention Sites

Three CFs in England: one in Yorkshire, one in Lincolnshire and one in Shropshire. The care farms all provide some form of farming activity as therapy to a range of clients including offenders serving COs. These three CFs have been chosen as they illustrate the variety in settings and approaches that can be found in CFs across the UK. Their activities and characteristics are detailed below:

CF 1 West Yorkshire: Provides aquaculture, building, environmental and conservation work. The site includes outdoor settings for gardening and conservation work in addition to indoor facilities for fish farming and building and carpentry work. Offenders can gain accreditation for skills developed and have access health trainers for lifestyle behaviour change advice.

60 participants will be recruited over a 1 year period from this CF, this will enable:

- initial learning on recruitment in this site to be shared with the 2 other CF sites
- assessment of outcomes over the entire year in order to identify any impact of seasonality on participants experience, activities and outcomes.

CF 2 Shropshire: Is run as a social enterprise and provides conservation activities in a woodland area with access to skills building and preparation for employment for a range of client groups including adult offenders. Accreditation for skills developed and access to occupational health support, particularly around mental health are provided.

CF 3: Lincolnshire: Has been working with offenders for over 20 years and offers specialist services in substance misuse rehabilitation. The activities offered include conservation and environmental work with woodland and fish ponds, skills building and accreditation for carpentry and engineering.

90 participants, 45 from CF2 and 45 from CF3 will be recruited 3 months later than those in CF1 for a 9 month period. A total of 150 participants will be recruited from CF 1, 2 and 3.

5.3 Comparator sites:

Offenders serving COs in settings other than a CF in West Yorkshire, Shropshire and Lincolnshire. The activities carried out whilst serving COs in these comparator areas include: building work, food handling, painting/decorating, recycling and cleaning.
60 participants will be recruited as comparators in WY
90 participants from Shropshire (45) and Lincolnshire (45).

5.4 Allocation Decisions

The Probation Trusts in each region take the decision on where to allocate offenders. Initial discussions with Probation Trusts indicate that these decisions are based on:

- a risk assessment: to ensure that the offender does not have particular risky behaviour toward certain population groups
- their physical ability and mobility
- location of the CO setting to avoid offenders having a long travel time
- whether the offender requires supervision by a specific probation officer or whether this can be done by project staff.

These factors will be measured and taken into consideration as potential confounders. The process of allocation will be monitored throughout the project. In-depth interviews will be conducted with staff responsible for making allocation in each of the Trusts to build an accurate picture of the basis for these decisions and their possible role as confounders. The characteristics of offenders allocated to CFs and comparator settings will be compared for statistically significant differences.

5.5 Primary outcome:

Quality of life and well-being derived from the Clinical Outcome in Routine Evaluation–Outcome Measure (CORE-OM). CORE-OM has been validated among offender populations (27; 28) and can be used to derive QALYs (31). The 34 items cover four dimensions: subjective well-being; problems/symptoms; life functioning; and risk/harm (29).

5.6 Secondary outcomes:

- Re-offending rates over a max 18 month period obtained from individual level data from the Police National Computer (PNC)
- Mental health derived from Warwick-Edinburgh Mental Well-being Scale (WEMWBS) (32)
- Measures of smoking, alcohol, drug use, diet and physical activity adapted from General Lifestyle Survey/ Health Survey of England.
- Exploration of health utility as derived from CORE-OM (29; 30). Based on CORE-OM, health states can be valued and QALYs derived permitting a cost-utility analysis (31).
- Exploration of the cost per re-offending event avoided due to CF.

5.7 Follow up:

Measures taken on entering the CF (or comparator), and then on completion of the CO (if achieved in the 1 year of pilot study) or at 6 months follow up if CO is not completed.

5.8 Potential Confounders:

While not all confounders are measurable and may not be relevant as they do not introduce bias into the assessment process, this study and systematic review will identify a list of relevant confounders and ways of measuring these. Potential confounding factors at individual level:

- Area of residence,
- Occupation,
- Deprivation,
- Age
- Gender
- Physical fitness
- Health
- Mental health
- Drug, smoking and alcohol use
- Social skills and ability to engage with others
- Offending history

Potential confounding factors at probation trust level:

- Seasonality
- PT staff may also be influenced by their perceptions/knowledge of individual factors above and this may in turn influence the allocation to CF or comparator sites

As allocation decisions may be based on some of these factors, confounding by indication will need to be address in the planned follow on study Therefore the pilot data will assess if it is feasible to collect information on these potential confounders and provide an initial examination of their relevancy.

5.9 Proposed Sample Size

As this is a pilot study, conventional sample size calculations are not appropriate as the study's main aim is to assess feasibility, recruitment and follow-up rates, clarify selection biases and effects of confounding. There are no hard and fast rules for judging the sample size for a pilot study. However, we and the literature (41) judge an appropriate sample size that will allow us to determine a sample size for the follow-on study taking account of between-CF effects and the possible effects of bias (i.e. response rates and drop-out), to be a total of 300 participants recruited across the 3 CFs and comparator sites. With an expected loss to follow up of 40% (as experienced by WY Probation exit surveys) this will result in 30 cases (i.e. attend CF) and 30 controls (i.e. attend comparator CO settings in same region) recruited from 3 CFs (i.e. n=180). Using 3 sites will enable the assessment of variation at different CFs/comparator sites: recruitment and follow-up rates, allocation decisions (i.e. confounders), selection biases and outcome measures.

If differences are found between the sites, appropriate adjustments will be made to the design of the follow-on study. In particular, differences in the outcome measures will require adjustment in the sample size of the follow-on study to account for the clustering/site effect. The measure of the degree of correlation within sites used to adjust the sample size calculation is the intracluster correlation coefficient (ICC). Estimating the ICC from just the pilot study will not be feasible due in part to the impractical large numbers required to obtain precision (34). Estimation of the ICC is more feasible from pre-existing data which will be identified in the systematic review (including the pilot data) incorporating a sensitivity analysis framework (34),

Recruitment to the pilot study is achievable in the timescales outlined, for example one CF has approx. 6 new offenders each week, while for the year 2009/10, 2875 offenders completed CO at settings other than CFs in the same region. In recognition of the challenges in recruiting, and gaining informed consent among this group, we will use qualitative methods to better understand ways to maximise recruitment.

5.10 Statistical Analyses:

A number of issues required for the follow-on study will be addressed using the pilot data. There are various factors that might drive the decision to place the offender at the CF or other CO settings (see section 5.4 and 5.8 above). These confounders will need to be accounted for in order to appropriately assess differences in effectiveness and cost-effectiveness of the CFs compared to other CO settings in the follow-on study. By comparing these factors and the other potential confounders identified in section 5.8 between those allocated to the CFs and those allocated to the comparator settings we will identify any potential confounders. These confounders will be assessed and those found to be suitable (i.e. measurable and relevant) will be used in the main study to appropriately account for allocation decisions to different locations (either by matching, or more likely adjusting directly/indirectly, i.e. propensity scores).

To assess if those recruited to the pilot represent all offenders serving COs the demographics of those recruited will be compared to the population characteristics of the offenders serving COs in each of the regions in which the 3 CFs are based. The demographic information on all offenders serving COs will be made available from the respective Probation Trusts. The identification of potential selection biases from the pilot will inform recruitment strategies to ensure that those recruited in the follow-on study are representative.

CORE-OM scores and the other outcomes will be collected at the start and end of the CO for each person both in the pilot and the main study. The correlation between scores for the same person will be estimated from the pilot data and will used in the sample size calculations for the main

study. Additionally, the estimated differences in the outcomes between those offenders at CFs and other COs will be estimated from the pilot data. The results from studies indentified in the literature review will also be drawn on for sample size calculations for the follow-on study. A sensitivity analysis framework will be used to account for any variance in these effect estimates.

The most appropriate method for analysing the pilot data to address the various issues (including those outlined in the sample size calculations) will be multi-level models. These models will not only account for the repeated measures, but also the multiple sites with their potential clustering effect. Exploring the pilot data using these approaches provides an estimate of the various relationships to inform the follow-on study analysis plan. The type of multi-level model employed for the different analysis will be reliant on the dependent variable to be used to address the various issues and the outcome measure (i.e. linear, logistic, or multinomial).

5.11 Health Economics

As this is a pilot study, the economic analysis will be exploratory. The main purpose will be to identify issues, particular in terms of collecting cost data, which will influence the follow-on study. In order to explore these issues fully, the data will be analysed much as it would be within a full trial, although the results will not be definitive. The economic evaluation will examine the data needs and processes in order to be able to answer two questions 'What is the incremental cost-utility of care farms compared to other types of community services for offenders?' and 'what is the incremental cost-effectiveness in the management of re-offending?'

This exploratory primary analysis will consider costs incurred in the provision of the intervention, health care resource utilisation and the utilisation of social services by clients. QALYs will be the outcome measure. Utility weights will be obtained from the CORE-OM data.

The secondary analysis will estimate the expected incremental cost per re-offending event avoided due to care farm at 12 months and consider the same costs as the primary analysis. We will also explore the suitability of a cost-benefit analysis of care farms to the society incorporating reoffending and crime rates and also employability of offenders after care farms.

The results of the follow on study will be presented as the expected incremental cost effectiveness of care farms compared to other settings, including cost effectiveness acceptability curves and the expected net benefit will also be calculated. This pilot will help determine sufficient power to identify cost effectiveness of CFs in improving QoL using a decision analysis model.

5.12 Qualitative Methods

Objective 2: Understanding Allocation Decisions

Participants: 3 Probation Trust staff members. *Sampling:* purposive sampling of 2 staff members from each of the 3 Probation Trusts who are currently responsible for making allocation decisions on where offenders will serve their CO.

Method: 3 semi-structured interviews. Key topics: level of details of court order given and room to make allocations, central and/or local guidance used, assessments and discussions routinely conducted with offenders, factors taken into account, extent to which offenders are able to influence the process. *Analysis*: Framework Approach (33): as the information required from these interviews is to a large extent pre-specified, this more deductive approach is appropriate.

Objective 3: Maximising recruitment, maximising follow up and minimising drop out, consent and data collection.

Participants: 12 semi structured interviews: 3 in each CF and Comparator at baseline and 3 in each CF and Comparator at follow up. *Sampling:* Purposive sampling, if informed consent can be given, of CF and/or comparator offenders, balanced by gender, who refused to consent to the main study but would be willing to be interviewed on why they refused. If these participants can not be reached, then 6 face-to-face interviews, 3 from CFs and 3 from comparators' participants will be conducted. To be purposively sampled based on information provided by the RAs on any participants who appeared to struggle in understanding the consent procedure or questionnaires. These 6 interviews will be conducted in the first month of recruitment in the region of CF 1, 3 CF and 3 comparator participants.

A further 6 interviews (3 in the CF and 3 comparators) will be conducted once follow up begins. Again attempts will be made to sample those that have been 'lost to follow up' in some way. If this is not possible, participants will be interviewed on the follow up process.

Method: 6 semi-structured face-to-face interviews. Key topics: understanding of the study, the meaning of informed consent, their perceptions of the research team (whether separate from probation), understanding of the tools, satisfaction with/experiences of the follow up process, suggestions for improvement. *Analysis*: Framework approach (33) as above due to deductive nature of the objective.

Objective 6: Understanding the CF mechanisms for improved health and wellbeing

Participants: 24 In-depth interviews: 8 in each CF. 3 Focus Group Discussions (FGDs): 1 in each CF. *Sampling*: Purposive based on early analysis of baseline and follow up outcome measures to identify those at the extremes of improvement or not, and some that remain the same.

Method: In-depth interviews (IIs). Key topics: details of their CO, experience of activities done, weather conditions, impact on health, well-being, social relations, lifestyle behaviours, health/social service use, role of CF staff, probation staff, improvements. FGDs: focus on experiences of CF, using participatory techniques e.g. ranking matrices, positive/negative balloons, chapatti diagrams (38) to show relative importance of different support . Visual methods: e.g. participants to photograph CF experience before FGD and IIs for discussion. Six in-depth interviews with CF staff working with CO participants. Key Issues: perceptions of what aspects of CF are most helpful for whom and in what situations, details of activities, support provided, challenges, improvements.

Document review of CF records of activities undertaken and support provided (e.g. health trainers) when and with which groups of offenders. Collection of local meteorological data to explore impacts of weather and seasonality through linkage to CF activity records and offenders' transcripts.

Analysis for Objective 6: Thematic analysis (39) using Nvivo 10 to include visual data in analysis: inductive analysis to allow themes to emerge from data rather than being driven by a priori questions. Researcher will keep a reflective log, paying particular attention to the dynamics/openness of participants during interviews. This will be included in the analysis inform decisions on recruitment and interviewing offenders for the follow-on study.

6 Learning for Follow-on Study

Drawing on the systematic reviews and triangulation of quantitative and qualitative findings this pilot study will inform the development of a follow on study by:

- informing the development of a logic model to understand the mechanisms that may explain the effectiveness of the CF approach in improving quality of life, health and well-being for whom and in what contexts.

- Building an understanding of most appropriate design for a follow on study, i.e. whether a natural experiment is feasible, and if so, the optimum methods for:
    - maximising recruitment,
    - gaining informed consent,
    - measuring quality of life, health and well-being,
    - measuring costs of health and social care and costs to society,
    - measuring confounders and any selection bias
    - maximising follow up.
- Estimating effect sizes in differences to be used in sample size calculations for the difference in the change of CORE-OM score between CF attendees and comparators.
- Providing a clear understanding of variation in outcome measures and setting size (35) to inform the estimations of the intracluster correlation coefficient to be used in the follow on study.

A 'way forward' workshop is planned in the last 6 months of the study. This workshop will provide an opportunity to present the findings of the pilot and to discuss with participants the feasibility and design options for a follow on study. The workshop will include participants from Probation Trusts, CFs, ex-offenders and academics including a statistician from the CTRU, University of Leeds as well as the core research team.

7 Ethical Arrangements

This research involves a highly vulnerable group. Offenders may be in a dependent relationship with the Probation Service, and by association with the research team. There are therefore legitimate concerns about the potential for coercion or with impairment of their ability to make autonomous choices. Irrespective of their status as offenders, most of the participants will originate from deprived communities and from social groups that experience exclusion and stigmatisation within society. They may have adversarial relationships with authority. In addition many will have low educational status and poor literacy. Any of which might impair ability to assimilate information about the study and their ability to make informed decisions as to whether they want to participate in the research. The response to these ethics concerns will be as follows:

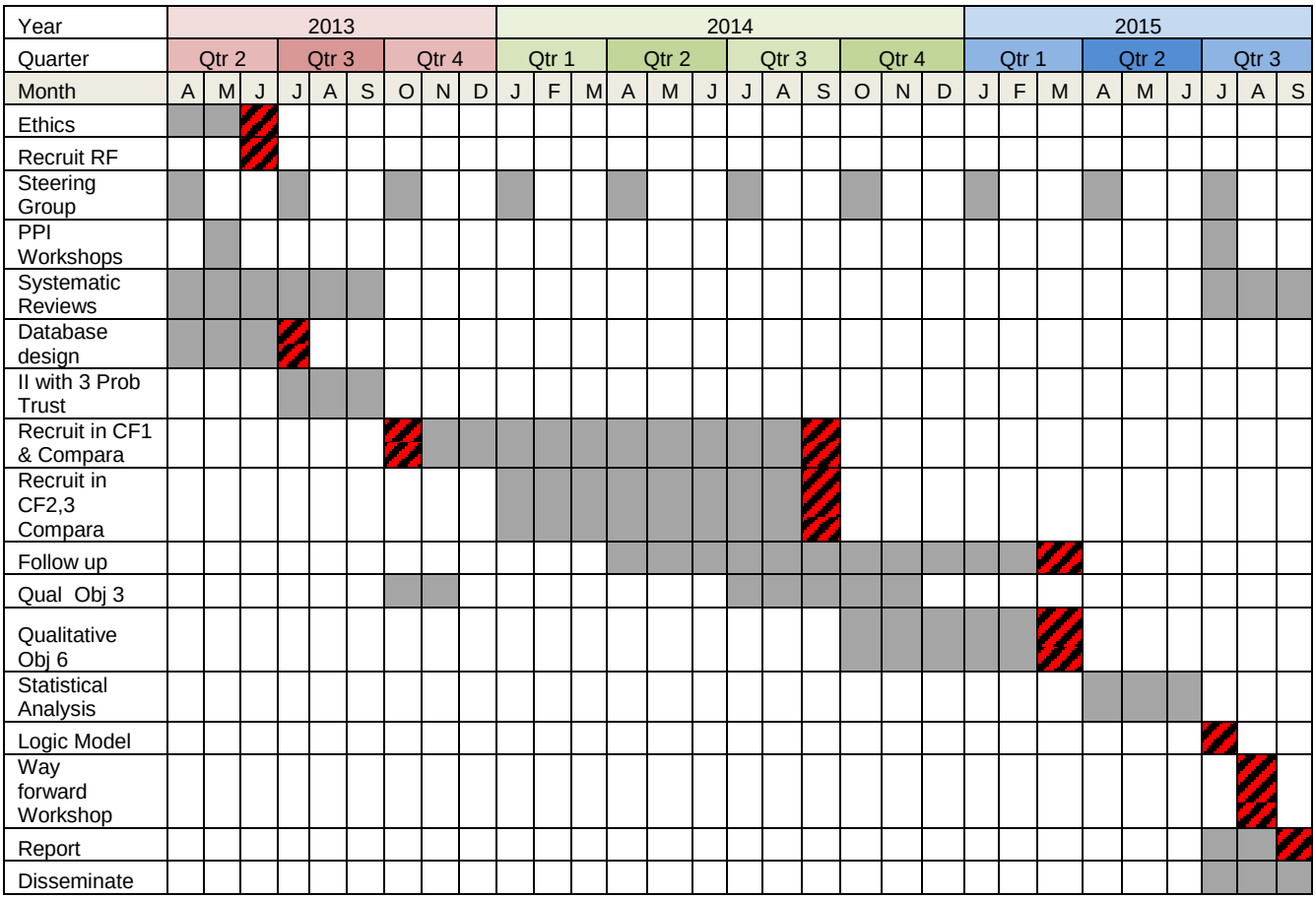
- Stress the independence of the study from Probation Trusts,
- Include ex-offenders within the steering group, with a role as advocates for the project to help dissociate the research from the Probation Service,
- Use various methods for conveying information about the research i.e., written, pictorial, and verbal. Ex-offenders (PPI) will be requested to help in the development of study documentation aimed at offenders particularly during first study PPI workshop.
- Maximise the time for potential subjects to consider whether they wish to consent,
- Maximise, simplify and clearly signpost opportunities for research participants to withdraw from the study.

The research does not involve NHS patients or NHS premises. Therefore ethics approval will be sought via the University of Leeds Research Ethics Committee process (www.leeds.ac.uk/ethics). The University of Leeds procedures are compliant with the research ethics framework formulated by the Economic and Social Research Council. Former chair of the Medicine and Health Research Ethics Committee, Professor Darren Shickle, will be responsible for ensuring that the methodology addresses the ethics concerns described above and will managing the research ethics application. He will have specific responsibility for ethics and governance issues within the steering group.

8 Research Governance

This study will be sponsored by the University of Leeds. The research team (PI, RF and 4 RAs) will meet regularly to ensure that recruitment targets and study milestones are met. A Steering Group will meet quarterly throughout the pilot project. All the co-applicants will be members of the Steering Group. It is hoped that two ex-offenders will also agree to join the group. Their expenses and travel will be paid in accordance with INVOLVE guidance and they will be offered the opportunity of attending PPI training to enable their effective participation in the group. Whilst the majority of the steering group members are based at University of Leeds, several are based further afield. For the majority of steering group meetings, teleconferencing/skype will be used. However, provision has been made in the budget for all steering group members to have at least one face to face meeting per year. The role of the steering group is to advise the research team on the implementation of the study, particularly in relation to methodology, care farming and probation developments, ethical issues and strategy decisions. The PI will be accountable to the Steering Group to ensure that project milestones are met.

9 Project Timetable and Milestones



Milestones are highlighted with a diagonally shaded square.

10 Expertise

PI: Dr Helen Elsey: Public Health Specialist Registrar and Lecturer with the Academic Unit of Public Health (AUPH) at the University of Leeds (UoL). She will supervise the overall implementation of the study, manage the research fellow and ensure key milestones are met. She will lead on systematic review 1 (CF effectiveness), the ethics submission, design of qualitative tools and analysis and final report writing and dissemination activities. Her experience in

community development and working directly with disadvantaged populations, as well as her public health and research expertise will provide the multi-disciplinary understanding required to lead this pilot study.

Dr Tracey Farragher: statistician and public health epidemiologist with AUPH, UoL. She will provide the main statistical support and guide the RF through the quantitative analysis. Her expertise in analysing routine data and using modelling techniques will guide the analysis of the data collected and its linkage to routine offending data and the analysis of potential confounders to inform the follow-on study.

Dr Rachel Bragg: Assistant Director of the interdisciplinary Centre for Environment and Society (iCES) at the University of Essex. As director of Care Farming UK she will provide the team with access to information and partnerships with CFs across England.

Rochelle Gold: Manager of the research department at West Yorkshire Probation Trust. She will manage the two research staff, who will collect data from offenders serving Cos and will enable the partnerships with other Probation Trusts and the police.

Dr Marjolein Elings: scientist and researcher in agriculture and health, Plant Research International, Wageningen University. She will play an advisory role, keeping the team updated on research and developments on care farming across Europe.

Dr Sandy Tubeuf: Lecturer in health economics, UoL. She will lead the health economics systematic review and supervise the health economics research assistant.

Professor Janet Cade: epidemiologist, leading the Nutritional Epidemiology Group, UoL. She will play an advisory role, measuring changes in diet and physical activity and in the design of the follow on natural experiment.

Professor Darren Shickle heads up the AUPH, UoL. He has provided ethics advice to the US government, EC and conducted research with vulnerable groups. He will play an advisory role in terms of ethics and working with disadvantaged populations.

Dr Cathy Brennan: public health lecturer with the AUPH, UoL. She has experience in qualitative research, particularly participatory and visual methods, mental health practice and research, systematic eviews and will provide advisory support in these areas.

Judy Wright: Senior Information Specialist, UoL: will conduct the searches for the systematic reviews.

Thomas Fleming: Data Management Manager, UoL: design databases for linkage with probation and police reoffending data.

Research Fellow: based within the AUPH, UoL, will lead the day to day running of the study, conduct all qualitative interviews, qualitative and quantitative analysis and report writing. To be managed by PI and supported by the wider team. RF will manage the RA (9 months part time to collect quantitative data CF2 & CF3) and coordinate with WY Probations' ROs (CF1).

Health Economics Research Assistant: based within the AUHE, UoL will assist the RF and Dr Tubeuf with the health economic systematic review and the collection of cost data.

11 Partner Collaboration

West Yorkshire Probation Trust (Gold, R.): will draw on their extensive knowledge of offenders and the CO system to provide advice on the design and conduct of the study. They will facilitate access to the Police National Computer data through their links with WY Police. The use of two WY

Probation Trust Research Officers will be a further practical contribution to the study. Their connections nationally will enable linkages to the Probation Trusts in Lincolnshire and Shropshire and other Trusts should a larger study is pursued. Probation Trusts commission CFs as a setting for offenders serving their COs.

The ABLE Project (CF1), West Yorkshire: facilitating the collection of data among the clients at the ABLE CF and also contributing their detailed knowledge of care farming for this client group. ABLE has 3 year funding from WY Probation Trust to provide CO placements for offenders.

Hill Holt Wood (CF 2), Lincolnshire and Willowdene Farm (CF3), Shropshire: have agreed to facilitate recruitment of participants from among the offenders serving their COs on their farms. Both CFs have long term funding from their respective Probation Trusts to provide CO settings.

Care Farming UK (Bragg, R.): will be key in the dissemination of findings from this pilot study. If a larger study is pursued, they will provide the link to other CFs in England for recruitment.

European Care Farming (Elings, M.): dissemination of findings and access to experience of other similar studies to guide the development of phase 2 and 3.

NHS Wakefield District through Director of Public Health, Dr Andrew Furber: Although NHS Wakefield District do not commission The Able Project Ltd., the benefit of the project to the population of Wakefield and to tackle health inequalities is important and the project is a key asset to the District. NHS Wakefield District will endeavour to support the research project and act as an advocate. The results of the study will hopefully demonstrate the benefits the project brings to some of our most vulnerable adults and young people and would provide an evidence base to support future commissioning priorities.

12 References:

1. Care Farming UK, (2012) www.carefarming.org.uk
2. Haubenhofer DK, Elings M, Hassink J and Hine RE. 2010. The Development of Green Care in Western European Countries. Explore 6(2) 106-111
3. Hine, R. Peacock, J., Pretty, J. (2008) Care Farming in the UK: A scoping study. Report for NCFI(UK).
4. MoJ (2010) Justice Compendium of reoffending statistics and analysis Statistics Bulleting (Nov 2010)
5. Youth Justice Board, Accommodation needs and experiences 2007 as cited in Legal Action February 2008
6. Sutton, C., Utting, D. and Farrington, D. (2004) Support from the Start: Working with young children and their families to reduce the risks of crime and anti-social behaviour Department for Education and Skills Research Report 524
7. Dodd, T. and Hunter, P. (1992) The National Prison Survey 1991 HMSO
8. Parke, S. (2009) HMIP and YJB Children and Young People in Custody 2006-08
9. Fazel S, Yu R. Psychotic disorders and repeat off ending: systematic review and meta-analysis. Schizophr Bull 2009; published online Dec 3. DOI:10.1093/schbul/sbp135.
10. Fazel, S and Baillargeon, J (2011) The Health of Prisoners The Lancet. 377: 9769 p. 956-965
11. Singleton, N. Bumpstead, R,. O'Brien, M. Lee, A., Meltzer, H. (2000) Psychiatric Morbidity Among Adults Living in Private Households.
12. Barton, J., Griffin, M. and Pretty, J. (2011) Exercise, Nature and Socially Interactive Based Initiatives Improve Mood and Self-esteem in the Clinical Population. Perspectives in Public Health, DOI: 10.1021/1757913910393862
13. Thompson Coon, J.; Boddy, K. Stein, K.. Whear, R Barton, J. Depledge, M. H. (2011) Does Participating in Physical Activity in Outdoor Natural Environments Have a Greater Effect on Physical and Mental Wellbeing than Physical Activity Indoors? A Systematic Review**.** *Environmental Science & Technology* DOI: 10.1021/es102947t

14. Barton J and Pretty J. (2010) What is the Best Dose of Nature and Green Exercise for Improving Mental Health? A Multi-Study Analysis. Environmental Science and Technology 44(10):3947-55
15. Haubenhofer DK, Elings M, Hassink J and Hine RE. (2010). The Development of Green Care in Western European Countries. Explore 6(2) 106-11
16. Hine R. (2008). Care farming: Bringing together agriculture and health. ECOS *29(2), 42-51*
17. Hine R, Peacock J and Pretty J. (2008) Care farming in the UK: Contexts, benefits and links with therapeutic communities. Int. Journal of Therapeutic Communities 29(3)
18. Berget B. (2006*)* Animal Asisted therapy: Effects on persons with psychiatric disorders working with farm animals. PhD Thesis. Norwegian University of Life Sciences.
19. Elings M. (2007). Effects of green-care farms on quality of life of people with a psychiatric and/or drug addict background. Paper presented at COST Action 866 conference: Green Care in Agriculture: Health effects, economics and policies. June 2007 Vienna, Austria.
20. Wallace C, Mullen P, Burgess P, (1998) Serious criminal off ending and mental disorder: case linkage study. Br J Psychiatry 1998;**172:** 477–84.
21. McNeill, F. and Weaver, B. (2010) Changing Lives? Desistance Research and Offender Management. Scottish Centre for Crime and Justice Research and Glasgow School of Social Work. Report No: 03/2010
22. Farrall, S. and Bowling, B. (1999) 'Structuration, Human Development and Desistance from Crime', British Journal of Criminology 17(2): 252–67
23. Farrall, S. and Calverley, A. (2005) Understanding Desistance from Crime: Theoretical Directions in Rehabilitation and Resettlement. Maidenhead: Open University Press.
24. McNeill, F. and Maruna, S. (2007) 'Giving Up and Giving Back: Desistance, Generativity and Social Work with Offenders' in McIvor, G. and Raynor, P. (eds.) Developments in Social Work with Offenders. Research Highlights in Social Work 48. London: Jessica Kingsley
25. LeBel, T.P., Burnett, R., Maruna, S. and Bushway, S. (2008) 'The "Chicken and Egg" of Subjective and Social Factors in Desistance From Crime'. European Journal of Criminology 5 (2) 131–59.
26. Ministry of Justice (2010) Breaking the Cycle: Effective Punishment, Rehabilitation and Sentencing of Offenders: Green Paper Evidence Report.
27. Tapp, J., Fellowes,E. Wallis, N., Blud, L. and M,oore, E. (2009) An Evaluation of the Enhanced Thinking Skills (ETS) programme with mentally disordered offenders in a high security hospital. Legal and Criminal Psychology 14: p. 201-212
28. Vallentine, V., Tapp, J., Dudley, A., Wilson, C.and Moore, E. (2010): Psycho-educational group work for detained offender patients: understanding mental illness, Journal of Forensic Psychiatry & Psychology, 21:3, 393-406
29. Gray, P. and Mellor-Clark, J. (2007) CORE: A decade in development. Page Bros, Rugby www.coreims.co.uk
30. Barkham M, Margison F, Leach C, (2001). Service profiling and outcomes benchmarking using the CORE-OM: toward practice-based evidence in the psychological therapies. Clinical Outcomes in Routine Evaluation-Outcome Measures. J Consult Clin Psychol;69:184–96
31. Brazier J., (2008) Measuring and valuing mental health for use in economic evaluation, Journal of Health Services Research Policy, 2008, Suppl 3:70-5
32. Tennant, R., Hiller, L., Fishwick, R., Platt, R., Joseph, S., Weich, S., Parkinson, J., Secker, J. and Stewart-Brown, S. (2007) The Warwick-Edinburgh Mental Well-being Scale (WEMWBS): development and UK validation Health and Quality of Life Outcomes, **5**:63 doi:10.1186/1477-7525-5-63
33. Bryman, A. and Burgess, R. (1994) Analyzing Qualitative Data. Chapt. 9: Ritchie, J. & Spencer, L. Qualitative Data Analysis for Applied Policy Research. Routledge, London.
34. Roberts, C. (1999) The implications of variation in outcome between health professionals for the design and analysis of randomized controlled trials Statistics in Medicine; 18, 2605-2615
35. Campbell, M., Fayersb, P. and Grimshaw, J. (2005) Determinants of the intracluster correlation coefficient in cluster randomized trials: the case of implementation research Clinical Trials. 2: 99-107

36. Greenhalgh, T. E. , Kristjasson et al. (2007) Realist review to understand the efficacy of school feeding programmes. BMJ 335 (7625): 858-861
37. Cresswell W & Plano Clark VL (2011) Designing and conducting mixed methods research. 2nd Ed, Sage. London
38. Chambers, R. (1997) Whose Reality Counts? Putting the First Last. ITDG Publishing, London.
39. Denzin & Lincoln (2000) Handbook of Qualitative Research. Sage, London.
40. Hine R.(2008) Care farming: Bringing together agriculture and health. ECOS 29(2), 42-51
41. Lancaster G., Dodd, S. and Williamson, P. (2002) Design and analysis of pilot studies: recommendations for good practice. Journal of Evaluation in Clinical Practice, **10**, 2, 307–312